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A Definite and Permanent Idea - Invention in the Pharmaceutical and Chemical Sciences and the Determination of Conception in Patent Law, 28 J. Marshall L. Rev. 687 (1995)

Jackie Hutter

A DEFINITE AND PERMANENT IDEA? INVENTION IN THE PHARMACEUTICAL AND CHEMICAL SCIENCES AND THE DETERMINATION OF CONCEPTION IN PATENT LAW

INTRODUCTION

In the November, 1994 patent infringement appeal of *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, the Court of Appeals for the Federal Circuit affirmed[1] that Burroughs Wellcome Company (BW) researchers invented the method for treating Human Immunodeficiency Virus (HIV) and Acquired Immunodeficiency Syndrome (AIDS)[2] with azidothymidine (AZT).[3] In so finding, the court ruled that an inventor completes conception of a pharmaceutical invention when the inventor shows possession of a definite and permanent idea of the invention, regardless of whether the inventor also held a "reasonable expectation" that the invention would work as intended.[4] The *Burroughs* decision settles the years-long controversy surrounding the patent rights to AZT by permitting BW to maintain the exclusive right to sell the drug as an AIDS therapy until the patents expire in the year 2005.[5]

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1. Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1232 (Fed. Cir. 1994), *aff'g in part* Burroughs Wellcome Co. v. Barr Labs., Inc., 828 F. Supp. 1208, 1213 (E.D.N.C. 1993).

2. HIV is a retrovirus determined in 1987 to cause AIDS. Robert Gallo, *The AIDS Virus; Human Retroviruses, Part II*, 256 SCI. AM., Jan. 1987, at 47. *See generally id., passim* for a background discussion of retroviruses, HIV and AIDS.

3. AZT is the common name of the drug zidovudine. Evan Ackiron, Note, *Patents for Critical Pharmaceuticals: The AZT Case*, 17 AM. J.L. & MED. 145, 145 (1991). Although not a cure for either HIV or AIDS, AZT effectively slows the onset of AIDS in an HIV-infected person and reduces the severity of infection in persons with AIDS, thereby extending the overall life expectancy of an afflicted person. *Study Provides Additional Confirmation that AZT Improves the Survival of People with AIDS*, PR NEWSWIRE, Mar. 4, 1992, *available in* LEXIS, ASAPII File.

4. *Burroughs*, 40 F.3d at 1228. See *infra* notes 166-90 and accompanying text for a further discussion of the *Burroughs* decision.

5. *Wellcome Wins AZT*, S.F. CHRON., Nov. 24, 1994, § B, at 2. However, the *Burroughs* court remanded the case to the district court for trial on the issue of inventorship of AZT as a method to improve a patient's immune system. *Burroughs*, 40 F.3d at 1232.

A patent gives its owner the right to exclude others from making, using, or selling an invention for seventeen years. 35 U.S.C. § 154 (1988). See infra notes 22-

In ruling that the BW researchers were the sole inventors of AZT therapy, the *Burroughs* court applied the *Mergenthaler* standard of conception.[6] This standard defines a complete conception as the formation of a definite and permanent idea sufficient to allow a person of ordinary skill in the art to put the idea into practice without the need for undue experimentation.[7] However, in the past, federal courts have recognized that when the subject matter of the invention is unpredictable, the *Mergenthaler* standard may not provide an accurate determination of conception.[8] In such cases, some courts applied the doctrine of simultaneous conception and reduction to practice to the invention at issue.[9] This doctrine states that separating conception from reduction to practice is impossible when an inventor must perform experiments before confirming that the idea results in a successful invention.[10] These two standards are mutually exclusive: an idea that requires confirming experiments to show its feasibility cannot exist in a definite and permanent form.[11] The need for two legal standards of conception reflects the fundamental differences be-

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60 and accompanying text for a discussion of the U.S. patent system.

Critics accused BW of "price gouging" as soon as it began marketing AZT in 1987. David Axinn, *Burroughs Wellcome Embroiled Over AZT*, 239 CHEMICAL MARKETING REP., May 27, 1991, at 7. When BW first introduced AZT it set the price per patient at more than $10,000 per year. Janet Kidd Stewart, *Drug Firm Here Seeks OK for Generic AZT*, CHI. SUN TIMES, Aug. 25, 1992, at 48. Subsequently, BW reduced the price twice to reach a low of about $2,500 per year per patient in 1992. *Id.*

In 1992, a Washington, D.C. based public interest group brought suit seeking a court's ruling that the BW patents for AZT were invalid. People with AIDS Health Group v. Burroughs Wellcome Co., No. 91-0574, 1992 WL 18834, at *3 (D.D.C. Jan. 17, 1992). The case was dismissed in 1992. *Id.* The court expressly noted the "public's concern surrounding AIDS and the availability of affordable AZT." *Id.* However, the court stated that in view of the (then) pending litigation between BW and Barr Laboratories, the interests of the parties were better served by awaiting the result of that litigation.

6. *Burroughs*, 40 F.3d at 1227. See *infra* notes 86-99 and accompanying text for a discussion of the *Mergenthaler* standard of conception.

7. *See* Coleman v. Dines, 754 F.2d 353, 359 (Fed. Cir. 1985).

8. *See* Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir. 1991), *cert. denied sub nom.* Genetics Inst. v. Amgen, Inc., 112 S. Ct. 169 (1991). Disciplines considered by the court to be "inherently unpredictable" include the chemical and biological sciences. Smith v. Bousquet, 111 F.2d 157, 158 (C.C.P.A. 1940). In recent years, the Federal Circuit has stated that the biotechnology arts are also unpredictable. *Amgen*, 927 F.2d at 1206.

9. *Amgen*, 927 F.2d at 1206. See *infra* notes 100-90 for a discussion of the doctrine of simultaneous conception and reduction to practice.

10. Alpert v. Slatin, 305 F.2d 891, 894 (C.C.P.A. 1962).

11. *See, e.g., id.* (stating that conception is not complete if the inventor must use trial and error to test the feasibility of an idea); *Smith*, 111 F.2d at 162-63 (stating that in chemistry and biology, invention conception does not exist in definite and permanent form before reduction to practice).

tween invention in engineering-related disciplines and the empirical sciences, such as pharmaceuticals and biotechnology.[12] Engineers typically focus on applied technology, using well-understood scientific principles to develop new products and processes.[13] In contrast, since the state of biomedical knowledge today is far from well-understood, pharmaceutical scientists and biotechnologists often conduct research and development without fully understanding the underlying biological and chemical mechanisms.[14] Therefore, even with recent advances in biotechnology, product development in these disciplines remains largely empirical.[15]

In recent years, the Federal Circuit, and other federal courts relying on Federal Circuit precedent, indicated a willingness to acknowledge the differences between engineering and the more empirically-based disciplines by applying the doctrine of simultaneous conception and reduction to practice to biotechnology invention.[16] Nevertheless, in the recent case of *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, the Federal Circuit refused to extend this doctrine to a case of a pharmaceutical invention of a new use for a known chemical compound.[17] This reluctance of the courts to accommodate the differences in the various scientific disciplines is not a new phenomenon since the law of patents developed at a time when inventions primarily involved engineering-related devices and processes.[18] While patent law today frequently addresses non-engineering-related invention, the law's view of conception today remains largely a relic of another time, utilizing a rule of law that has changed little since it was first applied in 1897.[19] Admittedly, application of the *Mergenthaler* standard to cases of invention resulting from experiment has not

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12. *See, e.g.*, Paul H. Eggert, *Uses, New Uses and Chemical Patents-A Proposal*, 51 J. PAT. OFF. SOC'Y 768, 783 (1969) (distinguishing mechanical invention from chemical invention); *see also* Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993) (stating that an inventor cannot show conception of a new gene sequence before producing it or possessing knowledge of its structure).

13. N. COPP & A. ZANELLA, DISCOVERY, INNOVATION, AND RISK: CASE STUDIES IN SCIENCE AND TECHNOLOGY 5 (1993).

14. DAVID SCHWARTZMAN, INNOVATION IN THE PHARMACEUTICAL INDUSTRY 32 (1977).

15. *See, e.g.*, OFF. TECH. ASSESSMENT, U.S. CONGRESS, PHARMACEUTICAL R & D: COSTS, RISKS & REWARDS 111 (1993) [hereinafter PHARMACEUTICAL R & D].

16. *See* Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993); Amgen, Inc. v. Chugai, Inc. 927 F.2d 1200, 1206 (Fed. Cir. 1991), *cert. denied sub. nom.* Genetics Inst., Inc. v. Amgen, Inc., 112 S. Ct. 169 (1991).

17. Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1232 (Fed. Cir. 1994).

18. William D. Noonan, *Patenting Medical Technology*, J.L. MED. 263, 268-69. See *infra* notes 226-38 and accompanying text for a discussion of the engineering bias in patent law.

19. See *infra* notes 86-99 and accompanying text for a discussion of the *Mergenthaler* standard.

been frequent in the past.[20] However, such cases are likely to increase in the future as the American research community begins to focus more on the development of not-yet-applied technology, especially in the area of pharmaceutical invention.[21]

This Note examines the legal definition of conception as an element of invention. Part I addresses the requirements for patent protection under United States patent law and discusses these requirements as a manifestation of the fundamental policy objectives of the patent system. Part II of this Note addresses invention by focusing on the two different legal standards of conception. Part II places particular emphasis on an historical analysis of cases applying the doctrine of simultaneous conception and reduction to practice. Part III of this Note highlights the differences between basic research, especially in pharmaceutical invention, and research in the applied sciences. Part III also addresses the failure of patent law to acknowledge these fundamental differences. Part IV discusses the current state of the law of conception and puts forth a proposal that the Federal Circuit extend the doctrine of simultaneous conception and reduction to practice to pharmaceutical invention.

I. THE STANDARDS FOR PATENTABILITY UNDER UNITED STATES PATENT LAW

This Section addresses the requirements for patentability as required by both the United States Constitution and the Patent Act. This Section also discusses federal court interpretation of these provisions. This Section then addresses the fundamental policy objectives of the United States patent system as exhibited in judicial interpretation of the Patent Act.

A. Statutory Requirements for Patent Protection of an Invention

The United States Constitution provides for the protection of inventions by conferring on Congress the authority to "promote the progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries."[22] Congress responded to this provision by enacting the Patent Act of 1790.[23] Since the inception of the Patent Act, Congress

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20. See *infra* notes 118-46, 166-90 and accompanying text for discussion of cases involving chemical or pharmaceutical inventions in which courts applied the *Mergenthaler* standard.

21. See *infra* notes 239-71 and accompanying text for a discussion of the changing nature of American research and the possible increase in patent litigation resulting from these changes.

22. U.S. CONST. art. I, § 8, cl 8.

23. Graham v. John Deere Co., 383 U.S. 1, 6 (1966). Congress implemented the Patent Act of 1790 by using its legislative discretion in the application of the direc-

has interpreted this Constitutional provision as authorizing the granting of patents for new and useful inventions.[24] Section 101 of the Patent Act provides that: "[w]hoever invents or discovers a new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."[25] Therefore, to qualify for patent protection an invention must consist of patentable subject matter and satisfy the further limitations of the Patent Act.[26]

1. Patentable Subject Matter

An invention cannot qualify for patent protection unless it embodies subject matter covered under the Patent Act.[27] Although neither the Constitution nor the Patent Act define patentable subject matter, courts have traditionally interpreted § 101 to allow patent protection for only those inventions relating to applied technology.[28] Thus, courts have held that "laws of nature, physical phenomena, and abstract ideas [are] not patentable."[29]

Moreover, even though an invention embodies potentially patentable subject matter, the invention must exist in complete enough form for immediate application without substantial modi-

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tives of the Framers. *Id.* (citing Gibbons v. Ogden, 22 U.S. (9 Wheat.) 1 (1824)). Accordingly, Congress set forth various conditions for patentability and created the forerunner to the current Patent and Trademark Office (PTO) as the administrative means by which to implement the Constitutional provision. *Id.*

24. Tallman I. Nguti, *Patent Law: Doctrinal Stability-A Research and Development Definition of Invention is Key*, 20 VAL. U. L. REV. 653, 667 (1986).

25. 35 U.S.C. § 101 (1988). The further requirements of novelty, utility, and unobviousness are set forth in 35 U.S.C. §§ 101-103, 112 (1988). For a discussion of these requirements, see *infra* notes 33-45 and accompanying text. The 1952 Patent Act is codified in 35 U.S.C. §§ 100-276 (1988).

26. 35 U.S.C. § 101.

27. *Id.*

28. Rebecca Eisenberg, *Proprietary Rights and the Norms of Science*, 97 YALE L.J. 177, 185-86 (1987). The Constitution uses the words "useful Arts" and "Discoveries." U.S. CONST. art. I, § 8, cl. 8. Although the Constitution does not expressly mention the word "invention," analysis indicates that the Framers appreciated the differences between basic scientific ideas and inventions embodying applied technology. Nguti, *supra* note 24, at 666.

29. Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980). The Court elaborated on the requirements for patentability of subject matter by stating:

> [A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of . . . nature, free to all men and reserved exclusively to none.

Id. (quoting Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)).

fication or experimentation.[30] By requiring an inventor to specifically define the parameters of the invention, the Patent Act forecloses patent protection for inventions that are not sufficiently "ripe."[31] An invention rises to the level of patentable subject matter only when the inventor shows either through his own experimentation or through analysis of existing technology that the invention relates to an applied discipline.[32]

2. Novelty, Utility, and Unobviousness

In addition to the requirement that an invention consist of patentable subject matter, an invention must be novel, useful, and unobvious in order to qualify for patent protection.[33] The novelty provision requires that an invention not be previously patented, described in published literature anywhere in the world, or in use or on sale in the United States prior to the date of invention by the applicant.[34] An invention also fails to exhibit novelty under the Patent Act if another person has filed a patent application on the same invention in the United States.[35] By requiring novelty in invention, United States patent law assures that a patent does not remove from unrestricted use knowledge that was previously freely available to society, merely because a person was the first to file a patent application.[36]

An inventor must also set forth the utility of an invention.[37] The utility requirement guarantees that an inventor obtains a patent for only that technology sufficiently well defined to allow description of a specific use.[38] Utility usually becomes an issue

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30. Eisenberg, *supra* note 28, at 186. Professor Eisenberg states that this requirement follows from 35 U.S.C. §§ 101, 112. Eisenberg, *supra* note 28, at 186. See *infra* notes 46-49 and accompanying text for discussion of § 101 and § 112.

31. Eisenberg, *supra* note 28, at 185-86. When an inventor cannot show the application of an idea, the invention more likely embodies unpatentable basic research. *Id.* In essence, the inventor seeking a patent under these circumstances is sent back to the laboratory to pursue further work. *Id.*

32. *Id.*

33. 35 U.S.C. §§ 101-103.

34. § 102(a), (b).

35. 35 U.S.C. § 102(e). In the United States, a patent application remains secret until the patent issues. Charles R.B. Macedo, *The First to File System: Is American Adoption of the International Standard in Patent Law Worth the Price?*, 18 AM. INTELL. PROP. L.J. 193, 205 (1990). If it does not issue, the invention is not disclosed. *Id.* In many foreign countries, the filing of a patent application results in disclosure of the invention to the public whether or not the patent is granted. *Id.*

36. Bonito Boats, Inc. v. Thunder Craft Boats, Inc., 489 U.S. 141, 149-50 (1989).

37. 35 U.S.C. § 101.

38. Brenner v. Manson, 383 U.S. 519, 534 (1966). The utility requirement serves three purposes: a useful invention will actually benefit society by providing a previously unavailable product or process; the disclosure of a beneficial new use stimulates other inventors to improve on the patented invention, thus further in-

only in chemical or biological inventions.[39] Since the intended use of a mechanical or electro-mechanical invention is usually apparent from the drawing or description contained within the patent disclosure, the Patent and Trademark Office (PTO) and the courts rarely question the utility of these inventions.[40] However, patents based on the chemical arts, such as pharmaceuticals and biotechnology invention, must demonstrate a specific utility.[41]

Lastly, for an invention to satisfy the statutory requirements for patentability, an inventor must show that the invention is not obvious.[42] An invention is not patentable, even though it satisfies all other requirements, if the difference between the subject matter sought to be patented and the prior art[43] is such that a person of ordinary skill in the art would find the invention obvious.[44] This precludes patent protection for those inventions embodying trivial improvements in existing technology that do not add significantly to the body of scientific knowledge.[45]

3. *Disclosure Requirement*

Section 112 of the Patent Act requires that an inventor who seeks a patent set forth the invention in sufficient detail "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 the invention."[46] Setting forth the invention in detail serves two purposes.[47] First, full disclosure assures that the public obtains the full benefit of the invention at the end of the patent term by providing the knowledge necessary to put the invention into practice.[48] Second, disclosure provides the PTO with the information necessary to determine whether the inven-

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creasing the technology available to society; and, patenting of an invention that is not sufficiently well-defined to allow the identification of a specific use could result in a monopoly for a broad field of scientific knowledge. *Id.* at 533-35.

39. Noonan, *supra* note 18, at 266.

40. *Id.*

41. *Id.* The Supreme Court has expressly stated that a chemical invention must show more than a usefulness in scientific research before the granting of a patent for the invention. *Brenner*, 383 U.S. at 535.

42. 35 U.S.C. § 103.

43. The term "prior art" denotes existing knowledge, literature references, patents, or known uses of the invention that antedate the invention at issue. Mooney v. Brunswick Corp., 663 F.2d 724, 733 (7th Cir. 1981).

44. Graham v. John Deere Co., 383 U.S. 1, 14 (1966). Although not existing by statute before the 1952 Patent Act, the addition of the unobviousness requirement of 35 U.S.C. § 103 codified more than one hundred years of case law. *Id.* at 14-15.

45. *Id.*

46. 35 U.S.C. § 112.

47. Eisenberg, *supra* note 28, at 207-08.

48. *Id.*

tion is, in fact, an operative and useful invention.[49]

B. Statutory Patent Requirements as a Reflection of Fundamental Policy Objectives

As Section A discussed, an idea must jump through several statutory "hoops" before qualifying for patent protection. These stringent requirements serve to effectuate the fundamental purpose of the United States patent system—to promote innovations in science and technology.[50] To motivate inventors to disclose innovations to the public, Congress set forth a period during which an inventor holds exclusive rights to an invention.[51] While not exactly a monopoly, patent protection does result in a government-sanctioned period during which limited competition occurs.[52] Since the period of patent exclusivity conflicts with the American tradition of free and open access to ideas, only substantial improvements in the body of scientific and technical knowledge are considered worthy of patent protection.[53] In the absence of patent protection, all ideas in the public domain inure for the good of society.[54]

When an inventor procures a patent, the public obtains access to the invention through the description contained in the patent.[55] Although the inventor retains exclusive rights to the invention for seventeen years, the public also receives substantial benefit by obtaining access to the description of the invention.[56] This disclosure of the invention increases the base of knowledge available in society by motivating further innovation which results when other inventors use the patent as a springboard to develop more technologically advanced ideas.[57]

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49. *Id.*

50. Nguti, *supra* note 24, at 667.

51. Graham v. John Deere Co., 383 U.S. 1, 6 (1966). The Patent Act provides the patentee with a seventeen year "right to exclude others from making, using, or selling the invention throughout the United States. . . ." 35 U.S.C. § 154.

52. *Graham*, 383 U.S. at 7. *Graham* sets forth a synopsis of the 1790 Patent Act and later judicial interpretations. *Id.* at 5-14. Of note is the integral part Thomas Jefferson played in the history of U.S. patent law as the first administrator of the patent system and as the author of the 1793 Patent Act. *Id.* at 7. His views on inventorship and the need for scientific progress were instrumental in the formulation of United States patent policy. *Id.*

53. *Id.* at 8-9. The *Graham* Court traces the American aversion to exclusive intellectual property rights to the practice of the English Crown to award property rights to court favorites in goods that previously belonged in the public domain, as well as the British monopoly on tea that partially instigated the Revolutionary War. *Id.* at 6-7.

54. Blonder-Tongue Lab. v. Universal Foundry, 402 U.S. 313, 345 (1971).

55. Macedo, *supra* note 35, at 205.

56. Nguti, *supra* note 24, at 658.

57. *Id.*

The United States patent system effectuates the dissemination of knowledge throughout society by providing economic incentives to the inventor in return for disclosure of the invention.[58] As such, the patent system effectively promotes innovation in American industry.[59] Moreover, research intensive industries, such as pharmaceuticals, consider patent protection indispensable to promoting research into new and useful products and processes.[60]

II. DETERMINATION OF INVENTORSHIP

Regardless of whether an invention satisfies all requirements for patentability, one may still not qualify for a patent if the party did not actually invent the subject matter of the patent.[61] Since patents reward inventors for disclosing beneficial technology to the public, a person cannot reap the reward of exclusive rights to an invention without being the true inventor.[62] Perhaps to reiterate the importance of this requirement, the Patent Act twice states that the person seeking patent protection must personally invent the subject matter of the invention.[63]

This Section discusses the requirements that allow a person to qualify for status as an inventor. First, this Section defines invention for the purposes of patent law. Next, this Section summarizes the requirement that an inventor reduce the invention to practice before qualifying for status as an inventor. The following two Sections provide a detailed analysis of conception by discussing the two legal standards applied to determine conception, with particular focus on an historical analysis of cases addressing the doctrine of simultaneous conception and reduction to practice.

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58. JOHN W. SCHLICHER, PATENT LAW: LEGAL AND ECONOMIC PRINCIPLES, § 1.05 (1994).

59. *Id.*; *see generally* Robert P. Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1, 4-9 (1992) (addressing and dismissing arguments that the patent system does not promote innovation); Eisenberg, *supra* note 28, at 195-96 (stating that the possibility of patent protection motivates research in biotechnology).

60. Merges, *supra* note 59, at 6; *See also* George deStevens, *A Chemist's View*, 62 J. PAT. OFF. SOC'Y 653, 657 (1965) (stating that the patent system motivates research that results in beneficial pharmaceutical products).

61. 35 U.S.C. § 102(f).

62. Agawam Co. v. Jordan, 74 U.S. (7 Wall.) 583, 602 (1869).

63. SCHLICHER, *supra* note 58, at § 1.07. Section 102(f) of the Patent Act expressly states that a person will lose patent rights if "he did not himself invent the subject matter sought to be patented." 35 U.S.C. § 102(f). Whereas, § 101 states by implication that a person must invent the subject matter with use of the words "whoever invents or discovers . . . may obtain a patent thereof. . . ." 35 U.S.C. § 101.

A. Definition of Invention

An inventor is one who invents.[64] In non-patent terms, a person invents when thinking up, devising, or fabricating something in the mind.[65] However, to qualify for status as an inventor for the purposes of patent law, a person must do more than mentally formulate an abstract idea with a desirable result.[66] In legal terms, invention requires both a conception of the idea and reduction to practice.[67] Conception looks to the subjective mental state of the inventor; it is the "full and complete mental act of formulating the invention to be claimed."[68] Reduction to practice pertains to the objective nature of the inventive act; that is, whether the inventor proved that the idea worked as anticipated.[69] Since familiarity with reduction to practice is necessary for an understanding of the doctrine of simultaneous conception and reduction to practice, this Section first addresses reduction to practice.

B. Reduction to Practice

Reduction to practice consists of the "physical act of producing the desired results by the means conceived by the inventor."[70] Reduction to practice can be either actual or constructive.[71] An actual reduction to practice occurs when the inventor tests the idea and shows that it works for its intended purpose.[72]

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64. WEBSTER'S NEW UNIVERSAL UNABRIDGED DICTIONARY 965 (2d ed. 1983).

65. *Id.*

66. Poyle v. Uhl, 328 F.2d 893, 897-88 (C.C.P.A. 1964).

67. Rex-Chainbelt, Inc. v. Borg-Warner Corp., 477 F.2d 481, 487 (7th Cir. 1973) (stating that "it requires no citation of authority to state that invention has not occurred until the subject of the invention has been both conceived and reduced to practice.").

68. Rohm & Haas Co. v. Dawson Chem. Co., 557 F. Supp. 739, 802 (S.D. Tex.), *rev'd on other grounds sub nom.* Rohm & Haas Co. v. Crystal Chem. Co., 722 F.2d 1556 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). See *infra* notes 78-190 and accompanying text for a discussion of the legal standards of conception.

69. Newkirk v. Lulejan, 825 F.2d 1581, 1583 (Fed. Cir. 1987).

70. Boyce v. Anderson, 451 F.2d 818, 820 (9th Cir. 1971) (quoting Corona Tire Co. v. Dovan Chem. Corp., 276 U.S. 358, 383 (1928)); *see also Rohm & Haas*, 557 F. Supp. at 803 (stating that reduction to practice requires the making of the product accompanied by sufficient testing and experimentation to demonstrate the utility of the invention).

71. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

72. *Rohm & Haas*, 557 F. Supp. at 803. The nature of testing required varies with the type of invention, but, generally, more complex inventions require more detailed testing showing the feasibility of the idea. Scott v. Finney, 34 F.3d 1058, 1061 (Fed. Cir. 1994). Moreover, reduction to practice need only show that an idea will probably work, not that it exists in a form ready for commercial application.

Constructive reduction to practice results when the inventor files a patent application.[73] Provided the application meets the disclosure requirements of § 112 of the Patent Act, the PTO does not require the inventor to show actual reduction to practice.[74]

Reduction to practice is a question of law determined by examination of the relevant evidence.[75] A court determines actual reduction to practice by analyzing the evidence to determine whether the inventor actually formulated the idea into a working model or performed experiments showing the feasibility of the idea.[76] When determining whether an inventor actually reduced an idea to practice, courts review the record in its entirety and apply a rule of reason in assessing the adequacy of the evidence.[77]

C. Conception

Although an inventor must show both conception and reduction to practice of the invention, conception operates as a threshold issue in determining inventorship.[78] Unless a person participates in the conception of the invention, one does not qualify as an inventor.[79] This remains true even if the party is the only participant in the reduction to practice.[80]

Courts have described conception as a "pivotal if somewhat nebulous notion in patent law."[81] In order to establish that one, in fact, fully conceived the invention, the inventor must show evidence of subjective mental state at the time of formation of the

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Id.

73. *Hybritech*, 802 F.2d at 1376. See *supra* notes 46-49 and accompanying text for a discussion of the disclosure requirement.

74. Weil v. Fritz, 572 F.2d 856, 866 (C.C.P.A. 1978).

75. Radio Corp. of Am. v. Philco Corp., 201 F. Supp. 135, 151 (E.D. Pa. 1961), *aff'd*, 309 F.2d 397 (3d Cir. 1962).

76. *See, e.g.*, *Hybritech*, 802 F.2d at 1377-78, (using a "reasoned examination, analysis, and evaluation of [the] pertinent evidence" to determine whether claimed inventors reduced the claimed invention to practice); Knorr v. Pearson, 671 F.2d 1368, 1373-74 (C.C.P.A. 1982) (analyzing presented evidence for third party corroboration of inventor's reduction to practice); Mikus v. Watchel, 542 F.2d 1157, 1161-62 (C.C.P.A. 1976) (requiring sufficient evidence showing that others read and understood experimentation to mean an actual reduction to practice); Fredkin v. Irasek, 397 F.2d 342, 347-48 (C.C.P.A.), *cert. denied*, 393 U.S. 980 (1968) (examining presented evidence for adequate proof of inventor's claimed reduction to practice).

77. *Mikus*, 542 F.2d at 1378.

78. *In re* Hardee, 223 U.S.P.Q. (BNA) 1122, 1123 (Dec. Comm'r Pat. 1984) (citing Mueller Brass Co. v. Reading Indus., 352 F. Supp. 1357 (E.D. Pa. 1984).

79. *Id.*

80. *Id.*

81. Technitrol, Inc. v. United States, 440 F.2d. 1362, 1369 (Ct. Cl. 1972).

idea.[82] Moreover, since inventive thought occurs only in the mind of the party asserting inventorship, the would-be inventor must also present independent corroborating evidence that supports the claim of conception.[83] Like reduction to practice, courts determine conception as a question of law by analyzing the presented evidence.[84] However, since determination of a person's state of mind is inherently more difficult than application of an objective standard, establishing conception is not as clear-cut as reduction to practice.[85] In assessing whether an inventor's subjective mental formulation of an idea rose to the level of conception, courts traditionally apply the *Mergenthaler* standard of conception.

1. The Mergenthaler *Standard: Conception Consists of a Definite and Permanent Idea*

The landmark case of *Mergenthaler v. Scudder*[86] defined conception as follows:

> The conception of an invention consists in the complete performance of the mental part of the inventive act. All that remains to be accomplished in order to perfect the act or instruments belongs to the department of construction, not invention. It is therefore the formation in the mind of the inventor of a definite and permanent idea of the complete and operative invention as it is thereafter to be applied in practice that constitutes an available conception within the meaning of the patent law.[87]

The Court of Customs and Patent Appeals (CCPA)[88] adopted this standard for use in interference and infringement cases[89] as ear-

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82. Coleman v. Dines, 754 F.2d 353, 359 (Fed. Cir. 1985).

83. AMP, Inc. v. Fujitsu Microelectronics, 853 F. Supp. 808, 821 (M.D. Pa. 1994). The corroboration requirement assures that an inventor does not misrepresent the facts surrounding the alleged conception in the quest for a patent. *Id.*

84. Price v. Symsek, 988 F.2d 1187, 1190 (Fed. Cir. 1993).

85. *See generally* Intermedics, Inc. v. Sweeney, 775 F. Supp. 1269, 1274 (N.D. Cal. 1991) (stating that disposing of issues involving an inventor's state of mind in patent infringement suit difficult to show in motion for summary judgment) *aff'd*, 991 F.2d 808 (Fed. Cir. 1993); United States v. Scarpa, 701 F. Supp. 379, 382 (E.D.N.Y. 1988) (stating that objective standards are preferable to subjective standards because of potential difficulty, or possible "futility," of satisfactorily determining subjective states of mind) *aff'd*, 991 F.2d. 63 (2d Cir. 1990).

86. Mergenthaler v. Scudder, 11 App. D.C. 264, 276 (D.C. Cir. 1897).

87. *Id.* Professor Chisum traces the history of this standard to two 1871 decisions by a Commissioner of Patents, as well as an 1890 treatise on patent law. 3 DONALD CHISUM, PATENTS: A TREATISE ON THE LAW OF PATENTABILITY, VALIDITY AND INFRINGEMENT § 10.04[1] (1994).

88. The CCPA was the predecessor court to the Court of Appeals for the Federal Circuit. Donald W. Banner, *The Creation of the Federal Circuit Court of Appeals and the Resulting Revitalization of the Patent System*, 50 ALB. L. REV. 585 (1986).

89. 3 CHISUM, *supra* note 87, at § 10.04. An interference proceeding arises when

ly as 1929.[90] The CCPA later modified the *Mergenthaler* standard to require that the definite and permanent idea exist in a sufficiently complete form to allow one skilled in the art to put the idea into practice without the need for further inventive skill.[91]

Under the *Mergenthaler* standard, a party claiming inventorship must show not only a perception of the desired result, but also how to practice the invention.[92] If the inventor must utilize further inventive skill to show the feasibility of the idea, it did not rise to the level of definite and permanent.[93] Moreover, if the inventor seemingly conceives an invention, but later finds that extensive research is necessary before achieving successful results, conception did not result.[94] Instead, the mental form of the idea at the time of claimed conception "was a mere hope or expectation, a statement of the problem, but not an inventive conception."[95] However, the need for further experimentation does not operate as an absolute bar to a claim of earlier conception if the subsequent work required no more than routine skill.[96]

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two or more parties claim invention of the same subject matter. BLACK'S LAW DICTIONARY 562 (Abridged 6th ed. 1991). This proceeding determines priority of invention between two or more patent applications or between at least one patent applicant and one or more parties previously awarded patents. *Id.* A patent infringement action results when a patentee brings a suit alleging that at least one other party used, made and/or sold the subject matter of a valid patent belonging to the plaintiff. *Id.* at 538.

90. Townsend v. Smith, 36 F.2d 292, 295 (C.C.P.A. 1929).

91. Land v. Dreyer, 155 F.2d 383, 387 (C.C.P.A. 1946).

92. Coleman v. Dines, 754 F.2d 353, 359 (Fed. Cir. 1985); *see also* Technitrol, Inc. v. United States, 440 F.2d 1362, 1369 (Ct. Cl. 1971) (defining the date of conception as the date when "the inventive idea . . . becomes so clearly defined in the mind of the inventor as to be capable of being converted to reality and reduced to practice by the inventor or one skilled in the art"); Meitzner v. Corte, 410 F.2d. 433, 437 (C.C.P.A. 1969) (stating that conception does not occur unless the inventor possesses the means to reduce the idea to practice).

93. Bac v. Loomis, 252 F.2d 571, 577 (C.C.P.A. 1958) (holding that the need for an extensive program of experimentation and design of parts before manifestation of an operative invention negates a claim of earlier conception); *see also* Gunter v. Stream, 573 F.2d 77, 79-80 (C.C.P.A. 1978) (ruling that an inventor establishes conception when he discloses the idea to another to an extent that the second party could "reduce the idea to practical form without the exercise of inventive faculty"); Jacobs v. Sohl, 280 F.2d 140, 143-44 (C.C.P.A. 1960) (holding that an idea does not rise to the level of definite and permanent if the inventor is still searching for a material needed to make the invention).

94. Alpert v. Slatin, 305 F.2d 891, 894 (C.C.P.A. 1962); *see also* Bourne v. Jones, 114 F. Supp. 413, 418 (S.D. Fla. 1951) (stating that "[i]nvention cannot be predicated on mere speculation or conjecture; it must be based on something ascertained, something definite and certain"), *aff'd*, 207 F.2d 173 (5th Cir. 1953), *cert. denied*, 346 U.S. 897 (1953).

95. *Alpert*, 305 F.2d at 894.

96. Bell Tel. Lab. v. Hughes Aircraft Co., 422 F. Supp. 372, 379 (D. Del. 1976), *aff'd*, 564 F.2d 654 (3d Cir. 1977), *cert. denied*, 435 U.S. 924 (1978); *see also* Mattor

Courts have applied the *Mergenthaler* standard either expressly or by implication in dozens of cases since its original enunciation in 1897.[97] The consistent application of the *Mergenthaler* standard makes it clear that the patent system rewards the person who possesses both the mental formulation of the idea and the means to apply the idea to practical use.[98] More simply, the patent system rewards "the doer and not the dreamer."[99]

2. Doctrine of Simultaneous Conception and Reduction to Practice: Conception When an Inventor Cannot Form a Definite and Permanent Idea Without Experimentation

In his seminal 1890 treatise on patent law, Professor William Robinson recognized that in some instances conception of an invention cannot be separated from reduction to practice.[100] He stated:

> In many inventions the act of conception is clearly distinct, in point of time, from that of reduction [and the definite and permanent idea standard can be applied]. . . . In many others the work of conception and reduction goes forward almost simultaneously, so nearly that no date can be fixed as that before which the conception was complete and after which the reduction to practice was begun. This is true in nearly all inventions which are the result of experiment, — where the inventor, instead of evolving the entire art or instrument out of his own thought, conjectures that such an act or substance will subserve a given purpose, and having tried it, finds that it accomplishes the end . . . at no instant before the experiment succeeds can it be said that the conception of the invention exists in the inventor's mind . . . the first to bring the art or instrument into successful operation is the first conceiver of the entire invention.[101]

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v. Coolegem, 530 F.2d 1391, 1395 (C.C.P.A. 1976) (holding that a work of a technician carrying out the oral instructions of the inventor did not negate claim of prior conception); Hobbs v. United States Atomic Energy Comm'n., 451 F.2d 849, 865 (5th Cir. 1971) (holding that a person may use the services of others to complete an invention without losing a right to a patent).

97. *See* 3 CHISUM, *supra* note 87, at § 10.04 nn.8-9 for a comprehensive listing of cases applying the *Mergenthaler* standard to both interference and infringement cases.

98. *Compare* Townsend v. Smith, 36 F.2d 292, 295 (C.C.P.A. 1929) (stating *Mergenthaler* established law for defining conception) *with* Burroughs Wellcome Co. v. Barr Labs., Inc., 828 F. Supp. 1200, 1205 (E.D.N.C. 1993) (applying *Mergenthaler* as enunciated in an earlier case).

99. John O. Tresansky, *Inventorship Determination*, 56 J. PAT. OFF. SOC'Y 551, 557 (1974).

100. 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS FOR USEFUL INVENTIONS 381 (1890).

101. *Id.*

The CCPA did not expressly apply this view of conception until the 1940 interference case of *Smith v. Bousquet*.[102] In *Smith*, two inventors formed independent hypotheses that a group of chemical compounds might exhibit insecticidal activity.[103] However, neither scientist could predict the effectiveness of the compounds on specific insects unless he actually performed experiments.[104] The *Smith* court stated that in the "unpredictable" fields of biology and chemistry, conception and reduction to practice are inseparable.[105] In such cases, conception does not occur until the inventor successfully completes experiments showing the feasibility of the idea, and, as a result, conception and reduction to practice occur simultaneously.[106] Prior to this time, the idea remains "mere speculation or possibly a probable deduction from facts already known" but not conceived for the purposes of patent law.[107]

Although the *Smith* court provided the opportunity for federal courts to apply the doctrine of simultaneous conception and reduction to practice to cases involving chemical and biological inventions, the CCPA did not again expressly recognize the standard until the 1962 case of *Alpert v. Slatin*.[108] *Alpert* was also an interference case where two independent inventors claimed invention of the same chemical process.[109] One of the inventors attempted to show an earlier date of conception with evidence that he suggested a research program to investigate the idea prior to the other inventor's awarded date of invention.[110] The *Alpert* court ruled this proof insufficient to show conception because extensive experimentation was later required to secure a successful reduction to practice.[111] The *Alpert* court stated that the doctrine of simultaneous conception and reduction to practice should be applied in those "unusual" and "rare" cases when the inventor does not know whether the idea will successfully result without

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102. Smith v. Bousquet, 111 F.2d 157, 162-63 (C.C.P.A. 1940).

103. *Id.* at 159.

104. *Id.* The court acknowledged that in 1934 there existed no known correlation between insecticidal activity and chemical structure. *Id.*

105. *Id.*

106. *Id.*

107. *Id.*

108. Alpert v. Slatin, 305 F.2d 891, 894 (C.C.P.A. 1962). *But c.f.* Bourne v. Jones, 114 F. Supp. 413, 418 (S.D. Fla. 1951) (equating the development of a new plant variety with the invention of a chemical compound, thus requiring application of the doctrine of simultaneous conception and reduction to practice as stated in *Smith*), *aff'd*, 207 F.2d 173 (5th Cir.), *cert. denied*, 346 U.S. 897 (1953).

109. *Alpert*, 305 F.2d at 892.

110. *Id.* at 894.

111. *Id.* Six months was required to obtain a clearly successful reduction to practice of the idea. *Id.*

first obtaining empirical information from actual attempts to reduce the idea to practice.[112] In such cases, the inventor cannot possess a complete mental realization of the invention before experimentation.[113]

In 1964, the CCPA again applied the doctrine of simultaneous conception and reduction to practice to an invention resulting from experiment.[114] In an appeal from a Patent Office rejection of a patent for the invention of the element Americium, *In re Seaborg*,[115] the reduction to practice took about one month and, until its completion, the inventor possessed no knowledge that the experiments would actually produce the element.[116] As such, the *Seaborg* court stated that the invention required application of the doctrine of simultaneous conception and reduction to practice to determine the date of conception.[117]

Examination of the above cases illustrates that by 1964 the doctrine of simultaneous conception and reduction to practice was evolving into an established alternative to the *Mergenthaler* standard of conception. Nevertheless, several months after the *Seaborg* decision, the CCPA significantly limited the application of this doctrine.[118] In *Applegate v. Scherer*, two parties claimed inventorship of a chemical method to control marine pests.[119] Like the insecticide invention in *Smith v. Bousquet*, neither party

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112. *Id.* The *Alpert* court cited the doctrine of simultaneous conception and reduction to practice as enunciated by Professor Robinson and as applied in *Smith v. Bousquet*. See *supra* text accompanying notes 100-01 and a discussion of Professor Robinson's view of the doctrine and *supra* notes 102-07 and accompanying text for a discussion of the *Smith* court's view of the doctrine.

113. *Alpert*, 305 F.2d at 894.

114. *In re* Seaborg, 328 F.2d 996, 999 (C.C.P.A. 1964).

115. 328 F.2d 996 (C.C.P.A. 1964). The PTO rejected the patent application because it believed the element was inherently produced during the operation of a previously patented nuclear reactor. *Id.* As such, the PTO ruled the invention unpatentable over the prior art. *Id.* at 997.

116. *Id.* at 997, 999. To produce about six billionths of a gram of the element Americium, the inventor bombarded the element plutonium with deuterons or neutrons at high power for approximately one hundred days in a nuclear reactor. *Id.* at 996.

117. *Id.* at 999. The court expressly cited the doctrine of simultaneous conception and reduction to practice as applied in *Smith v. Bousquet*. *Id.* See *supra* notes 102-07 and accompanying text for a discussion of *Smith*.

118. Applegate v. Scherer, 332 F.2d 571, 573 (C.C.P.A. 1964).

119. *Id.* at 571. Inventor Applegate discovered a chemical to combat the pest, but the compound could not be adapted for field use. *Id.* at 571-72. Scherer was an employee of a German chemical company who, after reading an article describing the Applegate group's research in a trade publication, contacted Applegate to suggest use of a related compound. *Id.* Inventor Scherer learned of this discovery and informed inventor Applegate that a related chemical compound might show similar efficacy. *Id.* Applegate used the chemical compound as directed by Scherer and found it highly effective. *Id.* at 572. Both parties filed patent applications on the invention and an interference was declared. *Id.*

in *Applegate* possessed knowledge that the chemical compound would actually show effectiveness as a pesticide prior to actual reduction to practice.[120] Thus, the *Applegate* court should have applied the doctrine of simultaneous conception and reduction to practice to the determination of conception.[121] Nonetheless, the *Applegate* court applied the *Mergenthaler* standard to the invention, ruling that inventor Scherer possessed a complete conception of the invention before disclosing it to inventor Applegate, even though Scherer did not test his idea.[122] The court distinguished the case from *Smith v. Bousquet* by stating that the previous case involved independent inventors, while *Applegate* centered on the issue of whether one inventor derived the invention from another.[123]

The *Applegate* court's view that Scherer possessed a complete conception of the chemical invention before he reduced his idea to practice contradicted previous CCPA holdings dictating application of the doctrine of simultaneous conception and reduction to practice in cases of chemical invention resulting from experiment.[124] However, an examination of the court's reasoning sheds light on the apparent inconsistency. The issue in *Applegate* involved originality of the invention, thus requiring a determination of whether Applegate derived the invention from Scherer.[125] Derivation results when one party communicates a complete conception to another who then reduces the idea to practice, usually only using routine skill.[126] Thus, by definition, derivation cannot exist when an idea requires reduction to practice before a complete conception results.[127] As such, the *Applegate* court could not apply the doctrine of simultaneous conception and reduction to

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120. *Id.* at 572-73.

121. *See* Alpert v. Slatin, 305 F.2d 891, 894 (C.C.P.A. 1962); Smith v. Bousquet, 111 F.2d 157, 162-63 (C.C.P.A. 1940). See *supra* notes 102-13 and accompanying text for a discussion of these cases.

122. *Applegate*, 332 F.2d at 573-74.

123. *Id.* at 573.

124. See *supra* notes 102-17 and accompanying text for a discussion of previous cases applying the doctrine of simultaneous conception and reduction to practice.

125. *Applegate*, 332 F.2d at 572-73. An originality case involves the "who" of invention. *Id.* at 573 n.1. In contrast, a priority action determines the times when two independent parties completed the inventive act. *Id.* at 573. Although both center on the issue of inventorship and are resolved in an interference proceeding, they are distinct concepts in patent law. Sewall v. Walters, 21 F.3d 411, 415 (Fed. Cir. 1994).

126. Hedgewick v. Akers, 497 F.2d 905, 908 (C.C.P.A. 1974). Derivation may be either intentional or innocent. *Applegate*, 332 F.2d at 573 n.1. However, regardless of the means one acquires the invention, one cannot obtain status as an inventor if he derived the invention from another. *See* 35 U.S.C § 102(f) (1988).

127. *See generally* 2 PETER D. ROSENBERG, PATENT LAW FUNDAMENTALS § 10.01(5) (2d ed. 1994) (providing a summary of derivation law).

practice without also ruling that Applegate did not derive the invention from Scherer.[128] Notably, the *Applegate* court gave only a perfunctory analysis to the issue of conception, stating only that Scherer's disclosure to Applegate showed a completed conception prior to the actual testing of the invention.[129] In so ruling, the court failed to reconcile its decision with earlier cases holding that, in analogous inventions, conception occurs simultaneously with reduction to practice[130] The court's focus on the parties, rather than the nature of the invention, resulted in a substantial limiting of the doctrine of simultaneous conception and reduction to practice by foreclosing its application in originality cases.[131]

The CCPA followed the *Applegate* holding in the 1970 interference case of *MacMillan v. Moffett*.[132] In this case, scientist Moffett submitted a large number of chemical compounds to scientist MacMillan.[133] The court ruled that Moffett completely conceived the invention prior to MacMillan's testing, even though he did not specifically realize that only one of the many compounds would exhibit effectiveness.[134] The court rebuffed MacMillan's attempt at invoking the doctrine of simultaneous conception and reduction to practice as applied in *Smith v. Bousquet* by stating that the *Applegate* decision made it "abundantly clear that such a doctrine does not apply in cases where the issue is originality or derivation."[135] As in *Applegate*, the court did not give a detailed analysis to the issue of conception, instead focusing on the parties rather than the nature of the invention.[136] In separate findings, the *MacMillan* court also held that a conceiving party need not

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128. *See generally id.* (detailing proper analysis of derivation). A contrary decision would have resulted in the court's awarding the invention to Applegate, even though he exercised no inventive skill. *Applegate*, 332 F.2d at 573.

129. *Applegate*, 332 F.2d at 573. The court cited an earlier case applying the *Mergenthaler* standard to the conception of a mechanical invention. *Id.* at 572-73.

130. *See, e.g., id.* at 573. The court distinguished the case from *Smith v. Bousquet* stating that the previous case involved independent inventors, while *Applegate* centered on the issue of whether one inventor derived the invention from another. *Id.* Thus, the court's refusal to follow precedent centered on the form of the invention, rather than the substance.

131. See *infra* notes 132-38 and accompanying text for a discussion of a later case relying on the *Applegate* holding to find the doctrine of simultaneous conception and reduction to practice does not apply in cases of originality.

132. MacMillan v. Moffett, 432 F.2d 1237, 1240 (C.C.P.A. 1970).

133. *Id.* at 1238. The court noted that both scientists were "recognized experts" in their respective fields. *Id.*

134. *Id.* at 1239-40.

135. *Id.* Moreover, the *MacMillan* court also expressed doubt that the *Smith* decision was based on such a doctrine, although the court did not explain the rationale for its view. *Id.* at 1240. See *supra* notes 102-07 and accompanying text for a discussion of *Smith*.

136. See *supra* notes 125-31 and accompanying text for a discussion of the rationale of the *Applegate* decision.

"appreciate" the special properties of the invention to show a complete conception[137] and that an inventor can show a complete conception of one compound submitted for screening with many other compounds.[138]

In a later interference case not involving originality, the CCPA again restricted application of the doctrine of simultaneous conception and reduction to practice.[139] In the interference case of *Rey-Bellet v. Englehardt*, two chemists claimed invention of a drug compound.[140] However, the chemists could not establish the pharmaceutical effectiveness of the compound without successful experimentation on animals.[141] The opposing party attempted to show that inventor Englehardt did not fully conceive the

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137. *MacMillan*, 432 F.2d at 1239. The *MacMillan* court termed the anti-perspirant activity of the chemical compound as an "unexpected propert[y]." *Id.* at 1239. However, the record indicates that the invention involved a method to control perspiration with the chemical compound. *Id.* at 1237. It thus appears that the properties of the invention termed by the court as "unexpected" actually constituted the substance of the invention. Therefore, the *MacMillan* court essentially held that one does not need to recognize the substantive properties of an invention to obtain a patent. This result does not mesh with the requirement under the *Mergenthaler* standard that an inventor possess a definite and permanent idea of his invention to show a complete conception. *See* Land v. Dreyer, 155 F.2d 383, 387 (C.C.P.A. 1946). See *supra* notes 86-99 and accompanying text for a discussion of the *Mergenthaler* standard.

138. *MacMillan*, 432 F.2d at 1239-40. Moffett submitted 69 compounds for screening, but only one compound showed anti-perspirant efficacy. *Id.* at 1238-39. The court stated that Moffett "thought specifically about 69 different compounds . . . and of a use for each in a method for controlling perspiration." *Id.* at 1239. The *MacMillan* court found the inventor's rationale for including the specific compound irrelevant to showing a complete conception of the invention. *Id.* Again, this reasoning conflicts with the *Mergenthaler* standard which requires that an inventor clearly delineate the parameters of his invention to show conception. *See, e.g.*, Coleman v. Dines, 754 F.2d 353, 359 (Fed. Cir. 1985) (stating that to establish conception a party must "show possession of every feature recited in the count, and that every limitation . . . must have been known to the inventor at the time of the alleged conception."). See *supra* notes 86-99 and accompanying text for a discussion of the *Mergenthaler* standard.

139. Rey-Bellet v. Englehardt, 493 F.2d 1380, 1387 (C.C.P.A. 1974).

140. 493 F.2d 1380, 1385-86 (C.C.P.A. 1974). The chemist Rey-Bellet synthesized a chemical compound similar in structure to a well-known anti-depressant. *Id.* at 1382. The claimed date of Englehardt's invention occurred after Rey-Bellet synthesized the compound, but before he ran extensive testing showing the efficacy of the compound as an anti-depressant. *Id.* at 1385.

141. *Id.* at 1387. In pharmaceutical invention, structural similarity to a compound of known activity often does not indicate the medicinal activity of another compound. As such, an inventor often cannot predict pharmacological activity, if any, without extensive testing. Noonan, *supra* note 18; *see also* Harry Goldsmith, *Pharmaceutical Invention*, 47 J. PAT. OFF. SOC'Y 648, 649 (1965) (stating that out of hundreds of thousands of compounds synthesized by chemists for use as potential new drug products, only about one in 8,500 passes the stringent tests required before a new drug product reaches the consumer). See *infra* notes 211-25 and accompanying text for a discussion of invention in the pharmaceutical sciences.

invention until obtaining the confirming test results.[142] The *Rey-Bellet* court rejected this argument by stating that the need for extensive testing did not preclude a finding that Englehardt formed a complete conception at the time he synthesized the compound and recognized its possible anti-depressant effects.[143] In effect, the *Rey-Bellet* court held that a complete conception results when an inventor initially recognizes the potential effectiveness of a pharmaceutical invention.[144] The amount of testing needed to prove the actual effectiveness of a compound does not influence the completeness of a claimed conception, if the tests are routinely performed in the discipline.[145] Moreover, the *Rey-Bellet* court also questioned whether the *Alpert v. Slatin* decision actually applied the doctrine of simultaneous conception and reduction to practice but did not state the rationale for this view.[146]

Taken together, the *Applegate*, *MacMillan* and *Rey-Bellet* decisions markedly limited the application of the doctrine of simultaneous conception and reduction to practice to chemical and pharmaceutical inventions. An examination of cases addressing the issue of conception between 1974 and 1988 reveals only one instance where a federal court applied the doctrine in a case of chemical invention.[147] Moreover, some doubt was also expressed

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142. *Rey-Bellet*, 493 F.2d at 1386-87. The opposing party specifically attempted to invoke the doctrine of simultaneous conception and reduction to practice as applied in *Alpert v. Slatin*. *Id.* He stated that the extensive testing needed to show the efficacy of the chemical compound as an anti-depressant was analogous to the "perplexing intricate difficulties" cited by the *Alpert* court as requiring application of the doctrine of simultaneous conception and reduction to practice. *Id.* See *supra* notes 108-13 and accompanying text for a discussion of *Alpert*.

143. *Rey-Bellet*, 493 F.2d at 1387. As such, the *Rey-Bellet* court focused on the nature of the testing required to show the feasibility of an idea, rather than the amount. *Id.*

144. *Id.* at 1386-87.

145. *Id.* at 1387. This ruling modified the holding of the *Alpert* court by substituting the amount of testing required to show viability of an idea for the nature of the testing. *See* Alpert v. Slatin, 305 F.2d 891, 894 (C.C.P.A. 1962). See *supra* notes 108-13 and accompanying text for a discussion of *Alpert*.

146. *Rey-Bellet*, 493 F.2d at 1387. The court's statement was, of course, dicta. However, the dearth of cases applying the doctrine of simultaneous conception and reduction to practice after this decision is notable. See *infra* note 147 for a discussion of the one case applying the doctrine of simultaneous conception and reduction to practice between 1974 and 1991.

147. *See* Standard Oil Co. (Ind.) v. Montedison, S.p.A., 494 F. Supp. 370, 408 (D. Del. 1980), *aff'd*, 664 F.2d 356 (3rd Cir. 1981). *Standard Oil* involved the invention of a new structural form of an existing polymer. *Id.* at 374. At the time of the invention, polymer chemists did not know whether the form desired could be synthesized. *Id.* The court expressly applied the doctrine of simultaneous conception and reduction to practice as enunciated by Professor Robinson and *Alpert v. Slatin*. *Id.* at 407-08. The court did not cite either *Applegate* or *Rey-Bellet*. *Id.*; *cf.* Rohm & Haas Co. v. Dawson Chem. Co., 557 F. Supp. 739, 802-04 (S.D. Tex. 1983), *rev'd on other grounds sub nom.* Rohm & Haas Co. v. Crystal Chem. Co., 722 F.2d 1556

questioning the existence of the doctrine of simultaneous conception as a standard of conception separate from the *Mergenthaler* standard.[148]

Nevertheless, in a 1988 chemical interference case the Federal Circuit again recognized the existence of the doctrine of simultaneous conception and reduction to practice.[149] In *Oka v. Youssefyeh*, the Federal Circuit cited cases applying the doctrine to rule that conception of a chemical compound requires an idea of the chemical structure and possession of the means for making the compound.[150] While stopping short of adopting a view that equated conception with reduction to practice, the *Oka* court's acknowledgment provided the opportunity for subsequent application of the doctrine of simultaneous conception and reduction to practice.[151]

The Federal Circuit responded to the lead of the *Oka* court by applying the doctrine of simultaneous conception and reduction to practice in the 1991 patent infringement case of *Amgen, Inc. v. Chugai Pharmaceutical Co.*[152] One of the alleged infringing par-

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(Fed. Cir. 1983) (applying *Applegate* and *Rey-Bellet* to hold that conception of an herbicide completed before testing showing specific effectiveness), *cert. denied*, 469 U.S. 851 (1984); GAF Corp. v. Amchem Prod., 514 F. Supp. 943, 968 (E.D. Pa. 1981) (applying *Applegate* to hold that a party submitting chemicals for screening does not qualify as an inventor unless he possesses a conception that a result should or could occur).

148. 3 CHISUM, *supra* note 87, at § 10.04(5). Professor Chisum argues that the *Rey-Bellet* decision shows that the doctrine of simultaneous conception and reduction to practice is not a doctrine at all, but is actually an application of the *Mergenthaler* standard. *Id.* He reasons that the *Rey-Bellet* court's emphasis on the routine nature of experiments capable of performance by one of ordinary skill in the art, no matter how extensive, shows a classic example of reduction to practice. *Id.* Thus, conception of a chemical invention can be completed even before necessary extensive testing to the satisfaction of the *Mergenthaler* standard. *Id.* However, this analysis ignores subsequent application of the doctrine of simultaneous conception and reduction to practice discussed *infra* at notes 152-63 and accompanying text.

149. Oka v. Youssefyeh, 849 F.2d 581, 584 n.1 (Fed. Cir. 1988).

150. *Id.* at 583. The court cited *Alpert* and *Standard Oil*, two chemical cases applying the doctrine of simultaneous conception and reduction to practice. *Id.* Interestingly, the court also cited a chemical case applying the *Mergenthaler* standard in its holding that the party did not conceive the invention (Coleman v. Dines, 754 F.2d 353, 359 (Fed. Cir. 1985)). *Id.*

151. *Id.* at 584 n.1. The *Oka* court did not address application of the doctrine of simultaneous conception and reduction to practice because neither party argued that the conception of a chemical compound equated conception with reduction to practice. *Id.* However, the court stated that if the parties had raised the issue they would be required to show the utility of the compound as well. *Id.*

152. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir.), *cert. denied sub nom.* Genetics Inst., Inc. v. Amgen, Inc., 112 S. Ct. 169 (1991). The *Amgen* court cited the "well-established" rule of chemical invention as stated in *Oka v. Youssefyeh*. *Id.*

ties claimed that its researcher was the first to conceive a method to produce a gene sequence useful as a therapeutic agent.[153] Although the gene occurred naturally, at the time of the research scientists could not accurately determine its structure.[154] Moreover, Amgen researchers did not determine the exact structure until after successfully cloning the gene.[155] The *Amgen* court ruled that in such a case conception of a new gene sequence does not occur until the inventor isolates the gene.[156] In other words, conception of a gene occurs simultaneously with reduction to practice.[157] The court further noted that description of a chemical compound by its principal biological property does not constitute conception, but only a "wish to know the identity of any material with that biological property."[158]

The Federal Circuit subsequently strengthened the *Amgen* holding in the 1993 interference case of *Fiers v. Revel*.[159] The *Fiers* court reiterated that conception of a biologically active gene sequence does not occur until the inventor successfully isolates the gene and further added that the ease of preparation of the gene does not negate the requirement for actual reduction to practice.[160] Mere description of the gene by its hoped-for biological activity is insufficient to show conception, even though the method used will almost certainly produce the gene.[161] The *Fiers* court noted that to hold otherwise would conflict with the stated policy of the patent statute, which requires disclosure of inventions, not

153. *Id.* at 1205-06. Although the Genetics Institute (the allegedly infringing company) did not isolate the gene until after the Amgen scientist, Genetics Institute attempted to show the inventor's prior conception, coupled with his diligence in reducing the idea to practice, invalidated Amgen's prior date of invention. *Id.* Section 102(g) of the Patent Act provides that a party who conceives prior to another, but reduces to practice after the second party's date of invention (conception and reduction to practice), is entitled to a patent if the first conceiver exercised diligence in reducing the idea to practice. 35 U.S.C. § 102(g) (1988). In 1981, the Genetics Institute researcher designed a method that would theoretically result in successful isolation of the gene. *Amgen*, 927 F.2d at 1205-06. Although the research did eventually lead to a method to obtain the gene, the Genetics Institute scientist did not complete his work until after the Amgen work was completed. *Id.*

154. *Amgen*, 927 F.2d at 1206.

155. *Id.*

156. *Id.*

157. *Id.*

158. *Id.*

159. Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993).

160. *Id.* The inventor attempted to distinguish *Fiers* from *Amgen* by showing that the method subsequently used to isolate the gene was less sophisticated than that used in *Amgen*. *Id.* As such, he argued that *Amgen* should have been limited to its facts and that only a difficult-to-isolate gene should require a showing of both conception and reduction to practice. *Id.* The court refused to accept this argument. *Id.*

161. *Id.*

research plans.[162] Interestingly, this holding seems to contradict the *Rey-Bellet* ruling that an inventor may complete conception of a biologically active gene sequence if the tests required to show efficacy are straightforward and routine.[163]

Although *Fiers* applied the doctrine of simultaneous conception and reduction to practice in a case of routine reduction to practice, the Federal Circuit did not overrule the holding of *Rey-Bellet*. However, the decision certainly called into question whether *Rey-Bellet* remained a viable statement of the law of chemical and pharmaceutical invention. Moreover, even though the Federal Circuit did not address a case involving both the originality and the conception of a chemical or pharmaceutical invention, a 1994 district court case questioned whether the Federal Circuit would adhere to the *Applegate* holding in a more modern case of invention.[164] At the very least, it appeared that cases calling for application of the doctrine were no longer "rare" or "unusual."[165]

Nonetheless, in the November, 1994 infringement case of *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, the Federal Circuit refused to completely revitalize the doctrine of simultaneous conception and reduction to practice.[166] In *Burroughs*, National Institutes of Health (NIH) scientists assisted BW scientists in determining the effectiveness of AZT as a therapy for HIV and AIDS.[167] Notably, at the time of the invention, NIH scien-

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162. *Id.* at 1169.

163. *See* Rey-Bellet v. Englehardt, 493 F.2d 1380, 1387 (C.C.P.A. 1974).

164. *See* Brown v. University of Cal., 866 F. Supp 439, 444-45 (N.D. Cal. 1994), *appeal dismissed, remanded by* Brown v. Regents Univ. of Cal., 1994 U.S. App. LEXIS 36761 (Fed. Cir. Dec. 21, 1994) (reviewing the law of conception in the federal courts and concluding that if faced with the question, the Federal Circuit would overrule *Applegate* and *MacMillan*); *see also* Regents of the Univ. of Cal. v. Synbiotics Corp., 849 F. Supp. 740, 742 (S.D. Cal. 1994), *appeal dismissed, remanded sub nom.* Brown v. Regents Univ. of Cal., 1994 U.S. App. LEXIS 36761 (Fed. Cir. Dec. 21, 1994) (casting doubt on the validity of the *Applegate* holding by applying the doctrine of simultaneous conception and reduction to practice in a case of originality). Both of these cases were likely remanded based on the result of the *Burroughs* decision discussed *infra* at notes 166-90 and accompanying text.

165. *See* Applegate v. Scherer, 332 F.2d 571, 573 (C.C.P.A. 1964).

166. Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1229 (Fed. Cir. 1994).

167. *Id.* at 1225. NIH scientist Dr. Samuel Broder solicited several pharmaceutical companies for samples of chemical compounds with potential for activity against the virus. *Id.* BW then conducted initial screening experiments using non-human retroviruses that showed AZT's effectiveness against these viruses. *Id.* In February 1985, BW sent Broder a coded sample of AZT, along with approximately 50 other compounds for testing on human HIV. Brian O'Reilly, *The Inside Story of the AIDS Drug*, FORTUNE, Nov. 5, 1990, at 112, 120. Before receiving confirmation of the positive results of the test, BW prepared a draft patent application for filing in the United Kingdom. *Burroughs*, 40 F.3d at 1225. Shortly thereafter, Dr. Broder informed BW of AZT's effectiveness against human HIV and at this time BW revealed the identity of the compound to him as AZT. *Id.* In subsequent months, Dr.

tists were the only researchers in the world who could perform tests utilizing human HIV.[168] However, the patents granted to BW for the invention of AZT therapy listed only the BW scientists as inventors.[169] In a later suit for infringement of the AZT patents, the defendant pharmaceutical companies alleged that the patent did not name all inventors of AZT therapy.[170] As such, the defendants contended that BW's failure to list all inventors rendered the patents invalid or subject to correction of inventorship, thereby allowing the defendants to sell AZT without infringing the claims of any valid patents.[171] The Federal Circuit rejected this argument, instead applying the *Mergenthaler* standard of conception to rule that BW scientists formed a complete conception of the invention before the NIH scientists performed the tests showing the efficacy of AZT in humans.[172] In

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Broder and another NIH scientist conducted a human clinical trial that showed that AZT could increase the immune system strength of a person with HIV. *Id.*

168. Gallo, *supra* note 2, at 50. NIH scientists later obtained a patent for their method to maintain viable human HIV in the laboratory for the purpose of testing potential AIDS therapies. U.S. Patent No. 4,704,357, "Immortalized T-Lymphocyte Cell Line for Testing HLTV-III Inactivation," *issued* November 3, 1987.

169. *Burroughs*, 40 F.3d. at 1225. BW holds six patents covering methods and formulations of using AZT to treat humans afflicted with HIV: (1) U.S. Patent No. 4,724,232, *issued* Feb. 9, 1988; (2) U.S. Patent No. 4,828,130, *issued* May 9, 1989; (3) U.S. Patent No. 4,833,130, *issued* May 23, 1989; (4) U.S. Patent No. 4,837,208, *issued* June 6, 1989; (5) U.S. Patent No. 4,818,538, *issued* Apr. 4, 1989; and (6) U.S. Patent No. 4,818,750, *issued* Apr. 4, 1989. *Burroughs*, 40 F.3d. at 1225 n.2.

170. *Id.* at 1226-27. Specifically, defendants Barr and Novopharm contended that BW researchers did not completely conceive the invention of AZT until NIH scientists performed testing showing the efficacy of the drug against human HIV. *Id.* at 1227. The lawsuit commenced when the defendants individually applied to the Food and Drug Administration for permission to manufacture and sell a generic form of AZT. *Id.* at 1226. BW then instituted actions for patent infringement against each company. *Id.* The district court granted judgment as a matter of law in favor of BW after three weeks of trial, ruling that BW fully conceived the invention before submitting it to NIH scientists for testing. Burroughs Wellcome Co. v. Barr Labs., Inc., 828 F. Supp. 1208, 1213 (E.D.N.C. 1993) *rev'd in part by* Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1232 (Fed. Cir. 1994).

171. *Burroughs*, 40 F.3d at 1227. The Patent Act sets forth the procedure for correction of inventorship. 35 U.S.C. § 256 (1988). Although the choice of remedy is discretionary, courts rarely invalidate an issued patent on the basis of incorrect inventorship, instead requiring correction of inventorship as permitted in § 256 of the Patent Act. Lucy Gamon, Note, *Patent Law in the Context of Corporate Research*, 8 J. CORP. L. 497, 517 (1983). Courts will not invalidate an issued patent lightly because it holds a presumption of validity. *Id.*

172. *Burroughs*, 40 F.3d at 1231. However, the *Burroughs* court remanded the case on the issue of whether NIH scientists sufficiently contributed to the invention of AZT as a method to improve the immune system of a human afflicted with HIV to require joint inventorship. *Id.* at 1232. The court found the record at the district court level insufficient to justify judgment as a matter of law that BW scientists fully conceived the invention before the assistance given by the NIH scientists in designing and conducting human clinical trials. *Id.* at 1231-32.

reaching its decision, the court stated that "an inventor need not know that his invention will work" in order for conception to exist in definite and permanent form.[173] While the *Burroughs* court acknowledged that in some cases an inventor cannot show conception until a successful reduction to practice, in such cases conception fails because it is incomplete, not because the particular field of the invention exhibits inherent unpredictability.[174] In the court's view, reduction to practice serves a corroborative function, showing that the inventor did not actually possess a definite and permanent idea of an invention.[175]

Under the reasoning of the *Burroughs* decision, an idea otherwise considered definite and permanent can fail to constitute a complete conception if subsequent experimentation, especially experimental failure, shows that the supposed conception was not, in fact, certain.[176] However, the *Burroughs* court's view of reduction to practice as a corroboration of conception does not correspond to the established view of invention that considers conception as a process separate from reduction to practice.[177] Under the *Mergenthaler* standard, conception operates distinctly from reduction to practice; that is, an idea either exists in definite and permanent form or it does not.[178] However, while seemingly ap-

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173. *Id.* The *Burroughs* court followed the reasoning of *MacMillan* to hold that an inventor need not possess a "reasonable expectation" that an invention will work as expected. MacMillan v. Moffett, 432 F.2d 1237, 1239 (C.C.P.A. 1970). See *supra* notes 132-38 and accompanying text for a discussion of *MacMillan*.

174. *Burroughs*, 40 F.3d at 1229. In reaching this conclusion, the *Burroughs* court re-examined the facts of *Smith v. Bousquet* to determine that the decision in that case resulted not from the nature of the invention, but from the failure of either party to show a complete conception prior to reduction to practice. *Id.* at 1228-29. See *supra* notes 102-07 and accompanying text for a discussion of *Smith*.

175. *Burroughs*, 40 F.3d at 1229.

176. *Id.* Although he agreed with the result of the case, Judge Lourie declined to join the majority's reasoning with respect to the interaction between conception and reduction to practice. *Id.* at 1233 (Lourie, J., dissenting in part). He cautioned the court not to confuse concepts and stated that the completeness of conception must be determined independently of the reduction to practice. *Id.* He also expressed the view that a conception still remains complete even though it may never culminate in a successful reduction to practice. *Id.*

177. *See* 2 ROSENBERG, *supra* note 127, at § 10.01 (stating that the inventive process consists of two necessary steps, conception and reduction to practice); *see, e.g.*, 35 U.S.C. § 102(g) (1988) (requiring the consideration of both conception and reduction to practice in determining priority of invention); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1376 (Fed. Cir. 1986) (implying an individual analysis of conception and reduction to practice), *cert. denied*, 480 U.S. 947 (1987).

178. *See, e.g.*, Oka v. Youssefyeh, 849 F.2d 581, 584 (Fed. Cir. 1988) (ruling that conception not complete when an inventor possesses an idea for a desired result but not the means for effectively carrying out the idea); Meitzner v. Corte, 410 F.2d 433, 437 (C.C.P.A. 1969) (holding that conception not complete when an inventor recognizes that an idea could work but not the manner in which an idea

plying the *Mergenthaler* standard to the invention of AZT, the *Burroughs* court did not actually determine the existence of a definite and permanent idea "as it is thereafter to be reduced to practice."[179] Rather, the court reasoned that BW scientists formed a definite and permanent idea of the invention *because* it was later applied in practice.[180] Although the distinction is subtle, it is crucial, because the law does not recognize a *nunc pro tunc* conception.[181] Thus, the *Burroughs* court's attempt to fit the facts surrounding the invention of AZT into the confines of the *Mergenthaler* standard resulted in a decision that is incongruous with the established law of conception. Contrary to the view of the *Burroughs* court, the subject matter of the invention may very well influence the issue of conception.[182]

Unlike the *Burroughs* court, the *Amgen* and *Fiers* courts did recognize that some inventions are inherently unpredictable.[183] While these decisions signaled a possible resurgence of the doctrine of simultaneous conception and reduction to practice in the law of conception in chemical and pharmaceutical invention, the *Burroughs* court expressly declined to extend the doctrine outside of the field of gene invention.[184] The court distinguished *Amgen* and *Fiers* from *Burroughs* on the ground that the former cases involved a new invention of a compound of previously unknown structure, while *Burroughs* centered on the invention of a new use for a known compound.[185] However, this distinction is arbitrary—in either case, conception prior to reduction to practice can amount to nothing more than a description of the invention by "its hoped for biological activity."[186] The *Burroughs* court attempted

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will work).

179. Technitrol, Inc. v. United States, 440 F.2d 1362, 1369 (Ct. Cl. 1972).

180. *See, e.g.*, *Burroughs*, 40 F.3d at 1230. The *Burroughs* court expressly stated that since the NIH testing of AZT using human HIV confirmed the operability of the invention, the BW scientists showed complete conception. *Id.*

181. *See* Spero v. Ringold, 377 F.2d 652, 659 (C.C.P.A. 1967) (stating that *nunc pro tunc* conception neither exists nor would it be recognized); *see, e.g.*, Langer v. Kaufman, 465 F.2d 915, 929 (C.C.P.A. 1972) (citing the rule that conception and reduction to practice cannot be established *nunc pro tunc*).

182. *Cf. In re* Ross, 305 F.2d 878, 883-84 (C.C.P.A. 1962) (Smith, J., dissenting in part) (cautioning that inventions in highly technical fields, such as pharmaceuticals, may not fit into the neat categories of invention existing in patent law). See *infra* notes 194-210 and accompanying text for a discussion of the manner in which different scientific disciplines conduct research.

183. See *supra* notes 152-63 and accompanying text for a discussion of these decisions.

184. *Burroughs*, 40 F.3d at 1229.

185. *Id.*

186. *See, e.g.*, Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993) (stating that an inventor does not complete conception of a biologically active gene sequence until the completion of successful reduction to practice); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir.) (holding that conception does

to avoid justifying such a conclusion by reasoning that the BW scientists showed complete conception because they "thoroughly and particularly set out the inventions as they would later be used."[187] However, such detailed description does not negate the fact that BW claimed the invention of AZT therapy for use in humans without fully knowing that the invention would exhibit effectiveness in humans.[188] Therefore, such documentation amounted to nothing more than a definite and permanent *hope* that AZT would show effectiveness in humans.[189] Granting of a patent under such circumstances conflicts with the policy of patent law: "to promote the disclosure of inventions, not of research plans."[190]

III. CHEMICAL AND BIOCHEMICAL INVENTION AS INHERENTLY DIFFERENT FROM ENGINEERING-RELATED INVENTION

The Federal Circuit's decision in *Burroughs* not to extend the doctrine of simultaneous conception and reduction to practice to cases involving non-biochemical pharmaceutical invention reflects a continuation of the reluctance of federal courts to address the substantive differences of the inventive process in experimental-based sciences. These disciplines function in an inherently different manner from engineering-related invention and thus often do not fit into a body of patent law created to address mechanical and electrical invention.[191] This Section focuses on these differences by distinguishing the invention process in experimental-

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not result when an inventor merely describes an invention by its primary biological property) *cert. denied sub nom.* Genetic Inst., Inc. v. Amgen, Inc., 112 S. Ct. 69 (1991).

187. *Burroughs*, 40 F.3d at 1231.

188. *See, e.g., id.* at 1225-26 (describing the events surrounding the invention of AZT).

189. *See, e.g., Fiers*, 984 F.2d at 1169 (stating that disclosure of method to obtain a gene sequence shows only a disclosure of a "research plan"). Interestingly, the *Burroughs* court found the predictiveness of the *in vitro* non-human retrovirus tests used by BW to screen AZT irrelevant to the issue of conception. *Id.* However, in a case involving a therapy for AIDS utilizing previously known compounds, the Board of Patent Appeals rejected a patent application based on the lack of predictiveness of *in vitro* tests to show efficacy in humans as of the time of the invention (1987). *Ex parte* Balzarini, 21 U.S.P.Q. (BNA) 1892, 1897 (Bd. Pat. App. 1991). *Id.* A commentator believes that this decision requires an inventor to show more than *in vitro* testing in order to obtain a patent for a pharmaceutical invention involving a new use for a known compound. B. P. O'Shaughnessy, *Patentable Subject Matter*, *in* THE LAW AND STRATEGY OF BIOTECHNOLOGY PATENTS 72 (K. D. Sibley ed., 1994).

190. Fiers, 984 F.2d at 1169; *see, e.g.*, Brenner v. Manson, 383 U.S. 519, 535 (1966) (stating that a patent is not a reward for the search, but compensation for its successful conclusion).

191. See *infra* notes 226-38 and accompanying text for a discussion of the engineering bias present in patent law.

based disciplines, especially pharmaceuticals, from that of the engineering-oriented fields. Moreover, this Section discusses the traditional failure of patent law in addressing these differences. Additionally, this Section suggests that the changing nature of American research will result in increased litigation resulting from attempts to patent experimental based inventions that might not yet be sufficiently "ripe."

A. Inherent Differences Between the Experimental Sciences and Engineering

As noted previously, in his landmark 1890 treatise on patent law, Professor William Robinson recognized that some inventions require confirmation through experimentation before completion of the inventive process.[192] This view was an early acknowledgment of the inherent differences between the experimental sciences and the more "applied" sciences, such as mechanical engineering. The functional differences between the experimental sciences and applied technology is now well recognized outside of patent law.[193]

Fundamentally, scientists and engineers work in very different manners.[194] Scientists generally focus their work on the collection of knowledge, often with no goal of eventual practical application.[195] Since scientists aim their work toward an understanding of previously unknown or misunderstood theories of nature, a scientist frequently holds no rational expectation of the viability of a hypothesis until the completion of experimentation.[196] Instead, the scientist uses empirical methodology to discern general patterns which can then be developed into predictive models.[197] Moreover, the scientist's research frequently culminates in a published article, rather than a finished product.[198]

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192. 1 ROBINSON, *supra* note 100, § 381.

193. *See, e.g.*, COPP & ZANELLA, *supra* note 13, at 5 (describing the difference between scientists and engineers); *see also* Thomas J. Allen, *Distinguishing Engineers from Scientists*, *in* MANAGING PROFESSIONALS IN CREATIVE ORGANIZATIONS: A COLLECTION OF READINGS 3 (Ralph Katz ed., 1988) (stating that vast differences exist between scientists and engineers); JOHN D. KEMPER, THE ENGINEER AND HIS PROFESSION 90 (3d ed. 1982) (stating that scientists produce "knowledge," while engineers produce "things").

194. COPP & ZANELLA, *supra* note 13, at 5; *see also* KEMPER *supra* note 193, at 90-91.

195. COPP & ZANELLA, *supra* note 13, at 5. Such research is generally referred to as "basic research." *See* SCHWARTZMAN, *supra* note 14, at 7.

196. *See generally* ROBERT TEITELMAN, PROFITS OF SCIENCE: THE AMERICAN MARRIAGE OF BUSINESS AND TECHNOLOGY 8 (1994) [hereinafter PROFITS OF SCIENCE] (stating that "empiricism rules" in the experimental sciences).

197. COPP & ZANELLA, *supra* note 13, at 5.

198. KEMPER, *supra* note 193, at 91; *see also* Allen, *supra* note 193, at 8. Dissemination of scientific knowledge through the published article effectuates the goal of

In contrast, an engineer focuses on the practical application of technology.[199] An engineer generally engages in the design of tools and systems for use by mankind; more simply, an engineer produces "things."[200] Accordingly, the goals of engineering focus primarily to the practical application of scientific principles rather than a desire to gain knowledge for knowledge's sake.[201]

Nonetheless, it should not be construed that engineers act merely as technicians. On the contrary, since scientific knowledge forms the foundation for all engineering principles, engineers must necessarily understand and utilize the theories developed by scientists.[202] Basic science and engineering thus operate in an interactive manner which has been described as "cross-fertilization."[203] That is, engineers do not just passively accept the theories developed by their scientist counterparts; instead, information gathered in engineering research and development frequently leads to a greater understanding of the underlying scientific theories.[204]

Basic research in the various scientific disciplines does not lend itself equally to applied technology. The degree to which engineers can develop new products or processes depends largely on the maturity of the relevant scientific discipline.[205] For example, the scientific theories underlying physics have been well understood for many decades and, as such, engineers working in these areas can more predictably develop products and processes.[206] In contrast, in some scientific disciplines well-defined

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scientists to contribute to the shared body of knowledge. Eisenberg, *supra* note 28, at 184-85. As such, scientists view the published article as the necessary means by which to gain recognition and to gauge productivity in the scientific community. *Id.*

199. COPP & ZANELLA, *supra* note 13, at 5; *see also*, KEMPER, *supra* note 193, at 90.

200. KEMPER, *supra* note 193, at 90; *see also*, COPP & ZANELLA, *supra* note 13, at 5 (describing engineers as concerned with the development of "better machines, structures, systems, chemicals or processes").

201. *See* S. C. FLORMAN, THE EXISTENTIAL PLEASURES OF ENGINEERING 178 (2d ed. 1994) (stating that engineers focus on utility, rather than on understanding basic scientific principles); COPP & ZANELLA, *supra* note 13, at 5 (stating that engineers utilize a different point of scientific inquiry from that of scientists).

202. *See, e.g.*, COPP & ZANELLA, *supra* note 13, at 5 (describing the interaction between basic science and engineering).

203. *Id.* at 7-8.

204. *Id.*

205. *See* SCHWARTZMAN, *supra* note 14, at 32; *see also* PROFITS OF SCIENCE, *supra* note 196, at 198 (implying that predictability of new product development exists as a function of the maturity of the underlying scientific principle).

206. *See* SCHWARTZMAN, *supra* note 14, at 32 (stating that theoretical physics was sufficiently mature in the 1930s to allow scientists to develop the atomic bomb in a relatively short time); *see also* COPP & ZANELLA, *supra* note 13, at 8 (describing the development of the Apollo Project in the 1960s as utilizing well understood scientific principles); PROFITS OF SCIENCE, *supra* note 196, at 198 (discussing the

knowledge of the underlying scientific principles does not yet exist.[207] In these fields, both basic research and product development progress in a largely empirical manner.[208] This trial and error approach necessarily makes the development of applied technology in these fields less predictable than in more mature fields.[209] Pharmaceutical research presents a classic example of a discipline which places substantial emphasis on such empirical methodology.[210]

C. The Unpredictable Nature of Pharmaceutical Research

Nowhere has the gap between basic scientific knowledge and applied technology been more evident than in the relationship between the biological sciences and pharmaceutical research.[211] Traditionally, basic biological research led to few advances in medicinal products because scientists knew little about the underlying relationship between biological mechanisms and drug therapy.[212] Drug research thus was an "intricate and complex process, differing in important ways from other forms of scientific research."[213] The field progressed in a largely empirical fashion, relying heavily on experimentation and observation.[214] Moreover, drug research generally focused more on developing effective

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development of the transistor as resulting from the use of well-understood principles of physics).

207. PROFITS OF SCIENCE, *supra* note 196, at 198 (stating that biotechnology not yet sufficiently mature to allow predicable development of drugs and diagnostic methods); *see also* SCHWARTZMAN, *supra* note 14, at 32 (stating that pharmaceutical research operates on the "borderline of the unknown").

208. SCHWARTZMAN, *supra* note 14, at 48.

209. *Id.*

210. *Id.* at 32; *see also* ROBERT TEITELMAN, GENE DREAMS: WALL STREET, ACADEMIA, AND THE RISE OF BIOTECHNOLOGY 15 (1989) [hereinafter GENE DREAMS].

211. PROFITS OF SCIENCE, *supra* note 196, at 156-57.

212. SCHWARTZMAN, *supra* note 14, at 32; *see also* PROFITS OF SCIENCE, *supra* note 196, at 156-57. Even important inroads into basic biological phenomena, such as the discovery of DNA in 1953, initially failed to result in pharmaceutical discovery because the gap between basic science and applied technology was too wide. *Id.* Additionally, research into biological processes generally took place in academic or government laboratory settings thus affording little opportunity for technology transfer to pharmaceutical companies. *Id.* at 156-57.

213. SCHWARTZMAN, *supra* note 14, at 29. This differs from product development in the engineering-related disciplines, where the underlying scientific principles are usually better understood. *Id.* at 32. See *supra* notes 192-210 and accompanying text for discussion of the differences between engineering and basic scientific research.

214. *See id.* Schwartzman describes the traditional method of drug discovery as an ongoing series of hypothesis generation and experimentation. *Id.* The researcher refines the original hypothesis based on the results of the experiments. *Id.* As a result, drug discovery consists of many "false starts" which make the process exceptionally labor intensive and expensive. *Id.*

chemical compounds, rather than on an understanding of the underlying disease-causing biological mechanisms.[215] Consequently, pharmaceutical companies acted as large-scale chemical screening houses—producing successful pharmaceutical products not because they understood how drugs worked in biological systems, but because they developed effective screening programs that allowed them to test hundreds of thousands of chemical compounds a year.[216] Discovery did not occur predictably; rather, it resulted from these highly structured, albeit scientifically sophisticated, mechanical screening programs and, often, mere luck.[217]

Understandably unhappy with the unpredictable nature of pharmaceutical research, by the 1980s major pharmaceutical companies had begun to branch out into the area of rational drug research. Rational drug development attempts to relate chemical structure with biological activity.[218] Rational research methods became possible because the discipline of biotechnology had progressed to the point where scientists could begin implementing its

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215. GENE DREAMS, *supra* note 210, at 15. Large pharmaceutical companies did perform basic biological research. SCHWARTZMAN, *supra* note 14, at 31. However, the approach focused more on applied research, using the results of work with chemical entities on biological systems to develop new theories on which to base further experimentation. *Id.* at 34. In contrast, academic institutions and government laboratories performed more fundamental biomedical research, focusing on the biological mechanisms themselves. GENE DREAMS, *supra* note 210, at 15.

216. PROFITS OF SCIENCE, *supra* note 196, at 156-57; *see also* SCHWARTZMAN, *supra* note 14, at 48. Under this methodology, only one out of ten thousand chemical compounds tested successfully reach the market. E. Whittaker & D. J. Walker, *A Shift to External Alliances for Product Development in the Pharmaceutical Industry*, R & D MGMT. 249, 250 (1994).

217. *See* GENE DREAMS, *supra* note 210, at 15 (describing traditional drug research as "an attempt to organize and rationalize serendipity.") This is not to say that drug research stemmed from irrationality, however the rationale of drug development did not emanate from a knowledge of the manner in which chemical compound interacted with a biological system. PROFITS OF SCIENCE, *supra* note 196, at 165. While not clearly understanding basic biological processes, pharmaceutical companies utilized advances in chemistry to synthesize new chemical compounds on a continual basis. *Id.* This enabled them to effectuate small changes in chemical compounds which would hopefully lead to large differences in therapeutic effects. *Id.*

218. PROFITS OF SCIENCE, *supra* note 196, at 177. Rational drug research endeavors to identify and eradicate disease causing mechanisms in biological systems by utilizing the functional aspects of chemical compounds to attack the disease without harming necessary cellular function. Deborah Erickson, *Rational Drugs; Transforming Drug Research from an Art into a Science*, 262 SCI. AM., Jan. 1990, at 102. In essence, a scientist works "backwards," first identifying a disease and then attempting to modify it. PHARMACEUTICAL R & D, *supra* note 15, at 108-09. This approach differs from the traditional mass screening approach to pharmaceutical research in which drug discovery focused primarily on screening chemicals to serve desired functions. *Id.* The growth of rational drug development has been aided by the continuously increasing power of computers that allow sophisticated modeling and the automation of previously labor intensive laboratory techniques. *Id.* at 132.

theories into applied drug research.[219] The growth of biotechnology allowed scientists to genetically modify molecules to provide more effective biotherapeutic compounds.[220] However, since universities historically conducted most of the biotechnology research, pharmaceutical companies found it necessary to form joint partnerships with academic scientists.[221] As such, the lines between industrial research and development and academic research became blurred because scientists who formerly conducted primarily basic research now began to direct their work toward the development of new and commercially viable drug products and processes.[222]

Although experts initially predicted that the marriage of molecular biology and drug research would result in rapid discovery of new and useful pharmaceutical products, biotherapeutic research did not progress as quickly as expected.[223] Neverthe-

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219. PROFITS OF SCIENCE, *supra* note 196, at 180-81. Molecular biology relates to the study of the structural and functional aspects of DNA and RNA, as well as the analysis of the structure of proteins. *Id.* at 183. More abstractly, molecular biology is a "discipline exploring the most fundamental order of biological reality." *Id.* Molecular biology discovery provided insights into the underlying workings of the biological systems. *See* Erickson, *supra* note 218, at 102. Thus, by understanding the biological functions at the cellular level, researchers could match biological function with a corresponding chemical process and block or modify a reaction which caused a diseased state in the body. *Id.*; *see generally* Dan L. Burk, *Introduction: A Biotechnology Primer*, 55 U. PITT. L. REV. 611, 612-13 (1994). Burk provides a basic description of molecular biology for the non-biotechnologist. *Id.*

220. Burk, *supra* note 219, at 621. The term "biotechnology" refers to the practical application of molecular biology to manipulate the biological processes of cells. *Id.* at 614. Early biotechnology aimed at synthesizing naturally occurring proteins. *Id.* Biotherapeutics are the "second wave" of biotechnology research. *Id.* at 622. Scientists bioengineer molecules to alter or block cellular functions. *Id.* In so doing, scientists can make new and more effective drug therapies, not possible with existing and known chemical compounds. Erickson, *supra* note 218, at 102.

221. Burk, *supra* note 219, at 629. Most early research into molecular biology took place primarily at universities. PROFITS OF SCIENCE, *supra* note 196, at 184. As an academic discipline, the field grew rapidly as a result of vast government funding and by the 1970s had become a mature area of university research. *Id.* at 184-85. Even while universities explored the vast potential of biotechnology, few corporations developed expertise in biotechnology. David E. Korn, *Patent and Trade Secret Protection in University-Industry Research Relationships in Biotechnology*, 24 HARV. J. ON LEGIS. 191, 197 (1987). When the commercial possibilities became evident, corporations were forced to utilize the skills of university researchers by forming joint research programs with academia. *Id.*

222. Eisenberg, *supra* note 28, at 196. The basic techniques resulting from commercial development of biotechnology are: cell culture, hybridoma culture, recombinant DNA, antisense and DNA amplification techniques. Burk, *supra* note 219, at 614. Today, biotechnology shows extensive application in the chemical and pharmaceutical industries, as well as in agriculture, materials science, bioremediation and natural resource operations. *Id.* at 621.

223. GENE DREAMS, *supra* note 210, at 7. Biotechnology research failed to yield consistently predictable models; thus, today, drug development still remains some-

less, research did result in several new medicinal treatments.[224] Today, the field remains an active area of pharmaceutical research.[225]

D. Conflicts Between Patent Law and the Experimental Sciences

Even though marked improvements in pharmaceutical research resulted from the advent of rational drug development, drug discovery today remains largely a matter of scientific "guesswork."[226] This unpredictability has frequently resulted in uncertainty when companies seek to patent new pharmaceutical products.[227] This is not a new problem; practitioners have long recognized that the PTO fails to accommodate the differences between chemical and biological inventions and mechanical inventions.[228]

This inconsistency has been traced to the evolution of United States patent law.[229] Most early patents pertained to mechanical devices.[230] Consequently, judicial interpretation of the patent statutes, and the language of the statutes themselves, adapted to

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what unpredictable, just as in traditional pharmaceutical research. PROFITS OF SCIENCE, *supra* note 196, at 198.

224. *See generally* Michael A. Sanzo, *Patenting Biotherapeutics*, 20 HOFSTRA L. REV. 387, 387 (1991) (noting four drugs emerging from biotechnology research: insulin, human growth hormone, alpha-interferon, and tissue plasminogen activator).

225. *See Reshaping Things to Come*, ECONOMIST, Aug. 6, 1994, at 65, 66.

226. Erickson, *supra* note 218, at 102; *see also* PHARMACEUTICAL R & D, *supra* note 15, at 111. Drug research today remains largely qualitative. *Id.* Recent advances in biotechnology have failed to yield predictable methods to generate new drugs. *Id.* Interestingly, the drug discovery progress is slowed somewhat by the ever increasing wealth of medical knowledge gained from biotechnology itself. *Id.* at 133. That is, as scientists discover more about biological mechanisms, the possible routes of investigation become increasingly more complex. *Id.* As such, groundbreaking biotechnology advances can frequently provide more questions than answers. *Id.*

227. *See generally* Sanzo, *supra* note 224, at 391-405 (discussing legal difficulties resulting from attempts to patent pharmaceuticals emanating from biotechnology research).

228. *See* Noonan, *supra* note 18, at 263, 268-69; *see also* Eggert, *supra* note 12, at 783; E. THOMAS, CHEMICAL INVENTIONS AND CHEMICAL PATENTS 8 (M. A. Auslander ed., 1964) (distinguishing mechanical invention from chemical invention).

229. Noonan, *supra* note 18, at 263, 268-69; *see also* Eggert, *supra* note 12, at 783. Noonan hypothesizes that the different treatment of chemical and biological inventions stems from attempts to prevent patenting of "quack" medicinal products at the turn of the century. Noonan, *supra* note 18, at 266-67. In order to curb attempts to patent these products, the courts began to require that inventors show the usefulness of their inventions. *Id.* at 266. Today, inventors are still required to show specific utility of their pharmaceutical inventions, while inventors of mechanical devices usually need not show utility. *Id.* at 276. See *supra* notes 37-41 and accompanying text for a discussion of the utility requirement.

230. Noonan, *supra* note 18, at 263, 268-69; *see also* Eggert, *supra* note 12, at 783.

best suit mechanical and, later, electronic invention.[231] However, when chemical and biological invention became more prevalent, the existing law proved ill-suited to handle the special requirement of these types of invention.[232] Some courts attempted to modify the existing law to fit chemical and biological invention, however, these changes were largely ineffectual.[233] Accordingly, the law of chemical patents has been referred to as a "child (or orphan) of the mechanical patent law."[234]

Failure to treat invention in the experimental science differently than engineering-related invention indicates that the federal courts cannot, or will not, recognize the inherent differences between the methodologies used in the disciplines. Admittedly, the Federal Circuit recently recognized that the unpredictable nature of new gene invention requires application of the doctrine of simultaneous conception and reduction to practice to conception of a new gene.[235] Nevertheless, in the later case of *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*, the Federal Circuit failed to extend the doctrine to a pharmaceutical invention of a new pharmaceutical use for a known chemical compound.[236] Thus, the Federal Circuit has not reinstated the previously held view that inventions resulting from empirical research, as a general rule, require application of a standard of conception tailored to meet the specific needs of these disciplines.[237] As such, the rule of law currently governing pharmaceutical invention fails to recog-

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231. Eggert, *supra* note 12, at 783; *see also* Noonan, *supra* note 18, at 263, 268-69.

232. Noonan, *supra* note 18, at 263, 268-69. For example, in the early days of pharmaceutical invention, the Patent Office absolutely refused to issue a patent for a chemical compound if the chemical structure appeared anywhere in the published literature. *Id.* at 281. This reflected the view of mechanical invention that if a drawing existed, an invention was unpatentable over the prior art. *Id.* Of course, this view ignored the fact that a mere drawing of a chemical structure did not necessarily mean that one could actually synthesize the compound. *Id.* Although prior art limitations are no longer this strict, the example remains as an illustration of the difficulty of attempting to fit chemical invention into the fixed confines of a body of law developed for mechanical invention. *Id.* at 283-84.

233. *Id.* at 269.

234. Eggert, *supra* note 12, at 783.

235. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir.), *cert. denied sub nom.* Genetics Inst., Inc. v. Amgen, Inc., 112 S. Ct. 169 (1991); *see also* Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993). For a discussion of these decisions, see *supra* notes 152-63 and accompanying text.

236. Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1229 (Fed. Cir. 1994).

237. *See, e.g.*, Alpert v. Slatin, 305 F.2d 891, 894 (C.C.P.A. 1962) (holding that conception and reduction to practice occur simultaneously when an invention requires experimentation to show feasibility); Smith v. Bousquet, 111 F.2d 157, 158 (C.C.P.A. 1940) (stating that chemical and biological inventions require application of separate standard of conception because of their unpredictability).

nize what otherwise exists as a well recognized principal: that drug discovery is an unpredictable process differing markedly from other invention.[238]

E. Change in the Nature of American Research

Traditionally, the United States government provided much of the support for basic science by funding university research or by performing research at government laboratories.[239] The United States government directed a large portion of this funding toward biomedical research which was in turn utilized by pharmaceutical companies to develop new drugs.[240] Yet, in recent years, government funding of basic research has decreased markedly.[241] Similarly, American corporations are also cutting funding of knowledge-driven research in favor of product-oriented applied research.[242]

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238. *See* Schwartzman, *supra* note 14, at 29; *see also* PHARMACEUTICAL R & D, *supra* note 15, at 111 (stating that recent technological advances in drug developments are "far from providing a cookbook to produce new drugs."). See *supra* notes 211-25 and accompanying text for a discussion of the empirical nature of pharmaceutical research.

239. Linda R. Cohen & Roger G. Noll, *Privatizing Public Research*, 271 SCI. AM., Sept. 1994, at 72, 74.

240. *See* PHARMACEUTICAL R & D, *supra* note 15, at 201-02. In 1990, the federal government accounted for 45% of health-related research and development. *Id.* at 203. Over 25% of pharmaceutical products and processes developed by drug companies between 1975 and 1985 would have taken much more time to develop without government funded academic research. *Id.* at 201. Biomedical research performed at government laboratories has also resulted in technological advances utilized by pharmaceutical companies. *Id.* at 202. Moreover, the United States government also provides direct subsidies to the drug companies to encourage the development of new drug therapies which do not have large commercial markets. *Id.* These so-called "orphan drugs" would probably not be developed without substantial government subsidies because of low potential sales. *Id.*

241. *Id.* at 75. In 1988, the federal government provided 61% of university research funding; by 1993 the figure decreased to 56%. *Id.* Moreover, the role of government laboratories in research and development has steadily decreased since World War II from a high of 28% in 1945 to about 11% of total basic research in 1988. James V. Lacy et al., *Technology Transfer Law Governing Federally Funded Research and Development*, 19 PEPP. L. REV. 1, 4-5 (1991).

242. John Markoff, *Corporate Lag in Research Funds is Causing Worry*, N.Y. TIMES, Jan. 23, 1990, § A, at 1. *See generally* Elizabeth Corcoran, *Rethinking Research: Bell Labs Seeks New Model for Industrial Research*, 265 SCI. AM., Dec. 1991, at 136, 136-38 (citing AT&T as an example of an American corporation cutting basic research programs in favor of product-directed programs offering faster return on investment); Jon Van, *Applied Versus Basic Research: the Debate Escalates*, CHI. TRIB., Feb. 28, 1993, § 4, at 1 (noting that few United States corporations allow scientists to explore basic science, even while recognizing its importance).

It should be noted that while basic research accounts for about one-half of total research and development spending in the United States, corporations typically dedicate only 6% of their research and development budgets to basic research.

The across-the-board decrease in basic research is causing changes in the way American organizations perform scientific research, particularly in the manner in which pharmaceutical research is conducted. Starting in the late 1970s, pharmaceutical companies began seeking collaborative ventures with universities in an effort to increase the productivity of research and development.[243] Universities welcomed such alliances with industry because government support of basic academic research began to decline.[244] As a result of these joint research programs, the amount of basic research performed by universities continues to decrease because corporations generally focus their research efforts on product-driven technology.[245] Additionally, government laboratories that previously performed basic research for public use are facing closure as funding decreases.[246] In an effort to remain open, these laboratories increasingly seek joint research projects with industry to work on largely commercially motivated research.[247]

The trend away from the funding of basic research will continue into the 1990s.[248] This will thus necessitate that universities and government laboratories continue seeking greater funding

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Cohen & Noll, *supra* note 239, at 75. However, in some industries, spending on basic research reached historical levels of 10%. Markoff, *supra* at 1. Pharmaceutical manufacturers historically tended to perform more basic research than other science-related industries. *See* SCHWARTZMAN, *supra* note 14, at 30.

243. PHARMACEUTICAL R & D, *supra* note 15, at 207. This increase can be traced to the pharmaceutical industry's need for the biotechnology expertise which existed primarily at academic laboratories. *Id.*

244. *See, e.g.*, Lita Nelsen, *Identifying, Evaluating, and Reporting Innovative Research Developments at the University*, *in* UNDERSTANDING BIOTECHNOLOGY LAW: PROTECTION, LICENSING, AND INTELLECTUAL PROPERTY POLICIES 25, 28 (Gale R. Peterson ed., 1993) (noting that universities are pursuing industrial support because government research funds are increasingly difficult to obtain).

245. *See, e.g.*, Cohen & Noll, *supra* note 239, at 75 (implying that the amount of basic research at universities has decreased because of the greater involvement of corporate sponsorship); *see also* PHARMACEUTICAL R & D, *supra* note 15, at 201 (stating that a private industrial firm will not extensively support basic research because such support may not lead to a certain return on investment).

246. Cohen & Noll, *supra* note 239, at 73.

247. *Id.* The Federal Technology Transfer Act of 1986 permits government laboratories to enter into agreements with private industry to perform joint research projects. Lacy et al., *supra* note 241, at 18.

248. *See, e.g.*, Roland W. Schmitt, *Beyond Competitiveness: Technology Policy for the 1990's*, 5:1 STAN. L. & POL'Y REV. 119, 120 (1993) (citing statistics showing industrial spending on research will decrease through 1993). Moreover, the Clinton Administration expressed a policy to further cut spending for basic research in favor of a focus on applied technology. *Id.* at 124. As a result, former major government sources of basic science funding, such as the National Institutes of Health, now direct substantial support to applied science, at the expense of basic research. Victor F. Weisskopf, *Endangered Support for Basic Science*, 270 SCI. AM., May 1994, at 128.

from industry. The foreseeable result of these collaborations will be an even greater emphasis on applied technology because the primary purpose of corporate sponsorship is to develop new products.[249] Moreover, a corporate sponsor will seek to lessen the needed capital investment by choosing projects with a greater potential for success and a shorter development timeline.[250] Such projects will almost certainly focus on applied technology.[251] This is especially true in the area of pharmaceutical research because research collaborations can result in financially lucrative commercial products.[252] Moreover, as pharmaceutical companies begin to tackle more complex disease mechanisms, they will increasingly find it necessary to look outside of their corporations for innovative ideas.[253]

The pharmaceutical industry also increasingly participates in joint research programs with specialized biotechnology firms.[254] In these arrangements, a pharmaceutical company collaborates with a biotechnology company to develop novel technology into commercial pharmaceutical products.[255] These companies generally possess new technology garnered from universities.[256] Moreover, the technologies generally are at an early stage of development, requiring a large investment of capital to develop into viable commercial products.[257] Starting with the biotechnology "rev-

249. *See generally* Nelsen, *supra* note 244, at 25 (implying that the ultimate objective of university-industry relationships is to develop products); Van, *supra* note 242, at 1 (describing a Massachusetts Institute of Technology joint program with industry in which graduate students work directly with industrial sponsors to develop new products without performing basic research). Focus on applied technology makes complete sense from the standpoint of a corporation since applied research produces short-term results much more frequently. Daniel E. Koshland, Jr., *Basic Research; Government Policy; Part 1; Editorial*, 259 SCI. 291, 291 (Jan. 15, 1993). Koshland states: "[i]n-applied research the successful application is expected; in basic research a successful application is astonishing." *Id.*

250. *See generally* Nelsen, *supra* note 244, at 25 (stating that the newer and the more basic the technology, the higher the risk that development will not result in a successful product); Corcoran, *supra* note 242, at 136-37 (describing new research structure at AT&T requiring research groups to work with product groups in order to shorten development time); Markoff, *supra* note 242, at A1 (discussing shift in corporate research from basic research to applied technology).

251. *See generally* Cohen & Noll, *supra* note 239, at 75 (noting that companies generally obtain greater economic value from improvements in products, rather than from advances in fundamental knowledge); Koshland, *supra* note 249, at 291 (stating that applied technology results in greater probability of success and shorter development times).

252. Eisenberg, *supra* note 28, at 195.

253. *See, e.g.*, Whittaker & Walker, *supra* note 216, at 257-58 (describing the increasing tendency of pharmaceutical companies to seek novel and innovative ideas from outside sources).

254. *Id.* at 250.

255. *Id.*

256. *Id.*

257. *Id.* at 257. Additionally, collaborative research serves to decrease the finan-

olution"[258] of the early 1980s, these joint programs have become an important source of innovation for pharmaceutical companies and will likely remain an important aspect of drug development for years to come.[259]

Patent protection forms a crucial aspect of these joint research programs as it motivates investment into research by providing the best opportunity for a return on capital.[260] In fact, the number of patent applications emanating from joint research serves as an indicator of the success of the collaborations.[261] Yet, in the rush to protect research investment, corporations and their research partners will likely seek patent protection earlier in the development process.[262] In other words, parties may obtain patent protection for a technology that is not yet sufficiently "ripe."[263] A patent obtained under such circumstances is vulnerable if litigation later arises, especially in light of uncertain patent laws.[264] Since conception operates as the cornerstone of the inventive process, it is crucial that a conception exist in a

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cial risk involved in developing a novel therapeutic agent. *Id.*

258. *See generally*, GENE DREAMS, *supra* note 210, at 8. GENE DREAMS provides a comprehensive history of the biotechnology "revolution," focusing primarily on the industry's growth as an important aspect of the United States financial markets.

259. Whittaker & Walker, *supra* note 216, at 258.

260. Nelsen, *supra* note 244, at 25. Secrecy provides protection for research organizations either in the form of state trade secret law or actual secrecy. Eisenberg, *supra* note 28, at 190. Trade secrecy allows tort recovery against persons who breached a duty of confidentiality or who misappropriated information. *Id.* However, protection may not extend to ongoing research projects which have not yet resulted in commercial products or processes. *Id.* at 192-93. Actual secrecy provides protection when a company closely guards confidential information. *Id.* Although both of these methods can be effective in some instances, they conflict with the academic philosophy of promoting disclosure of research results. *Id.* at 185. Patents do not pose this problem because the information may be disclosed and yet still allow the patentee to retain exclusive rights to the invention. *Id.* at 185.

261. David Blumenthal et al., *Industrial Support of University Research in Biotechnology*, 231 SCI. 242, 244 (Jan. 17, 1986).

262. *See, e.g.*, G. S. BURRILL, BIOTECH 89: COMMERCIALIZATION 67 (1989) (discussing the effects of potential patent litigation on commercial investment in biotechnology firms); *see generally* Nelsen, *supra* note 244, at 25. Nelsen states that corporations will not usually undertake the risk of developing a new technology without exclusive rights. *Id.* Moreover, the risk increases as the age of the technology decreases. *Id.* Thus, before agreeing to fund budding and not yet applied research, corporate sponsors will demand patent protection for the basic ideas. *Id.*

263. *See generally* Nelsen, *supra* note 244, at 49. Nelsen suggests that in cases of very new discoveries, the best course may be to allow the technology to ripen before seeking patent protection. *Id.* In "seminal" inventions, research might continue for two to five years before scientists realize the full commercial potential of the invention. *Id.* at 45.

264. While a patent holds a presumption of validity, a court can render it invalid with a showing by clear and convincing evidence that the invention did not warrant patent protection. *See* Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1375 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987).

definite and permanent form before an inventor seeks patent protection.[265] While an idea may appear definite and permanent enough for the PTO to grant a patent, the intensive examination of the facts provided by litigation may show that conception was not actually complete at the time claimed.[266] Thus, a premature attempt to patent an invention may cause companies to lose valuable patent protection if the patent later falls in litigation due to a failure to show complete conception at the time claimed.[267]

Moreover, increased emphasis on collaborative efforts directed toward the commercial development of novel, but not yet applied, technology will likely result in a greater number of cases in which researchers contest inventorship. That is, the parties participating in joint research may claim ownership of the invention separately and in conflict with one another.[268] Since conception operates as a threshold issue in invention, the courts will, out of necessity, increasingly address this issue in patent litigation. Moreover, much of the work flowing from industry research collaborations involves experimental-based disciplines, such as pharmaceuticals or biotechnology.[269] Consequently, the federal courts will need to address more frequently the issue of conception in inventions resulting from experiment.[270]

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265. See *supra* notes 86-99 and accompanying text for a discussion of the requirements for conception under the *Mergenthaler* standard.

266. *See* 35 U.S.C. § 102(g) (1988). Section 102(g) is commonly used in patent interference proceedings to prove a date of conception prior to another patent applicant. *See, e.g.*, Price v. Symsek, 98 F.2d 1187, 1196 (Fed. Cir. 1993) (vacating and remanding Board of Patent Appeals decision awarding priority of invention to senior party in interference). However, the section can also be used by a party seeking to invalidate an issued patent by showing that the patent holder failed to conceive the invention as claimed. *See* New Idea Farm Equipment Corp. v. Sperry Corp., 916 F.2d 1561, 1566 (Fed. Cir. 1990).

267. *See, e.g.*, *New Idea*, 916 F.2d at 1566 (upholding a district court decision invalidating a patent in an infringement case because the defendant showed prior conception of the patented invention by a third party).

268. *See generally* Katherine L. Chapman, *Intellectual Property Policies, Research Agreements, Consulting Agreements, and Conflicts of Interest*, *in* UNDERSTANDING BIOTECHNOLOGY LAW: PROTECTION, LICENSING, AND INTELLECTUAL PROPERTY POLICIES, *supra* note 244, at 333-36. Of course, research partners can and should formally develop agreements directed to allocating the intellectual property rights of inventions emanating from joint research before commencing research. *Id.* at 310-11. However, parties may disagree one the meanings of the prior agreements, especially if commercial improvements to the invention took place after the termination of the joint research project. *Id.* at 334-35.

269. *See generally* Thomas Bulliet, Jr., *Public Private Partnerships in Biomedical Research: Resolving Conflicts of Interest Arising Under the Federal Technology Transfer Act of 1986*, 4 J.L. & HEALTH 1, 2 (1989-1990) (stating that corporations forming cooperative ventures with government laboratories to perform biomedical and biotechnology research); Korn, *supra* note 221, at 191-92 (stating that corporations are increasingly forming agreements with academic scientists to perform biotechnology research).

270. *See generally* Chapman, *supra* note 268, at 334 (recommending that re-

IV. CURRENT STATE OF THE LAW OF CONCEPTION AND A RECOMMENDATION FOR CHANGE

This Section examines the current state of the law of conception. This Section also addresses the failure of the *Mergenthaler* standard to adequately accommodate the special concerns of inventions resulting from empirical methodology, such as pharmaceutical invention. Lastly, this Section suggests that the doctrine of simultaneous conception and reduction to practice better addresses the nature of invention in the experimental sciences and that the Federal Circuit should extend the doctrine to cases of pharmaceutical invention.

A. Current State of the Law of Conception

As the law stands currently, federal courts must apply the *Mergenthaler* standard of conception in almost all cases of invention. While the Federal Circuit has carved a limited exception in the case of invention of a new biotherapeutic gene sequence,[271] the doctrine of simultaneous conception and reduction to practice does not exist currently as a viable alternative to the *Mergenthaler* standard of conception. Moreover, with the Federal Circuit's recent decision in *Burroughs Wellcome Co. v. Barr Laboratories, Inc.*[272] not to extend the doctrine to the invention of a new use for a known pharmaceutical compound, it does not appear that the doctrine will soon experience a revitalization.

Thus, under current law, federal courts must generally apply the *Mergenthaler* standard to determine conception in pharmaceutical invention.[273] As a result, courts view conception of a therapeutic compound as definite and permanent at the time when the inventor possessed an idea of the potential effectiveness of the compound.[274] That is, if the inventor can show that reduction to practice resulted as expected and without undue experimentation of a complex nature, a court will fix the date of conception at the time at which the inventor formulated a belief that the compound would work as intended.[275] Under such circumstances, reduction to practice serves a corroborative function, confirming that the

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search agreements clearly state the rights of parties to patents emanating from joint research to avoid disputes over which party is entitled to inventions).

271. *See* Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir.), *cert. denied sub nom.* Genetics Inst., Inc. v. Amgen, Inc., 112 S. Ct. 169 (1991).

272. Burroughs Wellcome Co. v. Barr Labs., Inc., 40 F.3d 1223, 1232 (Fed. Cir. 1994). See *supra* notes 166-90 for a discussion of the *Burroughs* case.

273. *See Burroughs*, 40 F.3d at 1232.

274. *See id.* at 1230-31; *see also* Rey-Bellet v. Englehardt, 493 F.2d 1380, 1387 (C.C.P.A. 1974). See *supra* notes 139-46 for a discussion of *Rey-Bellet*.

275. *See Burroughs*, 40 F.3d at 1230-31.

idea did, in fact, exist in definite and permanent form.[276] Moreover, the Federal Circuit does not require that the belief be "reasonable"; on the contrary, an inventor is only required to show another person of skill in the art would understand the idea as represented.[277]

Fixing the date of conception as that time when the inventor believed the invention would work as intended can have a profound effect on the outcome of priority contests involving pharmaceutical invention.[278] Since the date of claimed conception will only be negated if subsequent reduction to practice required more than routine testing to show the feasibility of an idea, any invention of a new therapeutic compound will be fixed at the time when the inventor recognizes the potential effectiveness of the compound.[279] In determining whether testing is routine, courts generally examine whether the party reducing the idea to practice needed to solve problems specifically addressing the invention at issue.[280] If not, the courts find that the idea existed in definite and permanent form to the satisfaction of the *Mergenthaler* standard prior to reduction to practice.[281] Since researchers generally have standard screening methods in place to test biological activity of compounds, new methods are rarely developed to test a specific compound.[282] As a result, a court will rarely find that the work required to reduce an idea to practice negated a prior claim of possession of a definite and permanent idea.[283] Thus, in priority contests, a court will almost certainly award inventorship to the party who shows the earlier date of formulation of the idea.[284]

Moreover, application of *Mergenthaler* to the invention of a pharmaceutical compound can effect the outcome of originality contests. In cases where two parties claim an invention emerging from joint research, any work performed in the reduction to practice inures to the benefit of the conceiving party.[285] Any in-

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276. *Id.* at 1229-30.

277. *Id.* at 1228.

278. See *supra* note 125 for a definition of a priority case.

279. Rey-Bellet v. Englehardt, 493 F.2d 1380, 1387 (C.C.P.A. 1974). See *supra* notes 139-46 for a discussion of *Rey-Bellet*.

280. *See Rey-Bellet*, 493 F.2d at 1387. The *Rey-Bellet* court considered testing routine if utilized as a standard procedure in the discipline.

281. *See id.*; *see also* GAF v. Amchem, 514 F. Supp. 943, 968 (E.D. Pa. 1981); Applegate v. Scherer, 332 F.2d 571, 573 (C.C.P.A. 1964).

282. *See* PROFITS OF SCIENCE, *supra* note 196, at 165.

283. *See Rey-Bellet*, 493 F.2d at 1387; *see also GAF*, 514 F. Supp. at 968.

284. *See Rey-Bellet*, 493 F.2d at 1387; *see also GAF*, 514 F. Supp. at 968.

285. Rohm & Haas Co. v. Dawson Chem. Co., 557 F. Supp. 739, 803-04 (S.D. Tex.), *rev'd on other grounds sub nom.* Rohm & Haas Co. v. Crystal Chem. Co., 722 F.2d 1556 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); *Applegate*, 332 F.2d at 573.

ventive skill exercised by a second party during the reduction to practice is essentially negated by fixing the date of conception as equivalent to that of formulation of the idea.[286] Thus, courts will classify a party who participates only in the reduction to practice as a mere technician and not as a co-inventor.[287]

1. Failure of the Mergenthaler *Standard to Address Conception in Experimental-Science Based Invention*

Application of the *Mergenthaler* standard to pharmaceutical invention, as well as chemical invention, ignores the fact that ideas in these disciplines always contain an element of uncertainty.[288] In such cases, a researcher does not definitively know that an idea works as intended until the completion of successful reduction to practice.[289] Therefore, the type of testing performed is irrelevant; in experimental-based invention an idea cannot exist in definite and permanent form until the inventor reduces the invention to practice.[290]

An examination of cases applying the *Mergenthaler* standard to pharmaceutical and chemical inventions shows a common pattern. Courts applying the standard to these inventions consistently equate the existence of a definite and permanent *plan* for research with a definite and permanent *idea* required for conception under the *Mergenthaler* standard.[291] The distinction is subtle, but fundamental; the clear policy of patent law requires the disclosure of a complete and operative invention, not merely research

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286. *See* 35 U.S.C. § 116 (1988). Section 116 requires the naming as joint inventors of all parties participating in the conception of the invention. *Id.* This provision expressly states that a party need not participate in all aspects of the conception. *Id.*

287. Of course, not all reduction to practice involves inventive skill. Hobbs v. United States Atomic Energy Comm'n., 451 F.2d 849, 865 (5th Cir. 1971). An inventor is entitled to use the services of a second party in reducing an idea to practice. *Id.* However, a party who performs activities "embracing the substance of all that is embodied in the patent subsequently issued" contributes to the conception of the invention and is properly named as joint inventor. *Id.*

288. See *supra* notes 192-210 and accompanying text for a discussion of the inherent differences between experimental science-based and engineering-related research.

289. *See* Alpert v. Slatin, 305 F.2d 891, 894 (C.C.P.A. 1962); Smith v. Bousquet, 111 F.2d 157, 162-63 (C.C.P.A. 1940).

290. *See, e.g., Alpert*, 305 F.2d at 894 (holding that conception of a new chemical method not complete if six months of research required to reduce the idea to practice); *Smith*, 111 F.2d at 162-63 (ruling that conception of a pesticide not complete until successful reduction to practice).

291. *See* Rohm & Haas Co. v. Dawson Chem. Co., 557 F. Supp. 739, 803-04 (S.D. Tex.), *rev'd on other grounds sub nom.* Rohm & Haas Co. v. Crystal Chem. Co., 722 F.2d 1556 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984); GAF v. Amchem, 514 F. Supp. 943, 968 (E.D. Pa. 1981); Rey-Bellet v. Englehardt, 493 F.2d 1380, 1387 (C.C.P.A. 1974); Applegate v. Scherer, 332 F.2d 571, 573 (C.C.P.A. 1964).

plans.[292] Thus, application of the *Mergenthaler* standard to pharmaceutical invention not only fails to address the different nature of the inventive process, but also fails to effectuate the policy of patent law.

2. *The Doctrine of Simultaneous Conception and Reduction as a Better Standard of Conception in Experimental-Based Sciences*

The doctrine of simultaneous conception and reduction to practice is better suited to address the empirical nature of experimental-based invention. This doctrine views conception as complete only when the inventor shows that reduction to practice proved that the hoped-for result actually followed from the idea.[293] Moreover, the doctrine does not arbitrarily classify reduction to practice on the basis of complexity, but instead, considers it as an essential aspect of conception.[294] As such, application of the doctrine of simultaneous conception and reduction to practice assures that an inventor obtains patent protection only for those ideas that are certain to work as claimed.[295]

The Federal Circuit recently expressed the view that invention of a gene sequence with claimed biological activity requires application of the doctrine of simultaneous conception and reduction to practice.[296] Nonetheless, in the recent *Burroughs* decision, the Federal Circuit refused to extend the doctrine to the invention of a new use for a known compound.[297] Such a distinction makes little sense in light of the fact that in either case the idea remains speculative until reduction to practice shows that the invention works as intended. That is, whether or not the inventor knows the structure of a compound, the invention of a therapeutic use for which a party seeks patent protection does not definitively exist until the inventor knows with certainty that the invention will result from reduction to practice.[298]

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292. Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993).

293. *See Fiers*, 984 F.2d at 1169; *see also* Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1206 (Fed. Cir.), *cert. denied sub nom.* Genetics Inst., Inc. v. Amgen, Inc., 112 S. Ct. 169 (1991); *Alpert*, 305 F.2d at 894; *Smith*, 111 F.2d at 162-63.

294. *See Alpert*, 305 F.2d at 894; *Smith*, 111 F.2d at 162-63; *see also* 1 ROBINSON, *supra* note 100, at 381.

295. *See, e.g., Fiers*, 984 F.2d at 1169 (stating that an inventor may not claim conception of a gene sequence by describing its "hoped-for" activity).

296. *Id.*; *Amgen*, 927 F.2d at 1206.

297. Burroughs Wellcome Co. v. Barr Labs., Inc. 40 F.3d 1223, 1229 (Fed. Cir. 1994).

298. *See Fiers*, 984 F.2d at 1169 (expressing the view conception not complete when an inventor by defines an invention by its "hoped-for function"); *see also Amgen*, 927 F.2d at 1206 (stating that conception not complete when an inventor defines a compound by its principal biological property).

The need for application of the doctrine of simultaneous conception and reduction to practice becomes more urgent in light of increasing collaborations between university or government scientists with corporations.[299] Very frequently, these joint projects involve biomedical technology.[300] If the court incorrectly equates a research proposal with complete conception by applying the *Mergenthaler* standard, a corporation may acquire the sole rights to an invention that properly belongs to both research partners.[301] Since a patent gives the holder exclusive rights to the invention, the public may be denied ready access to the invention.[302] Moreover, if the United States government subsidizes the research by funding the academic or government laboratory aspect of the joint project, the public may end up paying for the invention twice: once for the research, and a second time by paying a higher price for a patented product.[303]

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299. See *supra* notes 239-70 for a discussion of the changing nature of American research.

300. *See generally* Bulliet, *supra* note 269, at 2 (stating that corporations are forming cooperative ventures with government laboratories to perform biomedical and biotechnology research); Korn, *supra* note 221, at 227-28 n.213 (describing several research agreements between universities and pharmaceutical companies).

301. *See* 35 U.S.C. § 116 (1988).

302. *See* William L. LaFuze & Peter Mims, *Ownership of Laboratory Discoveries and Work Product*, *in* UNDERSTANDING BIOTECHNOLOGY LAW: PROTECTION, LICENSING, AND INTELLECTUAL PROPERTY POLICIES, *supra* note 224, at 223. Joint inventors hold an undivided interest in a patent emanating from collaborative research. *Id.* As such, any owner may exercise the patent rights to the invention without consent or a requirement of accounting by the other owner(s). *Id.* The standard practice of university researchers is to provide free exchange of knowledge with colleagues and the public. *Id.* at 225. Thus, it follows that a university will be more inclined to provide the public with easy access to a beneficial new technology. Research flowing out of government laboratory collaborations are governed by a complex statutory scheme that is beyond the scope of this Note. For a detailed discussion of the property rights in these collaborations, see Lacy et al., *supra* note 241, *passim*. However, government laboratories have traditionally made patents available for use by the whole population. *Id.* at 4.

303. *See* PHARMACEUTICAL R & D, *supra* note 15 at 235. The patent protection afforded to AZT has been criticized in this manner. Jonathan L. Mezrich, *The Patentability and Patent Term Extension of Deadly Lifesaving Drugs: A Deadly Mistake*, 74 J. PAT. & TRADEMARK OFF. SOC'Y 77, 83-84 (1992). Government scientists originally developed AZT as a therapy for cancer in 1964 but it proved too toxic for that use. Ackiron, *supra* note 3, at 166. The United States government directly assisted BW in developing AZT as an effective therapy for HIV and AIDS. *Id.* at 83. BW was initially reticent to develop a large-scale project with the small number of AIDS sufferers that existed in 1985, the government afforded orphan drug status to AZT to spur BW's research. *Id.* at 167. This gave BW a seven-year exclusive license to sell the drug. *Id.* However, the patents granted in 1988 supplanted the importance of the exclusive license. *Id.* Today, the market for AZT has increased proportionate to the increase in the number of persons suffering from AIDS and HIV. *Id.* The United States government purchases a large amount of AZT from BW because many persons afflicted with HIV and AIDS are uninsured

CONCLUSION

Application of the *Mergenthaler* standard of conception to inventions based on experimental observation, such as chemical and pharmaceutical inventions, allows an inventor to obtain patent protection before fully possessing knowledge that the invention will work as intended. Such a view ignores the inherent differences between invention in the engineering-related sciences and that in the more empirically based disciplines.[304] While the fundamental differences between engineering and the experimental sciences are well-recognized outside of patent law, the courts continue to adhere to a standard of conception that has changed little for almost 100 years. Instead, the federal courts should acknowledge that invention in the pharmaceutical and chemical sciences requires application of the doctrine of simultaneous conception and reduction to practice to determine accurately the date and circumstances of conception in these disciplines. The need for courts to apply the doctrine to invention in the pharmaceutical and chemical sciences is all the more urgent because the current trend toward research collaborations between corporations and other organizations will likely increase the incidence of litigation involving empirically based inventions.[305]

It is important to keep in mind that the United States patent system exists to effectuate the public's access to beneficial technology.[306] The granting of patent rights to an inventor is but a means to this important end; it provides an inducement to motivate research that will lead to improvements useful to all of society.[307] Under the scheme of the patent system, the rewarding of inventors by granting them patent protection is subordinate to this primary goal.[308] However, application of the *Mergenthaler* standard of conception to cases of pharmaceutical and chemical invention can result in the inventor's reward of patent protection being elevated above the right of the public to obtain free and open access to ideas. Any aspect of the law that restricts the public's rightful access to beneficial technology violates the central purpose of the United States patent system and cannot be tolerated under any circumstances.[309] Therefore, courts should discard the narrow view that a "one size fits all"

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and thus covered under the Medicare program. *Id.* at 168-69.

304. See *supra* notes 192-210 and accompanying text for a discussion of the differences between engineering-related and empirically-based invention.

305. See *supra* note 239-70 for a discussion of the changing nature of American research.

306. *See* Graham v. John Deere Co., 383 U.S. 1, 9 (1966).

307. *See id.*

308. *Id.*

309. *Id.*

standard of conception satisfactorily addresses the inventive process in all the disciplines for which inventors seek patent protection. Courts should therefore begin to apply the doctrine of simultaneous conception and reduction to practice as a general rule to invention in the pharmaceutical and chemical sciences.

Jackie Hutter, M.S.