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Patent Law: Best Mode Disclosure—Genetic Engineers Get Their Trade Secret and Their Patent Too?

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PATENT LAW: BEST MODE DISCLOSURE—GENETIC ENGINEERS GET THEIR TRADE SECRET AND THEIR PATENT TOO? — *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (interim ed. 1991).

I. INTRODUCTION

The United States Constitution grants Congress the authority "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."[1] Pursuant to this authority, Congress enacted the Patent Act which grants successful patentees a monopoly for a limited time in return for the disclosure of the invention and the eventual entry of the invention into the public domain.[2] The limited monopoly is granted provided that the invention satisfies the substantive and procedural statutory requirements.[3]

To satisfy the procedural statutory requirements governing patentability, the inventor must fully disclose his invention. Disclosure requirements are set out in Title Thirty-Five, Section 112 of the United States Code.[4] "Under Section 112, the inventor must adequately set

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1. U.S. CONST. art. I, § 8, cl. 8.

2. 35 U.S.C. § 154 (1988). This section provides:

> Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, subject to the payment of fees as provided for in this title, of the right to exclude others from making, using, or selling the invention throughout the United States . . . referring to the specification for the particulars thereof. A copy of the specification and drawings shall be annexed to the patent and be a part thereof.

Id.

3. The substantive statutory requirements for patentability are as follows: (1) patentable subject matter; (2) novelty; (3) utility; and (4) non-obviousness. *See* 35 U.S.C. §§ 101-03 (1988). The procedural statutory requirements require the inventor or a representative to file an application with the United States Patent and Trademark Office. 35 U.S.C. § 111 (1988). This section provides in part:

> [An] application for [a] patent shall be made, or authorized to be made, by the inventor, except as otherwise provided in this title, in writing to the commissioner. Such application shall include (1) a specification as prescribed by section 112 of this title; (2) a drawing as prescribed by section 113 of this title; and (3) an oath by the applicant as prescribed by section 115 of this title. The application must be accompanied by the fee as required by law.

Id.

4. 35 U.S.C. § 112 (1988). This section provides in part:

> 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.

forth and describe three items: (1) the invention (the description requirement); (2) "the manner and process of making and using" the invention (the enablement requirement); and (3) "the best mode contemplated by the inventor of carrying out his invention" (the best mode requirement)."[5] The inventor's disclosure of the invention is the consideration given by the inventor in exchange for the right to a limited monopoly. The disclosure requirements assure that the public receives a *quid pro quo*. The *quid pro quo* is that the invention will be available to the public once the statutory period of the monopoly expires.[6]

Failure to satisfy the disclosure requirements can lead to a patent grant refusal by a patent examiner. Additionally, if a patent is issued without proper disclosure it can be invalidated by the courts when an alleged infringer claims inadequate disclosure as a defense in an infringement suit.[7] The claim of inadequate disclosure can include the enablement and best mode defenses. The enablement and best mode defenses are available in all fields of technology, but are especially prevalent in the area of biotechnology and computer-related inventions.[8] One problem with the best mode requirement in such areas is that collateral means for practicing the invention, such as cell cultures, may be developed at great expense and may be valuable as trade secrets. If the best mode requirement requires disclosure of the collateral means in a patent for an invention in the same subject area, the inventor may choose trade secret protection rather than patent protection.

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Id. (emphasis added).

5. 2 DONALD S. CHISUM, PATENTS § 7.01 (1992).

6. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 150-52 (1989). The Supreme Court stated:

> The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years. . . . We have long held that after the expiration of a federal patent, the subject matter of the patent passes to the free use of the public as a matter of federal law.

Id.

7. *See* William F. Herbert, *Failure to Disclose the "Best Mode": What the Public Doesn't Know Will Hurt Them*, 64 J. PAT. OFF. SOC'Y 12, 13 (1982). In addition to invalidation of the patent, there is the possibility that (1) the patentee will be held liable for antitrust violations, (2) priority will be awarded to another party in a patent interference proceeding, or (3) a court will refuse to protect a party's trade secret. Michael J. Walsh, Comment, *The Disclosure Requirements of 35 U.S.C. § 112 and Software-Related Patent Applications: Debugging the System*, 18 CONN. L. REV. 855, 874 n.99 (1986).

8. Stephen G. Rudisill & Richard C. Auchterlonie, *The Classic Defenses Updated*, 15 AM. INTELL. PROP. L. ASSN. Q.J. 209, 216 (1987).

This Note focuses on the application of the best mode requirement by the United States Court of Appeals for the Federal Circuit[9] in *Amgen, Inc. v. Chugai Pharmaceutical Co.*[10] The Note examines the policy behind the disclosure requirements of section 112,[11] discusses the case law applicable to the best mode requirement,[12] presents the fundamentals of recombinant DNA technology,[13] and explores how the best mode requirement applies to biotechnology patents.[14] This Note then presents the facts in *Amgen*[15] and the rationales used by both the district court and the Federal Circuit in reaching their respective decisions.[16] The Note also analyzes the Federal Circuit holding in light of the policy and case law applicable to the best mode requirement.[17] Finally, this Note concludes that the Federal Circuit's holding was warranted because a balance between too much disclosure and too little disclosure is necessary to maintain an effective patent system.[18]

II. BACKGROUND

The best mode analysis of a biotechnology patent requires a fundamental understanding of both law and technology. The following sections present background information which explains both the best mode requirement and some of the fundamentals of biotechnology. First, the history and purpose of the best mode requirement is examined. Second, the judicial interpretation of the best mode requirement is discussed. Third, the fundamentals of recombinant DNA technology are presented. Finally, the application of the best mode requirement to biotechnology patents is discussed.

A. The Purpose of the Best Mode Requirement

The requirement of complete disclosure originated in the Patent Act of 1790 which contained the defense of deceptive concealment. The deceptive concealment defense allowed an infringer to claim as a defense that a disclosed specification in the infringed patent did not con-

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9. The Court of Appeals for the Federal Circuit was created in 1982 and was granted exclusive jurisdiction over cases arising in whole or in part under federal patent law. 28 U.S.C. § 1295 (1984). One of the primary purposes for the creation of the Federal Circuit was to facilitate greater uniformity in the standards governing patentability and the validity of patents. 2 CHISUM, *supra* note 5, § 5.02[6].

10. 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

11. *See infra* text accompanying notes 19-34.

12. *See infra* text accompanying notes 35-76.

13. *See infra* text accompanying notes 77-98.

14. *See infra* text accompanying notes 99-138.

15. *See infra* text accompanying notes 139-55.

16. *See infra* text accompanying notes 156-242.

17. *See infra* text accompanying notes 243-96.

18. *See infra* text accompanying notes 297-301.

tain the whole truth concerning the applicant's invention.[19] The defense was successful if the lack of truth was for the purpose of deceiving the public.[20] The best mode requirement dates back to the Patent Act of 1836, when federal patent law required inventors, in the case of machines, to fully disclose several modes in which the inventor contemplated carrying out his invention.[21] The requirement was modified in the Patent Act of 1870 to demand disclosure of only the inventor's best mode.[22] The legislative history of the Patent Act of 1952 suggests that the best mode requirement subsumed the deceptive concealment defense.[23] The Patent Act of 1952 also broadened the best mode requirement to cover all kinds of inventions, not just machines.[24] Although few cases prior to 1965 involved the best mode requirement, in recent years it has gained considerable attention through challenges to the validity of patents.[25] The recent trend among Federal Circuit decisions is to uphold the validity of patents challenged for the failure to disclose the best mode.[26]

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19. 2 CHISUM, *supra* note 5, § 7.05, at 7-117; *see also* Edward C. Walterscheid, *Insufficient Disclosure Rejections (Part VI-Conclusion)*, 62 J. PAT. OFF. SOC'Y 546, 553 (1980).

20. 2 CHISUM, *supra* note 5, § 7.05, at 7-117.

21. Herbert, *supra* note 7, at 14 n.7.

22. 2 CHISUM, *supra* note 5, § 7.05, at 7-117.

23. 2 CHISUM, *supra* note 5, § 7.05, at 7-117. The whole truth defense was omitted because intention to deceive the public was an element of the defense thus making the defense difficult to prove and seldom raised. Defendants would more often raise the defense of failure to give a description of the invention, which is a defense without regard to intention. *Id.* § 7.02[4] at 7-6 to 7-7.

24. *Id.* § 7.05, at 7-117.

25. Herbert, *supra* note 7, at 15.

26. Rudisill & Auchterlonie, *supra* note 8, at 216. For examples of some of the recent cases in which patents were challenged for failure to disclose the best mode, see Wahl Instruments, Inc. v. Acvious, 950 F.2d 1575 (Fed. Cir. 1991); Engel Indus., Inc., v. Lockformer Co., 946 F.2d 1528 (Fed. Cir. 1991); Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923 (Fed. Cir. 1990); Consolidated Aluminum Corp. v. Foseco Int'l Ltd., 910 F.2d 804 (Fed. Cir. 1990); Northern Telecom, Inc. v. Datapoint Corp., 908 F.2d 931 (Fed. Cir.), *cert. denied*, 111 S.Ct. 296 (1990); Dana Corp. v. NOK, Inc., 882 F.2d 505 (Fed. Cir. 1989); Racing Strollers, Inc. v. TRI Indus., Inc., 878 F.2d 1418 (Fed. Cir. 1989); Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 871 F.2d 1054 (Fed. Cir. 1989); Dana Corp. v. IPC Ltd. Partn., 860 F.2d 415 (Fed. Cir. 1988), *cert. denied*, 490 U.S. 1067 (1989); *In re* Wands, 858 F.2d 731 (Fed. Cir. 1988); Bigham v. Godtfredsen, 857 F.2d 1415 (Fed. Cir. 1988); Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675 (Fed. Cir. 1988); Randomex, Inc. v. Scopus Corp., 849 F.2d 585 (Fed. Cir. 1988); Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524 (Fed. Cir.), *cert. denied*, 484 U.S. 954 (1987); Christianson v. Colt Indus. Operating Corp., 822 F.2d 1544 (Fed. Cir.), *cert. granted*, 484 U.S. 985 (1987), *cert. vacated*, 486 U.S. 800 (1988); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987); *In re* Kaplan, 789 F.2d 1574 (Fed. Cir. 1986); DeGeorge v. Bernier, 768 F.2d 1318 (Fed. Cir. 1985); McGill, Inc. v. John Zink Co., 736 F.2d 666 (Fed. Cir.), *cert. denied*, 469 U.S. 1037 (1984); W.L. Gore & Assocs, Inc. v. Garlock, Inc., 721 F.2d 1540 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

Judge Rich's opinion in *In re Nelson*[27] presents not only the purposes behind the best mode requirement, but also the entire disclosure requirement. Judge Rich stated that the basic purpose of the disclosure requirement is to enable those skilled in the art to make and use the invention.[28] In particular, he stated that the purpose regarding the best mode requirement is as follows:

> One cannot read the wording of section 112 without appreciating that strong language has been used for the purpose of compelling complete disclosure. There always exists, on the part of some people, a selfish desire to obtain patent protection without making a full disclosure, which the law, in the public interest, must guard against. Hence section 112 calls for description in " 'full, clear, concise, and exact terms' and the 'best mode' requirement does not permit an inventor to disclose only what he knows to be his second best embodiment, retaining the best for himself."[29]

This statement of the purpose of the best mode requirement is still accurate today.

The best mode requirement is important for three reasons. First, the best mode requirement assures that, by examining the disclosure of the patent, every person will know what the patentee claims and will be able to determine infringement. The early determination of infringement will minimize future patent controversies.[30] Second, the best mode requirement assures that the specification[31] provides information to the public concerning what the invention is and how it can be practiced. Thus, when the patent expires, the public can benefit from the patentee's full disclosure.[32] Finally, the best mode requirement assures that the disclosure provides the public with information that can be used to encourage current and future research in the art of the invention by both the public and the patentee's competitors.[33] To effectuate the purpose of the best mode requirement and to satisfy the constitutional mandate of promoting the progress of the arts and sciences, full

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27. 280 F.2d 172 (C.C.P.A. 1960).

28. *Id.* at 184.

29. *Id.; see also* Dana Corp. v. IPC Ltd. Partn., 860 F.2d 415, 418 (Fed. Cir. 1988) ("The purpose of the best mode requirement is to ensure that the public, in exchange for the rights given the inventor under the patent laws, obtains from the inventor a full disclosure of the preferred embodiment of the invention.").

30. *In re Nelson*, 280 F.2d at 181.

31. The specification is defined by Title 35, § 112 (1988) and contains the disclosure of the invention. *See supra* note 4.

32. Herbert, *supra* note 7, at 32.

33. 2 IRVING KAYTON *et al.*, Patent Practice, 9-1 to 9-3 (1985).

disclosure and satisfaction of the best mode requirement are necessary.[34]

B. Judicial Interpretation of the Best Mode Requirement

There is a clear distinction between the enablement and the best mode requirements of section 112.[35] This distinction has been noted in a number of cases.[36] The enabling requirement ensures that a specification discloses an invention, such that one skilled in the art can make and use the invention.[37] In contrast, the best mode requirement ensures that the inventor does not apply for a patent and, at the same time, conceal from the public what he or she considers to be the best mode of carrying out the invention.[38] An analysis of whether the enablement requirement is satisfied is an objective inquiry.[39] In contrast, evaluation of whether the best mode requirement is satisfied depends on what is contemplated by the inventor and, therefore, requires a subjective inquiry.[40]

The distinction between the enablement requirement and the best mode requirement is illustrated by *Spectra-Physics, Inc. v. Coherent, Inc.*[41] In *Spectra-Physics*, two patents relating to gas lasers were at issue. One patent protected a laser discharge tube structure, and the other protected a method of making the tube.[42] The disclosed method for connecting parts of the laser involved fastening a tungsten disc to center openings of copper cups, which in turn attached to the inside wall of a ceramic laser discharge tube, using the alternative procedures

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34. Herbert, *supra* note 7, at 32.

35. *Id.* at 19.

36. *See, e.g.*, Bigham v. Godtfredsen, 857 F.2d 1415 (Fed. Cir. 1988) (questions of best mode requirement are not resolved in terms of enablement); *In re* Glass, 492 F.2d 1228, 1233 (C.C.P.A. 1974) (failure to disclose even one example of a claimed process can raise enablement issues, but not best mode issues); *In re* Gay, 309 F.2d 769, 772 (C.C.P.A. 1962) (the best mode clause is distinct and separate from the enabling requirement).

37. *In re* Nelson, 280 F.2d 172, 183 (C.C.P.A. 1960).

38. Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1535-36 (Fed. Cir.) (the enablement requirement places the subject matter of the invention in the public's possession generally, and also requires the inventor to disclose to the public the best way to carry out the invention), *cert. denied*, 484 U.S. 954 (1987).

39. *Spectra-Physics*, 827 F.2d at 1532 (requiring an analysis scrutinizing the patent specification to ascertain whether the disclosure is enabling).

40. Christianson v. Colt Indus. Operating Corp., 870 F.2d 1292, 1301 (7th Cir. 1989) ("The requirement contains a subjective standard; we will find non-compliance only if the patentee has concealed, whether knowingly or unwittingly, his or her preferred embodiment of the claimed invention."), *cert. denied*, 493 U.S. 822 (1989); Spectra-Physics, 827 F.2d at 1536 (there is no objective standard by which to evaluate the best mode requirement); *see also* 2 CHISUM, *supra* note 5, § 7.05[1].

41. 827 F.2d 1524.

42. *Id.* at 1527-28.

of moly-maganese brazing and pulse soldering.[43] The disclosure identified brazing as the preferred method and Ti Cu Sil alloy as the preferred brazing material.[44] The *Spectra-Physics* court deemed this disclosure sufficient to satisfy the enablement requirement of section 112.[45]

The inventor, however, withheld the details of his actual preferred brazing method which used the Ti Cu Sil alloy brazing material in a six-stage active metal brazing cycle.[46] The specific conditions and brazing techniques were not set forth in the patent specification.[47] These techniques were actually contrary to other prior art techniques known for brazing, as well as to known techniques for the use of Ti Cu Sil alloy which were disclosed in reference literature used by one of ordinary skill in the art.[48] The lack of any teaching[49] in the prior art led to the finding that the description was so incomplete in disclosing the necessary details of the new techniques as to effectively result in concealment of the best mode.[50] The *Spectra-Physics* court invalidated the patent for failing to satisfy the best mode requirement, even though the undisclosed best mode was not an element of any of the patentee's claims.[51]

A best mode analysis considers any evidence of concealment by the inventor because its purpose is to prevent the inventor from concealing from the public the best way to carry out the invention.[52] Any inquiry of concealment is limited to the knowledge of the inventor at

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43. *Id.* at 1528-30.

44. *Id.* at 1529-30.

45. *Id.* at 1533-34.

46. *Id.* at 1530-31.

47. *Id.* at 1531.

48. *Id.* at 1536.

49. To combine references, case law requires that there be some teaching, suggestion, or inference in either or both references, of the prior art, or knowledge generally available that would lead one skilled in the art to combine the relevant information. *See* Ashland Oil, Inc. v. Delta Resins & Refactories, Inc., 776 F.2d 281, 293 (Fed. Cir. 1985), *cert denied*, 475 U.S. 1017 (1986).

50. *Spectra-Physics,* 827 F.2d at 1536-37.

51. *Id.* at 1537.

52. *Spectra-Physics*, 827 F.2d at 1535 ("only evidence of 'concealment', whether accidental or intentional, is considered"); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986) (Failing to meet "the best mode requirement amounts to concealing the preferred mode contemplated by the applicant at the time of filing; in order to find that the best mode requirement is not satisfied, it must be shown that the applicant knew of and concealed a better mode than he disclosed."); DeGeorge v. Berneir, 768 F.2d 1318, 1324 (Fed. Cir. 1985) ("Not complying with the best mode requirement amounts to concealing the preferred mode contemplated by the applicant at the time of filing.") (citing *In re* Gay, 309 F.2d 769, 772-73 (C.C.P.A. 1962)).

the time the inventor's application was filed.[53] The focus of the inquiry is on the invention claimed[54] and not on the nonessential elements of the invention.[55] The best mode does not have to be identified in the specification[56] and need not be the actual optimum mode of carrying out the invention. The best mode need only be the one contemplated by the inventor as the best mode at the time of the filing.[57]

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53. Dana Corp. v. IPC Ltd. Partnership, 860 F.2d 415, 418 (Fed. Cir. 1988) ("Whether or not a specific disclosure is adequate for best mode purposes is determined by comparing the disclosure with the facts concerning the invention known to the inventor at the time the application was filed."); Bigham v. Godtfredsen, 857 F.2d 1415, 1418 (Fed. Cir. 1988) ("[T]he 'best mode' requirement refers to concealment of what the applicant believed to be the best mode at the time of filing the application."); *Spectra-Physics*, 827 F.2d at 1535 ("The specificity of the disclosure required to comply with the best mode requirement must be determined by the knowledge of facts within the possession of the inventor at the time of filing the application."); *see also* 2 CHISUM, *supra* note 5, § 7.05[2] ("Thus, a preferred or superior mode of carrying out the invention developed or discovered after the filing of the application need not be added to the specification by amendment or otherwise.").

54. Title 35 § 112 (1988) provides that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." *Id*; *see also* Alco Standard Corp. v. Tennessee Valley Auth., 808 F.2d 1490, 1495 (Fed. Cir.) (The sole function of the claims is to delineate the scope of the patent, not to describe what the patentee has invented.), *cert. dismissed*, 483 U.S. 1052 (1986).

55. Plastic Container Corp. v. Continental Plastics of Oklahoma, Inc., 607 F.2d 885, 897 (10th Cir. 1979)("it is the best mode of carrying out the claimed invention that must be set forth pursuant to section 112"), *cert denied*, 444 U.S. 1018 (1980), *on remand*, 515 F. Supp. 834 (W.D. Okla. 1980), *aff'd in part, rev'd in part*, 708 F.2d 1554 (10th Cir. 1983); Int'l Tel. & Tel. Corp. v. Raychem Corp., 538 F.2d 453, 459-60 (1st Cir. 1976) (claim to product; patentee need not disclose preferred mode of making product), *cert denied*, 429 U.S. 886 (1976); *In re* Brebner, 455 F.2d 1402 (C.C.P.A. 1972). *But see* Randomex Inc. v. Scopus Corp., 2 U.S.P.Q.2d (BNA) 1622, 1623 (D. Mass. 1987) (patent on an apparatus for cleaning discs was invalidated for failure to specify the best mode when the inventor failed to set forth the cleaning fluid that he had developed prior to filing the application for the patent), *vacated, reversed, and remanded*, 849 F.2d 585 (Fed. Cir. 1988), *further appeal*, 883 F.2d 1026 (Fed. Cir. 1989).

56. Randomex, Inc. v. Scopus, Inc., 849 F.2d 585, 589 (Fed. Cir. 1988) (the preferred cleaning fluid which was indiscriminately disclosed with other cleaners used with prior art, one of which was clearly inferior, satisfied the best mode requirement); Weil v. Fritz, 601 F.2d 551, 555 (C.C.P.A. 1979) (court does not need to decide how the applicant displays the best mode, but only that it is included in the specification); Ernsthausen v. Nakayama 1 U.S.P.Q.2d (BNA) 1539, 1549 (Bd. Pat. App. & Int'f 1985) ("There is no requirement in 35 U.S.C. § 112 that an applicant point out which of his embodiments he considers his best mode; that the disclosure includes the best mode contemplated by the applicant is enough to satisfy the statute."). *But see Randomex*, 849 F.2d at 591-92 (Mayer, J. dissenting) ("This is the antithesis of the good-faith full disclosure that is mandated by section 112's best mode requirement . . . he buried his best mode in a list of less satisfactory ones . . . if there is a best mode known to the inventor he must say so; he cannot require the public to hunt for it.").

57. Texas Instruments, Inc. v. United States Int'l Trade Comm'n, 871 F.2d 1054, 1061 (Fed. Cir. 1989) (the fact that the assignee of the patent manufactured products containing a different or better form of the product than that disclosed in the patent "is not pertinent to whether the specification disclosed 'the best mode' "); O'Hara Mfg. Ltd. v. Eli Lilly & Co., 231 U.S.P.Q. (BNA) 753, 765 (N.D. Ill. 1986) ("the omission from the patents of a feature used in a commercial embodiment of the invention does not, by itself, mandate a finding of noncompliance with the best mode requirement"); Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 588 F.

Because the best mode inquiry is a fact based analysis focused on concealment, a jury's determination must be upheld on appeal unless it is clearly erroneous.[58] The decision of whether a jury's determination is clearly erroneous, however, depends upon whether there was a "proper legal understanding of the best mode requirement."[59] The evidence to be considered by the fact finder is whether the best mode was concealed. The fact finder is not required to find intentional concealment, because unintentional concealment is sufficient to establish a failure to satisfy the best mode requirement.[60]

The degree of concealment that gives rise to a failure to disclose the best mode is not clear. The reasoning used by the Federal Circuit[61] is that "[i]t is not up to this court to state how the applicant displays his information, but only, under proper circumstances, to review whether he has done so adequately under the statute."[62] According to the Federal Circuit, the appropriate question when analyzing whether a particular disclosure satisfies the best mode requirement is not simply whether the best mode has been disclosed, but also whether it has been disclosed adequately.[63]

Supp 1455, 1467 (N.D. Tex. 1983) ("Failure to cite the marketed version of the . . . product did not violate the best mode requirement."), *aff'd*, 750 F.2d 1569 (Fed. Cir. 1984).

58. Diversitech Corp. v. Century Steps, Inc., 850 F.2d 675, 680 (Fed. Cir. 1988) (the district court finding of no violation of the best mode requirement was not clearly erroneous; "[c]ompliance with the best mode requirement is a question of fact."); Spectra-Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1535-36 (Fed. Cir.) ("Compliance with the best mode requirement, because it depends on the applicant's state of mind, is a question of fact subject to the clearly erroneous standard of review."), *cert denied*, 484 U.S. 954 (1987) ; McGill, Inc. v. John Zink Co., 736 F.2d 666, 676 (Fed. Cir.) (compliance with the best mode requirement is a question of fact for the jury and is reviewed under the clearly erroneous standard), *cert. denied*, 469 U.S. 1037 (1984) Union Carbide Corp. v. Borg-Warner Corp., 550 F.2d 355, 360 (6th Cir. 1977) (the best mode inquiry should be reviewed under the clearly erroneous standard).

59. *Spectra-Physics*, 827 F.2d at 1536.

60. *Id.*; Crane Co. v. Goodyear Tire & Rubber Co., 577 F. Supp. 186, 200 (N.D. Ohio 1983) ("The omission of the best mode need not have been an intentional concealment; it is enough that the best mode was not revealed."); Coal Processing Equip., Inc. v. Campbell, 578 F. Supp. 445, 461 (S.D. Ohio 1981) ("The inventor need only have known of the better mode and not disclosed it in order to suffer a finding of invalidity. The omission need not have been deliberately concealed.").

61. This was the view of the United States Court of Customs and Patent Appeals, the predecessor of the Court of Appeals for the Federal Circuit. South Corp. v. United States, 215 U.S.P.Q. (BNA) 257 (Fed. Cir. 1982) (the United States Court of Appeals for the Federal Circuit adopts, as binding precedent, holdings of the United States Court of Claims and United States Court of Customs and Patent Appeals). The Court of Customs and Patent Appeals was created in 1929 with jurisdiction to review decisions of the Board of Patent Appeals for adverse decisions on patent applications. In 1982, the Court of Customs and Patent Appeals merged with the Court of Claims to form the Court of Appeals for the Federal Circuit. 3 CHISUM, *supra* note 5, § 11.06[3][b].

62. Weil v. Fritz, 601 F.2d 551, 555 (C.C.P.A. 1979) ("[A]n applicant, in drafting an application, may choose any method he deems desirable in portraying essential information.").

63. *Spectra-Physics*, 827 F.2d at 1536.

The Federal Circuit, in *Chemcast Corp. v. Arco Industries Corp.*,[64] set out a two part analysis to determine whether the best mode disclosure requirement has been satisfied.[65] The court stated that:

> In short, a proper best mode analysis has two components. The first is whether, at the time the inventor filed his application, he knew of a mode of practicing his claimed invention that he considered to be better than any other. This part of the inquiry is wholly subjective, and revolves around whether the inventor must disclose any facts in addition to those sufficient for enablement. If the inventor in fact contemplated such a preferred mode, the second part of the analysis compares what he knew with what he disclosed - is the disclosure adequate to enable one skilled in the art to practice the best mode or, in other words, has the inventor 'concealed' his preferred mode from the 'public'? Assessing the adequacy of the disclosure, as opposed to its necessity, is largely an objective inquiry that depends upon the scope of the claimed invention and the level of skill in the art.[66]

Noncompliance with the best mode requirement is found only when the evidence shows that the inventor has concealed, either accidentally or intentionally, the preferred embodiment of his claimed invention at the time of the filing of the application. When analyzing whether the best mode has been adequately disclosed, several details must be considered. The focus is not on generic information in the disclosure, but rather on the specific information known to the inventor.[67] "Even though there may be a general reference to the best mode, the quality of the disclosure may be so poor as to effectively result in concealment."[68] The disclosure, however, need not set forth minute details that would be obvious to one of ordinary skill in the art.[69] The specificity required need

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64. 913 F.2d 923 (Fed. Cir. 1990).

65. *Id.*

66. *Id.* at 927-28.

67. Scripps Clinic & Research Found. v. Genentech Inc., 707 F. Supp. 1547, 1552 (N.D. Calif. 1989) ("The best mode requirement mandates disclosure by the inventor not simply of generic information for carrying out the invention but also of the *best mode contemplated* by the inventor.") (citing *Spectra-Physics*, 827 F.2d at 1536)).

68. *Spectra-Physics*, 827 F.2d at 1536.

69. Dow Chem. Co. v. American Cynamid Co., 615 F. Supp. 471, 482-83, (E.D. La. 1985) ("an applicant need not divulge every piece of information which a lay person would need to operate the invention most effectively"), *aff'd*, 816 F.2d 617 (Fed. Cir.), *cert. denied*, 484 U.S. 849 (1987); H.H. Robertson Co. v. Barger Metal Fabricating Co., 225 U.S.P.Q. (BNA) 1191, 1204 (N.D. Ohio 1984) ("a failure to disclose all the information in possession of the inventor is not fatal where application of routine skill in the art would allow practice of the invention."); Foseco Int'l Ltd. v. Fireline Inc., 224 U.S.P.Q. (BNA) 888, 901 (N.D. Ohio 1984) ("a failure to disclose all the information in the possession of the inventor is not fatal where application of routine skill in the art would allow practice of the invention."); *see also* 2 CHISUM, *supra* note 5, § 7.05[3].

not be more than is required under the enablement requirement.[70] The enablement requirement requires that the patent contain sufficient information to enable a person with ordinary skill in the art to implement the best mode without undue experimentation.[71] Although some experimentation may be necessary, the specificity of the disclosure would be lacking if extensive experimentation was needed to make or use the invention.[72] The specific claims against which the best mode disclosure requirement is gauged are thus central to the analysis, as is the question of enablement. The *Chemcast* court treated these factors and their interplay at some length.[73]

The *Chemcast* court reiterated the principle that the best mode inquiry presents a subjective factual question and focuses on the inventor's state of mind at the time he filed his application.[74] The court clarified, however, that this subjective state-of-mind focus is not the exclusive fact to be considered.[75] The court stated that application of the standard assumed preliminarily that both the level of skill in the art and the scope of the claimed invention were additional objective factors to be considered under a best mode analysis.[76] These objective considerations are now identified as the second part of the best mode test. The second part determines whether the inventor concealed what he knew by examining what he disclosed in light of the scope of the invention and the level of skill in the art.

C. *Fundamentals of Recombinant DNA Technology*

The business of biotechnology is founded upon the study of the genetics of living organisms and, in particular, those methods that characterize recombinant DNA technology.[77] Recombinant DNA techniques make it possible for researchers to move genetic material in a

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70. *See supra* note 4.

71. *In re* Stephens, 529 F.2d 1343, 1345 (C.C.P.A. 1976) ("The test is whether there is sufficient working procedure for one skilled in the art to practice the invention without undue experimentation."); *In re* Gay, 309 F.2d 769, 774 (C.C.P.A. 1962) ("Obviously, it is not necessary that an applicant be more specific than is required by section 112, portion [A]. Not every last detail is to be described, else patent specifications turn into production specifications, which they were never intended to be."); *see also* 2 CHISUM, *supra* note 5, § 7.05[3] (1992).

72. *In re Stephens*, 529 F.2d at 1346.

73. Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 927 (Fed. Cir. 1990).

74. *Id.*

75. *Id.*

76. *Id.*

77. Biotechnology is defined as "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses." OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE, Pub. No. OTA-BA-370, 101st Cong., 1st Sess. 3 (1989). *See generally* OFFICE OF TECHNOLOGY ASSESSMENT, BIOTECHNOLOGY IN A GLOBAL ECONOMY, Pub. No. OTA-BA-494, 102d Cong., 1st Sess. (1991); JAMES WATSON ET AL., RECOMBINANT DNA, A SHORT

functional form from one organism to another, thus creating genetic constructs that have never before existed in nature.[78] For example, the gene[79] that produces a protein such as insulin can be isolated from human cells and inserted into another host cell, such as bacterium. The bacterium can then be reproduced or cloned,[80] creating many identical copies of the gene. If the gene can then be coaxed into the manufacture of the same protein in bacteria that it does in a human cell, large quantities of the protein can be produced for pharmaceutical applications.[81]

The gene that is expressed in the host cell consists of a defined segment of deoxyribonucleic acid (DNA). DNA is the basic hereditary component of all living matter and contains all of the information needed to make the organism and carry on its functions, including complete instructions on what proteins to produce.[82] DNA is itself a duplex molecule: a double helix formed by the annealing of two nucleic acid polymers or strands.[83] Each strand of the DNA molecule is assembled from chemical building blocks called nucleotides which are made up of nucleotide bases.[84] The formation of the double stranded DNA molecule results from the inherent property of nucleic acid polymers to combine with one another through complementary base pairing.[85]

The specific sequence of the nucleotide bases along a strand of DNA encodes the information necessary to produce the protein.[86] A cell's protein synthesis machinery reads the sequence of nucleotide bases in groups of threes, called codons.[87] Each of the possible sixty-four groups of codons corresponds to a particular amino acid or acts as a signal to start or stop protein synthesis.[88] Amino acids are the building

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COURSE (1983); GEOFFREY ZUBAY, GENETICS (1987); Walter Gilbert & Lydia Villa-Komaroff, *Useful Proteins from Recombinant Bacteria*, SCI. AM., Apr. 1980, at 74.

78. Gilbert & Villa-Komaroff, *supra* note 77, at 74.

79. A gene is the "functional unit of heredity which occupies a specific place . . . on a chromosome, is capable of reproducing itself exactly at each cell division, and is capable of directing the formation of an enzyme or other protein." STEDMAN'S MEDICAL DICTIONARY, 639 (25th ed. 1990).

80. Cloning produces a group of cells derived from a single cell by asexual reproduction, all of which have an identical genetic constitution. STEDMAN'S, *supra* note 79, at 318.

81. Irving S. Johnson, *Human Insulin from Recombinant DNA Technology*, 219 SCI. 632 (1983).

82. *See generally*, ZUBAY, *supra* note 77.

83. ZUBAY, *supra* note 77, at 74-79.

84. ZUBAY, *supra* note 77, at 69-71. Each nucleotide contains a phosphate group linked to a sugar molecule which, in turn, is joined to one of four chemicals: adenine (A); thymine (T); guanine (G); or cytosine (C). These four chemicals are called nucleotide bases. *Id.*

85. ZUBAY, *supra* note 77, at 75. Complementary base pairing occurs when an A on one strand becomes paired with a T on the other strand, and a G on one strand becomes paired with a C on the other strand. *Id.*

86. ZUBAY, *supra* note 77, at 198-201.

87. ZUBAY, *supra* note 77, at 203

88. ZUBAY, *supra* note 77, at 198-201.

blocks of proteins. Just as the sequence of codons within a gene specifies the sequence of amino acids in a protein, the sequence of amino acids within each protein specifies its physical structure and its characteristic properties.[89]

The production of a desired protein in a foreign host cell requires two basic steps: (1) identifying and isolating the gene encoding of the desired protein; and (2) transferring the gene into the host cell.[90] Identifying the gene for a specific protein typically requires that at least part of the nucleotide sequence of the gene be known.[91] This usually involves inferring the nucleic acid sequence from the amino acid sequence of the protein.[92] Although the techniques for sequencing are well known, obtaining a sample of the protein in a sufficient quantity and purity for analysis can be quite difficult.[93] The decision to produce a protein by methods of recombinant DNA technology is usually prompted by the fact that limited quantities of the protein are available from natural sources.[94] Once a portion of the sequence of the gene is determined, a short single-stranded nucleic acid, oligonucleotide, may be synthesized which has a nucleotide sequence complementary to the derived genetic sequence.[95] The oligonucleotide may then act as a probe for isolating the gene from the natural source.[96] This process of determining the sequence is like searching for a needle in a haystack because of the quantity and complexity of DNA in the cells of living organisms. Isolating a single gene entails picking out a specific sequence of hundreds or thousands of nucleotides from among a total of perhaps several billion nucleotides.[97] In comparison, the second step of transferring the gene into the host cell is much less difficult.[98] Once the gene is transferred into the host cell, the production of the protein is the same as in a natural cell.

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89. ZUBAY, *supra* note 77, at 198-201.

90. ZUBAY, *supra* note 77, at 404-42.

91. ZUBAY, *supra* note 77, at 404-42.

92. ZUBAY, *supra* note 77, at 404-42.

93. *See* OFFICE OF TECHNOLOGY ASSESSMENT. COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS, Pub. No. OTA-BA-218, 98th Cong., 2d Sess. 119-36 (1984).

94. *Id.* For example, erythropoietin (EPO) was obtained by purifying the urine of patients suffering from aplastic anemia. This urine is in short supply. Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1754 (D. Mass. 1989).

95. ZUBAY, *supra* note 77, at 404-42.

96. ZUBAY, *supra* note 77, at 404-42; *see, e.g.*, Jane Gitschier et al., *Expression of Active Human Factor VIII from Recombinant DNA Clones*, 312 NATURE 330, 331-34 (1984) (describing the use of synthetic oligonucletides to isolate the gene for human factor VIII).

97. ZUBAY, *supra* note 77, at 404-442.

98. ZUBAY, *supra* note 77, at 404-42.

D. *Biotechnology Patents and the Best Mode Requirement*

The same rules and concepts governing the best mode disclosure requirement apply to each patent application irrespective of the technical subject matter of the disclosed invention.[99] Best mode issues in biotechnology cases, however, have focused on certain aspects unique to that science.

One unique problem encountered by biological patent applicants is that it is unclear whether a written description of the invention will enable one skilled in the art to accurately reproduce the invention absent undue experimentation. The Patent and Trademark Office has adopted the position, that if the description alone does not satisfy the enablement requirement, inventors are required to place samples or cultures in depositories accessible to the public.[100] The United States Court of Customs and Patent Appeals,[101] in *In re Argoudelis*,[102] affirmed the need for the deposit requirement.[103] The court found that the current state of the art of biotechnology procedures was unpredictable.[104] This unpredictability required undue experimentation that did not satisfy the enablement requirement.[105] An inventor, however, could overcome this problem by making the microorganism starting material available to the public.[106] Currently, when the Patent and Trademark Office determines that a written description of a biological invention is inadequate, the applicant may deposit a sample of the "biological starting material" to supplement the description.[107] The United States Court of Appeals for the Federal Circuit, in *In re Wands*,[108] stated that

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99. The subject matter that is patentable is set forth in Title 35 § 101 (1988). This section provides in full: "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 therefore, subject to the conditions and requirements of this title." *Id.* The best mode requirement makes no distinction between the various subject matters. 35 U.S.C. § 112 (1988).

100. *Ex parte* Kropp, 143 U.S.P.Q. (BNA) 148, 152 (Pat. Bd. App. 1959) (failure to deposit microorganism or to disclose its source rendered specification insufficient); *see also* Berge Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. PAT. [& TRADEMARK] OFF. SOC'Y 569, 607 (1985); Virginia H. Meyer, *Problems and Issues in Depositing Microorganisms for Patent Purposes*, 65 J. PAT. [& TRADEMARK] OFF. SOC'Y 455 (1983); John E. Schneider, Comment, *Microorganisms and the Patent Office: To Deposit or Not to Deposit, That is the Question*, 52 FORDHAM L. REVIEW 592 (1984).

101. *See supra* note 61.

102. 434 F.2d 1390 (C.C.P.A. 1970).

103. *Id.* at 1392-93.

104. *See id.*

105. *Id.*

106. *Id.*

107. PTO Biotechnology Invention Disclosure Rule, 37 C.F.R. § 1.802(a) (1991). This regulation states: "Where an invention is, or relies on, a biological material, the disclosure may include reference to a deposit of such biological material." *Id.*

108. 858 F.2d 731 (Fed. Cir. 1988).

such a deposit may satisfy the best mode requirement.[109] No deposit is necessary, however, when widely used methods and materials are employed to practice the invention.[110]

The Patent and Trademark Office (PTO) recently promulgated Rules for the Deposit of Biological Material (Rules).[111] Under the Rules, biological material includes any "material that is capable of self-replication either directly or indirectly."[112] Applicants must deposit biological material when it is necessary to fully comply with the requirements of section 112. Thus, a deposit is necessary when a written description of the invention would be inadequate.[113] A deposit of the biological material is not required, however, if the original material is known and readily available to the public or can be made or isolated easily.[114] The patent examiner determines the necessity and adequacy of each deposit.[115]

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109. *Id.* (a deposit of biological material, such as a hybridoma cell line that secretes monoclonal antibodies that fall within a generic claim to antibodies of a specified type, may satisfy the best mode requirement).

110. 37 C.F.R. § 1.802(b). This regulation states in full:

> Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. If a deposit is necessary, it shall be acceptable if made in accordance with these regulations. Biological material need not be deposited, inter alia, if it is known and readily available to the public or can be made or isolated without undue experimentation. Once deposited in a depository complying with these regulations, a biological material will be considered to be readily available even though some requirement of law or regulation of the United States or of the country in which the depository institution is located permits access to the material only under conditions imposed for safety, public health or similar reasons.

Id.

111. 37 C.F.R. §§ 1.801-.809.

112. *Id.* § 1.801. This regulation states:

> For the purposes of these regulations pertaining to the deposit of biological material for the purposes of patents for inventions under 35 U.S.C. 101, the term biological material shall include material that is capable of self-replication either directly or indirectly. Representative examples include bacteria, fungi including yeast, algae, protozoa, eukaryotic cells, cell lines, hybridomas, plasmids, viruses, plant tissue cells, lichens and seeds. Viruses, vectors, cell organelles and other non-living material existing in and reproducible from a living cell may be deposited by deposit of the host cell capable of reproducing the non-living material.

Id.

113. 37 C.F.R. § 1.802(b).

114. *Id.* Some factors to be considered in determining whether a biological material is known and readily available to the public include: (1) commercial availability; (2) references to the biological material in printed publications; (3) declarations of accessibility by those working in the field; (4) evidence of predictable isolation techniques; or (5) an existing deposit made in accordance with these rules. Each factor may or may not be sufficient alone to demonstrate that the biological material is known and readily available. 54 Fed. Reg. 34,882 (1989) (codified at 37 C.F.R. § 1.802(b) (1991)).

115. 37 C.F.R. § 1.809(a) (1991). This regulation states in full:

> The examiner shall determine pursuant to § 1.104 in each application for patent, application for reissue patent or reexamination proceeding if a deposit is needed, and if

According to the Rules, a patent applicant who makes a deposit of a biological material must do so at an appropriate facility.[116] An appropriate facility is any International Depository Authority (IDA) or other depository recognized as suitable by the Patent and Trademark Office.[117] An applicant must make any necessary deposit of biological material either before filing the patent application or while the application is pending.[118] The depository will maintain a deposit "for a term of at least thirty . . . years and at least five . . . years after the most recent request for the furnishing of a sample of the deposit was received by the depository."[119] Finally, the deposit must be capable of self-replication, either directly or indirectly, at the time of the deposit.[120]

In the earliest biotechnology case presenting a substantial best mode issue, *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*,[121] the Federal Circuit reversed the trial court's invalidation of the patent.[122] The allegedly withheld disclosure was the procedure to make the particular monoclonal antibodies[123] used in the claimed process of employing monoclonal antibodies in a sandwich assay.[124] The alleged evidence of

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needed, if a deposit actually made is acceptable for patent purposes. If a deposit is needed and has not been made or replaced or supplemented in accordance with these regulations, the examiner, where appropriate, shall reject the affected claims under 35 U.S.C. 112, explaining why a deposit is needed and/or why a deposit actually made cannot be accepted.

Id.

116. 37 C.F.R. § 1.803.

117. *Id.* Criteria for determining the adequacy of a non-IDA depository include whether the depository: (1) has had a continuous existence; (2) is independent of the depositor's control; (3) possesses sufficient staff and facilities to preserve the deposit properly; (4) follows sufficient safety measures to guard against loss of biological material; (5) exhibits impartiality and objectivity; (6) furnishes samples of deposited matter in a proper and timely manner; and (7) promptly notifies depositors if unable to furnish samples. *Id.*

118. *Id.* § 1.804 (1991).

119. *Id.* § 1.806 (1991).

120. *Id.* § 1.807 (1991).

121. 802 F.2d 1367 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

122. *Hybritech*, 802 F.2d at 1385.

123. A monoclonal antibody is an antibody produced by a clone or genetically homogeneous population of hybrid cells. The hybrid cells are cloned to establish cell lines producing a specific antibody. Antibodies are proteins that defend vertebrates from invading microorganisms. STEDMAN'S, *supra* note 79, at 86.

124. *Hybritech*, 802 F.2d at 1370-71. An assay is a test to determine purity. Immunoassays are methods for determining the presence or amount of antigens, which are foreign molecules, in body fluids such as urine by employing the ability of an antibody to recognize and bind to that antigen. The extent to which the antibody binds to the antigen to be quantified is an indication of the amount of antigen present. In the case of a sandwich assay, a quantity of unlabeled antibody reagent is bound to a solid support surface, such as the inside wall of a test tube, containing a complex of the fluid sample which contains the antigen to be detected and a labelled antibody reagent. The result is an insoluble three part complex referred to as a sandwich having antibody bread and antigen filling. An antigen induces synthesis of antibodies when injected into a suitable host. *Id.*

concealment was that the screening methods used to identify the monoclonal antibodies with the necessary characteristics were labor intensive, time-consuming, and had to be carried out by sophisticated persons. The *Hybritech* court found that the evidence did not show concealment of the best mode.[125] The court concluded that one of ordinary skill in the art could reproduce such sandwich assays employing monoclonal antibodies.[126]

A similar issue appeared in *Scripps Clinic & Research Found. v. Genentech, Inc.*[127] In *Scripps*, Genentech alleged concealment of a better mode for carrying out the claimed invention than was set forth in the specification.[128] The alleged concealment related to the claimed method of separating the monoclonal antibodies that bind Factor VIII complex[129] from plasma.[130] Genentech did not dispute that the specification described the inventors' preferred method of obtaining these monoclonal antibodies.[131] There was no charge of concealment, special manipulation, or undisclosed techniques.[132] Genentech's argument was primarily that, because of the laborious nature of the process of screening monoclonal antibodies, the inventors should have voluntarily deposited a sample and made available to the public the antibody to Factor VIII:RP designated 2.2.9.[133] This antibody was the first effective antibody obtained by Scripps' screening, the preferred antibody, and the antibody used by Scripps in carrying out the claimed invention.[134]

The Federal Circuit reversed the trial court's finding of concealment of the best mode.[135] The court pointed out that there was no requirement that a deposit be made and that Scripps need not have made a voluntary deposit.[136] Relying on *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, Judge Newman stated:

> There was no evidence by Genentech that the antibodies used by [the inventors] differed from those obtainable according to the process described in the specification. The laborious nature of this work was recognized in *Hybritech*, and again in *In re Wands*. . . . In the context of best

125. *Id.* at 1384-85.
126. *Id.* at 1384.
127. 927 F.2d 1565 (Fed. Cir. 1991).
128. *Id.* at 1578.
129. Factor VIII:C is a complex protein found in blood and is essential to the clotting of blood. *Id.* at 1568.
130. *Id.* at 1578.
131. *Id.*
132. *Id.* at 1579.
133. *Id.*
134. *Id.*
135. *Id.* at 1580.
136. *Id.* at 1579.

> mode, on facts similar to those at bar, this court's holding in *Hybritech* settled the issue: "The only evidence even colorably relating to concealment is testimony by various Hybritech employees that sophisticated, competent people perform the screening and that the screening process is labor intensive and time consuming. *It is not plausible that this evidence amounts to proof of concealment* of the best mode for screening or producing monoclonal antibodies for use in the claimed 110 process and therefore we are of the firm conviction that the district court's finding that the best mode requirement was not satisfied is clearly erroneous." Applying *Hybritech* to the undisputed facts, a finding of concealment cannot be supported. The claims were incorrectly held invalid on this ground.[137]

With this case law and purpose in mind, this Note will review the application of the best mode requirement by the Federal Circuit in its decision in *Amgen, Inc. v. Chugai Pharmaceutical Co.*[138]

III. FACTS AND HOLDING

A. *Facts*

The litigation in *Amgen, Inc. v. Chugai Pharmaceutical Co.* arose as a result of a race between two leading biotechnology companies to clone the gene for the human hormone erythropoietin (EPO).[139] EPO is a naturally occurring protein in blood that stimulates the production of red blood cells. It is useful in treating anemia in kidney dialysis patients and for other pharmaceutical purposes.[140] The preparation of EPO products has generally been accomplished through the concentration and purification of the urine of both healthy individuals and those with high levels of EPO.[141] A new technique for producing EPO utilizes recombinant DNA technology to produce EPO from cell cultures where genetically engineered vectors[142] containing the EPO gene have been introduced.[143]

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137. *Id.* at 1579-80 (citations omitted) (quoting Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385 (Fed Cir 1986), *cert denied*, 480 U.S. 947 (1987) (emphasis in original)).

138. 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

139. Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1738 (D. Mass. 1989). Plaintiff Amgen, Inc., a biotechnology company located in Thousand Oaks, California, was the first to clone the gene. Defendant Genetics Institute, Inc., a biotechnology company located in Cambridge, Massachusetts, was the second to clone the gene. *Id.*

140. *Id.* EPO is a useful therapeutic agent in the treatment of blood disorders characterized by low or defective bone marrow production of red blood cells. *See id.* at 1741.

141. *Id.*

142. A vector is "[a] DNA molecule that autonomously replicates in a cell to which another DNA segment may be artificially attached and itself be replicated." STEDMAN'S, *supra* note 79, at 1691.

143. *See supra* notes 77-97 and accompanying text.

Both Amgen, Inc., (Amgen) and Genetics Institute, Inc., (GI) produced therapeutic EPO and held patents on that technology. GI's patent (the GI '195 patent) covered a method of purifying EPO from human urine and compositions thereof.[144] Amgen's patent (the Amgen '008 patent) covered DNA sequences encoding EPO and host cells transformed with a DNA sequence.[145] On October 27, 1987, the Patent

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144. U.S. Patent No. 4,677,195 (Hewick 1987). The patent is entitled "[Method for the Purification of Erythropoietin and Erythropoietin compositions] Homogeneous Erythropoietin" and claims both homogeneous EPO and compositions thereof as well as a method for purifying human EPO using reverse phase high performance liquid chromatograph. *Id.* The method claims are not at issue. The relevant composition claims are:

1. Homogeneous erythropoietin characterized by a molecular weight of about 34,000 daltons on SDS PAGE, movement as a single peak on reverse phase high performance liquid chromatography and a specific activity of at least 160,000 IU per absorbance unit at 280 nanometers.

. . . .

3. A pharmaceutical composition for the treatment of anemia comprising a therapeutically effective amount of the homogeneous erythropoietin of claim 1 in a pharmaceutically acceptable vehicle.

4. Homogeneous erythropoietin characterized by a molecular weight of about 34,000 daltons on SDS PAGE, movement as a single peak on reverse phase high performance liquid chromatography and a specific activity of at least about 160,000 IU per absorbance unit at 280 nanometers.

. . . .

6. A pharmaceutical composition for the treatment of anemia comprising a therapeutically effective amount of the homogeneous erythropoietin of claim 4 in a pharmaceutically acceptable vehicle.

Id.

145. U.S. Patent No. 4,703,008 (Lin 1987). The patent is entitled "DNA Sequences Encoding Erythropoietin" and the claims cover purified and isolated DNA sequences encoding erythropoietin and host cells transformed or transfected with a DNA sequence. The relevant claims are:

2. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin.

. . . .

4. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA sequence according to claim 1, 2 or 3 in a manner allowing the host cell to express erythropoietin.

. . . .

6. A procaryotic or eucaryotic host cell stably transformed or transfected with a DNA vector according to claim 5.

7. A purified and isolated DNA sequence consisting essentially of a DNA sequence encoding a polypeptide having an amino acid sequence sufficiently duplicative of that 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 hemoglobin synthesis or iron uptake.

8. A cDNA sequence according to claim 7.

. . . .

23. A procaryotic or eucaryotic host cell transformed or transfected with DNA sequence according to claim 7, 8, or 11 in a manner allowing the host cell to express said polypeptide.

24. A transformed or transfected host cell according to claim 23 which host cell is capable of glycosylating said polypeptide.

and Trademark Office issued the Amgen '008 patent. On the same day, Amgen sued GI and its licensee, Chugai Pharmaceutical, Co. (Chugai) for infringement and for a declaration that GI's patent was invalid or, in the alternative, that the EPO produced under the Amgen '008 patent did not infringe.[146] Amgen alleged that GI had infringed upon the Amgen '008 patent by producing recombinant EPO (rEPO) and by using transformed mammalian host cells containing vectors with DNA coding for the production of human EPO.[147] Amgen further sought a declaratory judgment that GI's patent was invalid,[148] or, in the alternative, that Amgen had not infringed the claims of the GI '195 patent and that GI and Chugai's future activities in the production and sale of rEPO would infringe the Amgen '008 patent.[149]

GI filed an answer on December 17, 1987, asserting that the Amgen '008 patent was invalid, unenforceable, and not infringed by the production of EPO under the GI '195 patent.[150] In its answer, GI raised sixteen affirmative defenses including: (1) the Amgen '008 patent was invalid;[151] (2) non-infringement; (3) failure to make deposits at a public depository of biological materials allegedly necessary for enabling the best mode of practicing the invention; and (4) unenforceability of the patent because of Amgen's alleged inequitable conduct before the Patent and Trademark Office.[152]

Chugai filed an amended answer and counterclaim on May 3, 1988, asserting the "same affirmative defenses as GI and adding a seventeenth . . . defense that Amgen misused[153] the Amgen '008 patent by attempting to extend the monopoly granted beyond any reasonable . . .

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25. A transformed or transfected mammalian host cell according to claim 24.

26. A transformed or transfected COS cell according to claim 25.

Id.

146. Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1739 (D. Mass. 1989).

147. *Id.* Amgen also alleged that Chugai, as a result of a collaborative relationship with GI, had induced and/or contributed to the direct infringement of the Amgen '008 patent. *Id.*

148. Amgen alleged patent invalidity under Title 35 §§ 102, 103, and 112. *Id.*

149. *Id.*

150. *Id.* at 1739-40.

151. GI alleged patent invalidity under 35 U.S.C. §§ 101, 102, 103, and 112. *Id.*

152. *Id.* at 1739-40. The alleged misconduct was that worthless cell material was deposited in order to deceive the examiner after the examiner's initial rejection of the patent application for failure to make a publicly accessible biological deposit, even though the rejection was later withdrawn. *See id.* at 1771-74.

153. *Id.* at 1740. A patent owner who engages in activity that ostensibly involves a patent, but is outside the scope of the grant, is guilty of misuse of the patent. *See* Morton Salt Co. v. Suppiger Co., 314 U.S. 488, 491 (1942). The theory is that the improper and unprotected activity serves to extend unjustly the scope of the limited patent monopoly. *Id.* at 491-93. This doctrine does not invalidate the patent, but bars the owner from enforcing it until the improper activity is abandoned. *Id.* at 493.

interpretation of the claims by pursuing a complaint before the International Trade Commission ('ITC') in 'bad faith.' "[154] Chugai also asserted four counterclaims: (1) that Amgen had infringed the GI '195 patent; (2) "unfair competition arising from Amgen's complaint with the ITC;" (3) a request for a "declaratory judgment of invalidity and noninfringement of the [Amgen] '008 patent;" and (4) an antitrust violation "in monopolizing and attempting to exclude Chugai from the rEPO market."[155]

B. United States District Court, District of Massachusetts

1. Pretrial Motions and Orders

GI and Chugai each filed a joint motion for summary judgment arguing that Amgen had infringed the claims of the GI '195 patent.[156] After hearing oral arguments, the court granted partial summary judgment.[157] On May 12, 1988, Chugai filed a second motion for summary judgment "seeking a determination that the [Amgen] '008 patent was unenforceable due to Amgen's alleged acts of patent misuse or, in the alternative, that the [Amgen] '008 patent contained no process claims, and thus did not cover Chugai's process of manufacturing [rEPO]."[158] On January 31, 1989, the court issued an opinion explaining its rationale for the February 1988 infringement ruling and granting Chugai's partial summary judgment motion on the grounds that the Amgen " '008 patent [did] not contain a process claim."[159]

The proceedings before the ITC were ongoing during this time.[160] On January 4, 1988, Amgen filed its first complaint against Chugai with the ITC.[161] The administrative law judge made an initial determination that the claims made by the Amgen '008 patent did not cover a process for the manufacture of EPO.[162] Amgen filed a second complaint with the ITC on February 3, 1989.[163] The first complaint was dismissed for lack of subject matter jurisdiction on April 10, 1989. The ITC subsequently decided not to investigate the second complaint on May 23, 1989.[164]

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154. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1740.
155. *Id.*
156. *Id.*
157. *Id.*
158. *Id.*
159. *Id.*; *see also* Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94, 110 (D. Mass. 1989).
160. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1740.
161. *Id.*
162. *Id.*
163. *Id.*
164. *Id.*

In response to Amgen's motion for a preliminary injunction, the district court issued a temporary restraining order enjoining GI and Chugai from exporting, shipping, or delivering rEPO.[165] The district court issued an order on February 7, 1989, finding:

> that Amgen had shown a reasonable likelihood of success on the merits of the validity of its patent; that it would suffer irreparable injury due to the needs of an incipient market and the burdens on a new company; . . . and as to public interest, recombinant EPO [(rEPO)] is an extraordinarily valuable medicine that promises marked relief from renal failure.[166]

The court concluded by stating that, "because of this public interest, the court would not enter an order to delay or prevent production or shipping of erythropoietin" but required "GI to place with the court all profits from the sale of EPO."[167]

2. Trial Before United States Magistrate

The parties consented to a trial before a magistrate in order to expedite the litigation.[168] The district court entered judgment upon findings of fact and conclusions of law set forth by the magistrate.[169] With respect to the Amgen '008 patent, the court held that the defendants did not show by clear and convincing evidence that the "patent is invalid for failure to disclose the best mode of carrying out the invention, despite Amgen's failure to deposit a mammalian host cell with a publicly accessible depository," and concluded that it was infringed by GI.[170] With respect to the GI '195 patent, the court concluded that it was infringed by Amgen.[171]

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165. *Id.*

166. *Id.*; Smith Int'l, Inc. v. Hughes Tool Co., 718 F.2d 1573, 1578-79 (Fed. Cir.), *cert. denied*, 464 U.S. 996 (1983) (stating that the test for granting a motion for a preliminary injunction is no different for patents than for other areas of the law). The movant must show: (1) likelihood of success on the merits (validity of patent); (2) immediate irreparable harm if injunction is not granted; and (3) the possibility of harm to other interested persons, and the public interest. The district court must consider the above factors and balance all of the elements. *Id.*

167. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1740.

168. *Id.* In addition, the trial was expedited in other ways: (1) by agreement "to share documents and deposition transcripts produced during discovery before the ITC"; (2) by agreement "the trial was bifurcated into a liability and damage phase;" and (3) the counterclaims of unfair competition and antitrust violations were not included in the first phase. *Id.* at 1740-41.

169. *Id.* at 1738-39.

170. *Id.* at 1739. The court also held that: (1) patent claims 2, 4, and 6 were valid, enforceable, and infringed by GI; (2) infringement was not willful; (3) patent claims 7, 8, 23-27, and 29 are invalid for lack of enablement under Title Thirty-Five § 112, but if valid were infringed, and; Chugai did not infringe, contributorily infringe, or induce infringement of any claim of the Amgen '008 patent. *Id.*; *see supra* note 145.

171. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1739. The court held that: (1) patent claims 1 and 3 were valid, enforceable, and infringed by Amgen; (2) Amgen did not infringe patent claims 2 and 5; (3) Amgen's infringement was not willful; and (4) patent claims 4 and 6 were invalid for

In addressing the defendants' argument that the Amgen '008 patent was invalid for failure to comply with the best mode requirement, the court first noted that the enablement requirement and the best mode requirement are separate and distinct.[172] The court then pointed out that all prior "cases addressing the deposit requirement have discussed the issue in terms of enablement only, without addressing the best mode requirement."[173] The Manual of Patent Examining Procedure's[174] deposit provision draws no distinction between the enablement and best mode provisions and requires deposits to satisfy both requirements.[175]

After reviewing prior cases addressing the best mode requirement, the court stated that the question was extremely close as to whether the best mode was adequately disclosed in the Amgen '008 patent specification.[176] The court then reviewed the pertinent facts.[177] The record indicated that Amgen gave testimony that the best mode host cell was disclosed in Example 10.[178] Example 10 described expression systems employing CHO DHFR cells[179] which are publicly available.[180] The

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indefiniteness under Title Thirty-Five § 112 but, if valid, were infringed by Amgen. *Id.*; *see supra* note 144.

172. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1769 (citing *In re* Gay, 309 F.2d 769, 772 (C.C.P.A. 1962); *see supra* note 4 and accompanying text.

173. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1770 (citing *In re* Wands, 858 F.2d 731, 735-36 (Fed. Cir. 1989)); *see also In re* Lundak, 773 F.2d 1216, 1220-21 (Fed. Cir. 1985); *In re* Argoudelis, 434 F.2d 1390, 1392-93 (C.C.P.A. 1970); *Ex parte* Forman, 230 U.S.P.Q. (BNA) 546, 547 (PTO Bd. App. & Int. 1986); *Ex parte* Jackson, 217 U.S.P.Q. (BNA) 804, 806-07 (PTO Bd. Pat. App. & Int. 1983)).

174. The Manual of Patent Examining Procedure (MPEP) is published to provide patent examiners, applicants, attorneys, agents and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the Patent and Trademark office. The MPEP does not have the force of law or the Patent Rules of Practice in Title 37, Code of Federal Regulations.

175. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1770; MPEP 608.01¶(C) (1988).

176. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1771.

177. *Id.* at 1771-72.

178. *Id.* at 1772. Specific examples are often included in patent specifications because such examples can be the best method of teaching how to make and use the invention. Such examples need not be based on actual experiments. Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, (Fed. Cir. 1985).

179. There are two kinds of host cells, prokaryotic and eukaryotic. Eukaryotic cells are mammalian, and prokaryotic cells are bacterial. Examples of prokaryotic cells are E. Coli and yeast. One disadvantage of the prokaryotic cells is that the protein will not be biologically active *in vivo*. There are different kinds of mammalian host cells. One kind of mammalian cell is the chinese hamster ovary (CHO) cell, which is the host cell used for the stable transformation and expression of EPO. Another mammalian cell is the COS-1 cell which is a monkey cell. The vector that is used to transfect the COS cell is not stable and over a period of time the DNA in that cell, while expressing EPO or some other protein early on, will be lost from the cells. It is a short-term expression system. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1744.

180. *Id.* at 1772.

example did not set forth the steps for transfection[181] of the cells with plasmids[182] containing the DNA, as well as the DHFR gene necessary for the cells to survive.[183]

GI and Chugai conceded that the Amgen '008 patent would have enabled skilled scientists, as of November 30, 1984, to make a host cell yielding *some* degree of EPO production.[184] GI and Chugai argued, however, that Amgen did not meet the best mode requirement because it did not deposit any CHO Bll 3,.1 cells[185] with a publicly accessible repository, or identify or describe CHO Bll 3,.1 or any of its derivative cell lines in the Amgen '008 patent. They argued that the inventor knew that a limited number of promising CHO Bll 3,.1 cell lines were selected for commercial production prior to the filing of the Amgen '008 patent application.[186]

The court found that the defendants had established by clear and convincing evidence that the inventor knew by the filing date "that the best way to express EPO was from mammalian cells, not yeast cells or E. Coli cells, and that a cell line derived from 11 possible clones from the CHO Bll 3,.1 cell strain was to be used [by] Amgen."[187] Despite

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181. Transfection is a method of gene transfer utilizing artificial infection of a cell nucleus with DNA resulting in integration of the endogenous nucleic acid with the host cell nucleic acid, with subsequent replication in the transfected cell and cloning of the genetically engineered cell. STEDMAN'S, *supra* note 79, at 1622.

182. A plasmid is a genetic particle which is not essential to the cells basic functioning and which can stably function and replicate while physically separate from the chromosome of the host cell. STEDMAN'S, *supra* note 79, at 1211.

183. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1772; DHFR cells are enzymes called dihydrolotate reductase. The cells are important to produce bases for the DNA, for nucleus synthesis and for cell growth. The DNFR cells are used in a methotrexate (MTX) amplification process which determines which cells have been transfected. MTX is an inhibitor which kills the cells that do not contain the DHFR cells. The DHFR cells are included with the protein to be produced in the vector that is introduced into the host cells. *Id.* at 1745.

The MTX first kills all of the cells which have not been transfected with the vector containing the DHFR and protein of interest. Additional MTX is introduced which prevents the making of nucleic acid and thus reduces the cell growth in the population. This sends the cells into a state of crisis and causes the cells to amplify their DHFR genes. The cells which are successful in increasing their DHFR cell level are not killed by the MTX. The cells that do survive are ones which the DHFR cells and everything else in the vector have been increased by as many as a thousand times. The cell population is considered heterogeneous because the cells have differing amounts of the vector gene. The cell that produces the highest level of the recombinant protein is then isolated. This cell is then grown back into a homogeneous population which can produce a very high level of the recombinant protein. *Id.*

184. *Id.* at 1772.

185. CHO Bll 3,.1 is scientific shorthand indicating that the host cell resulted from the amplification of CHO DHFR cells transfected with the plasmid vector pDSVL-gHuEPO and methotrexate selection at the levels of 30, 50, and 100 nanomolars of MTX. *Id.*

186. *Id.*

187. *Id.*; *see also* Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1517 (Fed. Cir.) (stating the defendants bear the burden of establishing that the plaintiff failed to set forth the best mode by clear and convincing evidence), *cert. denied*, 469 U.S. 871 (1984).

this knowledge, the inventor made no deposits when he filed his patent application.[188] The inventor had only deposited the best E. Coli cell strain and the best yeast cell strain without the EPO gene nine days prior to the filing of the patent application.[189] One week before the patent issued, on October 27, 1987, the inventor had deposited an E. Coli cell, which was transfected with the monkey cDNA EPO clone and a human EPO clone in "lambda phage,"[190] and transmitted a Declaration as to Deposit of Microorganism with the PTO indicating the deposit of two clones.[191] Amgen did not apply to correct the patent to identify the 1987 deposits until April 1989 and never deposited any mammalian host cell strain including any CHO cell.[192]

Amgen countered by arguing that the patent adequately described the best mode of the invention.[193] The court held that, although Amgen did not specifically name the cell strain as CHO Bll 3.,1 in the patent, it did disclose the best mode in Example 10, when it described the production rates of the 100 nanomolar-amplified cells and the one micromolar-treated cell.[194] The court thus noted that "[t]he tough question is whether this disclosure was so inadequate as to effectively amount to concealment."[195]

The court used a two-step analysis to answer this question.[196] First, the patent disclosed many embodiments of the claimed invention of a CHO, E. Coli, or yeast host cell transfected with the EPO sequence, but never disclosed that the preferred embodiment was the CHO cell. The evidence, however, was clear that an EPO glycosylated protein[197] cannot be expressed in sialated form in prokaryotic cells, like E. Coli or yeast.[198] There are also recognized problems with using COS

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188. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1772.

189. *Id.*

190. The entire central section of lambda phage DNA is not necessary for its replication in E. Coli thus making them more stable than plasmids for large chromosomal DNA fragments. This is a consequence of the fact that the less DNA a plasmid has, the faster it can multiply. Thus, genetic segments unnecessary for multiplication tend to be lost. WATSON, *supra* note 77, at 82.

191. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1772.

192. *Id.*

193. *Id.*

194. *Id.*

195. *Id.* at 1772-73.

196. *Id.* at 1773.

197. EPO is a glycoprotein. Specifically, sugar residues capped with a molecule called sialic acid are linked to a particular amino acid. An EPO protein contains four glycosylatin sites. As well, the two disulfide bridges between amino acids form important bonds necessary to ensure the proper folding of the molecule. Without glycosylation and the disulfide bridges, the EPO molecule is unstable and is lethargic in the body. *Id.* at 1742.

198. *Id.* at 1773. The EPO gene cannot be expressed in sialated form in prokaryotic cells because the cells are not capable of adding the n-linked glycosylation onto the polypeptide chain.

cells to express proteins due to their instability.[199] Therefore, the court concluded that there was "no clear and convincing evidence that one skilled in the art would not understand that CHO host cells as described in Example 10 were the best mode."[200] Second, while the inventor did not distinguish between the two cells described in Example 10, in order "to indicate which cell strain was the preferred best mode, the indiscriminate disclosure . . . of the preferred best mode along with one other possible mode satisfie[d] the best mode requirement."[201]

The defendants argued that the disclosure of the best mode was not adequate.[202] Testimony indicated that by following Example 10, one skilled in the art may not have been able to reproduce the results and certainly would not have been able to generate identical cell lines.[203] "Nor would [such individual have been] able to isolate an identical cell population to that described in the patent . . . [because the individual] wouldn't know if the properties [were] the same."[204] The court noted that this argument was "bolstered by the . . . fact that Amgen did not deposit any CHO cell, much less a sample of the CHO Bll 3,.1 cell strain . . . despite the patent examiner's specific request that a deposit be made."[205]

Amgen argued that a deposit was not required. It never adequately explained why it deposited E. Coli and yeast cells, however, which were available to the scientific community, but did not deposit the best mode mammalian cells.[206] The court stated that the "failure to deposit a CHO host cell despite the [MPEP] provision and the patent examiner's directive, particularly in light of Amgen's willingness to deposit other kinds of host cells, constitutes evidence of concealment of the best mode."[207]

The court concluded, however, that the failure to deposit a CHO host cell was not clear and convincing evidence of concealment.[208] There was no evidence that the inventor knew of a better mode that he had failed to disclose.[209] The details presented in Example 10 were suf-

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"This means the polypeptide, or protein, will not be biologically active." *Id.* at 1744; *see supra* note 179.

199. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1744; *see supra* note 179.
200. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1773.
201. *Id.*
202. *Id.*
203. *Id.*
204. *Id.*
205. *Id.*
206. *Id.*
207. *Id.*
208. *Id.*
209. *Id.*

ficient to enable one of ordinary skill in the art to make the best mode of the invention.[210] There was "no evidence . . . that the patent examiner was misled [by the] fact that an E. Coli cell transfected with a monkey cDNA clone and a lambda phage clone were deposited, instead of a CHO cell."[211] Furthermore, there was no evidence that Amgen had information before the filing date about other characteristics which would have better enabled those of ordinary skill in the art to identify the best mode host cell, or that the description of the production rate combined with the amplification procedure was so poor as to effectively constitute concealment.[212]

The court declined "to hold that the only way to meet the best mode requirement for a transfected host cell is to [make a] deposit."[213] The court stated that "the testimony is clear that no scientist could ever duplicate exactly the best mode used by Amgen, but that those of ordinary skill in the art could produce mammalian host cell strains or lines with similar levels of production."[214] Therefore, the court concluded that the defendants did not show clearly and convincingly that the best mode requirement of section 112 was not met.[215]

C. *The United States Court of Appeals for the Federal Circuit*

The Court of Appeals affirmed in part and reversed in part, holding that Amgen's '008 patent satisfied the best mode requirement.[216] Therefore, the lower court's judgment regarding the Amgen '008 patent was affirmed.[217] The district court's judgment regarding the GI '195 patent was, however, affirmed in part and reversed in part.[218]

With regard to the best mode requirement, the court stated that the issue was "whether the district court erred in concluding that Ex-

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210. *Id.*
211. *Id.*
212. *Id.*
213. *Id.* at 1774.
214. *Id.*
215. *Id.*
216. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1219 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).
217. *Amgen*, 927 F.2d at 1219. The court also held that: (1) Amgen's invention had priority; (2) Amgen's '008 patent claims 2, 4, and 6 were not obvious; (3) Amgen's '008 patent claims 7, 8, 23-27, and 29 were invalid for lack of enablement; (4) there was no inequitable conduct by Amgen; (5) GI's '195 patent claims 1 and 3 were invalid for lack of enablement; and (6) GI's '195 patent claims 4, and 6 were invalid for indefiniteness. *Id.*; *see also supra* notes 144-45.
218. *Amgen*, 927 F.2d at 1219. The district court, with regard to the GI '195 patent, held that claims 1 and 3 were valid, enforceable, and infringed by Amgen, and that claims 4 and 6 were invalid for indefiniteness under Title 35 § 112. Amgen Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1739 (D. Mass. 1989). Because the court concluded that claims 1, 3, 4, and 6 of the GI '195 patent were invalid, the judgment regarding claims 4 and 6 was affirmed, and the judgment regarding claims 1 and 3 was reversed. *Id.*; *see supra* note 144.

ample 10 of the [Amgen] '008 patent satisfied the best mode requirement . . . and that a deposit of the preferred CHO cells was not necessary."[219] The court first noted that because the best mode requirement is a question of fact, the appropriate standard of review is the clearly erroneous standard.[220]

The court pointed out that there are two components to a best mode analysis as articulated by the court in *Chemcast Corp. v. Arco Indus. Corp.*[221] "The first [inquiry] is a subjective one, asking whether at the time [of filing the application,] the inventor . . . contemplated a best mode of practicing his invention."[222] If so, "the second inquiry is whether [the] disclosure is adequate to enable one skilled in the art to practice the best mode."[223] These two components determine whether the best mode was concealed from the public.[224] The court then recognized that the best mode requirement is the *quid pro quo* for a patent grant.[225]

Judge Lourie observed that the contention that a deposit is required to satisfy the best mode requirement "presents us with a question of first impression concerning the best mode requirement for patents involving novel genetically-engineered biological subject matter."[226] The court then reviewed the history of deposits, noting that it has been customary for patent applicants to place microbiological samples in a public depository when such a sample is necessary to carry out a claimed invention.[227] The court noted that the practice arose out of the development of antibiotics, where microorganisms were obtained from soil samples to synthesize antibiotics which could not be prepared otherwise.[228] Case law states that such a deposit adequately satisfies the enablement requirement when a written description alone will not place the invention in the hands of the public.[229]

After reviewing the findings of the district court, the appellate court agreed with its determination.[230] The court pointed out that the testimony reflected that the invention, as it relates to the best mode

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219. *Amgen*, 927 F.2d at 1209.

220. *Id.*

221. *Id.*; Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923 (Fed. Cir. 1990); *see supra* notes 64-76 and accompanying text.

222. *Amgen*, 927 F.2d at 1209.

223. *Id.*

224. *Id.*

225. *Id.* at 1210.

226. *Id.*

227. *Id.*

228. *Id.*

229. *Id.*; *In re* Wands, 858 F.2d 731, 735-36 (Fed. Cir. 1988); *In re* Lundack, 773 F.2d 1216, 1220 (Fed. Cir. 1985).

230. *Id.* at 1210-11.

host cells, could be practiced by one skilled in the art following the disclosure, and that therefore the best mode was adequately disclosed.[231]

The court then contrasted the starting materials of the rEPO to those of cells obtained from unique soil samples.[232] When the required material is obtained from nature, the invention may be incapable of being practiced without access to that organism.[233] Therefore, a deposit is required.[234] When the organism is created by insertion of genetic material into a cell obtained from generally available sources, however, all that is required is a description of the best mode and an adequate description of the means of carrying out the invention.[235] The court then concluded that, because the district court had found that the Amgen '008 patent claimed an invention created by the insertion of genetic material into a cell obtained from generally available sources, there is no failure to comply with the best mode requirement for the lack of a deposit of the CHO cells when the best mode of preparing the cells was disclosed and the best mode cells were enabled.[236]

The court also noted that the PTO had "recently prescribed guidelines concerning the deposit of biological materials."[237] The guidelines stated that biological material need not be deposited "if it is known and readily available to the public or can be made or isolated without undue experimentation."[238] The court concluded that no inconsistency existed between the district court's decision and the guidelines.[239] The appellate court pointed out that "the issue [was] whether the disclosure [was] 'adequate', not that an exact duplication is necessary . . . . What is required is an adequate disclosure of the best mode, not a guarantee that every aspect of the specification be precisely and universally reproducible."[240]

The appellate court finally held that the deposit of essentially worthless cell material was irrelevant.[241] The court stated that because a deposit of the host cells containing the rEPO gene was not required

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231. *Id.* at 1211.
232. *Id.*
233. *Id.*
234. *Id.*
235. *Id.*
236. *Id.*
237. *Id.*; *see supra* notes 110-20 and accompanying text.
238. *Amgen*, 927 F.2d at 1209; 37 C.F.R. § 1.802(b) (1990).
239. *Amgen*, 927 F.2d at 1209.
240. *Id.* at 1212.
241. *Id.*

to satisfy the best mode requirement, the fact that some cells were deposited, but not others, is irrelevant.[242]

IV. ANALYSIS

The Federal Circuit, in *Amgen, Inc. v. Chugai Pharmaceutical Co.*,[243] properly applied the case law to the issues presented in its analysis, but should have also required more specificity of the best mode disclosure for policy reasons. The *Amgen* court conducted the two part best mode analysis first articulated by the court in *Chemcast*.[244] The following section critiques the court's analysis in consideration of patent law and the policy behind the best mode requirement. First, the analysis considers the issue of whether a deposit for all biotechnology patents is necessary in order to satisfy the best mode requirement. Second, the analysis discusses the issue of what degree of specificity is required for an "adequate" disclosure. Finally, the analysis discusses the relevence of a bad faith disclosure or intentional concealment when making a best mode evaluation.

A. Deposit Requirement

In analyzing whether a deposit of material is necessary to satisfy the best mode requirement for patents involving novel, genetically-engineered biological subject matter, the *Amgen* court looked to the history of the practice of depositing biological material.[245] The history indicated that "the practice arose out of the development of antibiotics, when microorganisms obtained from soil samples uniquely synthesized antibiotics which could not be readily prepared chemically."[246] Such deposits are adequate to satisfy the enablement requirement of section 112 when a written description alone would not place the invention in the hands of the public.[247] It follows that, if a written description alone would put the invention in the hands of the public, a deposit is not required. Thus, the court's refusal to impose an absolute deposit requirement for biological patents seems justified. The *Amgen* court took great steps to distinguish between naturally occurring material and genetically produced material. A deposit is therefore still required when

242. *Id.*

243. 927 F.2d 1200 (Fed. Cir.), *cert. denied*, 112 S. Ct. 169 (1991).

244. 913 F.2d 923 (Fed. Cir. 1990); *see supra* notes 64-76 and accompanying text.

245. *Amgen*, 927 F.2d at 1210.

246. *In re* Argoudelis, 434 F.2d 1390 (C.C.P.A. 1970); *Ex parte* Kropp, 143 U.S.P.Q. (BNA) 148 (Pat. Bd. App. 1959).

247. *In re* Wands, 858 F.2d 731, 735-36 (Fed. Cir. 1989); *In re* Lundak, 773 F.2d 1216, 1220-21 (Fed. Cir. 1985); *Argoudelis*, 434 F.2d at 1392-93; *Ex parte* Forman, 230 U.S.P.Q. (BNA) 546, 547 (PTO Bd. Pat. App. & Int. 1986); *Ex parte* Jackson, 217 U.S.P.Q. (BNA) 804, 806-07 (PTO Bd. Pat. App. & Int. 1983).

the invention is incapable of being practiced without undue access to that organism.

In contrast to naturally occurring material, the production of materials through the use of rDNA technology can often be accomplished by using starting materials and methods which are readily available to those skilled in the art. Therefore, the claimed material may be novel and unavailable, but the written disclosure may suffice to describe the invention "in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same."[248] A deposit should not be required when these conditions are present.

While routine deposits were necessary in the past, they are now not always necessary.[249] Until the last decade, even if the starting materials were publicly available, and the procedures described in detail in the patent specification, production could not be assured by repeating the disclosed procedure.[250] The technology of the time did not assure that one skilled in the art could reproduce the invention by following the disclosure in the patent. The advent of rDNA technology alleviated the necessity of depositing genetic material for all biological patents.[251] For recombinant inventions, "technology exists to permit one skilled in the art to cleave the DNA strand, separate and identify the cleaved DNA fragment, recombine selected DNA fragments, and build them into the disclosed novel material which can then be selected using standard screening techniques."[252] This procedure now makes "it possible to include sufficient information in the written disclosure to allow one skilled in the art who has access to the known . . . starting materials to reproduce the invention without undue experimentation."[253] The court's conclusion is consistent with the language of cases that deal with the issue of when a deposit is necessary to satisfy the enablement requirement.[254] The court's conclusion is also consistent with the policy of the best mode requirement because it requires that the best mode of the invention be put in the hands of the public.

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248. 35 U.S.C. § 112 (1988); Schneider, *supra* note 100, at 600 (using rDNA technology "an inventor can create a new organism and describe the process in such full, clear and concise terms that others in the field can achieve the same result solely by following the specification"); Meyer, *supra* note 100, at 459-60 ("it is possible to include sufficient information in the written disclosure to allow one skilled in the art who has access to the known and available starting material to reproduce the invention without undue experimentation").

249. Meyer, *supra* note 100, at 458.

250. *Id.*

251. *Id.* at 459.

252. *Id.*

253. *Id.*

254. *See* cases cited *supra* note 247.

There are practical difficulties, however, with a rule that does not require a deposit in all biological patent cases. Instead of a bright-line test, the question of whether someone who develops a new cell line must make a deposit depends upon a case-by-case inquiry by the patent office and by the federal courts. The inquiry looks to whether a written description of the genetic engineering method and the cell line will suffice. At least one commentator has stated that the decision creates a hard-to-predict inquiry that invites patent applicants to gamble on not placing a sample of their cell line in a public depository, so that they might have a good chance of getting a patent and maintaining their best mode cell line as a trade secret.[255] Fulfilling the purpose of the constitutional mandate, however, sometimes requires a difficult test.[256]

A bright-line test of requiring a deposit for all biological patents would not fulfill the constitutional mandate of promoting the progress of science and the useful arts. When a written description of biological material is not sufficient to place the invention in the hands of the public, the *quid pro quo* of the patent bargain justifies the deposit. When the patent specification describes biological matter in a manner sufficient to put the invention in the hands of the public, however, requiring the inventor to make a deposit for disclosure purposes upsets the balance of the patent bargain because the patentee must give more than is necessary to place the invention in the hands of the public. Inventors who feel that the *quid pro quo* of the patent bargain is not being fairly applied may elect to exploit their invention by means of trade secrets rather than through the use of the patent system.[257]

Either the patent laws or the trade secret laws can protect inventions. To receive patent protection, an invention must satisfy the statutory requirements.[258] In contrast, trade secret law requires that the invention be actively kept secret from both the public and the market place by the holder of the invention, and that the invention give one an

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255. *Interview With Laurence Tribe on Supreme Court Review of* Amgen, Inc. v. Chugai Pharmaceutical Co., 42 PAT., TRADEMARK & COPYRIGHT J. 466 (September 12, 1991).

256. The Supreme Court in announcing requirements for determining obviousness or nonobviousness stated:

> This is not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter, and should be amenable to a case-by-case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definiteness which Congress called for in the 1952 Act.

Graham v. John Deere Co., 383 U.S. 1, 18 (1966).

257. Meyer, *supra* note 100, at 458-59.

258. The substantive statutory requirements for patentability are as follows: (1) patentable subject matter; (2) novelty; (3) utility; and (4) non-obviousness. 35 U.S.C. §§ 101-03 (1988).

advantage over one's competitors.[259] The inventor can elect trade secrecy for all of the following types of discoveries: "(1) clearly unpatentable, (2) doubtfully patentable, or (3) clearly patentable" inventions.[260]

An inventor must elect between patent and trade secret protection for a given invention.[261] The best mode disclosure requirement attempts to force this election. Without the best mode disclosure requirement, it would be possible for the inventor to receive patent protection for a seventeen year period in exchange for knowingly disclosing only a second-best mode. In addition, the inventor could enjoy trade secret protection for an unlimited time on the undisclosed best mode. Such a result deprives the public of full enjoyment of the invention upon expiration of the patent term and therefore dilutes the effectiveness of the patent system. The best mode requirement effectively removes the problem of simultaneous enjoyment of patent and trade secrecy protection by ensuring that the best mode of carrying out the invention is disclosed in the patent application.

The election of trade secret protection rather than patent protection, results in the invention never reaching the public. A rule that encourages the election of trade secret protection thus does not promote the progress of the arts and sciences.[262] Likewise, when the best mode is not adequately disclosed, the public does not get full enjoyment of the patented invention. Thus, a rule that does not require full disclosure

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259. A common law trade secret may consist of:

> Any, formula, pattern, device, or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers.

RESTATEMENT OF TORTS § 757 cmt. b (1939).

260. Kewanee Oil v. Bicron Corp., 416 U.S. 470, 471 (1974). Trade secret law, however, provides far weaker protection:

> While trade secret law does not forbid the discovery of the trade secret by fair and honest means, e.g., independent creation or reverse engineering, patent law operates "against the world," forbidding any use of the invention for whatever purpose for a significant length of time. The holder of a trade secret also takes a substantial risk that the secret will be passed on to his competitors, by theft or breach of a confidential relationship, in a manner not easily susceptible of discovery or proof.

Id. at 476.

261. *Id.*; *see* Jeffrey L. Ihnen, *Patenting Biotechnology: A Practical Approach*, 11 RUTGERS COMPUTER & TECH. L.J. 407, 407-08 (1985) ("At the present time patent protection is preferred to trade secret protection for biotechnology."). Patent law protection is preferred for several reasons: (1) start up companies need tangible assets to raise capital; (2) companies need protection of their particular area of expertise in order to stay in business; (3) the inventions are easily reproducible so that the compromise of a small sample can result in the loss of a trade secret; and (4) granting patent rights engenders competition which spurs new innovations. *Id.* at 408 n.6.

262. An example would be a bright-line rule that requires a deposit for all biological patents.

does not promote the progress of the arts and sciences.[263] A balance must be reached between these two extremes in order to promote the progress of the arts. Neither extreme approach should be taken to maintain an effective patent system.

A bright-line test of requiring a deposit for all biological patents is also not wise because the added cost may cause inventors to forgo patent protection. One commentator believes that the rapid increase in patent fees "has turned the U.S. Patent System into a system for the rich."[264] He states that by the large increase in fees, "we have substantially eliminated the would-be Edisons, Ketterings, Fords, Whitneys, Goodyears, Wrights, McCormicks, Westinghouses, and John Deeres to name only a few from the inventors Hall of Fame."[265] If you add the average minimum cost of a biological deposit, the cost becomes even further out of reach for some inventors.[266] Thus, a bright-line test of requiring a deposit for all biological patents would not fulfill the constitutional mandate to promote the progress of science and the useful arts. In fact, it would act as an impediment.

At least one commentator has addressed the issue of when a deposit should be required for genetically engineered materials.[267] Specifically, a deposit should be required where the specification is per se deficient because it employs a "shotgun" procedure.[268] In all other cases, a detailed analysis could determine the sufficiency of the specification based upon the availability of the starting materials to the public and the adequacy of the disclosure for allowing one skilled in the art to practice the invention.[269]

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263. An example is a rule that does not require a deposit when the written disclosure does not adequately disclose the best mode of the invention. The Advisory Commission on Patent Law Reform takes the extreme position of recommending the deletion of the best mode requirement from Title 35 § 112 because it unduly complicates litigation with marginal public benefit. *Advisory Commission Reviews Draft Recommendations on Patent Law Reforms*, 43 PAT., TRADEMARK & COPYRIGHT J. 384 (March 5, 1992).

264. B. Edward Schlesinger, Jr., An Open Letter to President George Bush, J. PAT. OFF. SOC'Y 484 (1991) ("The minimum legal charges for an individual obtaining a patent on a relatively simple device will run in the neighborhood of $2,000.00 to $2,500.00. Add this to the government fees for obtaining a 17 year grant and you have a minimum cost of a single patent running approximately $6,000.00 to $6,500.00.").

265. *Id.* at 485.

266. The average minimum cost of a deposit is $2,000.00, making the minimum cost of a single patent approximately $8,000.00 to $8,500.00. Examples of United States depositories are: American Type Culture Collection (ATCC), 12301 Parklawn Drive, Rockville, Maryland 20852; In Vitro International, Inc. (IVI), 6111 Hammonds Ferry Road, Linthicum, Maryland 21090.

267. Hampar, *supra* note 100, at 570-71.

268. Hampar, *supra* note 100, at 570-71. In a "shotgun" procedure, the probability of success remains constant regardless of the number of attempts, while for a "nonshotgun" procedure, the probability of success should increase as the operator gains experience through repetition. *Id.* at 586.

269. Hampar, *supra* note 100, at 589-90.

The patent practitioner must now determine on a case-by-case basis whether an application requires a deposit. If a deposit is not necessary, the practitioner must weigh the advantages of avoiding potential prosecution problems against the disadvantage of enabling others to have access to the deposited matter upon issuance of the patent.

If the application discloses a novel type of plasmid or microorganism strain that can be reproduced with certainty on the basis of the written disclosure, a deposit is both unnecessary and unwise. The deposit of particular organisms could limit the scope of the inventions to the deposited material, even though more generic claims are sought or allowed.[270] If the sufficiency of the disclosure is questionable, however, the safest course of action is to make a deposit in order to avoid subsequent refusal of the patent application or cancellation of the patent in an infringement action.

C. *Adequate Disclosure*

The *Amgen* court next analyzed the question of whether the written disclosure was adequate to enable a person skilled in the art to practice the best mode of the invention.[271] The court stated that the proper analysis is the two part test articulated by the court in *Chemcast*.[272] There was no controversy over the first element. The controversy concerned the second element which determines if the disclosure is adequate.[273] Although the court consistently applied the case law authority in this area, it should have required more specificity of the best mode for policy reasons.

The court noted that GI's own expert testified that with the information disclosed in Example 10, someone could generate cell strains making some level of EPO.[274] The cell strains, however, could be better or worse in terms of production.[275] It seems clear that, by this testimony, the defendants did not meet the burden of proof on the issue of their affirmative defense. The party attempting to establish invalidity carries the burden of proof.[276] The defendants essentially offered proof that the written description may or may not be adequate. This is not

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270. *Ex parte* Jackson, 217 U.S.P.Q. (BNA) 804, 808 (Bd. Pat. App. & Int. 1983).

271. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1209 (Fed. Cir. 1991).

272. *Id.* at 1209; Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923 (Fed. Cir. 1990); *see supra* notes 64-76 and accompanying text.

273. *Amgen*, 927 F.2d at 1210.

274. *Id.* at 1211.

275. *Id.*

276. 35 U.S.C. § 282 (1988).

enough to meet the burden.[277] The plaintiffs successfully proved that, from the written description, exact duplication of the cell strain was not possible. The court responded that exact duplication was not necessary.[278] Citing *In re Gay*,[279] the court stated that what is required is an adequate disclosure of the best mode, not that every aspect of the specification be precisely and universally reproducible.[280] Requiring this additional disclosure would encourage the use of trade secret protection rather than patent protection.

The Federal Circuit did not analyze the district court's conclusion that an indiscriminate disclosure[281] of the best mode satisfies the best mode requirement. The court simply stated that the district court found that, while it was not clear which of the two possible strains disclosed in Example 10 the inventor considered the best, the best mode was disclosed because both were disclosed.[282] The district court conducted a brief analysis of this issue.[283] The district court's position was consistent with the language of those decisions which propose that courts should not decide how the best mode should be displayed in the application, but only whether it is contained in the disclosure.[284] The disclosure of the best mode among other modes, however, seems to be contrary to the policy behind the best mode requirement because the disclosure may require undue experimentation by someone trying to find the best mode of carrying out the invention.[285] The policy underlying the disclosure requirement necessitates that the inventor make a good faith disclosure and promote the arts by allowing the public the ability to experiment and advance the inventor's invention.[286] Thus, indiscriminate disclosure of the best mode among other modes should satisfy the disclosure requirement only if the inventor mentions the other modes in good faith. An example of such a situation is when the inven-

277. Railroad Dynamics, Inc. v. A. Stucki Co., 727 F.2d 1506, 1517 (Fed. Cir.) (stating the defendants bear the burden of establishing that the plaintiff failed to set forth the best mode by clear and convincing evidence), *cert. denied*, 469 U.S. 871 (1984).

278. *Amgen*, 927 F.2d at 1212.

279. 309 F.2d 769, 773 (C.C.P.A. 1962).

280. *Amgen*, 927 F.2d at 1212.

281. An indiscriminate disclosure is a disclosure that lists several modes without identifying which is the preferred mode. 2 CHISUM, *supra* note 5, § 7.05[1] at 7-140.

282. *Amgen*, 927 F.2d at 1210.

283. Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1771 (D. Mass. 1989).

284. *See supra* note 56.

285. Randomex, Inc. v. Scopus Corp., 849 F.2d 585, 591-92 (Fed. Cir. 1988) (Mayer, J. dissenting) ("This is the antithesis of the good faith full disclosure that is mandated by section 112's best mode requirement . . . he buried his best mode in a list of less satisfactory ones . . . if there is a best mode known to the inventor he must say so; he cannot require the public to hunt for it.").

286. *See supra* notes 19-34 and accompanying text.

tor is not sure which of the modes disclosed is the best mode or where it is obvious to one skilled in the art which mode is the best mode. In *Amgen,* the record shows that the inventor knew, but did not identify, which of the modes disclosed he considered to be the best at the time of application.[287] It was obvious, however, to one skilled in the art which mode disclosed was the best mode.[288]

C. *Factors of Concealment or Bad Faith*

Finally, the *Amgen* court brushed aside facts showing that Amgen attempted to conceal the best mode of the invention by depositing essentially worthless cells.[289] The court's opinion is inconsistent with other decisions regarding the best mode requirement and its underlying policies. Most decisions prohibit concealment[290] and require good faith disclosure of the best mode.[291]

Although the deposit of worthless cells needs to be considered when deciding whether the best mode requirement is satisfied, it should not be conclusive evidence justifying the invalidation of the patent. Evidence of the deposit of worthless cells should be a factor even if, as the *Amgen* court indicated, the examiner later withdrew his requirement that a deposit be made.[292] Direct evidence of deliberate concealment should be considered regardless of whether a disclosure enables those skilled in the art to practice the invention.[293] When evidence of intentional concealment is present, a higher degree of specificity in the disclosure should be required. If intentional concealment leads to a slightly higher required level of specificity, it would deter inventors from making less than full public disclosure. This would ensure that the public receives the utmost benefit in exchange for granting the inventor a monopoly on an invention.

Requiring a slightly higher degree of specificity is consistent with the policy set forth in section 112.[294] It is consistent because higher specificity would be required only when the inventor gives the court some indication of less than a good faith disclosure to the public. In

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287. *Amgen*, 13 U.S.P.Q.2d (BNA) at 1772.

288. *See supra* notes 197-200 and accompanying text.

289. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1212 (Fed. Cir.) *cert denied*, 112 S. Ct. 169 (1991).

290. *See supra* notes 52-60 and accompanying text.

291. *In re* Nelson, 280 F.2d 172, 184 (C.C.P.A. 1960) (stating that there is a "selfish desire" by people to obtain patent protection without making a full disclosure and the best mode requirement does not allow them to do so).

292. *Amgen*, 927 F.2d at 1211.

293. *See* General Motors Corp. v. United States Int'l Trade Comm'n, 687 F.2d 476 (C.C.P.A. 1982), *cert. denied*, 459 U.S. 1105 (1983); O'Hara Mfg. v. Elli Lilly & Co., 231 U.S.P.Q. (BNA) 753 (N.D. Ill. 1986).

294. *See supra* notes 19-34 and accompanying text.

Amgen this would have required the court to consider the deposit of worthless cell material. Although this higher specificity may not have changed the outcome of *Amgen,* the court should have addressed the issue so that, in future cases, the best mode policy would be furthered and inventors would think more carefully about intentionally concealing the best mode. This represents the spirit of Judge Rich's words in *In re Nelson,*[295] as well as the Supreme Court's view that full disclosure is absolutely necessary to maintain a successful patent system.[296]

V. CONCLUSION

The Federal Circuit held in *Amgen, Inc. v. Chugai Pharmaceutical Co.* that a deposit of a host cell for a genetic engineering patent is not needed to comply with the best mode requirement when the cells can be prepared by one skilled in the art from known materials using the description in the specification.[297] The holding distinguishes genetically engineered cells from naturally occurring microbiological materials that are not readily available.[298] It also establishes an inquiry on a case-by-case basis of whether a deposit is required.[299] Requiring a deposit for all biological patents would, in some cases, result in more disclosure than is necessary to meet the requirements of section 112. If inventors think they are giving more than is required, they will elect trade secret protection rather than patent protection.[300] Collateral means for practicing the invention, such as cell cultures, may be developed at great expense and may be very valuable as trade secrets. The inventor should be allowed to maintain trade secret protection for the information that need not be disclosed in order to meet the requirements of section 112. The election of trade secret protection should not be encouraged, however, because the invention never reaches the public. This does not fulfill the constitutional mandate of promoting the arts and sciences. Great care must therefore be taken to ensure that adequate disclosure of the best mode is made in each patent so that the public will receive full enjoyment of the invention. Maintaining an ef-

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295. 280 F.2d 172, 184 (C.C.P.A. 1960); *see supra* note 29 and accompanying text.

296. *See* Universal Oil Co. v. Globe Oil & Ref.Co., 322 U.S. 471 (1944); United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 237 (1942); General Electric Co. v. Wabash Appliance Corp., 304 U.S. 364, 368 (1938); Merrill v. Yoemans, 94 U.S. 568, 573-74 (1876).

297. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir.), *cert. denied,* 112 S. Ct. 169 (1991).

298. *Amgen,* 927 F.2d at 1210-11.

299. *See supra* text accompanying notes 255-56.

300. *See supra* text accompanying notes 257-62

fective patent system necessitates a balance between requiring too much disclosure and requiring too little disclosure.[301]

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301. *See supra* notes 262-63 and accompanying text.