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ARTICLES

ENABLEMENT IN BIOTECHNOLOGY CASES AFTER *IN RE GOODMAN*

John C. Todaro*

INTRODUCTION

One of the most ubiquitous issues in patent law is whether a patent or patent application is “enabling.” To be considered enabling, the patent or patent application must sufficiently disclose the elements of an invention to allow a person skilled in the art to make and use the invention. This legal issue, often referred to as the “enablement requirement,”¹ arises in the course of both patent prosecution and patent litigation.

The enablement requirement was part of the original federal patent law statute, the Patent Act of 1790.² Today, patent examiners and courts generally look to the patent specification, which discloses or describes the invention, to determine whether an application is enabling. In that regard, 35 U.S.C. § 112, first paragraph, directs:

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1. 2 PETER D. ROSENBERG, PATENT LAW FUNDAMENTALS § 13.04[5][b], at 13-45 (2d ed. 1994).

2. *See id.* § 7.02[1]. In pertinent part, the Patent Act of 1790 stated that the patent must contain a description of the invention sufficient

to enable a workman or other person skilled in the art of manufacture, whereof it is a branch, or wherewith it may be nearest connected, to make, construct or use the same to the end that the public may have the full benefit thereof, after expiration of the patent term.

Act of Apr. 10, 1790, ch. 7, § 2, 1 Stat. 109.

For a detailed review of the statutory embodiments of the enablement requirement, see 2 DONALD S. CHISUM, PATENTS § 7.02 (1991).

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.³

The theory behind the enablement requirement, and the patent statutes in general, is that in exchange for the full disclosure of an invention, the inventor is granted the right to exclude others from making, using, or selling the invention for a term of seventeen years.⁴ Thus, as Donald Chisum comments:

[F]ull disclosure of the invention and the manner of making and using it on issuance of the patent immediately increases the storehouse of public information available for further research and innovation and assures that the invention will

3. 35 U.S.C. § 112 (1988). The contents of a proper specification are further set forth in the regulations promulgated pursuant to 37 C.F.R. § 1.71 (1993), which states in pertinent part:

(a) The specification must include a written description of the invention or discovery and of the manner and process of making or using the same, and is required to be in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which the invention or discovery appertains, or with which it is most nearly connected, to make and use the same.

(b) The specification must set forth the precise invention for which a patent is solicited, in such a manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.

(c) In the case of an improvement, the specification must particularly point out the part or parts of the process, machine, manufacture, or composition of matter to which the improvement relates, and the description should be confined to the specific improvement and to such parts as necessarily cooperate with it or as may be necessary to a complete understanding or description of it.

37 C.F.R. § 1.71. *See also* MANUAL OF PATENT EXAMINING PROCEDURE § 608.01 (1994) [hereinafter MPEP]. The MPEP contains instructions to patent examiners, and is published for the benefit of examiners as well as for patent applicants and attorneys. The MPEP does not have the force of law. *See* MPEP foreword (1994).

4. *See* *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150 (1989) (citing 35 U.S.C. § 154 (1988)).

be freely available to all once the statutory period of monopoly expires.⁵

The application of the enablement requirement to the fast-growing field of modern biotechnology has created a complex body of case law. Modern biotechnology involves the use or engineering of the principles of "cell and tissue culture, cell fusion, molecular biology, and . . . recombinant deoxyribonucleic (DNA) technology to generate unique organisms with new traits or organisms that have the potential to produce specific products."⁶

The biotechnology industry has grown at a "stunning" rate over the last fifteen years.⁷ According to Roger C. Herdman, the Director of the United States Office of Technology Assessment:

Today there are over 1,000 small- to medium-sized biotechnology firms developing or manufacturing pharmaceuticals for human use, of which about 200 are public companies. Financial capital continues to be invested in the industry at a fast pace: in fiscal years 1992 and 1993, more than \$11.5 billion of new external capital financing was raised by biotechnology firms.⁸

While research in biotechnology is now conducted all around the world, the United States is considered to be the preeminent site of

5. 2 CHISUM, *supra* note 2, § 7.01, at 7-2.

6. 2 MCGRAW-HILL ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 648 (7th ed. 1992). See also JAMES D. WATSON ET AL., RECOMBINANT DNA 453 (2d ed. 1992). A full discussion of the concepts of molecular biology and recombinant DNA technology are beyond the scope of this article. However, in the text of this article, certain concepts which are necessary to understand the legal discussion will be explained. For a fuller understanding of biotechnology, the reader is referred to any recent textbook in the field of molecular biology, including the above-referenced text by Dr. Watson. A simplified discussion of the important points of biotechnology can also be found in *In re O'Farrell*, 853 F.2d 894, 895-99 (Fed. Cir. 1988). See also 2 CHISUM, *supra* note 2, § 5.04[6][i], at 5-476 to -486.

7. OTA Testimony/Statement of Roger C. Herdman, Director, Office of Technology Assessment, *The Biotechnology Industry, Testimony Before the Joint Economic Committee*, June 24, 1994, available in LEXIS, News Library, Fed. News Serv. File [hereinafter *Herdman, OTA Testimony/Statement*].

8. *Id.* (citations omitted). "These figures do not include in-house biotechnology research and development (R&D) conducted by large pharmaceutical firms." *Id.* See also WATSON, *supra* note 6, at 468.

biotechnology research and manufacture.⁹ Consequently, as technology has developed, the number of patent applications filed in the United States in the field of biotechnology has soared.¹⁰

This article reviews the key issues in enablement cases involving biotechnology inventions. Part I explores the purpose of the enablement requirement and its application in both patent prosecution and patent litigation. Part II discusses common legal issues that arise in enablement cases. Part III examines the recent U.S. Court of Appeals for the Federal Circuit case *In re Goodman*.¹¹ Part IV considers the scope of the enablement requirement in biotechnology cases after *In re Goodman*. This Article concludes that the enablement requirement is needed to prevent persons from obtaining patent protection in the field of biotechnology for compounds or processes that have not yet been discovered or fully understood.

I. PURPOSE AND APPLICATION OF ENABLEMENT REQUIREMENT

The first paragraph of 35 U.S.C. § 112 states that the patent specification must provide "a written description of the invention, and of the manner and process of making it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same," and must "set forth the best mode contemplated by the inventor of carrying out his invention."¹² The "written description" and "best mode" elements of section 112 have been interpreted as requirements that are separate from the enablement requirement.¹³

9. *Herdman, OTA Testimony/Statement, supra* note 7.

10. The number of patent applications in the field of biotechnology before the U.S. Patent and Trademark Office has increased from approximately 7,300 filed per year in 1987 to 13,300 filed per year in 1993. Eliot Marshall, *Biotech Leaders Give Patent Office a Litany of Complaints*, *SCIENCE*, Oct. 28, 1994, at 537.

11. 11 F.3d 1046 (Fed. Cir. 1993).

12. 35 U.S.C. § 112 (1988).

13. *See, e.g., Fiers v. Revel*, 984 F.2d 1164, 1169-71 (Fed. Cir. 1993). In *Fiers*, the U.S. Court of Appeals for the Federal Circuit held that an application for "DNA which codes for a human fibroblast interferon-beta polypeptide" did not comply with 35 U.S.C. § 112 on the grounds that the specification did not contain a "written description" of the subject matter of the claim. *Id.* at 1170-71. The court added that "[i]n light of our

It is imperative in patent law that the disclosure of the patent or patent application satisfies the enablement requirement of 35 U.S.C. § 112. Failure to satisfy the enablement requirement is grounds for the rejection of a patent application or for the invalidation of a patent.

A. *The Purpose of the Enablement Requirement*

The requirement of an adequate disclosure (also called an enabling disclosure) is based in part on the rule that an inventor is entitled to priority of invention, or the rights to the invention under the patent laws, from the date of invention.¹⁴ In order to satisfy the patent laws, the invention must be "reduced to practice."¹⁵ There are two types of reduction to practice recognized in patent law. First, there is *actual* reduction to practice, in which the inventor makes or produces the invention.¹⁶ The second type is *constructive* reduction to practice, which is obtained when a patent application for the invention is filed, provided that the application satisfies the

disposition of the written description requirement question, we do not address whether . . . [the] application satisfies the enablement requirement." *Id.* at 1171 n.12. See ROSENBERG, *supra* note 1, § 13.04[5], at 13-33. See also *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1560-64 (Fed. Cir. 1991) (reviewing case law on the "written description" requirement in order to clarify the law of the Federal Circuit in this area).

14. See 3 CHISUM, *supra* note 2, § 10.01, at 10-4.

15. *Id.* § 10.03[1], at 10-21 ("the first to reduce the subject matter in question to practice—either actually or constructively—is the first inventor"). There is an exception under 35 U.S.C. § 102(g), however, which provides in part:

In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

35 U.S.C. § 102(g) (1988).

Under the statute, "[t]he first to conceive the subject matter in question is the first inventor provided he exercises reasonable diligence in reducing to practice from a time just prior to when the first person to reduce to practice enters the field." 3 CHISUM, *supra* note 2, § 10.03[1], at 10-21.

16. See, e.g., *Hahn v. Wong*, 892 F.2d 1028, 1032 (Fed. Cir. 1989) ("To establish reduction to practice of a chemical composition, it is sufficient to prove 'that the inventor actually prepared the composition and knew it would work.'" (quoting *Mikus v. Wachtel* [II], 542 F.2d 1157, 1159 (C.C.P.A. 1976))).

enablement requirement of 35 U.S.C. § 112.¹⁷

Unless an inventor can prove invention at an earlier date, he or she must rely on the filing date of the patent application as the date for which priority of invention can be claimed. However, in order to obtain the benefit of a filing date, the disclosure as filed must be enabling as to the claims of the invention. Any reference cited against the application in an effort to invalidate the patent, such as a printed publication,¹⁸ an incident of public use or sale,¹⁹ another United States patent application,²⁰ or a foreign patent application,²¹ must be measured against the filing date.

There are several circumstances under which an application can be entitled to the filing date of a prior related application. However, each of these situations requires that the prior application be enabling for the subject matter of the new application. Thus, the enablement requirement ensures that the benefit of an earlier filing date is only obtained in cases where the invention was fully disclosed as of the earlier date.

For example, a continuation application is, in simple terms, "a second application for the same invention claimed in a prior application and filed before the original becomes abandoned."²² By

17. See, e.g., *Boyce v. Anderson*, 451 F.2d 818, 822 (9th Cir. 1971).

18. See 35 U.S.C. § 102(a), (b) (1988). An applicant is not entitled to a patent on an invention patented or described in a printed publication in the United States or in a foreign country (1) before the applicant's invention, or (2) more than one year prior to the applicant's filing date. 35 U.S.C. § 102(a), (b).

19. 35 U.S.C. § 102(b) (1988). An applicant is not entitled to a patent on an invention in public use or on sale in the United States more than one year prior to the filing date. 35 U.S.C. § 102(b).

20. 35 U.S.C. § 102(e) (1988). An applicant is not entitled to a patent on an invention described in a patent granted on an application for a patent filed by another person in the United States before the applicant's invention, or by an international patent application filed pursuant to 35 U.S.C. § 371 (1988). 35 U.S.C. § 102(e).

21. 35 U.S.C. § 102(d) (1988). An applicant is not entitled to a patent on an invention which was filed by the applicant, or the applicant's representative or assignee, on a foreign application more than one year prior to filing in the United States. 35 U.S.C. § 102(d).

22. 2 ROSENBERG, *supra* note 1, § 15.02[3][a], at 15-49 (citing MPEP, *supra* note 3, § 201.07). See also *Transco Prods. Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 555 (Fed. Cir. 1994) (discussing continuation applications).

definition the continuation application is for the same invention as that disclosed in the first or original application; therefore, a continuation application is entitled to the same filing date as the original application.²³

Another example is a divisional application, which is "one carved out of an earlier application, which disclosed and claimed more than one independent invention, the result being that the divisional application claims only one or more, but not all, of the independent inventions of the earlier application."²⁴ It is filed in response to a restriction requirement by the Examiner, in which the Examiner determines that two or more independent and distinct inventions are claimed in one application, and restricts the inventor to a single invention.²⁵ Under 35 U.S.C. § 121, "[i]f the other invention is made the subject of a divisional application which complies with the requirements of section 120 of this title it shall

23. See 35 U.S.C. § 120 (1988), which provides as follows:

An application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in an application previously filed in the United States, or as provided by section 363 of this title, which is filed by an inventor or inventors named in the previously filed application shall have the same effect, as to such invention, as though filed on the date of the prior application, if filed before the patenting or abandonment of or termination of proceedings on the first application or on an application similarly entitled to the benefit of the filing date of the first application and if it contains or is amended to contain a specific reference to the earlier filed application.

35 U.S.C. § 120.

In contrast to the continuation application, the continuation-in-part application "is an application filed during the lifetime of an earlier application by the same applicant, repeating some substantial portion or all of the earlier application *and adding matter not disclosed* in the earlier case." 2 ROSENBERG, *supra* note 1, § 15.02[3][b], at 15-54 (citing MPEP, *supra* note 3, § 201.08). The continuation-in-part application, or "CIP application," "enjoys the benefit of the filing date of the parent application from which it is derived only with respect to subject matter adequately disclosed in the earlier, supporting application." *Id.* However, the Patent Office will generally treat a CIP application as entitled to the filing date of its parent application unless, because of a cited reference or an interference proceeding, it becomes necessary to determine the actual date of disclosure of the particular subject matter sought to be patented. See MPEP, *supra* note 3, § 201.08.

24. *Transco*, 38 F.3d at 555. See also 2 ROSENBERG, *supra* note 1, § 15.02[3][c], at 15-56 (describing elements of divisional applications).

25. 35 U.S.C. § 121 (1988).

be entitled to the benefit of the filing date of the original application."²⁶

Similarly, for an applicant who claims a filing date of a prior foreign application under 35 U.S.C. § 119²⁷ to obtain priority, the application filed in the foreign country must be enabling under 35 U.S.C. § 112.²⁸

B. *Enablement in Patent Prosecution*

Patent prosecution is the process by which an applicant obtains patent protection.²⁹ The first step in obtaining patent protection is the filing of a patent application.³⁰ Thereafter, the application is assigned to an examining group based on its subject matter.³¹ The examination includes a search of the prior art relating to the subject matter of the invention.³²

The Examiner has the discretion to reject any of the claims of the application.³³ If the Examiner does so, the applicant may re-

26. *Id.* The relevant test of 35 U.S.C. § 120 is contained *supra*, note 23. See also 37 C.F.R. §§ 1.141, 1.142 (1993). The restriction requirement is the subject of an entire chapter in the MPEP, *supra* note 3, ch. 800.

27. 35 U.S.C. § 119 (1988) provides in part:

An application for patent for an invention filed in this country by any person who has, or whose legal representatives or assigns have, previously regularly filed an application for a patent for the same invention in a foreign country which affords similar privileges in the case of applications filed in the United States or to citizens of the United States, shall have the same effect as the same application would have if filed in this country on the date on which the application for patent for the same invention was first filed in such foreign country, if the application in this country is filed within twelve months from the earliest date on which such foreign application was filed; but no patent shall be granted on any application for patent for an invention which had been patented or described in a printed publication in any country more than one year before the date of the actual filing of the application in this country, or which had been in public use or on sale in this country more than one year prior to such filing.

35 U.S.C. § 119.

28. See *Freerksen v. Gass*, 21 U.S.P.Q.2d 2007, 2008 (Bd. Pat. App. & Int. 1991).

29. See generally 3 CHISUM, *supra* note 2, ch. 11.

30. *Id.* § 11.02, at 11-6.

31. *Id.* § 11.03, at 11-49 to -55. See also 37 C.F.R. § 1.104 (1993).

32. See 37 C.F.R. § 1.104 (1993).

33. See 37 C.F.R. § 1.106 (1993).

spond to the Examiner's action by amending or dropping claims, amending the specification, or presenting arguments in response to the Examiner's decision.³⁴ The Examiner will then allow the claims of the invention, thereby letting the applicant obtain a patent, or "the process of action and response continues until the Examiner indicates that the rejection is final."³⁵ After a final action has been issued by an Examiner, the amendments that the applicant can make are limited.³⁶ An applicant may appeal a final rejection to the Board of Patent Appeals and Interferences.³⁷

The enablement requirement arises in the first step of patent prosecution. To obtain a filing date for a patent application, the inventor must file with the U.S. Patent and Trademark Office a specification which satisfies the requirements of 37 C.F.R. § 1.71,³⁸ contains at least one patent claim, and contains any drawings which are necessary to understand the invention. The filing must be made in the name of the inventor or inventors.³⁹

Once the specification containing its disclosure has been filed and the filing date has been obtained, new matter may not be introduced into the application. This requirement is clearly set forth in 37 C.F.R. § 1.118(a), which provides:

No amendment shall introduce new matter into the disclosure of an application after the filing date of the application (§ 1.53(b)). All amendments to the specification, including the claims, and the drawings filed after the filing date of the application must conform to at least one of them as it was at the time of the filing of the application. Matter not found in either, involving a departure from or an addition

34. 3 CHISUM, *supra* note 2, § 11.03[2], at 11-55 to -58. *See also* 37 C.F.R. § 1.111 (1993).

35. *Id.* § 11.03[2], at 11-68.

36. *See id.* § 11.03[2][c], at 11-68 to -69. *See* 37 C.F.R. § 1.116 (1993). Amendments after final rejection "may be admitted upon a showing of good and sufficient reasons why they are necessary and were not earlier presented." *Id.* § 1.116(b). However, amendments are discretionary, rather than as of right, in appealed cases. *Id.* § 1.116(c).

37. *See* 37 C.F.R. § 1.191 (1993).

38. *See* 35 U.S.C. § 112 (1988).

39. *See* 37 C.F.R. § 1.53(b) (1993).

to the original disclosure, cannot be added to the application after its filing date even though supported by an oath or declaration in accordance with § 1.63 or § 1.67 filed after the filing date of the application.⁴⁰

While the specification section is intended to set forth the full disclosure of the invention, the Examiner must view the entire patent application as constituting the full disclosure. Thus, the Examiner must also consider the drawings, abstracts, and claims as originally filed in order to determine the extent of the disclosure.⁴¹

An Examiner may reject a claim based on the insufficiency of the disclosure in the specification. There are primarily three types of circumstances that would warrant a rejection based on the lack of disclosure: (1) the claim is not supported by the disclosure in the specification or contains statements that conflict with statements made in the specification;⁴² (2) an amended claim introduces “new matter” that was not part of the original disclosure;⁴³ or (3) the claim seeks coverage that is unduly broad in light of the disclosure or specification.⁴⁴

40. See 37 C.F.R. § 1.118(a) (1993). The regulation carries out the rule of 35 U.S.C. § 132, which provides in pertinent part that “[n]o amendment shall introduce new matter into the disclosure of the invention.” 37 C.F.R. § 1.118(a).

41. See MPEP, *supra* note 3, § 608.04. “In establishing a disclosure applicant may rely not only on the specification and drawing as filed but also on the original claims if their content justifies it.” *Id.*

42. See MPEP, *supra* note 3, § 706.03(n). Section 706.03(n) notes further that: “It must be kept in mind that an original claim is part of the disclosure and might adequately set forth subject matter which is completely absent from the specification. Applicant is required in such an instance to add the subject matter to the specification.” The MPEP goes on to specifically point out that “[i]n chemical cases, a claim may be so broad as to not be supported by the disclosure, in which case it is rejected as unwarranted by the disclosure.” *Id.*

43. See *id.* § 706.03(o). Section 706.03(o) specifically provides that “[n]ew matter includes not only the addition of wholly unsupported subject matter, but also, adding specific percentages or compounds after a broader original disclosure, or even the omission of a step from a method.” *Id.*

44. See *id.* § 706.03(z). Section 706.03(z) provides that in certain arts, “where results are predictable, broad claims may properly be supported by the disclosure of a single species. . . .” (citation omitted). The section adds that in certain other arts where results are not predictable, the disclosure of a single species will not provide support for more generic claims. Section 706.03(z) specifically notes that “in arts such as chemistry it is

C. Enablement in Patent Litigation

Patents have been described as “an invitation to a lawsuit.”⁴⁵ Lawsuits alleging patent infringement are within the exclusive jurisdiction of the federal courts.⁴⁶ In addition, there are also a number of cases in which an alleged patent infringer sues in federal court for a declaratory judgment that the patent at issue is invalid.⁴⁷ These cases are brought under the federal declaratory judgment act and are therefore subject to federal jurisdiction.⁴⁸

The federal jurisdiction over patents does not extend to cases “which do not directly call into question the scope or integrity of a United States patent.”⁴⁹ Such lawsuits, which can involve patent license agreements, employment contracts related to patents, and the testamentary disposition of patent rights, are usually subject to state jurisdiction.⁵⁰

In patent litigation, the issue of whether there is an adequate disclosure arises when a party seeks to invalidate claims of an issued patent on the basis that the patent specification does not support the claims. Typically, the patent invalidity argument is raised as a defense in a lawsuit alleging patent infringement.⁵¹

not obvious from the disclosure of one species, what other species will work.” *Id.* (citing *In re Dreshfield*, C.D. 351, 518 O.G. 255 (1940)). A rejection on the grounds that a claim is “unduly broad” is a common rejection in biotechnology cases. See SaraLynn Mandel, *Biotechnology Patent Applications*, in *HOW TO WRITE A PATENT APPLICATION* § 14.5.1, at 14-26 to -28 (Jeffrey G. Sheldon ed., 1993).

45. ROSENBERG, *supra* note 1, § 17.00, at 17-3.

46. 35 U.S.C. § 281 (1988).

47. See ROSENBERG, *supra* note 1, § 17.03, at 17-38.

48. See *id.*; 28 U.S.C. § 2201 (1988 & Supp. V 1993).

49. ROSENBERG, *supra* note 1, § 17.00, at 17-4.

50. *Id.*

51. See, e.g., *New England Med. Ctr. Hosps., Inc. v. PeproTech, Inc.*, 29 U.S.P.Q.2d (BNA) 1852 (D.N.J. 1993). The statutory basis for raising this defense is 35 U.S.C. § 282, which provides in pertinent part:

The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:

....

(2) Invalidity of the patent or any claim in suit on any ground specified in part II of this title as a condition for patentability

35 U.S.C. § 282 (1988).

However, in asserting this argument, a party must overcome the presumption of validity that attaches to issued patents.⁵²

II. COMMON LEGAL ISSUES IN ENABLEMENT CASES

The issue of whether a patent or patent application satisfies the enablement requirement is often raised in the courts. Whether the question arises on appeal to the Board of Patent Appeals and Interferences (the "Board")⁵³ or to the United States Court of Appeals for the Federal Circuit ("CAFC"),⁵⁴ or as a defense to a patent infringement lawsuit,⁵⁵ there are several issues that are common to these cases. These include the following:

- (1) the extent of the knowledge of a "person skilled in the art;"
- (2) whether there is sufficient disclosure of how the invention is made;
- (3) whether there is sufficient disclosure of how the invention is used;
- (4) the relevant date for determining whether the disclosure is enabling; and
- (5) when the disclosure is not enabling because as written it requires "undue experimentation" in order to make or use the invention.⁵⁶

52. See 35 U.S.C. § 282 (1988).

53. Once an Examiner has finally rejected a claim or claims from an application, the applicant may appeal to the Board of Patent Appeals and Interferences (the "Board"). See 35 U.S.C. § 134 (1988). In its decision, the Board may affirm or reverse the decision of the Examiner in whole or in part, or it may remand to the Examiner for further consideration. See 37 C.F.R. § 1.196 (1993). See generally 37 C.F.R. §§ 1.191-1.198 (1993) for the regulations governing practice before the Board.

54. The Court of Appeals for the Federal Circuit hears appeals of decisions by the Board. See 37 C.F.R. § 1.301 (1993).

55. See 2 CHISUM, *supra* note 2, § 7.03[8][b].

56. In an effort to present the legal issues of enablement in an organized manner, this article has identified the key issues that arise in enablement questions and will discuss each separately. As a general rule, however, cases on enablement simultaneously address more than one of these issues.

A. *Person Skilled in the Art*

Under 35 U.S.C. § 112, the determination of whether a disclosure in a patent or patent application is enabling must be made from the point of view of a person “skilled in the art.”⁵⁷ The level of knowledge of a person skilled in the art to which the invention or subject matter pertains is a fact-based question, and is necessarily dependent on the particular art. There are several general rules that can be applied to the issue regardless of the art, and that are therefore relevant to biotechnology cases.

Generally, a “person skilled in the art” under § 112 is not presumed to know all prior art in the field.⁵⁸ However, in preparing a specification that satisfies the enablement requirement, it is common practice to incorporate by reference certain prior art material, such as patents or scientific texts,⁵⁹ because this material is presumed to be known by a person skilled in the art. Any such references cited by the applicant should be readily accessible to the public.

57. It is important to note that the knowledge of a person skilled in the art is also relevant to the determination that a patent or patent application is not obvious. 35 U.S.C. § 103 (1988). Essentially, § 103 provides that one cannot obtain a patent on subject matter that is obvious to a person of ordinary skill in the art. However, the language of the § 112, first paragraph, enablement requirement is different from the language of § 103, the “non-obviousness” statute, which requires courts to inquire into the state of knowledge of “a person having *ordinary* skill in the art to which [the] subject matter pertains.” 35 U.S.C. § 103 (emphasis added). As explained by Professor Chisum, there is a distinction between these two fictional persons:

Section 103 directs the person with ordinary skill in the art to consider the differences between the subject sought to be patented and the prior art—meaning all the prior art. The policy behind this conclusive presumption is to discourage wasteful or duplicative inventive activity by imposing an absolute duty to research the entire pertinent prior art for a solution to a problem at hand. Section 112 contains no reference to the prior art as such. The policy behind § 112 is to make a patented invention fully available to the public without any requirement of such arduous research.

2 CHISUM, *supra* note 2, § 7.03[2], at 7-27.

58. See 2 CHISUM, *supra* note 2, § 7.03[2][b], at 7-27. This is partly based on the difference in policy behind the enablement requirement and the nonobviousness statute.

59. See MPEP, *supra* note 3, § 608.01(p), cmt. B.

In the case *In re Howarth*,⁶⁰ the applicant appealed from the Examiner's rejection of all the claims in the application because of lack of enablement. The Examiner asserted that the application, which was for various derivatives of clavulanic acid, did not disclose the method of making the acid.⁶¹

On appeal before the Court of Customs and Patent Appeals, the predecessor to the Court of Appeals for the Federal Circuit,⁶² the applicant asserted that the manner of making clavulanic acid was disclosed in published patent specifications in Rhodesia, Panama and Luxembourg.⁶³ The applicant argued that those skilled in the art are presumed to know all prior art in United States and foreign patents.⁶⁴ The court rejected the applicant's argument, and affirmed the rejection of the application's claims.⁶⁵ It reasoned that "[t]o supplement a specification which on its face appears deficient under § 112, evidence must establish that the information which must be read into the specification to make it complete is known to those having ordinary skill in the art."⁶⁶ The court went on to conclude:

[N]othing in appellant's U.S. specification narrows the search to Rhodesia, Panama, or Luxembourg, and even had that much help been provided, no research aid has been shown to exist to lead one to particular documents. Appellant's personal knowledge of the existence of these commonly owned applications, and the information contained therein, cannot be imputed to others. Therefore, we do not see any basis for concluding that the source of information for the production of clavulanic acid is so likely to be within the knowledge of persons skilled in the art that appellant

60. 654 F.2d 103 (C.C.P.A. 1981).

61. See *infra* part II.B. for a more detailed discussion of the case law involving disclosure of the manner of making the invention.

62. See 3 CHISUM, *supra* note 2, § 11.06 [3][b], at 11-177 to -190.

63. *Howarth*, 654 F.2d at 104. The particular publications that applicant referred to in the argument were not referenced in the application. *Id.*

64. *Id.* at 105.

65. *Id.* at 106-07.

66. *Id.* at 106.

need say nothing about this essential part of practicing his invention in his application.⁶⁷

It is important to note that the relevant inquiry is to the level of knowledge of a person of ordinary skill in the art, and not to that of an expert. A Federal Circuit case illustrating this rule is *In re Buchner*.⁶⁸ In *Buchner*, the CAFC affirmed the Board's rejection of an application on the grounds that the disclosure was not enabling, and discounted the applicant's affidavit of an expert who swore the application was enabling.⁶⁹ The CAFC commented that enablement "requires that, unless the information is well known in the art, the application itself must contain this information; it is not sufficient to provide it only through an expert's declaration."⁷⁰

B. Manner of Making the Invention

Part of the enablement requirement of § 112 is a description of the manner of "making" the invention.⁷¹ While the inventor need not describe the particular circumstances under which the invention was first made, the inventor must teach a person of skill in the art how to make or obtain the invention.⁷² In cases involving biotech-

67. *Id.* at 107.

68. 929 F.2d 660 (Fed. Cir. 1991).

69. *Id.* at 660-61.

70. *Id.* at 661. The CAFC also commented about the expert's affidavit: "He did not provide adequate support for his conclusion. What he did describe was how *he* would construct the [structure at issue], but he did not demonstrate that such construction was well-known to those of ordinary skill in the art." *Id.*

71. See 35 U.S.C. § 112 (1988). See *supra* note 3 and accompanying text for the language of § 112.

72. In *In re Breslow*, 616 F.2d 516, 519 (C.C.P.A. 1980), the Court of Customs and Patent Appeals commented on the applicant's duty to disclose the manner of making the invention, a chemical compound:

[W]e interpret the enablement clause of the first paragraph of 35 U.S.C. [§] 112 as requiring that the claimed invention, i.e. the claimed compounds *per se* which constitute the invention at issue, must be taught in a manner such that the artisan will be in possession of the claimed invention. Appellant, however, does not disclose how this may be achieved nor, in fact, does he even assert that such may necessarily be possible. He only postulates that using very sophisticated techniques someone may one day possibly isolate and analyze the instant compounds. It is urged by him that investigations of this nature are unneces-

nology inventions, the manner of making the invention is complicated by the fact that the process may require the use of a particular microorganism as a starting material.⁷³ In such a case, enablement is met when a sample of the microorganism is deposited with an independent cell depository. The deposit may be made *after* the filing date of the application, provided that the material is deposited in a suitable depository before the patent is granted.⁷⁴ Generally, the depository must assure "permanence of the deposit and ready accessibility thereto by the public if a patent is granted."⁷⁵ According to the applicable regulations: the depository is entitled to review the material; the depository must be referred to in the specification by name and address; the deposit number must be provided; and the applicant must aver under oath that a sample of the material will be maintained in the depository.⁷⁶

sary for the purpose of this invention. We disagree. The invention at bar, as defined by the appealed claims, is the compounds, *per se*, and as long as appellant has failed to give directions to one skilled in the art which would put him into possession of the invention so claimed, he has not satisfied the enablement clause of 35 U.S.C. § 112.

Id.

73. See 2 CHISUM, *supra* note 2, § 7.03[5][b], at 7-60. See also Kiyoshi Nakayama, *Sources of Industrial Microorganisms*, in 1 BIOTECHNOLOGY 357 (1981).

74. See *In re Lundak*, 773 F.2d 1216, 1220-22 (Fed. Cir. 1985). In *Lundak*, the Court of Appeals for the Federal Circuit held that "35 U.S.C. § 112, first paragraph, does not require the transfer of a sample of the invention to an independent depository prior to the filing date of the patent application." *Id.* at 1222. The court reasoned that maintaining a sample of the material during the application process so that the PTO could have access, and filing a sample with a depository prior to the issuance of the patent, complies with the statutory requirements of 35 U.S.C. §§ 112 and 114. *Id.* 35 U.S.C. § 114 provides that "[t]he Commissioner may require the applicant to furnish a model of convenient size to exhibit advantageously the several parts of his invention. When the invention is a composition of matter, the Commissioner may require the applicant to furnish specimens or ingredients for the purpose of inspection or experiment." 35 U.S.C. § 114 (1988).

75. MPEP, *supra* note 3, § 608.01(p)C.

76. See *id.* The regulations governing the deposit of biological materials are found at 37 C.F.R. §§ 1.801 to 1.825 (1993). See also Volker Vossius, *Patent Protection for Biological Inventions*, in 1 BIOTECHNOLOGY 446-49 (1981) (discussing depositing of microorganisms).

The deposit requirement was explored in *Ex parte Hildebrand*,⁷⁷ a case in which the Board addressed the language of section 608.01(p)C of the MPEP, which requires that "all restrictions on the availability to the public of the cultures so deposited will be irrevocably removed upon the granting of the patent."⁷⁸ In *Hildebrand*, the applicant deposited a sample of the particular strains of a microorganism necessary to produce the invention with a depository under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purpose of Patent Procedure.⁷⁹ The Treaty provides for the deposit of a microorganism with a depository that will hold its existence in secret.⁸⁰ The CAFC affirmed the Examiner's rejection of the claims under 35 U.S.C. § 112, reasoning that the deposit under the Budapest Treaty did not comply with MPEP section 608.01(p)C.⁸¹

On the other hand, in *In re Wands*,⁸² the enablement requirement was satisfied in part by the deposit of a microorganism sample. *Wands* involved an appeal from a decision of the Board of Patent Appeals and Interferences sustaining a rejection of all the claims in an application for an immunoassay method for detecting certain hepatitis antigens.⁸³ For the purposes of complying with § 112, the applicant had deposited a sample of the cell line that was part of the invention with a recognized cell depository.⁸⁴

On appeal, the CAFC addressed the question of whether the Board erred, as a matter of law, by sustaining the Examiner's rejection for lack of enablement under § 112.⁸⁵ The CAFC held that the

77. 15 U.S.P.Q.2d (BNA) 1662 (Bd. Pat. App. & Int. 1990).

78. *Id.* at 1663 (quoting MPEP, *supra* note 3, § 608.01(p)C).

79. *See id.* at 1663 n.2; *see also* Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, Apr. 28, 1977, 32 U.S.T. 1241 [hereinafter Treaty].

80. Rule 9.2 of the Treaty provided in part that a depository "shall not give any information to anyone concerning any microorganism deposited with it under the treaty except to an authority, natural person or legal entity which is entitled to obtain a sample . . ." 15 U.S.P.Q.2d (BNA) at 1664 (quoting Treaty, *supra* note 79).

81. *Id.*

82. 858 F.2d 731 (Fed. Cir. 1988).

83. *Id.* at 733.

84. *See id.* at 734.

85. *Id.* at 733. Decisions of the Board on enablement are reviewed as a question of

written specification was, in fact, enabling.⁸⁶ However, in *dicta* the court commented at length on the method of obtaining enablement by the deposit of a sample.⁸⁷ The CAFC noted that “[a] deposit has been held necessary for enablement where the starting materials (i.e., the living cells used to practice the invention, or cells from which the required cells can be produced) are not readily available to the public.”⁸⁸

law by the CAFC. See *id.* at 735 (citing *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1268 (Fed. Cir. 1986), *cert. denied*, 479 U.S. 1030 (1987)).

86. *Id.* at 740.

87. *Id.* at 735-36.

88. *Id.* at 735 (citing *In re Jackson*, 217 U.S.P.Q. 804, 807-08 (Bd. Pat. App. & Int. 1982)). A more complete text of the CAFC's statements are as follows:

Where an invention depends on the use of living materials such as microorganisms or cultured cells, it may be impossible to enable the public to make the invention (*i.e.*, to obtain these living materials) solely by means of a written disclosure. One means that has been developed for complying with the enablement requirement is to deposit the living materials in cell depositories which will distribute samples to the public who wish to practice the invention after the patent issues. Administrative guidelines and judicial decisions have clarified the conditions under which a deposit of organisms can satisfy the requirements of section 112. A deposit has been held necessary for enablement where the starting materials (*i.e.*, the living cells used to practice the invention, or cells from which the required cells can be produced) are not readily available to the public. Even when starting materials are available, a deposit has been necessary where it would require undue experimentation to make the cells of the invention from the starting materials.

Id. (footnotes omitted).

With regard to patent protection of biotechnological inventions throughout the world, it has been stated:

It is not sufficient to describe a microbiological invention in terms of words, drawings and formulae if the invention makes use of a microorganism or virus which cannot readily be located, isolated or produced again. Where inventions of this type are concerned, disclosure at the filing date can only be considered adequate if: (1) the microorganism or virus has been deposited with a suitable depository for an adequate period of time; (2) the depository has been irrevocably authorized to issue propagable samples to the patent granting authorities at any time and to third parties subsequent to initial publication; (3) after initial publication[,] the depositor no longer has any power of disposition over the deposited microorganism or virus; (4) the depository has demonstrated its willingness to proceed in accordance with the declaration of release; (5) third parties can, on reasonable conditions, obtain propagable samples of the deposited microorganisms or viruses.

Vossius, *supra* note 76, at 446.

C. Manner of Using the Invention

The enablement requirement of § 112, first paragraph, also requires that the patent or patent application contain a description of the manner of using the invention.⁸⁹ An illustrative case in the field of chemistry is *In re Gardner*.⁹⁰ In *Gardner*, the applicant appealed from a decision of the Patent Office Board of Appeals, the predecessor of the Board of Patent Appeals and Interferences, that rejected claims 1-5 of the application, in part, on the grounds that the application was not enabling as to the use of the invention.⁹¹ The invention at issue was the purported discovery of the antidepressant activity in 2-aminomethyl-1, 3-benzodioxole compounds.⁹²

On appeal, the Court of Customs and Patent Appeals ("CCPA") affirmed the rejection of the claims by the Board of Patent Appeals. The court reviewed the specification and concluded that it was inadequate because it did not disclose how to use the drugs.⁹³ The court noted that the specification gave a range of daily dosages from 10 mg. to 450 mg. for the proper use of the drug. The application, however, did not disclose "at what point in the process of administering to a patient, say a 10 mg. capsule, an anti-depressant effect may be expected in the course of proceeding at some unspecified intervals toward the possible 45th capsule for the day."⁹⁴ The court also noted that the specification failed to disclose a host on whom the compound was to be used, although it stated that this alone did not render the claims indefinite.⁹⁵

89. See 35 U.S.C. § 112 (1988). See *supra* note 3 and accompanying text for the language of § 112.

90. 427 F.2d 786 (C.C.P.A. 1970).

91. *Id.* at 787.

92. *Id.* at 786.

93. *Id.* at 787.

94. *Id.* at 789.

95. See *id.* at 787-88. The MPEP has "Guidelines for Considering Disclosures of Utility in Drug Cases." See MPEP, *supra* note 3, § 608.01(p), cmt. A. The guidelines state that "[i]t is not necessary to specify the dosage or method of use if it is obvious to one skilled in the art that such information could be obtained without undue experimentation." *Id.*

More recently, in *In re Ziegler*,⁹⁶ the CAFC ruled that the “how to use” prong of 35 U.S.C. § 112, first paragraph, incorporates the statutory requirement of utility provided in 35 U.S.C. § 101,⁹⁷ and that if an application fails to satisfy the standards of § 101 then as a matter of law it is not enabling under § 112.⁹⁸ The Court further stated that “[i]t is axiomatic that an invention cannot be considered ‘useful’ in the sense that a patent can be granted on it, unless substantial or practical utility for the invention has been discovered and disclosed where such utility would not be obvious.”⁹⁹

A recent discussion of this principle in the field of biotechnology can be found in *Ex parte Aggarwal*.¹⁰⁰ In *Aggarwal*, the Board affirmed the Examiner’s rejection of certain claims for the treatment of tumors in animals by use of a cytotoxic protein known as lymphotoxin.¹⁰¹ An illustrative claim in that case was claim 57, which reads as follows:

A method for the treatment of tumors comprising administering to an animal in a physiologically innocuous dosage form a therapeutically effective amount of a cytotoxic lymphotoxin as a product of expression in a recombinant host cell selected from the group of cells from multicellular organisms, eukaryotic microbes and prokaryotes.¹⁰²

The Board found that the specification contained “many broad statements regarding utility,” but that “the actual exemplification of

96. 992 F.2d 1197 (Fed. Cir. 1993).

97. *Id.* at 1200. Section 101 provides: “Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.” 35 U.S.C. § 101 (1988).

98. *See Ziegler*, 992 F.2d at 1201.

99. *Id.* (quoting *Cross v. Iizuka*, 753 F.2d 1040, 1044 (Fed. Cir. 1985)). It should be noted that rejections for lack of utility under 35 U.S.C. § 101 “are fairly common for biotechnology inventions.” Mandel, *supra* note 44, § 14.3.2.2., at 14-9. One reason for the number of § 101 rejections is the claiming of compounds, such as pharmaceuticals, for the treatment of humans where human testing has not yet occurred. *See id.*

100. 23 U.S.P.Q.2d (BNA) 1334 (Bd. Pat. App. & Int. 1992).

101. *Id.* at 1339.

102. *Id.* at 1335.

utility is sparse.”¹⁰³ The Board noted that examples 4 and 5 of the specification covered a single use, namely activity in tumor necrosis assay with mice as the host.¹⁰⁴ The Board then reviewed the prior art, and concluded that it raised doubts about the practical utility of lymphotoxin when used against tumors in humans.¹⁰⁵ In affirming the rejection, the Board noted that “[t]he [E]xaminer had more than adequate reason to doubt the objective truth of the broad statement of utility set forth in appellants’ specification.”¹⁰⁶

Rejection of an application for a biotechnology invention either under 35 U.S.C. § 112, first paragraph, on the grounds of lack of utility, or under 35 U.S.C. § 101, on the grounds of the lack of testing of a compound in humans, is a source of much concern in the biotechnology industry.¹⁰⁷ In response to these concerns it appears that the Patent and Trademark Office will ease its practice of rejecting biotechnology patents for lack of utility.¹⁰⁸

D. *Relevant Date for Determining Enablement*

Courts have consistently held that enablement must be considered in light of the state of the art as it exists on the date of filing.¹⁰⁹ For example, in the biotechnology field, the CAFC in *In re Wright*¹¹⁰ heard an appeal from a decision of the Board which rejected certain claims of an application directed to producing live,

103. *Id.* at 1337-38.

104. *Id.* at 1338.

105. *See id.*

106. *Id.* at 1339. A more complete discussion of recent cases in this area can be found in Antoinette F. Kanski, *The Utility Rejection in Biotechnology and Pharmaceutical Prosecution Practice*, 76 J. PAT. & TRADEMARK OFF. SOC’Y 821 (1994).

107. Marshall, *supra* note 10, at 537; *Biotech Industry Blasts PTO at San Diego Hearing*, 48 PAT., TRADEMARK & COPYRIGHT J. (BNA) 677, 678 (Oct. 20, 1994).

108. Robert Pear, *U.S. Easing Rules on Biotech Patents*, N.Y. TIMES, Dec. 22, 1994, at B11.

109. *See, e.g., In re Glass*, 492 F.2d 1228, 1232 (C.C.P.A. 1974) (“It is an applicant’s obligation to supply enabling disclosure without reliance on what others may publish after he has filed. . . . If he cannot supply enabling information, he is not yet in a position to file.”). *See also* *United States Steel Corp. v. Phillips Petroleum Co.*, 865 F.2d 1247, 1251 (Fed. Cir. 1989) (reaffirming this principle as enunciated in *Glass*).

110. 999 F.2d 1557 (Fed. Cir. 1993).

non-pathogenic vaccines against pathogenic RNA viruses.¹¹¹ The claims were rejected on the grounds that the disclosure was not enabling “because one of ordinary skill in the art would have had to engage in undue experimentation in February of 1983 (the effective filing date of Wright’s application) to practice the subject matter of these claims.”¹¹²

The CAFC affirmed the Board’s decision, noting that the claims at issue covered “*any and all* live, non-pathogenic vaccines, and processes for making such vaccines, which elicit immunoprotective activity in *any* animal toward *any* RNA virus.”¹¹³ The court further noted that the specification contained only a single working example of the invention.¹¹⁴ Finally, referring to certain prior art articles cited by Wright in the specification, the CAFC concluded:

Wright fails to point out with any particularity in this declaration, or in his arguments to this court, how the listed documents evidence that a skilled artisan in February of 1983 would have been able to carry out, without undue experimentation, the identification, isolation, cloning, recombination, and efficacy testing steps required to practice the full scope of the appealed claims.¹¹⁵

E. *Standard of Undue Experimentation*

Examiners or courts often find that the specification of a patent or patent application sets forth the basics of the invention to a person of ordinary skill in the art, but nevertheless requires a certain amount of experimentation for the invention to be practiced.¹¹⁶

111. *Id.* at 1559.

112. *Id.* at 1560. The standard of “undue experimentation” is discussed *infra* part II.E.

113. *Id.* at 1562.

114. *Id.* at 1559.

115. *Id.* at 1563. *See also* Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558 (Fed. Cir. 1990) (vacating summary judgment order because the record before the court did not establish the state of the art at the time that the application for the patent was filed).

116. *See, e.g.*, United States v. Teletronics, Inc., 857 F.2d 778, 785-86 (Fed. Cir. 1988); Lever Bros. v. Procter & Gamble, 139 F.2d 633, 638-39 (4th Cir. 1943).

Where a certain amount of experimentation is required in order to practice an invention, resolution of the issue of whether the disclosure is enabling typically turns on the question of when the amount of experimentation required by the disclosure becomes "undue" or "unreasonable."¹¹⁷

The rationale for holding that a patent specification which requires some experimentation is still enabling under the statute can be found in *In re Angstadt*.¹¹⁸ In *Angstadt*, the patent application at issue covered a method of using a catalyst to perform a desired chemical reaction. The method of the invention required the use of an organometallic complex having a certain formula as the catalyst.¹¹⁹ The formula, however, had variables so that a number of chemical compounds could have fallen within its terms.¹²⁰

The specification of the application did not list all of the possible compounds, and the application was rejected by the Examiner under § 112.¹²¹ The Examiner's decision was affirmed by the Board.¹²² The Court of Customs and Patent Appeals, however, reversed.¹²³ The court acknowledged that requiring a disclosure of every catalyst that would work or would not work could force applicants to disclose thousands of examples.¹²⁴ According to the court:

[S]uch a requirement would force an inventor seeking adequate patent protection to carry out a prohibitive number of actual experiments. This would tend to discourage inventors from filing patent applications in an unpredictable area

117. See ROSENBERG, *supra* note 1, § 13.04[5][b], at 13-49 to -50. The "undue experimentation" cases discussed in this section comprise what is perhaps the most important series of cases concerning enablement of biotechnological inventions. *In re Goodman* also addresses the level of experimentation necessary for a biotechnology patent application to be considered enabling.

118. 537 F.2d 498 (C.C.P.A. 1976).

119. See *id.* at 499-500.

120. See *id.* at 499. The catalyst of the invention had the following formula: $\text{MX}_n(\text{HAPA})_m$. HAPA is one of several possible hexaalkylphosphoramides, MX is a metal salt, m is an integer of from 1 to 8, and n is an integer of from 1 to 4. *Id.*

121. See *id.* at 500.

122. See *id.* at 500-01.

123. See *id.* at 502.

124. See *id.*

since the patent claims would have to be limited to those embodiments which are expressly disclosed.¹²⁵

The court concluded, however, that since the applicants had identified the catalysts and had detailed how to make and use them, "the experimentation required to determine which catalysts will produce hydroperoxides would not be undue and certainly would not 'require ingenuity beyond that to be expected of one of ordinary skill in the art.'"¹²⁶

The Board articulated the standard for determining what constitutes "undue" experimentation in *Ex parte Forman*.¹²⁷ In *Forman*, the applicant appealed from the Examiner's decision rejecting claims 1-33 of an application for an oral vaccine consisting of genetically engineered hybrid bacteria on the grounds of an insufficient disclosure.¹²⁸ The Examiner found, in part, that the disclosure required undue experimentation on the part of a person skilled in the art to practice the invention.¹²⁹

The Board noted that to determine if the amount of experimentation is "undue," one must apply a reasonableness standard, keeping in mind the nature of the invention and the state of the art.¹³⁰ The Board noted that in some circumstances, a "considerable amount of experimentation" is permitted if it is routine or if the disclosure "provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed."¹³¹ The Board listed the following factors to be considered when determining if experimentation is "undue":

- (1) the quantity of experimentation necessary;
- (2) the amount of direction or guidance presented;

125. *Id.* at 502-03.

126. *Id.* at 503 (quoting *Fields v. Conover*, 443 F.2d 1386, 1390-91 (C.C.P.A. 1971)).

127. 230 U.S.P.Q. (BNA) 546 (Bd. Pat. App. & Int. 1986).

128. *Id.* at 546-47.

129. *See id.* at 547.

130. *Id.* (citing *Ansul Co. v. Uniroyal, Inc.*, 448 F.2d 872 (2d Cir. 1971), *cert. denied*, 404 U.S. 1018 (1972)).

131. *Id.*

- (3) the presence or absence of working samples;
- (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.¹³²

The Board's factors were expressly adopted by the Court of Appeals for the Federal Circuit in the case *In re Wands*.¹³³

Along the same lines, in *Amgen, Inc. v. Chugai Pharmaceutical Co.*,¹³⁴ the CAFC decided an appeal from a decision of the Massachusetts District Court that ruled, in part, that claim 7 and certain other claims dependent from claim 7 of the plaintiff's U.S. Patent No. 4,703,008 ("the '008 patent") were not enabling.¹³⁵ The '008 patent covered "DNA Sequences Encoding Erythropoietin" ("EPO").¹³⁶ Claim 7 of the '008 patent provided:

A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that of erythropoietin to allow possession of the biological property of causing bone marrow cells to increase production of reticulocytes and red blood cells, and to increase hemoglo-

132. *Id.*

133. 858 F.2d 731, 737 (Fed. Cir. 1988). The *Wands* court further commented on the determination of what constitutes undue experimentation: "The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed." *Id.* (quoting *In re Jackson*, 217 U.S.P.Q. 804, 807 (Bd. Pat. App. & Int. 1982)). The *Wands* court explained that although the term "undue experimentation" does not appear in the enablement statute, "it is well established that enablement requires that the specification teach those in the art to make and use the invention *without undue experimentation*." *Id.* (emphasis added). The court explained that whether the amount of experimentation required is undue "is a conclusion reached by weighing many factual considerations." The court then restated the factors listed by the Board in *Ex parte Forman*. *Id.*

134. 927 F.2d 1200 (Fed. Cir.), cert. denied sub nom. Genetics Inst., Inc. v. Amgen, Inc., 112 S. Ct. 169 (1991).

135. *Id.* at 1205.

136. *Id.* at 1203.

bin synthesis or iron uptake.¹³⁷

The CAFC noted that claim 7 was a generic claim that covered “all possible DNA sequences that will encode any polypeptide having an amino acid sequence ‘sufficiently duplicative’ of EPO to possess the property of increasing production of red blood cells.”¹³⁸ The CAFC, in considering whether the scope of the specification of the ‘008 patent was commensurate with the scope of the claim, quoted sections from the ‘008 specification in which the patentees effectively claimed enablement for more than a million different DNA sequences, all analogs of EPO.¹³⁹

The CAFC, in affirming the district court’s finding that there was no enablement of claim 7, stated that for patents or patent applications claiming DNA sequences, enablement “means disclosing how to make and use enough sequences to justify grant of the claims sought.”¹⁴⁰ The court further noted that the specification contained little enabling disclosure of the particular analogs and how to make them.¹⁴¹ Thus, Amgen’s disclosure was ultimately found not to be enabling for claims drawn to all EPO gene analogs because Amgen had only explained how to make and use a few of

137. *Id.* at 1204.

138. *Id.* at 1212.

139. *See id.* at 1213.

140. *Id.*

141. *Id.* The section quoted from the specification was the following:

[O]ne may readily design and manufacture genes coding for microbial expression of polypeptides having primary conformations which differ from that herein specified for mature EPO in terms of the identity or location of one or more residues (*e.g.*, substitutions, terminal and intermediate additions and deletions)

DNA sequences provided by the present invention are thus seen to comprehend all DNA sequences suitable for use in securing expression in a procaryotic or eucaryotic host cell of a polypeptide product having at least a part of the primary structural conformation and one or more of the biological properties of erythropoietin, and selected from among: (a) the DNA sequences set out in FIGS. 5 and 6; (b) DNA sequences which hybridize to the DNA sequences defined in (a) or fragments thereof; and (c) DNA sequences which, but for the degeneracy of the genetic code, would hybridize to the DNA sequences defined in (a) and (b).

Id. at 1212-13 (quoting U.S. Patent No. 4,703,008).

the analogs.¹⁴²

A result similar to that in *Amgen* was reached by the CAFC in *In re Vaeck*.¹⁴³ In *Vaeck*, the applicant appealed from a decision of the PTO Board of Appeals rejecting certain claims of an application for "Hybrid Genes Incorporating a DNA Fragment Containing a Gene Coding for an Insecticidal Protein, Plasmids, Transformed Cyanobacteria Expressing Such Protein and Method for Use as a Biocontrol Agent."¹⁴⁴ The genes used in the invention were derived from the *bacillus* genus. They were capable of being expressed in cyanobacteria cells, and provided for the production of insecticidal proteins within the cyanobacteria.¹⁴⁵ One of the grounds of the Board's rejection was lack of enablement.¹⁴⁶

The claims of the invention at issue in *Vaeck* covered preferred

142. *Id.* at 1213-14. The court summed up its conclusions on the enablement issue of the '008 patent:

Considering the structural complexity of the EPO gene, the manifold possibilities for change in its structure, with attendant uncertainty as to what utility will be possessed by these analogs, we consider that more is needed concerning identifying the various analogs that are within the scope of the claim, methods for making them, and structural requirements for producing compounds with EPO-like activity. It is not sufficient, having made the gene and a handful of analogs whose activity has not been clearly ascertained, to claim all possible genetic sequences that have EPO-like activity. Under the circumstances, we find no error in the court's conclusion that the generic DNA sequence claims are invalid under Section 112.

Id. at 1214.

The *Amgen* case also involved an enablement issue with regard to claims 1 and 3 of U.S. Patent No. 4,677,195, owned by co-defendant Genetics Institute ("GI"). *See id.* at 1202. Claims 1 and 3 covered EPO having a specific activity of at least 160,000 IU/AU (International Units/Absorbance Units) *in vivo*. *See id.* at 1215-16.

The CAFC found that the patent was not enabling for claims 1-3. The CAFC relied on its findings that GI had no evidence that it had even prepared EPO with a specific activity of 160,000 IU/AU *in vivo*, and also cited literature that cast doubt on whether an EPO with this specific activity could be produced. *See id.* at 1216-17. The court's holding was limited, as the court stated that "[w]e do not hold that one must always prove that a disclosed process operates effectively to produce a claimed product." *Id.* at 1217.

143. 947 F.2d 488 (Fed. Cir. 1991).

144. *See id.* at 489-90.

145. *See id.* at 490.

146. *See id.* at 492-93. The claims were also rejected as obvious over the prior art under 35 U.S.C. § 103.

species of the gene, gene promoters and selectable markers (claims 1-15); a hybrid plasmid vector which included the preferred species of claim 1 (claims 17-31); a bacterial strain (claim 32); a cyanobacterium (claims 34-48); an insecticidal composition (claims 50-51); and a plasmid that had been deposited (claim 52).¹⁴⁷ The claims of the application were directed to the *bacillus* gene in generic terms.¹⁴⁸ The specification disclosed two *bacillus* species and nine separate genera as host cyanobacteria that would be within the invention.¹⁴⁹ However, the examples contained in the specification described the transformation of only a single strain of cyanobacteria, cyanobacterium *synechocystis* 6803.¹⁵⁰ Two different promoters were also disclosed, both for *synechocystis* 6803.¹⁵¹

On appeal, the applicant argued to the CAFC that the disclosure in the application was enabling. The court first noted that, with the exception of claims 47 and 48, all the claims rejected under § 112 were not restricted to any particular genus or species of cyanobacteria.¹⁵² The court then considered the somewhat incomplete understanding of the biology of cyanobacteria at the time of appellants' filing date, as well as the limited disclosure contained in the specification.¹⁵³ The court affirmed the Board's rejection of claims 1-46 and 50-51, noting that "[t]here is no reasonable correlation between the narrow disclosure in appellants' specification and the broad scope of protection sought in the claims encompassing gene expression in any and all cyanobacteria."¹⁵⁴

147. *Vaeck*, 947 F.2d at 490.

148. *See id.*

149. *See id.* In the classification of bacteria, a "species" is designated from an investigation of a large number of strains of bacteria. A species is determined to have features that are identical with those of other bacteria. A genus, of which the plural form is genera, is a group of related species. *See* 2 MCGRAW-HILL ENCYCLOPEDIA OF SCIENCE AND TECHNOLOGY 8-9 (1977).

150. *See In re Vaeck*, 947 F.2d 488, 490 (Fed. Cir. 1991).

151. *See id.*

152. *Id.* at 495. Claim 47 limited the cyanobacterium of claim 1 to a cyanobacterium from among the genera *anacystis* and *synchechocystis*, and claim 48 limited the cyanobacterium to *synchechocystis* 6803. *See id.* at 496.

153. *Id.*

154. *Id.*

The CAFC in *Vaeck* cautioned, however, that its reasoning did not suggest that patent applicants in “unpredictable” arts cannot obtain claims covering a particular genus when the specification only discloses a species of the genus.¹⁵⁵ Citing *Angstadt*, the court assured applicants that they need not disclose every species encompassed by the claims.¹⁵⁶ The court went on to state:

[T]he disclosure must adequately guide the art worker to determine, without undue experimentation, which species among all those encompassed by the claimed genus possess the disclosed utility. Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a “predictable” factor such as a mechanical or electrical element.¹⁵⁷

The CAFC reversed the Board’s rejection of claims 47 and 48, which were directed to the expression of the gene of claim 1.¹⁵⁸ The court found that the subject matter of claims 47 and 48 was disclosed in the specification.¹⁵⁹

III. *IN RE GOODMAN*

With this background of case law on enablement in the context of biotechnology inventions, the CAFC considered *In re Goodman*.

A. *Background*

In the case *In re Goodman*,¹⁶⁰ the CAFC affirmed, on appeal, the Board’s rejection of all claims in an application by Goodman, et al., for a method of manufacturing mammalian peptides in plant

155. *See id.* at 496.

156. *Id.* (citing *In re Angstadt*, 537 F.2d 498 (C.C.P.A. 1976)). *See also supra* notes 118-126 and accompanying text.

157. *Id.*

158. *Id.*

159. *Id.*

160. 11 F.3d 1046 (Fed. Cir. 1993).

cells, on the basis of an inadequate disclosure.¹⁶¹ The patent application at issue in *Goodman*, U.S. Serial No. 07/507,380 (“the ‘380 application”), was a continuation application of a prior application which issued as U.S. Patent No. 4,956,282 (“the ‘282 patent”).¹⁶² Claims 1-13 of the ‘380 application were on appeal, and all of them were directed to a method of manufacturing mammalian peptides in plant cells.¹⁶³

The use of biotechnology or genetic engineering in plants is a modern adaptation of the centuries-old practice of plant breeding.¹⁶⁴ Plant breeding grew out of the discovery that plants reproduce sexually, and that the generation of plants is dependent upon pollination (i.e., the introduction of pollen from a male part, a stamen, to a female part, an ovule).¹⁶⁵ It requires the crossing of two plant lines and the recording of characteristics over generations.¹⁶⁶ In addition, plant breeding involves the passing on of additional genes other than the desired genes.¹⁶⁷

In contrast to plant breeding, modern methods of genetic engineering in plants allow scientists to transfer specific desired genes (e.g., resistance to a particular insect) and introduce these genes into plants.¹⁶⁸ Modern genetic engineering consequently allows for faster results than plant breeding.¹⁶⁹

161. *Id.* at 1048. The practice of obtaining a particular gene for medical or industrial use requires first cloning the gene, then incorporating the gene into a host cell for production. The choice of the particular host cell “depends on the project goals and on the properties of the protein to be produced.” WATSON, *supra* note 6, at 454.

162. *Goodman*, 11 F.3d at 1048. Since the ‘380 application was a continuation of a prior application, it has the same specification of the prior application. *See supra* note 23 for the text of 35 U.S.C. § 120.

163. *Goodman*, 11 F.3d at 1048.

164. WATSON, *supra* note 6, at 273. *See generally* Charles F. Wimpee, *Plant Biotechnology*, in 7b BIOTECHNOLOGY 333-47 (1989).

165. *See* WATSON, *supra* note 6. It is believed that the first instances of plant breeding occurred in ancient Mesopotamia, after the discovery of pollination in date trees. Wimpee, *supra* note 164, at 334. Date trees are one of the many kinds of trees that are dioecious, i.e., they can be divided into separate male trees and female trees. *See id.*

166. *See* WATSON, *supra* note 6, at 273.

167. *See id.*

168. *See id.*

169. *See id.*

Generally, the method of the '380 application referred to in *Goodman* is achieved by integrating the plant cells of a DNA construct coding for a mammalian peptide, whereby the plant cell transcribes the region of coding for the mammalian peptide and the peptide is harvested.¹⁷⁰ The '380 application described a method involving the introduction of the desired gene into the Ti plasmid.¹⁷¹ The CAFC characterized the process as follows:

[U]pon insertion of a foreign DNA segment into the T-region of the Ti plasmid, the natural genetic transfer functions of these bacteria introduce the foreign segment into the plant cell genome. Using its own cell machinery, the plant cell then dutifully strives to transcribe the T-DNA segment and translate the peptide it encodes. Numerous factors affect successful transcription and translation, including the regulatory gene regions (i.e., initiation and termination sequences) preceding and following the T-DNA segment as well as intracellular compounds present during protein formation. If a stable translation product results, the peptide can be harvested from the plant cells.¹⁷²

The claims of the '380 application were broad. For example, claim 1 described:

1. A method for producing a mammalian peptide which comprises: growing plant cells containing an integrated sequence comprising, a first expression cassette having in the direction of transcription (1) a transcriptional and translational initiation region functional in said plant cells, (2) a structural gene coding for said mammalian peptide, and (3) a termination region, whereby said structural gene is expressed to produce said mammalian peptide; and isolating said mammalian peptide substantially free of plant cell

170. *See In re Goodman*, 11 F.3d 1046, 1048 (Fed. Cir. 1993).

171. *See id.* The plasmid of a cell is a type of minichromosome contained in a cell. It is not linked to the main chromosome of the cell. Plasmids are often used for recombinant DNA research. *WATSON*, *supra* note 6, at 27-28. The Ti plasmid is a particularly large plasmid that is often used for research. *See id.* at 277.

172. *Goodman*, 11 F.3d at 1048.

components.¹⁷³

Claims 2-6 were dependent on claim 1, and all involved “methods for producing mammalian peptides in plant cells using expression cassettes with initiation codons recognized by plant cells.”¹⁷⁴ Thus, claims 1-6 attempted to encompass all mammalian peptide produced in any plant cell.¹⁷⁵ Although claims 2-6 added some limitations to claim 1, they did not limit the type of mammalian peptide or the type of plant cell.

Claim 7, which was an independent claim, claim 8, which depended on claim 7, and claim 9, which depended on claim 8, all recited the production of the peptide interferon in plant cells.¹⁷⁶ Claims 10-13 covered a nucleic acid construct to be used in the method claims of the application.¹⁷⁷ Only claims 1-9 were relevant for purposes of the enablement issue.

B. '282 Patent Disclosure

Since the '380 application was a continuation of the application which resulted in the '282 patent, both the '380 application and the '282 patent have the same disclosure.¹⁷⁸ The '282 patent was entitled “Mammalian Peptide Expression in Plant Cells.” In the summary of the invention, it was explained that “[e]fficient production of physiologically active mammalian proteins is provided by introducing functional constructs containing the mammalian structural gene into a plant cell.”¹⁷⁹

173. *Id.*

174. *Id.* (footnote omitted).

175. *Id.* at 1049.

176. *Id.*

177. *Id.* As the CAFC explained, there is a close relationship between the claims of the '380 application and the claims of its parent '282 patent. *Id.* at 1048-49. Claim 8 of the application is identical to claim 1 of the '282 patent except that the application claim covers “plant cells” while the patent claim is limited to “dicotyledonous plant cells.” *Id.* at 1048. Claim 9 of the application broadens the language of claim 1 of the issued patent in the same manner. *Id.* at 1049. Application claim 13 is identical to claim 3 of the patent except that the application claim covers “an interferon” while the patent claim is limited to gamma-interferon. *See id.*

178. *See supra* notes 22-23 and accompanying text.

179. U.S. Patent No. 4,956,282, col. 1, lines 64-67.

The '282 patent specification disclosed the advantages of growing mammalian peptides in plants rather than in unicellular organisms, which are more economical to maintain.¹⁸⁰ The specification stated that because of the difference in structure between mammalian cells and unicellular organisms, the mammalian protein does not properly fold in the unicellular organism. For example, certain mammalian peptides, such as enzymes, "may require folding and/or processing that is unavailable in unicellular microorganisms."¹⁸¹

According to the specification, mammalian proteins grown in unicellular organisms are sometimes not able to obtain "a substantial proportion or all of the physiological activity of the naturally occurring peptide obtained from a native host."¹⁸² The specification further disclosed that the growth of peptides in plants that are intended to be administered physiologically "diminishes the probability of contaminants causing an adverse response upon administration to a mammalian host."¹⁸³

With respect to the transfer of the DNA construct into the plant cell, the specification stated that transfer could be effected by way of "infection *A. tumefaciens* or *A. rhizogenes*, microinjection, liposome fusion, viral infection, or the like."¹⁸⁴ The method of integration was not considered critical to the invention.¹⁸⁵

The types of plant cells that were covered by the invention, as set out in the specification, were as follows:

Plant cells which are employed may be either monocots or dicots and will be chosen in accordance with the manner in which the desired gene is to be produced and harvested. Plants which may find use include tobacco, sunflower, corn, sugar cane, soybean, tomato, alfalfa, mustard, sugar beet, rapeseed, etc.¹⁸⁶

180. See *id.* col. 1, lines 22-38.

181. *Id.* col. 3, lines 44-46.

182. *Id.* col. 1, lines 36-38.

183. *Id.* col. 3, lines 39-41.

184. *Id.* col. 4, lines 44-46.

185. *Id.* col. 4, lines 47-48.

186. *Id.* col. 4, lines 55-60. The specification draws a distinction between "monocots" (monocotyledonous plants) and "dicots" (dicotyledonous plants). *Id.*

In the section of the specification entitled "Experimental," a single example of the invention was disclosed, namely growth of gamma-interferon in tobacco plants.¹⁸⁷

The Examiner rejected claims 1-9 on the grounds of lack of enablement, citing 35 U.S.C. § 112.¹⁸⁸

C. The Board Decision

The Board of Patent Appeals and Interferences affirmed the Examiner's rejection of claims 1-9.¹⁸⁹ The Board found that the specification did not disclose the particular "plant functional" regulatory regions beyond the previously described single example concerning the regulatory regions functional in tobacco plants.¹⁹⁰ The Board concluded that as a result, "one of skill in the art could not replicate the invention in 'all plants.'"¹⁹¹ The Board noted that the method disclosed in the specification covered only the expression of a mammalian protein in dicotyledonous plant cells.¹⁹²

D. The CAFC Decision

The applicant, Goodman, appealed the Board's decision and argued before the CAFC that the specification was enabling for the production of any type of mammalian protein in any type of plant

Monocots and dicots are the two types of angiosperms—plants that bear flowers and produce seeds enclosed within fruit. There are various distinctions between the two groups, including that the dicots contain an embryo with two cotyledons, or seed leaves. The monocots have an embryo with one cotyledon. See 1 *ENCYCLOPEDIA BRITANNICA*, *Angiosperms* (1967).

Such important agricultural plants as maize, rice, and wheat are monocots. See *WATSON*, *supra* note 6, at 274.

187. See U.S. Patent No. 4,956,282 col. 8, line 46; col. 9, line 9.

188. See *In re Goodman*, 11 F.3d 1046, 1049 (Fed. Cir. 1993). In addition, all of the claims of the invention, claims 1-13, were rejected as obvious. *Id.*

189. *Id.* at 1048.

190. See *id.* at 1049. The Board also rejected claims 10-13, which claimed nucleic acid constructs used in method claims, on the grounds of obviousness-type double patenting. *Id.*

191. *Id.*

192. *Id.*

cell.¹⁹³ In support of his argument, Goodman cited several scientific articles, and argued that these articles established the state of the art in 1985.¹⁹⁴

One of the articles cited by Goodman was by J.P. Hernalsteens.¹⁹⁵ The article recognized the success of the recombinant methods of the applicant's invention in dicotyledonous species of plants ("dicots"), and concluded that there was the possibility that the method could work with monocotyledonous plants ("monocots"). Another article cited by Goodman was by G.M.S. Hooykaas-Van Slogteren. It also failed to conclusively state that the method of the invention could work with monocots, but suggested that more experimentation was necessary in this area.¹⁹⁶

In its decision, however, the CAFC noted that a 1985 article by Ingo Potrykus "characterize[d] even the modest optimism of Hernalsteens and Hooykaas as a departure from mainstream expectations."¹⁹⁷ The CAFC further noted that in a 1987 article written by Goodman himself, Goodman recognized the difficulties in applying the method of the invention to monocots. In the article, the applicant stated that "[a]lthough data have been cited that *Agrobacterium* can transfer T-DNA to monocotyledonous hosts, clear evidence of T-DNA integration exists only for asparagus, and, even in that case, no transformed plants have been described."¹⁹⁸

In the alternative, Goodman argued that the specification was enabling with gene transfer by direct DNA uptake by the plant, by a microinjection method involving the use of micropipette, or by

193. *Id.*

194. *Id.* at 1050-51.

195. *Id.* at 1050. The article relied on by Goodman was J.P. Hernalsteens et al., *An Agrobacterium-Transformed Cell Culture from the Monocot Asparagus Officinalis*, 3 EMBO J. 3039-41 (1984).

196. G.M.S. Hooykaas-Van Slogteren et al., *Expression of Ti Plasmid Genes in Monocotyledonous Plants Infected with Agrobacterium Tumefaciens*, 311 NATURE 763 (1984).

197. *Goodman*, 11 F.3d at 1050 (referring to Ingo Potrykus et al., *Direct Gene Transfer to Cells of a Gramineous Monocot*, 199 MOLECULAR & GEN. GENETICS 183 (1985)).

198. *Id.* at 1051 (quoting Robert M. Goodman, *Gene Transfer in Crop Improvement*, 236 SCIENCE 48, 52 (1987) (citation omitted)) [hereinafter *Goodman, Gene Transfer*].

viral-mediated transformation.¹⁹⁹ However, the CAFC noted that all three methods were recognized as ineffective in Goodman's 1987 article.²⁰⁰ The court observed that "[t]he record, especially Goodman's own article, shows the need for extensive experimentation to practice the claimed method for just a few plants, let alone all plant cells as broadly claimed in the application."²⁰¹ Thus, the court held that, at the time of filing, the disclosure was not enabling for claims 1-9 covering a method of manufacturing mammalian peptide in all plant cells.²⁰² The court affirmed the decision of the Board.²⁰³

IV. SCOPE OF THE ENABLEMENT REQUIREMENT AFTER *IN RE GOODMAN*

As the decision in *In re Goodman* demonstrates, the key question raised by the enablement requirement in cases involving biotechnology inventions is how much an inventor in the biotechnology field can claim. In other words, once the inventor has isolated the particular inventive composition, or has discovered a new method of making or using a composition, how broadly can that invention be claimed? In cases involving a composition of matter, should it be limited to the particular protein isolated by the inventor, or is the inventor also entitled to claim other forms of the protein?

199. *See id.* at 1051-52.

200. The court noted that Goodman stated in his 1987 article that the "[i]ntegration into plant chromosomes of foreign DNA introduced by direct uptake is a relatively rare event. . . ." *Id.* at 1051 (quoting Goodman, *Gene Transfer*, *supra* note 198, at 52). As for microinjection, Goodman had stated that "transformation by microinjection of plant cells only worked with protoplasts." *Id.* (citing Goodman, *Gene Transfer*, *supra* note 198, at 53). Finally, with regard to viral-mediated transfer, the applicant's article had concluded that "[i]n plants, viral-based vectors are not likely to stably transform plant cells because integration of viral genes into plant chromosomes has not been detected." *Id.* at 1051-52 (quoting Goodman, *Gene Transfer*, *supra* note 198, at 53).

201. *Id.* at 1052.

202. *Id.*

203. *Id.* The court also affirmed the obviousness rejection of claims 1-13. *Id.* at 1053-54. *See infra* note 190.

Applicants in the field of biotechnology often seek claims that are undeniably broad in the light of the specification. This is due in part to the highly competitive nature of the biotechnology industry.²⁰⁴ The number of patent applications filed in the field of biotechnology increases annually at approximately twice the rate of patents in other fields.²⁰⁵ Much of the biotechnology research is performed at universities and teaching hospitals which place great emphasis on research and the early publication of discoveries.²⁰⁶ As a result, “[f]requent and early filings are the most prudent means to protect new inventions while still conceding to the academic nature of the university.”²⁰⁷

Limiting the scope of patent protection for biotechnological inventions is necessary when one considers the speed with which scientists are reaching new discoveries in the field. For example, the biotechnological field of introducing genes with desirable traits into the human body for treating diseases has developed from “pipe dream” to “experimental treatment” in only five years.²⁰⁸

In addition to major advances that have occurred in biotechnology, there are a multitude of improvements in the various compositions and processes of biotechnological inventions. These arise from DNA mutations made to obtain more effective or desirable organisms, as well as the isolation of DNA sequences that have greater effectiveness within the organisms.²⁰⁹ Enforcement of the enablement requirement ensures that future advances and discoveries are not encompassed by the language of claims issued prior to their discovery.

In *Goodman*, as in *Amgen*²¹⁰ and *Vaeck*,²¹¹ the court used the

204. See, e.g., *Herdman, OTA Testimony/Statement*, *supra* note 7.

205. *Id.*

206. See *Konski*, *supra* note 106.

207. *Id.*

208. Marcia Barinaga, *Steps Taken Toward Improved Vectors for Gene Transfer*, *SCIENCE*, Nov. 25, 1994, at 1326.

209. Mandel, *supra* note 44, § 14.2, at 14-3.

210. *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir.), *cert. denied sub nom. Genetics Inst., Inc. v. Amgen, Inc.*, 112 S. Ct. 169 (1991). See discussion *supra* notes 134-42 and accompanying text.

211. *In re Vaeck*, 947 F.2d 488 (Fed. Cir. 1991). See discussion *supra* notes 143-59

“undue experimentation” rule of the enablement requirement to prevent applicants from obtaining or enforcing what the CAFC considered overly broad patent rights.²¹² In *Amgen*, the patentee’s ability to provide an enabling disclosure for only a few of the EPO analogs resulted in a determination that certain broad claims were invalid on the grounds of lack of enablement.²¹³ The CAFC based the decision on its finding that the disclosure of the patent required undue experimentation in order to obtain the many analogs recited in the claims.²¹⁴ In *Vaeck*, the disclosure of examples for only a single strain of bacteria was not enabling for claims covering the genus.²¹⁵ Similarly, in *Goodman*, the CAFC rejected a claim directed to the production of a mammalian peptide in all plant cells, where the disclosure only provided enablement for a single type of plant.²¹⁶ The decision was based on the court’s finding that the disclosure required undue experimentation in order to achieve the method recited in the claims.²¹⁷

In re Goodman extends the reasoning of *Amgen* and *Vaeck* to a different type of biotechnological case. The *Amgen* decision was limited to claims covering a composition of matter, specifically, DNA sequences.²¹⁸ Similarly, the *Vaeck* decision was limited to claims for species of genes and other compositions of matter. *Goodman*, however, deals only with method claims, namely methods of manufacturing mammalian peptides in plant cells. Thus, the CAFC has extended its “undue experimentation” rulings to further limit the scope of patent protection for biotechnology inventions.

It can be argued that the CAFC’s ruling in *Goodman* is more appropriate in cases involving claims for a composition of matter than for cases involving method or process claims. Composition of matter claims are not limited to any particular method by which

and accompanying text.

212. See *In re Goodman*, 11 F.3d 1046, 1051-52 (Fed. Cir. 1993).

213. *Amgen*, 927 F.2d at 1213-14.

214. *Id.* at 1213.

215. See *Vaeck*, 947 F.2d at 495-96.

216. *Goodman*, 11 F.3d at 1052.

217. See *id.*

218. See *Amgen*, 927 F.2d at 1204.

the composition is made or used.²¹⁹ Thus, “[c]laims drawn to a composition of matter would entitle the patent owner to exclude another from any use of such composition even though the use is neither disclosed nor claimed in the patent specification.”²²⁰ However, claims for a method or process cover only the method of manufacture or use which is disclosed by the patent. Indeed, the patentability of the method claim is in the particular acts or transformation performed on the article or composition of matter.²²¹

Another trend illustrated by *Amgen*, *Vaeck* and *Goodman* is the refusal of the CAFC to conduct an extensive inquiry into the various undue experimentation factors set forth by the Board of Patent Appeals and Interferences in *Forman*.²²² In fact, the CAFC in *Amgen* stated that the *Wands* factors “are illustrative, not mandatory.”²²³ In *Goodman*, the CAFC made no reference to these factors, and cited neither *Amgen* nor *Forman*.

This development is unfortunate. The factors in *Forman* provided a checklist for patent applicants arguing that their patent disclosure did not require undue experimentation. It provided applicants with some information, albeit in general categories, as to what a court or patent examiner would consider, and thus generally promoted predictability in the law. While the CAFC in *Amgen* and *Goodman* did not reject outright the *Forman* factors, the CAFC decisions will leave applicants guessing as to what constitutes undue experimentation.

CONCLUSION

Biotechnology is a fast growing field, with scientists around the world working to discover gene sequences and their uses, and to perfect new methods of making or using the gene sequences. It is also characterized by an extensive amount of communication and

219. See 2 ROSENBERG, *supra* note 1, § 8.06, at 8-21.

220. *Id.*

221. See *Gottschalk v. Benson*, 409 U.S. 63, 69-70 (1972).

222. *Ex parte Forman*, 230 U.S.P.Q. (BNA) 546 (Bd. Pat. App. & Int. 1986). See *supra* notes 130-32 and accompanying text.

223. *Amgen*, 927 F.2d at 1213.

sharing of results and information among scientists.²²⁴ Thus, the Patent and Trademark Office and the courts must guard against allowing claims which may encompass subject matter discovered in the future. As *In re Goodman* illustrates, the enablement requirement, by limiting applicants to what is disclosed in the patent or patent application, operates to prevent overbroad interpretations of claims.

224. See Ellen P. Winner, *Enablement in Rapidly Developing Arts—Biotechnology*, 70 J. PAT. & TRADEMARK OFF. SOC'Y 608, 611 (1988).