# Maintaining the Constitutionality of the Patent System

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## I. Introduction

The Constitution authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries[.]"[1] This provision (hereinafter "the Clause") enables Congress to create patent protection[2] for inventors provided that such protection promotes the progress of "useful arts."[3] The scope and implementation of patent protection has changed significantly since the adoption of the Constitution: patentability requirements have changed,[4] patentable subject matter has expanded,[5] the Federal Circuit has been

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1. U.S. CONST. art. I, § 8, cl. 8.

2. This grant also permits Congress to create copyright protection, *see* U.S. CONST. art. I, § 8, cl. 8, but this paper only focuses on patent protection.

3. Note that "[i]n 1787 'science' meant knowledge or learning, and did not have the significance of technology it does today. Thomas Jefferson, who administered the first patent act, used science consistent with this meaning of knowledge and learning." Arthur H. Seidel, *The Constitution and a Standard of Patentability*, 48 J. PAT. & TRADEMARK OFF. SOC'Y., 5, 11-12 (1966) (internal citations omitted). "'[S]cience' . . . meant knowledge in any field and it included all fields. Dr. Samuel Johnson's Dictionary, contemporaneous with the Constitution, defines 'science' as: 1. Knowledge[,] 2. Certainty grounded on demonstration[,] 3. Art attained by precepts, or built on principles[,] 4. Any art or species of knowledge[.]" Giles S. Rich, *Principles of Patentability*, 42 J. PAT. & TRADEMARK OFF. SOC'Y., 75, 78 (1960).

4. For example, the non-obviousness requirement, not originally present in the Patent Act of 1793, was later introduced by the Court in *Hotchkiss. v. Greenwood*, 52 U.S. 248, 264-65, 268 (1850) (substituting clay for metal or wood in doorknobs did not create a patentable invention).

5. *See* Diamond v. Chakrabarty, 447 U.S. 303, 316-17 (1980) (holding that the language of

designated to handle all appeals of patent cases,[6] the number of patent filings with the Patent and Trademark Office ("PTO") has grown markedly,[7] antitrust law has created special exceptions for patent-derived monopolies,[8] and technologies have rapidly changed and developed. Although Congress continues to monitor it,[9] the patenting process has not adequately adapted to accommodate these changes, which have had the effect of expanding and strengthening patent rights. The result is a patent system that is slowly departing from its constitutional aim of "promot[ing] the progress of . . . useful arts."

This note will explore the constitutional dimensions of the current patent system. The Constitution requires any legislation for patent protection to promote the progress of useful arts. Patent legislation abides by this constitutional dictate by establishing a *quid pro quo* between patentee and the public. The PTO and the courts evaluate patents for compliance with this *quid pro quo* before the property right is either issued or upheld.

Several requirements enforce this *quid pro quo* relationship between patentee and society. These requirements, however, are not being enforced strictly enough to ensure that the *quid pro quo*, and therefore the constitutional aim of patenting, is satisfied. Rather, patentees are receiving strong and remunerative patent rights without sufficiently benefiting the public, and Congress, the courts, and the PTO are focused on promoting economic success—"patent commerce"—instead of "useful arts." Therefore, in order to preserve the *quid pro quo* of patenting, stricter patenting standards for patentable subject matter, disclosure, non-obviousness, utility, and filing are necessary. Patents should be less presumptively valid during litigation, and the PTO should spend more time evaluating patent applications. Congress, the courts, and the PTO each must be vigilant in enforcing heightened patentability standards to prevent the patent system from impeding scientific research and the quest for knowledge. Therefore, in the interests of preventing patent law from

35 U.S.C. § 101 encompasses as patentable subject matter "man-made" living organisms).

6. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 37, 37 (1982).

7. Tressa Jennifer James, *Implications of the Best Mode Requirement on Patents Involving Biotechnology*, 2 HOUS. BUS. & TAX L.J. 96, 97 (2001).

8. *See* PHILLIP AREEDA, LOUIS KAPLOW & AARON EDLIN, ANTITRUST ANALYSIS 104-05, 110-11 (Aspen Publishers, 6th ed. 2004).

9. Current legislation exists in Congress which proposes dramatic changes to the current patent system. *See* Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005). This Act proposes to change our first-to-invent system to a first-to-file system as well as eliminate the best mode disclosure requirement (thereby bringing it into harmony with the European Patent Organization and the Japanese Patent Organization). *Id.*

transgressing its constitutional remit, our courts and legislatures must enact policies to ensure that patents issued are not merely economically exploitative properties, but rather are proper, deserved, and effectively promote the progress of science.

## II. The Constitutional Language

The Clause in the Constitution that grants Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries [,]"[10] was one of the few provisions unanimously accepted without debate during the Convention.[11] Even during the process of state ratification, the Clause was never opposed, and only briefly mentioned.[12] As historian Sidney Diamond comments, "[t]he delegates clearly believed firmly that it was in the public interest to establish a patent and copyright system."[13] However, because of the limited objections, nearly nothing is known of the Framer's intent behind the Clause other than its evident facial meaning,[14] but the meaning of the Clause, even on its face, is ambiguous.[15] There is consensus, however, on the point that the

10. U.S. CONST. art. I, § 8, cl. 8.

11. James Madison noted that the proposition was adopted nem:con (*nemine contradicente*, or without dissent). 2 THE RECORDS OF THE FEDERAL CONSTITUTION OF 1787, 508-10 (Max Farrand ed., Yale Univ. Press. 1937).

12. For comments made during several state ratifying conventions, *see* 6 MATHEW CAREY, THE AMERICAN MUSEUM 303 (Philadelphia, Pa. 1789).

13. Sidney A. Diamond, *Our Patent System . . . The Past is Prologue*, 62 J. PAT. OFF. SOC'Y. 437, 440 (1980).

14. Howard B. Abrams, *The Historic Foundation of American Copyright Law: Exploding the Myth of Common Law Copyright*, 29 WAYNE L. REV. 1119, 1174-75 (1983) (stating "very little is known of the drafters' intentions regarding the Copyright-Patent Clause beyond what is apparent on its face").

15. Admittedly, many critics argue that much is lost by taking a "clausebound approach" to the Constitution. AKHIL REED AMAR, THE BILL OF RIGHTS: CREATION AND RECONSTRUCTION 124-25 (Yale Univ. Press 1998). However, commentators considering the Clause under both "clausebound" and "full constitutional" approaches do not deny the existence of ambiguity. *See* Edward C. Walterscheid, *To Promote the Progress of Science and Useful Arts: The Anatomy of a Congressional Power*, 43 IDEA 1, 18-21 (2003). Analysis under the two approaches tends to result in a different understanding of the constitutional limitations of the clause. *Id.* at 20. Most of this debate centers on whether Congress' power extends beyond the power to fulfill the generalized grants of power ("to promote science" and "to promote . . . useful arts") through patents and copyrights, or whether it is limited to such mechanisms. *Id.* at 18, 20. However, under the "full constitutional" approach, the language is obviously restrictive seeing as the Clause is the only grant of power in the Constitution that prescribes appropriate legislative actions to achieve a directed purpose. *See* Paul J. Heald & Suzanna Sherry, *Implied Limits on the Legislative Power: The Intellectual Property Clause as an Absolute Constraint on Congress*, 2000 U. ILL. L. REV. 1119, 1153-54 (2000).

Clause expressly enables Congress to create patent and copyright protection.[16] However, whether Congress is limited to creating only patent and copyright protection in order "to promote the progress of science and useful arts" is the subject of debate.[17]

For example, the judiciary has assumed many times that it is only through the creation of patent and copyright protection that Congress may legislate to promote science and the useful arts.[18] For example, in *In re Bergy*, Judge Rich advanced that "the only restraints placed on Congress [by the Clause] pertained to the means by which it could promote useful arts, namely, through the device of securing 'exclusive rights' which were required to be limited in time . . ."[19] Commentators and scholars, however, posit that the language in the Constitution and the Framers' intent does not limit Congress to acting only through the creation of these protections: "[t]he grant of power in the Clause is much broader than is generally supposed and is not limited to merely authority regarding patents and copyrights."[20] This means that the language "by" in the Clause should rather be read as "including," and that the entire generic grant of power remains in the "to" language, which keeps the Clause consistent with the other enumerated powers of Congress in the Constitution.[21] Although not all concur in this construction, the alternative construction that Congress can only act to promote the progress of the useful arts by creating patent protection is exceedingly and unnecessarily limited.

The aforementioned debate is not the focus of this paper, but it is important to note because it determines whether Congress can provide incentives other than patent protection under the Clause. However, given the Supreme Court's decision in *Eldred v. Ashcroft*,[22] it is unlikely that the

16. Many allocate the language of the Clause creating these abilities in Congress as follows: (1) "to promote the progress of science . . . by securing for limited times to authors . . . the exclusive right to their writings" (the creation of copyright protection); and (2) "to promote the progress of . . . useful arts by securing for limit times to . . . inventors the exclusive right to their . . . discoveries" (creation of patent protection). *See In re* Bergy, 596 F.2d 952, 958 (C.C.P.A. 1979) ("Scholars who have studied this provision, its origins, and its subsequent history, have, from time to time, pointed out that it is really two grants of power rolled into one; first, to establish a copyright system and , second, to establish a patent system.").

17. *See generally* Walterscheid, *supra* note 15, at 18, 80-81.

18. *See In re* Bergy, 596 F.2d 952, 958 (C.C.P.A. 1979).

19. *Id.* at 958 n. 2.

20. Walterscheid, *supra* note 15, at 80.

21. *See id.* at 18; *see also* U.S. CONST. art. 1, § 8, cl. 1-18.

22. Eldred v. Ashcroft, 537 U.S. 186, 204 (2003) (reiterating that Congress' legislation under the Clause is subject to rational basis review). The Court subjects Congressional legislation under the Clause to rational basis rather than heightened judicial review because legislating to create copyright and patent protection requires the balancing of myriad factors and

Court[23] would find Congressional legislation under the Clause in a form other than patent protection unconstitutional.

Most do agree, however, that the Clause is composed of two grants of power: (1) a generalized authorization of power contained within "to promote the progress of science and useful arts"; and (2) a method of effectuating this generalized power by "securing for limited times to authors and inventors the exclusive right to their writings and discoveries."[24] The generalized power granted to Congress "to promote the progress of science and useful arts"[25] is explicit in the Constitution.[26] In *Goldstein v. California*, Chief Justice Burger emphasized that the Clause "describes both the objective which Congress may seek and the means to achieve it. . . . The objective is to promote the progress of science and the [useful] arts."[27] Similarly Justice Douglas stated:

> [E]very patent case involving validity presents a question which requires reference to a standard written into the Constitution. Article I, § 8, contains a grant to the Congress of the power to permit patents to be issued. But, unlike most of the specific powers which Congress is given, that grant is qualified. The Congress does not have free rein, for example, to decide that patents should be easily or freely given. The Congress acts under the restraint imposed by the statement of purpose in Art. I, § 8. The purpose is "To promote the

for the Court to insert itself into this delicate process would be to run roughshod over years of careful drafting and fine tuning. *Id.* at 204 & n.10. Therefore, any legislation enacted by Congress under the Clause is evaluated by the Court for whether it is rationally related to a legitimate government interest which presents a high bar for the courts to hold any congressional legislation enacted under the Clause unconstitutional. *Id.* at 204.

23. The Supreme Court would be acting under its authority as the interpreter and protectorate of the Constitution. Marbury v. Madison, 5 U.S. 137, 177 (1803) (holding that once Congress has spoken it is "the province and duty of the judicial department to say what the law is" and determine its constitutionality).

24. U.S. CONST. art. I, § 8, cl. 8; Walterscheid, *supra* note 15, at 13 ("[The Clause] was intended not only as an express authority to promote the progress of science and useful arts generally, but also as a means of ensuring authority to do so in a particular way, namely, by securing exclusive rights for limited times to authors and inventors in their respective writings and discoveries.").

25. U.S. CONST. art. I, § 8, cl. 8.

26. This is clear through common cannons of interpretation. President James Monroe observed: "the order generally observed in grants [of power], an order founded on common sense, since it promotes a clear understanding of their import, is to grant the power intended to be conveyed in the most full and explicit manner, and then to explain or qualify it, if explanation or qualification should be necessary. This order has, it is believed, been invariably observed in all the grants contained in the Constitution." JAMES MONROE, VIEWS OF THE PRESIDENT OF THE UNITED STATES ON THE SUBJECT OF INTERNAL IMPROVEMENTS (1822), *reprinted in* 2 MESSAGES AND PAPERS OF THE PRESIDENTS, 1789-1897, 144, 163 (James D. Richardson ed., 1897).

27. Goldstein v. California, 412 U.S. 546, 555 (1973).

> Progress of Science and useful Arts . . . ." The means for achievement of that end is the grant for a limited time to inventors of the exclusive right to their inventions.[28]

As Edward Walterscheid explains:

> [In the Clause,] a grant of power is first set forth in a full and explicit manner, and then followed by an explanation or qualification. The phrase "to promote the progress of science and the useful arts" is an infinitive verb form that constitutes the grant of power to Congress, and the issue then becomes one of whether the phrase "by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries" constitutes an explanation or a qualification of this grant power.[29]

According to the language of the Constitution, patents are clearly a means to an end. Thus, under the Clause, Congress is only authorized to pass legislation if it promotes the progress of science; legislation must comply with this generalized aim for it to be constitutional.

## III. Permissible Grants of Monopoly Power

Although the Clause itself was barely mentioned during ratification, the Framers recognized that granting a patent right potentially conferred monopoly power[30] to the patentee. Before the Constitution was ratified, many voiced serious objections[31] about the creation of monopolies and grants of monopoly power,[32] although these complaints were not made in

28. Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 154 (1950) (Douglas, J., concurring).

29. Walterscheid, *supra* note 15, at 80-81.

30. It is important to note that although a patent right is often indiscernible from a monopolistic position in a market, it is the patentee's exploitation of the right rather than the PTO's conferral of the patent that creates a monopoly. A patent confers to a patentee only the negative right to exclude others from practicing his invention. 35 U.S.C. § 154(a)(1) (2007); 35 U.S.C. § 271(a) (2007). The patentee may elect to develop his invention commercially and then enforce his negative patent right so as to eliminate all competition and obtain a monopoly. *See* Crown Die & Tool Co. v. Nye Tool & Mach. Works, 261 U.S. 24, 36 (1923) (commenting that "it is the fact that the patentee has invented or discovered something useful, and thus has the common-law right to make, use, and vend it himself, which induces the Government to clothe him with power to exclude everyone else from making, using, or vending it"). Therefore, a patent enables a monopoly, but a patent in itself is not a monopoly.

31. Referring to the Necessary and Proper Clause, George Mason refused to sign the Constitution because "[u]nder their own construction of the general clause at the end of the enumerated powers, the congress may grant monopolies in trade and commerce." 2 MATHEW CAREY, THE AMERICAN MUSEUM 534-36 (Philadelphia, Pa. 1787).

32. Several state ratifying conventions recommended adding a limiting clause expressly preventing Congress from forming monopolies. New York suggested: "that congress do not grant

reference to the Clause.

After ratification, however, Thomas Jefferson expressed to James Madison concerns about the possibility of monopoly power enabled under the Clause.[33] Letters exchanged between Jefferson and Madison demonstrate their differing views about the Clause.[34] Jefferson argued that monopolies were inherently dangerous and therefore must be absolutely avoided regardless of the circumstances under which they developed.[35] He referred to the Clause specifically in one letter, writing, "[I]t is better . . . to abolish monopolies, in all cases, than not to do it in any."[36] Acknowledging that preventing monopolies by limiting patent and copyright protection "lessens the incitements to ingenuity, which is spurred by the hope of a monopoly for a limited time[,]" he added that even "the benefit even of limited monopolies is too doubtful to be opposed to that of their general suppression."[37]

Madison's opinions were the opposite: he firmly believed that the monopolies enabled by patent and copyright protection should be permitted because of the good they were poised to confer upon society.[38] Somewhat resigned to the presence of monopolies arising from patents and copyrights, Jefferson responded by advocating an explicit limitation on the grant of the Clause in the Bill of Rights that would prevent Congress from expanding an individual's ability to obtain a monopoly.[39] At least this way, Jefferson reasoned, monopolies created by patent or copyright protection would not exceed a certain scope.[40] This limitation was never adopted.

Jefferson was not alone in fearing monopolies. Many others involved

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monopolies, or erect any company with exclusive advantages of commerce"). 4 MATHEW CAREY, THE AMERICAN MUSEUM 156 (Philadelphia, Pa. 1788). Massachusetts, New Hampshire, and North Carolina recommended "that Congress erect no company of merchants, with exclusive advantages of commerce." 6 MATHEW CAREY, THE AMERICAN MUSEUM 303 (Philadelphia, Pa. 1789) (containing the remarks of Rev. Nicholas Cottin, D.D. on the amendments to the federal constitution proposed by states).

33. *See* Walterscheid, *supra* note 15, at 5-7; *see also* Letters between Jefferson and Madison *in* 1 THE REPUBLIC OF LETTERS 512 (James Morton Smith ed., Norton 1995) [hereinafter LETTERS].

34. *See* LETTERS, *supra* note 33, at 512.

35. Letter from Jefferson to Madison (July 31, 1788) *in* LETTERS, *supra* note 33, at 545.

36. *Id.*

37. *Id.*

38. Letter from Madison to Jefferson (October 17, 1788) *in* LETTERS, *supra* note 33, at 566.

39. Jefferson specifically advocated that the Bill of Rights include the following limitation: "Monopolies may be allowed to persons for their own productions in literature, and their own inventions in the arts for a term not exceeding ___ years, but for no longer term, and for no other purpose." Letter from Jefferson to Madison (August 28, 1789) *in* LETTERS, *supra* note 33, at 630. This limitation was not adopted. *See* U.S. CONST. amend. I-X.

40. Letter from Jefferson to Madison (August 28, 1789) *in* LETTERS, *supra* note 33, at 630.

in drafting and ratifying the Constitution were similarly concerned. One delegate even abandoned the drafting process because the document contained no express limiting section.[41] Nevertheless these concerns were never represented in any section of the resulting document.

Despite these objections, the majority of the Framers believed that enabling the limited monopolies that patents facilitate would effectively promote the useful arts.[42] Madison in particular believed that types of monopolies could be distinguished and sincerely thought that only good would come to society through this grant: innovation would be incentivized, and therefore more innovation would occur.[43] This would result in a net positive effect for society.[44]

However, "[t]he Framers plainly did not want those monopolies freely granted" because, although monopolies could benefit society, monopolies too easily obtained would do a disservice by permitting monopoly control over otherwise freely available goods and services.[45] Therefore the patent system must enforce a true exchange, or *quid pro quo*, between the inventor and society: the inventor must fully disclose to society his novel and useful invention, and, in exchange, society will undergo a short-term unilateral and possibly monopolistic control over the invention. In the words of the Supreme Court, there is a "basic *quid pro quo* contemplated by the Constitution and the Congress for granting a patent monopoly" and it "is the benefit derived by the public from an invention with substantial utility."[46]

Practically, this means that an invention must be truly worthy of a patent in order to receive one: monopolies formed from a patent must not be more injurious than the invention is beneficial to society; patents must not cover information that, if covered, would stagnate research and progress; society must benefit from the inventor's full knowledge regarding the invention; and, most importantly, the ultimate effect of the patent

41. Among others, George Mason, a delegate from Virginia who ultimately refused to sign the Constitution largely because it lacked a Bill of Rights, was opposed to the Constitution because "the congress may grant monopolies in trade and commerce." *See supra* note 31.

42. *See* U.S. CONST. art. I, § 8, cl. 8. This provision was adopted without debate. *See* THE RECORDS OF THE FEDERAL CONSTITUTION OF 1787 at 508-10, *supra* note 11.

43. *See* Walterscheid, *supra* note 15, at 6.

44. *Id.*

45. *Great Atl. & Pac. Tea Co.*, 340 U.S. at 154 (Douglas, J., concurring).

46. Brenner v. Manson, 383 U.S. 519, 534 (1966) (emphasis added). "The consideration an inventor gives in return for a patent is the benefit which he confers upon the public by placing in their hands a means through the use of their wants may be supplied." FEDERAL TRADE COMMISSION, TO PROMOTE INNOVATION: THE PROPER BALANCE OF COMPETITION AND PATENT LAW AND POLICY 2 n. 5 (2003), *available at* http://www.ftc.gov/ os/2003/10/innovationrpt.pdf [hereinafter FTC Report].

system must confer net benefits to society.

Since the adoption of the Constitution, scholars of intellectual property rights have developed more sophisticated rationales for justifying the patent system[47], including: (1) natural property rights;[48] (2) rewarding services rendered;[49] (3) monopoly profits incentives;[50] and, (4) encouraging information sharing through the publication of both patent applications and issued patents.[51] Inherent in each of these rationales is the basic exchange of patenting, the *quid pro quo*.[52]

The statutory patentability requirements maintain this *quid pro quo*. Novelty[53] ensures that nothing is removed from the public domain that was previously accessible and that the patentee does not benefit frivolously.[54] Obviousness[55] guarantees that there is at most a "flash of creative genius,"[56] and at least that the invention is not obvious to a person of

47. *See* Edwin C. Hettinger, *Justifying Intellectual Property*, 18 PHIL. & PUB. AFF. 31 (1989); Justin Hughes, *The Philosophy of Intellectual Property*, 77 GEO. L.J. 287 (1988).

48. This theory derives from the teachings of John Locke on natural labor theory. *See* JOHN LOCKE, THE SECOND TREATISE ON GOVERNMENT, ch. 5, para. 26 (1690), *available at* http://libertyonline.hypermall.com/Locke/second/second-frame.html. When a person puts work into a commonly held object, he may appropriate it; the appropriation is justified by his property right in his labor which was introduced into the object. *Id.*

49. The inventor has given a valuable service to society, so in return society rewards him with a patent.

50. The promise of profits that could be derived from successful exploitation of the negative property right provides necessary incentives to encourage people to invent and contribute to the pool of knowledge. Therefore patent monopolies encourage new discoveries.

51. People will be more willing to disclose information about their discoveries to the public if they can trade those disclosures for governmental protection of their ideas. Without this protection, people might invent, but would not disclose what they have discovered.

52. The *quid pro quo* that will ultimately promote the progress of the useful arts is satisfied when the patentee benefits from the deserved patent, and the public benefits both from disclosure of information about the invention, and from the utility it provides; however, the benefit to the patentee must not exceed the benefit to the public. *See Manson*, 383 U.S. at 534-35.

53. 35 U.S.C. § 102 (2000 & Supp. V.2005).

54. *See* Titanium Metals Corp. of Am. v. Banner, 778 F.2d 775, 780 (Fed. Cir. 1985); Cont'l Can Co. v. Monsanto Co., 948 F.2d 1264, 1267 (Fed. Cir. 1991) (discussing anticipation); Schering Corp. v. Geneva Pharms., Inc., 339 F.3d 1373, 1379-80 (Fed. Cir. 2003) (discussing inherency).

55. 35 U.S.C. § 103 (2000 & Supp. V. 2005).

56. Cuno Eng'g Corp. v. Automatic Devices Corp., 314 U.S. 84, 90-91 (1941) (referring to *Hotchkiss*, 52 U.S. at 270). The Patent Act of 1952 subsequently codified an obviousness standard. *See* 35 U.S.C. § 103. The Supreme Court's interpretation of the codification overruled the *Hotchkiss* standard. *See* Graham v. John Deere Co., 383 U.S. 1, 15 (1966) (interpreting section 103 "to abolish the test [Congress] believed [the Supreme Court] announced in the controversial phrase 'flash of creative genius,' used in *Cuno Corp.* . . ."). Currently, the inquiry for nonobviousness is a question of law that is based on an underlying multi-step factual inquiry into various factors. *Id.* 17-18. These factors that a court will consider are commonly referred to as the "Graham factors" and include: (1) the level of ordinary skill in the art; (2) scope and

ordinary skill in the pertinent art at the time the invention is made.[57] Utility[58] measures whether the invention provides use or benefit sufficient to warrant a patent.[59] The disclosure requirements[60] force the patentee to publish information about his invention sufficient to describe[61] and enable[62] it so that the invention is fully revealed to the public. Finally, our "first to invent"[63] system ensures that the patent rewards the one who demonstrated the desired inventive and inquisitive activity.

Each of these elements fortifies a balanced *quid pro quo* exchange, which is why each must be vigilantly enforced by the PTO and the courts. In the absence of aggressive application of these statutory requirements, patents will issue that fail the constitutional standard. Yet recent patent law alterations, actions by the Federal Circuit, and looming changes by Congress indicate a trend toward undermining or eliminating some of these requirements, which may affect continued satisfaction of the *quid pro quo*. This ultimately frustrates the constitutional aims of patenting.

## IV. Evidence of *Quid Pro Quo* Erosion

### A. Disclosure

The disclosure requirements contained within 35 U.S.C. § 112 are written description, enablement, and "best mode."[64] Because part of the

content of the prior art; (3) differences between the claimed invention and prior art; and (4) objective indicia of nonobviousness, including, but not limited to, commercial success of the invention, "long felt need" for the invention, and success where others have failed. *Id.*

57. *Graham*, 383 U.S. at 15.

58. 35 U.S.C. § 101 (2000).

59. *See Manson*, 383 U.S. at 532-33.

60. 35 U.S.C. § 112 (2000).

61. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1562-64 (Fed. Cir. 1991) (holding that drawings can be sufficient to provide the "written description" of invention).

62. *See* Atlas Powder Co. v. E. I. Du Pont de Nemours & Co., 750 F.2d 1569, 1576-77 (Fed. Cir. 1984) (holding that an enabling application must contain a general description that enables one skilled in the art to make and use the claimed invention without undue experimentation).

63. *See* 35 U.S.C. §§ 102(a), (e), and (g) (2000) (stating that the "inventor" can file for a patent). Only the first inventor of a technology can obtain a patent, regardless of whether a later person filed an earlier application on the same technology, because "inventor" under the Clause means precisely that (i.e. no such thing as a "second inventor" exists because inventor means the *first* person to invent something). *See* Seidel, *supra* note 3, at 11; *see also* BLACK'S LAW DICTIONARY 824 (6th Ed. 1990) (giving the definition of "invent," the verb from which the noun "inventor" derives, as "To find out something new. To devise, contrive, and produce something not previously known or existing, by the exercise of independent investigation and experiement[.]").

64. "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any

exchange for society is the receipt of information about how the invention or discovery works and why, lack of meaningful disclosure can have profound effects on the satisfaction of *quid pro quo*.[65]

The "best mode" requirement necessitates that the patentee not only provide a description of the invention and how to use it, but that he also disclose the best mode of practicing or carrying out the invention. Therefore, of the disclosure requirements, compliance with best mode extracts the most information from the patentee because, beyond sharing a description of the invention and explicating it's use, he must disclose his preferred embodiment of or best way of practicing his invention. Therefore the best mode disclosure requirement provides an interesting inquiry into whether the patentee is fulfilling his bargain with the public.

Best mode requires an inventor to disclose his best way of making and using the claimed[66] invention.[67] Determining compliance with best mode

person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C. § 112.

65. Interestingly, the disclosure requirements present more issues for the unpredictable arts, such as biotechnology, than the predictable arts. In the predictable arts, disclosure of a species is predictive of and enables a genus. In the unpredictable arts, however, a species does not necessarily enable the genus. Therefore, disclosure in biotechnology cases is more manipulable, whereas for software patents satisfaction of disclosure is more certain. *See, e.g.*, Regents of Univ. of Cal. v. Eli Lilly & Co., 119 F.3d 1559, 1568-69 (Fed. Cir. 1997) (holding that patent's specification did not adequately describe the claimed subject matter because it claimed an entire genus, but only described one species within the genus, and that species was not necessarily representative of all species within the genus).

66. Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 963 (Fed. Cir. 2001) ("[A]n inventor need not disclose a mode for obtaining unclaimed subject matter unless the subject matter is novel and essential for carrying out the best mode of the invention"); Bayer AG v. Schein Pharms., Inc., 301 F.3d 1306, 1314-16 (Fed. Cir. 2002) (holding that it is unnecessary to disclose the best mode of producing elements of an invention which the claims do not cover because "invention" under section 112 means the invention as defined by the claims). However, there is contradictory Federal Circuit law on this point and the court's inconsistent stance will be discussed in more detail *infra*. *See also* DeGeorge v. Bernier, 768 F.2d 1318, 1324-25 (Fed. Cir. 1985) (failure to disclose information about unclaimed subject matter—word processor preference—satisfied the best mode requirement); Randomex Inc. v. Scopus Corp., 849 F.2d 585, 589-90 (Fed. Cir. 1988) (disclosure of trade name and not chemical composition of claimed preferred solution complied with the best mode requirement); Dana Corp. v. IPC Ltd. P'ship, 860 F.2d 415, 418-20 (Fed. Cir. 1988) (failure to disclose an unclaimed surface treatment necessary to the practice of the invention did not meet the best mode requirement); Spectra Physics, Inc. v. Coherent, Inc., 827 F.2d 1524, 1527 n.2, 1536 (Fed. Cir. 1987) (failure to disclose preferred method relating to unclaimed elements of an invention did not comply with the best mode requirement); Engel Indus., Inc. v. Lockformer Co., 946 F.2d 1528, 1533 (Fed. Cir. 1991) (step of invention was not claimed and therefore no disclosure was necessary for best mode compliance: inventors need not disclose best mode for unclaimed subject matter); Wahl Instruments, Inc v. Acvious, Inc., 950 F.2d 1575, 1580 (Fed. Cir. 1991) (under a fact specific balancing test analysis, routine method of manufacturing a commercial embodiment of invention is not a mode of carrying out the invention and therefore best mode disclosure is unnecessary).

disclosure requires both a subjective and an objective inquiry; a patent application must disclose the subjective best mode in an objectively enabling way.[68]

Compliance with best mode is a question of fact composed of two subsidiary factual inquiries. "First, the factfinder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention."[69]

> The first prong . . . is highly subjective and focuses on the inventor's state of mind as of the date of filing the application. . . . Second, if the inventor subjectively considered one mode to be preferred over all others, then '[t]he second inquiry is whether the inventor's disclosure is adequate to enable one of ordinary skill in the art to practice the best mode of the invention. This inquiry is objective and depends upon the scope of the claimed invention and the level of skill in the relevant art.'[70]

Best mode disclosure has been a component of our patent system since Patent Act of 1793[71] although it was not codified until the Patent Act of 1952,[72] or extended to all inventions until 1982.[73] Congress did not delineate a policy behind best mode disclosure so courts have offered the explanation that best mode exists to prevent inventors' unjust enrichment without sharing their special knowledge,[74] reasoning that the public

67. Note also that to satisfy best mode, the inventor's preference need not necessarily be labeled as his "best mode," but it must not be buried amid numerous other modes for practicing the invention either. *Randomex*, 849 F.2d at 589-90 (failure to distinguish between preferred embodiment and other claimed embodiments is not a violation of the best mode requirement when inventor disclosed one other mode).

68. N. Telecom Ltd. v. Samsung Elecs. Co., 215 F.3d 1281, 1286 (Fed. Cir. 2000).

69. Bayer AG & Bayer Corp. v. Schein Pharm., Inc., 301 F.3d 1306, 1320 (Fed. Cir. 2002) (quoting Eli Lilly, 251 F.3d at 963).

70. *Id.* (quoting N. Telecom Ltd., 215 F.3d at 1286).

71. Patent Act of 1793, ch. 11, § 1, 1 Stat. 318, 318-323 (repealed 1836). The Patent Act of 1793 contained a provision substantially similar to our modern best mode requirement. *See* J. Phillip Anderegg, *The Best Mode Requirement of 35 U.S.C. Section 112*, 6 AM. PAT. L. ASS'N Q. J. 219, 220-21 (1978) (noting that the best mode requirement is traceable to the Patent Act of 1793).

72. *See* 35 U.S.C. § 112 (2000) (and "shall set forth the best mode. . .").

73. *See* 35 U.S.C. § 112 (1982) (Reviser's Note) (omitting previous clause limiting best mode coverage to machines and extending applicability to all inventions). *See also* P. J. Federico, Commentary, *Commentary of the New Patent Act,*, 35 U.S.C.A. § 1, 25 (West 1954) ("The clause in the old statute relating to machine patents and requiring the best mode in such cases has been omitted as unnecessary and [the current best mode] clause has been added . . ."); *In re* Honn, 364 F. 2d 454, 461-62 n.7 (C.C.P.A. 1996) (explaining best mode requirement history).

74. Wahl Instruments, Inc v. Acvious, Inc., 950 F.2d 1575, 1579 (Fed. Cir. 1991). In *In re Gay*, the Court of Customs and Patent Appeals asserted that there is only one best mode policy

benefits from the additional disclosure, and in order to satisfy the basic *quid pro quo* of patenting, the public is entitled to access the information.[75] In other words, the best mode requirement serves two purposes: "(1) to ensure the public receives not merely a disclosure of the invention, but the best way contemplated by the inventor of carrying out the invention; and (2) to allow the public to compete fairly with the patentee after the patent expires."[76] These justifications comport with the constitutional aims of patent protection; according to them, best mode compliance "promote[s] the progress of . . . useful arts"[77] by ensuring that both the patentee and society benefit sufficiently, but that net benefits accrue for society.

Unfortunately, Federal Circuit[78] case law on best mode is less than straight-forward. In the opinion of the author, the court fails to evaluate best mode compliance in a manner consistent with the policy considerations. To date, there have been only seven patent cases in which a patent was or patent claims were held *invalid* for failure to satisfy the best mode requirement,[79] even though best mode is the fourth most frequently

justification: "the sole purpose of this . . . requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived." 309 F.2d 769, 772 (C.C.P.A. 1962). But in *Christianson v. Colt Industries. Operating Corp.*, the Seventh Circuit advanced a different best mode justification: "the best mode requirement is intended to allow the public to compete fairly with the patentee following the expiration of the patents." 870 F.2d 1292, 1302 n.8 (7th Cir. 1989). And in *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, the Federal Circuit advanced yet another justification for best mode: it exists "to ensure that a patent applicant plays 'fair and square' with the patent system." 927 F.2d 1200, 1209-10 (Fed. Cir. 1991).

75. JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 84-85 (Aspen Publishers 2d ed. 2006).

76. Jerry R. Selinger, *In Defense of "Best Mode": Preserving the Benefit of the Bargain for the Public*, 43 CATH. U. L. REV. 1071, 1097 (1994).

77. U.S. CONST. art. I, § 8, cl. 8.

78. This court has been designated to handle all patent-related cases, which has had the effect of streamlining patent appellate litigation and strengthening the patent right. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 37, 37 (1982).

79. *See Spectra Physics*, 827 F.2d at 1537 (holding a patent covering a gas laser and a patent covering a method of constructing a gaseous laser invalid for "failure to disclose the best mode contemplated by the inventors for practicing their . . . inventions"); Dana Corp. v. IPC Ltd. P'ship, 860 F.2d 415, 420 (Fed. Cir. 1988) (patent covering a valve stem seal used in internal combustion engines invalid for failure to disclose the best mode of carrying out the invention); N. Telecom, Inc. v. Datapoint Corp., 908 F.2d 931, 940 (Fed. Cir. 1990) (patent for "programmable processor-based batch data entry terminal" invalid for failure to disclose preferred embodiment); Chemcast Corp. v. Arco Indus. Corp., 913 F.2d 923, 930 (Fed. Cir. 1990) (patent for a dual durometer grommet invalid for failure to disclose best mode for a claim); U.S. Gypsum Co. v. Nat'l Gypsum Co., 74 F.3d 1209, 1213-14 (Fed. Cir. 1996) (patent for lightweight joint compound used to fill joints during construction invalid for failure to disclose best mode for a claim); Great N. Corp. v. Henry Molded Prods., Inc., 94 F.3d 1569, 1572-73 (Fed. Cir. 1996) (patent covering elongated bar members used to support rolls of materials such as steel or cellophane invalid for failure to disclose best mode of carrying out invention); and Nobelpharma

asserted defense during patent litigation.[80] Also, each of these invalidated patents covered an invention in the predictable arts;[81] no patent has ever been invalidated for failure to comply with best mode in biotechnology patents,[82] even though the matter has been often litigated.

The following decisions involve best mode where the claims of the patent were not held invalid, but where failure to comply arguably existed. They highlight the Federal Circuit's unwillingness to aggressively enforce patenting requirements so that the *quid pro quo*, and therein constitutional objective, of patenting is realized.

In *Eli Lilly & Co. v. Barr Laboratories*,[83] Eli Lilly obtained patents for fluoxetine hydrochloride.[84] Before Eli Lilly's patents expired, Barr Laboratories filed an Abbreviated New Drug Application ("ANDA") under the Hatch-Waxman Act[85] to begin the process of Food and Drug Administration ("FDA") approval necessary to market fluoxetine hydrochloride.[86] Eli Lilly brought an infringement action against Barr Labs, which Barr Labs affirmatively defended arguing that Eli Lilly's

AB v. Implant Innovations, Inc., 141 F.3d 1059, 1064-66 (Fed. Cir. 1998) (patent covering titanium micro-pitted plates used as dental implants invalid for failure to disclose best mode of carrying out invention). *See Bayer AG*, 301 F.3d at 1316 (stating that the patents invalidated in previous cases because of best mode violations involved either "failure to disclose a preferred embodiment, or else failure to disclose a preference that materially affected making or using the invention").

80. Brandon Baum, Partner, Mayer Brown Rowe & Maw, and Greg Lanier, Partner, Jones Day, Lecture Notes and Remarks to the Patent Litigation Seminar at U.C. Hastings College of the Law (Mar. 1, 2007).

81. *See Spectra Physics*, 827 F.2d at 1526 (patent covering a laser); *Dana Corp.*, 860 F.2d at 416 (patent covering valve stems seals for an internal combustible engine); *N. Telecom*, 908 F.2d at 933 (patent covering a mode of batch processing data); *Chemcast Corp.*, 913 F.2d at 924-25 (patent covered a dual durometer grommet); *U.S. Gypsum Co.*, 74 F.3d at 1210 (patent covering a "lightweight joint compound"); *Great N. Corp.*, 94 F.3d at 1570-71 (patent covering protective roll stackers with diamond indentations); and *Nobelpharma*, 141 F.3d at 1062 (patent covering bone implant device with rivets).

82. Bayer AG & Bayer Corp. v. Schein Pharms., Inc., 301 F.3d 1306, 1316 (Fed. Cir. 2002); Eli Lilly & Co. v. Barr Labs., Inc., 251 F.3d 955, 963 (Fed. Cir. 2001); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1209 (Fed. Cir. 1991).

83. *Eli Lilly*, 251 F.3d at 958.

84. Fluoxetine hydrochloride is a selective serotonin reuptake inhibitor (SSRI). Wong DT, Bymaster FP, Horng JS, Molloy BB, *A new selective inhibitor for uptake of serotonin into synaptosomes of rat brain: 3-(p-Trifluoromethylphenoxy)-N-methyl-3-phenylpropylamine*, J PHARMACOL EXP THER. 1975 Jun;193(3):804-11. Fluoxetine hydrochloride is also the active ingredient in the antidepressant Prozac (Lilly 110140). *Id.*

85. 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (1994). The Hatch-Waxman Act permits generic drug makers to initiate the FDA approval process before the patent on the pioneer drug expires without infringing on the patent.

86. *Eli Lilly*, 251 F.3d at 958.

patents were invalid for lack of disclosure.[87] Barr argued that Eli Lilly's best mode of synthesizing p-trifluoromethylphenol,[88] a chemical that is expensive to buy, cumbersome to produce, but that Eli Lilly's scientists had discovered a way of synthesizing in "tank car quantities," was not disclosed.[89] The Federal Circuit held that Eli Lilly was not required to disclose its preferred method of synthesizing p-trifluoromethylphenol even though it was the recommended starting material to produce fluoxetine hydrochloride and would significantly affect other pharmaceutical companies' ability to compete upon patent expiration: "[i]n short, the reasons for using [the new method of synthesizing p-trifluoromethylphenol] were not linked to the intrinsic quality of fluoxetine hydrochloride, which is the thrust of the best mode requirement."[90]

Barr also challenged the patent's failure to disclose its preferred solvent used while recrystallizing fluoxetine hydrochloride. The Federal Circuit held that although additional experimentation was necessary to find a suitable solvent, Barr and others were able to purify and recrystallize fluoxetine hydrochloride without disclosing Eli Lilly's preference—in other words, that a patentee "complies with § 112 even though . . . experimentation is necessary to practice the best mode" and that section 112 "requires only an adequate disclosure of the best mode."[91] Further, the court stated that "a patentee's failure to disclose an unclaimed, preferred mode for accomplishing a routine detail does not violate the best mode requirement because one skilled in the art is aware of alternative means for accomplishing the routine detail that would still produce the best mode of the claimed invention."[92]

The holding of this case, in contravention of statutory patent requirements, essentially provides that to avoid patent invalidity for failure to disclose a best mode, a patentee need not disclose his entire best mode, but only portions of it. In other words, a patentee does not need to fully disclose his best mode to be in accordance with the requirement. This holding satisfies neither the policy aims behind best mode nor the *quid pro quo* of the patent system: society is not fully benefiting from the patentee's knowledge, and the patentee will retain a competitive advantage in the marketplace once the patent expires.

87. *Id.*

88. *Id.* at 964. P-trifluoromethylphenol is the chemical the patent recommends using as a starting material when making fluoxetine hydrochloride.

89. *Id.* at 961.

90. *Eli Lilly*, 251 F.3d at 965.

91. *Id.* at 966-67 (quotations and citations omitted).

92. *Id.* at 966.

In *Amgen Inc. v. Chugai Pharmaceutical Co., Ltd.*, Amgen alleged that Chugai infringed its patent covering a method for purifying and producing erythropoietin ("EPO") and EPO compositions.[93] Among other defenses, Chugai asserted that Amgen failed to comply with the best mode requirement because it did not sufficiently disclose the cells necessary to replicate Amgen's best mode.[94]

Amgen's best mode of producing EPO involved the use of Chinese hamster ovary ("CHO") cells that had been transfected[95] so that they would produce greater amounts of EPO.[96] However, Amgen neither made a deposit[97] of the cells nor disclosed sufficient information to enable Chugai to create the transfected cell line itself without undue experimentation. In fact, Chugai could not replicate the level of EPO production Amgen achieved using its own cells.[98]

The district court found that Amgen had a preferred best mode that involved its transfected cell line, but concluded that even though "the testimony is clear that no scientist could ever duplicate exactly the best mode used by Amgen, . . . those of ordinary skill in the art could produce mammalian host cell strains or lines with *similar* levels of production."[99] The Federal Circuit affirmed this conclusion.[100]

The holding of this case seems to obliterate the best mode requirement: where a great amount of experimentation is required to *approximate* a patentee's best mode, and that experimentation could be avoided had the patentee disclosed more, that patentee still has not violated the best mode. By maintaining exclusive control over its transfected cell line, Amgen retained a benefit that will translate into a commercial benefit over competitors who will be less efficient at making EPO upon patent expiration.

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93. Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d at 1204.

94. *Id.* at 1209.

95. Transfection refers to a biotechnical laboratory technique that introduces foreign genetic material into a cell's DNA. *See, e.g.*, Bacchetti S and F.L. Graham, *Transfer of the gene for thymidine kinase to thymidine kinase-deficient human cells by purified herpes simplex viral DNA,* PROC. NATL. ACAD. SCI. U.S.A. *1977 Apr;74(4):1590-94.*

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

97. *See* MARTIN J. ADELMAN, RANDALL R. RADER, JOHN R. THOMAS & HAROLD C. WEGNER, PATENT LAW 447-48 (Thompson West, 2003) (1998) (informing that the deposit of biological samples can satisfy the disclosure requirement). *See also* Sheryl Rubinstein Silverstein, *Biotechnology Patents and the Deposit Requirement: Removing Uncertainty After Amgen v. Chugai Pharmaceutical Co., Ltd.*, 66 S. CAL. L. REV. 937, 937-39 (1993).

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

99. Amgen, Inc. v. Chugai Pharm. Co., Ltd., 13 U.S.P.Q. 2d (BNA) 1737, 1772-73, 1742-44 (D. Mass 1989) (emphasis added).

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

In *Bayer AG & Bayer Corp. v. Schein Pharmaceuticals, Inc.*, Dr. Grohe, a scientist at Bayer, had conceived of the structure of ciprofloxacin[101] but encountered difficulties making the compound.[102] He turned to Bayer scientist Dr. Klauke for help, and they succeeded in making ciprofloxacin by using an intermediate referred to as the "Klauke compound," which, although it caused Dr. Grohe significant trouble to make, was his preferred method of producing ciprofloxacin.[103]

Dr. Grohe's patent applications[104] for ciprofloxacin did not disclose the Klauke compound, so, when sued for infringement, Schein attacked the patent's validity for failure to satisfy best mode.[105] The Federal Circuit held that failure to disclose Grohe's preferred mode did not violate best mode because the application only needed to disclose the preferred method of making ciprofloxacin itself and not intermediates *required* to make ciprofloxacin (and without which Grohe was unable to make the drug).[106]

Permitting Bayer to retain control over a necessary intermediate precursor to ciprofloxacin allows Bayer to control others' production so that competitors are unable to attain equal commercial success upon patent expiration. As a result, the public suffers higher drug prices from an unearned monopoly, society has not benefited from the patentee's full knowledge, and subsequent ciprofloxacin producers will be on unequal commercial footing with Bayer. In this case, the Federal Circuit seems to be creating a type of "trade secret/patent" protection that directly contradicts the overall aims of patent protection. The patentee is retaining

101. Ciprofloxacin is a general antibiotic. *See* Bayer Health Care Cipro Homepage, http://www.cipro.com. (last visited Nov. 18, 2007).

102. Bayer AG & Bayer Corp. v. Schein Pharmaceuticals, Inc., 301 F.3d 1306, 1309 (Fed. Cir. 2002).

103. *Id.*

104. Dr. Grohe filed patent applications claiming ciprofloxacin in several foreign countries. *Id.* at 1313. However, Grohe did not disclose the Klauke compound in any of these applications. *Id.* Under 35 U.S.C. § 119 (2000 & Supp. V.2005), a patentee is entitled to use foreign filing dates as priority dates in the United States in order to avoid prior art, however, if an applicant fails to disclose his best mode in any foreign application, that application cannot serve as the filing date for an application in the U.S. because it does not comply with U.S. patent laws. *See* 35 U.S.C. §§ 112, 119 (2000 & Supp. V.2005).

105. *Bayer AG*, 301 F.3d at 1313-14.

106. *Id.* at 1314, 1323. The Federal Circuit held that disclosing the method of making only ciprofloxacin from intermediaries derived from the Klauke compound (that Grohe was unable to make without using the Klauke compound) was sufficient disclosure because "the [patent] application contain[ed] an enabling disclosure of [the necessary intermediate]. Schein merely contend[ed] that this [wa]s not enough, that the application must disclose Dr. Grohe's preferred method of making [the intermediate]. But, because that preference does not materially affect carrying out the invention, ciprofloxacin, it need not be disclosed to comply with the best mode requirement." *Id.* at 1323.

secrets about his invention, and yet is excluding others from practicing it.

The Federal Circuit's management of best mode disclosure has been widely criticized and many have advocated altering the requirement because of its poor treatment.[107] These cases and criticisms make apparent

107. Christopher Marchese criticizes the current best mode requirement, which has produced an increasing volume of litigation in the last thirty-five years and raised many questions for prosecutors and litigators, and encourages a very specific reform that the Federal Circuit itself could perform. Christopher S. Marchese, *Confusion, Uncertainty, and the Best Mode Requirement*, 2 FED. CIR. B.J., Spring 1992, at 65 (1992); Christopher S. Marchese, *Promoting the Progress of the Useful Arts by Narrowing Best Mode Disclosure Requirements in Patent Law*, 54 U. PITT. L. REV. 589, 590-92 (1992-93). He argues that the Federal Circuit "has clouded the scope of disclosure" and its case law fails to resolve the issue of "whether inventors must disclose their preferred modes of carrying out *unclaimed* subject matter. *Id.* at 609 (emphasis in original). This issue has three possible resolutions: (1) compel inventors to reveal their best mode only for claimed subject matter; (2) require that inventors disclose all preferred modes, or (3) determine the significance of any preferred mode, and only find a best mode violation where a "material mode" was withheld. *Id.* Marchese concludes that the first resolution would be the best. *Id.* at 660. It is a clear standard and therefore promotes efficiency and reliance on the patent system (thereby promoting the useful arts), prevents trapping patent applicants because of their disclosures, and simplifies the already daunting patent process. *Id.*

Albert L. Jacobs, Jr. offers a more feasible, yet similarly minor, reform. Albert L. Jacobs, Jr., *The Best Mode Requirement: What the Law Is and What It Should Be*, 16 HOUS. J. INT'L L. 533, 535 (1994). Jacobs highlights some troublesome district and state court patent decisions and addresses international issues with the best mode requirement and arrives at the conclusion that although the best mode requirement is problematic, it would not be were it applied as intended: "[d]eleting the best mode requirement would be unnecessary if the requirement were applied in a reasonable and logical manner to give effect to the clear intent of the statute. Namely, to ensure that when an inventor chooses to file a patent application in an attempt to secure a temporary monopoly on the invention, he makes a full and complete disclosure, including any best or preferred mode of carrying out his invention." *Id.* at 563. This, he argues, will advance the Constitutional aims of patent protection, because it will ensure that the applicant does not intentionally conceal or suppress his preferred mode. *Id.*

Donald S. Chisum focuses on concerns arising from violations of best mode and inequitable conduct issues, proposing a very convincing suggestion that we alter best mode filing requirements by permitting applicants to modify their preferred embodiments throughout the life of a patent, therein giving the public the best possible disclosure (as later-developed best modes can be more sophisticated or efficacious). Donald S. Chisum, *Best Mode Concealment and Inequitable Conduct in Patent Procurement: A Nutshell, A Review of Recent Federal Circuit Cases and a Plea for Modest Reform*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 277, 318-19 (1997). After summarizing several Federal Circuit decisions involving best mode, he concludes that the requirement has "strong positive and negative effects on the patent system." *Id.* at 318. He dispenses with the suggestion of "completely review[ing] and revis[ing]" the best mode requirement, and argues instead to revise the timing element of the requirement, "for best mode compliance seem[s] to be needless and deleteriously rigid." *Id.* He explains that relaxing and extending the timing requirement so that the inventor may add or alter best mode disclosures made upon filing would benefit the public: later developed modes "are typically more sophisticated and developed than earlier ones," so an applicant would be in a better position after assessing the commercial viability of an invention to determine whether more disclosure would be necessary; and inventors could adopt others' improvements or commercial adaptations on the invention, and disclose those officially to the public. *Id.* at 319.

Tressa James argues that because attorneys employ the best mode defense as a way of

the Federal Circuit's lack of strict best mode disclosure enforcement and its unwillingness to invalidate a patent for best mode transgressions, especially in the biotechnology context. This tendency is particularly problematic because it establishes stronger patents based on more lenient patenting requirements, which invalidates the *quid pro quo* between the patentee and society. Further, the Patent Reform Act of 2005 proposes to eliminate the best mode requirement entirely in order to harmonize international patent systems, which will cement the lowered disclosure and its negative effects into law.[108] If these disclosure requirements are undermined, our patent system may slowly morph into an unconstitutional and restrictive system.

### B. Non-Obviousness

Obviousness is the most significant gatekeeper to patentability.[109] It involves several difficult determinations because it includes a "series of factual assessments culminating in an often-difficult qualitative judgment of the creative achievement involved in the invention" as a whole.[110]

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avoiding technical points at issue in a patent infringement suit (they focus on the subjective mindset of the inventor and "try the person, not the patent"), it enables the judge to assess the inventor as a person, allowing the judge "a window through which [the judge] can express [his or her] unique views on patent law and assess the moral culpability of the inventor." James, *supra* note 7, at 98-100. Therefore, the presence of the best mode requirement frees judges to impress their subjective and personal views onto an invention, rendering best mode decisions "highly subjective and open to the individual philosophy of the judge in question." *Id.* at 136-37. Interestingly, a review of patent invalidity cases from late 1980 to early 1990 revealed that federal judges handled best mode cases dissimilarly but in accordance with their backgrounds and experiences: "Specifically, judges with patent experience rejected best mode arguments 74.1% of the time, while judges without patent experience rejected best mode arguments only 61.5% of the time," indicating that best mode is highly subjective analysis which the judges need to be careful about when making decisions. *Id.* at 136.

Judge Rader of the Federal Circuit has criticized the existence of the best mode requirement and suggests its removal because no sane inventor would risk suppressing his best mode because then it would not be patentable. *See Bayer AG*, 301 F.3d at 1323-28 (Rader, J., concurring).

I believe that failing to rigorously require best mode compliance violates the *quid pro quo* behind patenting because the public does not benefit fully from the inventor's knowledge. I also think that inventors should under no circumstances be permitted to retain information that will give them a commercial advantage upon the expiration of the patent term because this continues a patentee's monopoly beyond the sanctioned period, and injures the public who will suffer higher drug costs and insurance premiums as a result. Therefore, I suggest that the courts employ a two-prong test that mirrors the dual policy objectives behind best mode when determining compliance to see (1) whether the inventor enabled the preferred embodiment of the invention, (2) in a way that guarantees the public an end to the governmental protection upon expiration of the patent.

108. *See* Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

109. ADELMAN, *supra* note 97, at 309.

110. *Id.*

Obviousness is intended to be "the standard that prevents trivial advances in the useful arts from winning patent protection."[111] It achieves this objective by "creat[ing] a 'patent-free' zone around the state of the art," allowing substitutions and improvements on patented products "only where a claimed invention surpasses this ordinary, continuous flow of technical progress."[112] Obviousness is measured at the time the invention was made, which creates a "hindsight" issue for the examiner who has to make the obviousness determination from the point of view of "a person having ordinary skill in the art" of the invention at the time of the invention.[113]

Obviousness developed as judge-made doctrine,[114] and was not codified until 1952.[115] The old test asked whether there was a "flash of creative genius" sufficient to warrant a patent.[116] In *Hotchkiss v. Greenwood*, the case that established this historical standard of invention, the Supreme Court invalidated a patent on a doorknob made from clay.[117] The Court held that a patent will not be held valid if it consists merely of improving an old device by the substitution of materials better suited to the purpose of the device: "[i]n other words, the improvement is the work of the skilful mechanic, not that of the inventor."[118]

The Supreme Court in *Graham v. John Deere Co.* interpreted the then-recently passed non-obviousness statutory requirements to overrule the high "flash of creative genius" standard.[119] The Court established the current lower non-obviousness inquiry as a question of law that is based on an underlying multi-step factual inquiry known as the "Graham factors."[120]

111. *Id.* at 310.

112. *Id.*

113. *Id.*

114. *See Hotchkiss v. Greenwood*, 52 U.S. 248, 270 (1850). Some refer to this decision as an example of judicial activism because there was no support for the development of a standard of non-obviousness in either the Patent Act or the Constitution. *See* Edward C. Walterscheid, *The Hotchkiss Unobviousness Standard: Early Judicial Activism in the Patent Law*, 13 J. INTELL. PROP. L. 103, 126-28 (2005).

115. *See* 35 U.S.C. § 103 (2000 & Supp. V.2005). Section 103(a) is the primary non-obviousness section (providing that "[a] patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made"). 35 U.S.C. § 103 (2000 & Supp. V.2005).

116. Cuno Eng'g Corp. v. Automatic Devices Corp., 314 U.S. 84, 90 (1941) (employing the test from *Hotchkiss*, 52 U.S. at 270).

117. *Hotchkiss*, 52 U.S. at 264.

118. *Id.* at 267.

119. Graham v. John Deere Co., 383 U.S. 1, 15 (1966).

120. *Id.*

The "Graham Factors" constitute the following four factors that the Court held to be essential to every non-obviousness analysis: (1) level of ordinary skill in the art; (2) scope and content of prior art; (3) differences between the claimed invention and the prior art; and, (4) secondary considerations which *may* be relevant to establishing the background upon which the invention was introduced (i.e., objective indicia of nonobviousness).[121]

The Supreme Court again spoke on obviousness in *Sakraida v. Ag Pro, Inc.*, reasserting its holding in *Great Atlantic and Pacific Tea Co.*, which stated that "[a] patent for a combination which only unites old elements with no change in their respective functions" is not patentable.[122] In its 2007 decision *Teleflex, Inc. v. KSR International Company*, the Supreme Court yet again addressed obviousness standards, and appeared to buttress a heightened, yet subjective, obviousness standard that the Federal Circuit had seemed intent upon eroding since its inception.[123]

There is evidence of the Federal Circuit's wear upon the standard in several decisions. In *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, decided after *Graham* but before *Teleflex*, the Federal Circuit reversed the district court's finding of invalidity due to obviousness.[124] In upholding the patent, the Federal Circuit concluded that the district court had given insufficient weight to the "secondary considerations" *Graham* factor: "objective evidence such as commercial success, failure of others, long-felt need, and unexpected results must be considered *before* a conclusion on obviousness is reached[.]"[125] This holding is not in direct conflict with *Graham*, yet it and the Federal Circuit's in-depth consideration of these secondary factors place undue emphasis on "secondary considerations," which were intended to be, as their name indicates, secondary.[126]

The Court in *Graham* established that

> [u]nder § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or

121. *Id.* at 17-18.

122. Sakraida v. Ag Pro, Inc., 425 U.S. 273, 281 (1976) (quoting Great Atlantic & Pacific Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 152 (1950)).

123. Teleflex, Inc. v. KSR Int'l Co., *From Lexis*: 127 S. Ct. 1727*, 1734-35; 167 L. Ed. 2d 705, 715; 2007 U.S. LEXIS 4745, 18-19 (2007). **All pagination subject to change pending release of final published version.*

124. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986).

125. *Id.* at 1380 (emphasis in original).

126. *See id.* at 1382-1385.

nonobviousness of the subject matter is determined.[127]

The Court then stated that "[s]uch secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., *might* be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented" and that "[a]s indicia of obviousness or nonobviousness, these inquiries *may* have relevancy."[128] The Court in *Graham* listed the first three requirements in an obviousness determination, whereas the secondary considerations "may" or "might" be considered.[129] Compare this to *Hybritech*, where the Federal Circuit criticized the district court for not fully taking the "secondary considerations" into account before making a finding of obviousness, which the Federal Circuit then reversed in light of the "secondary considerations."[130] The Federal Circuit in *Hybritech* placed an emphasis on the *Graham* factors that is not reflected in the Supreme Court's decision and that aids findings and holdings of non-obviousness.

In *In re Deuel*, the Federal Circuit again lowered the patentability standards, making it easier to establish nonobviousness.[131] The Federal Circuit reiterated its previous holding in *In re Bell* by asserting that "the PTO's focus on known methods for potentially isolating the claimed DNA molecules is also misplaced because the claims at issue define compounds, not methods."[132] Therefore "even if . . . the existence of general cloning techniques, coupled with knowledge of a protein's structure, might have provided motivation to prepare a cDNA or made it obvious to prepare a cDNA, that does not necessarily make obvious a particular claimed cDNA."[133] This Federal Circuit language created a per se rule for patenting DNA: any new DNA structures are nonobvious and therefore patentable.[134]

The Federal Circuit also expanded the scope of nonobviousness through its consideration of prior art references. Section 103(a) of the Patent Act establishes that prior art indicates obviousness "if the

127. Graham v. John Deere Co., 383 U.S. 1, 17 (1966).

128. *Id.* at 17-18 (emphasis added).

129. *Id.*

130. *Hybritech*, 802 F.2d at 1380.

131. In re Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995).

132. *Id.* (referring to *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993), which held that the PTO erred in resting a rejection upon the combination of a primary reference disclosing a protein with a secondary reference describing a general method of cloning genes: "the PTO's focus on Bell's method is misplaced. Bell does not claim a method. Bell claims compositions, and the issue is the obviousness of the claimed compositions, not of the method by which they are made").

133. *In re Deuel*, 51 F.3d at 1559.

134. *Id.*

differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[135] More than one prior art reference can be combined to establish obviousness, however, it is impermissible for evaluators with the knowledge of the invention to pick and choose from the range of prior art references to build a case of obviousness.[136] Rather, there must be a "teaching, suggestion or motivation to combine" the references in the way that would make the invention obvious.[137] This new "teaching-suggestion-motivation test" ("TSM test") permitted the combination of prior art references for obviousness determinations when there is some motivation, suggestion, or teaching to combine the prior art and supplanted all Supreme Court obviousness precedent at that time.[138]

Recently, in a series of unpublished decisions, the Federal Circuit expanded its test even further. The Federal Circuit began to require an *express* suggestion in the prior art to combine the prior art references. This measure significantly deviated from the statutory and precedential standard. As John Duffy noted:

> [The Federal Circuit's suggestion] test, which tends to make even seemingly trivial developments patentable, is entirely the Federal Circuit's product. It has no basis in the Supreme Court's case law and may, in fact, be inconsistent with the Court's most recent pronouncement on the subject (though that precedent is now more than a quarter century old).[139]

After permitting the Federal Circuit to continue to erode obviousness standards for twenty years, the Supreme Court belatedly, but finally, stepped in when it decided the much-anticipated *Teleflex*.[140] *Teleflex* involved claim 4 of U.S. Patent No. 6,237,565 ("the '565 patent"). Claim 4 recited a device that mounted a modular sensor onto a fixed pivot point on a specialized adjustable vehicle control pedal, such that the result was

135. 35 U.S.C. § 103(a) (2007).

136. *See* MUELLER, *supra* note 75, at 190.

137. *Id.* (explaining that "if the references themselves or other prior art do not suggest the viability of making the combination [of the references], it is a legally erroneous analysis").

138. *Id.* at 190-91. However, this test is still unable to surmount the considerable difficulties presented by the hindsight issue.

139. John Duffy, *The Festo Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 SUP. CT. REV. 273, 340-41 (2002).

140. Teleflex, Inc. v. KSR Int'l Co., *From Lexis*: 127 S. Ct. 1727*, 1734-35; 167 L. Ed. 2d 705, 715; 2007 U.S. LEXIS 4745, 18-19 (2007) **All pagination subject to change pending release of final published version.*

novel, but the comprising elements were not.[141] In the lower courts, the Federal Circuit applied its loose obviousness standard to reverse the district court's finding of obviousness.[142] The Supreme Court then reversed the Federal Circuit, and invalidated the patent claim.[143] Although much debate surrounds the meaning and effect of the decision, the Supreme Court rebuked the Federal Circuit and proclaimed that there is no clear test for obviousness,[144] but rather it is a subjective inquiry that employs common sense and depends on the objective reach of the patent claims, thus invalidating the Federal Circuit's TSM or express suggestion test.[145]

Although the reach and effect of *Teleflex* is currently unknown, perhaps it will serve as a final corrective to the Federal Circuit's previous unwillingness to invalidate a patent claim for lack of non-obviousness. Furthermore, the Supreme Court's strong language, although dicta, that "the results of ordinary invention are not the subject of exclusive rights under patent laws" because "were it otherwise patents might stifle, rather than promote, the progress of useful arts[,]" is encouraging.[146] Yet the Federal Circuit had previous Supreme Court precedent to follow, and nevertheless ended up creating its own extremely lenient test.

Obviousness determinations permit great flexibility to those evaluating the validity of patent claims because the factors are myriad, the standard is not concrete, the determination is challenging, and it is difficult to objectively conclude whether a person having ordinary skill in the art at the time the invention was created would think the invention obvious. As Judge Learned Hand commented, the test of invention "is as fugitive, impalpable, wayward, and vague a phantom as exists in the whole paraphernalia of legal concepts."[147] Even so, the determination of inventiveness is obviousness, and inventiveness is the heart of patenting. Courts and examiners should therefore be exceedingly strict in performing the non-obviousness inquiry in order to uphold the *quid pro quo* of patenting and enforce the constitutional objectives of the Clause.

141. *Id.* at 1736-37; Teleflex, Inc. v. KSR Int'l Co., 289 F.Supp.2d 581, 586-87 (E.D.Mich 2003).

142. Teleflex, Inc. v. KSR Int'l Co., 119 Fed. Appx. 282, 283 (Fed. Cir. 2005).

143. *Teleflex*, 127 S. Ct. at 1753.

144. *Id.* at 1741 ("The flaws in the analysis of the Court of Appeals relate for the most part to the court's narrow conception of the obviousness inquiry reflected in its application of the TSM test.").

145. *Id.* ("When a court transforms the general principle into a rigid rule that limits the obviousness inquiry, as the Court of Appeals did here, it errs.").

146. *Id.* at 1746.

147. Harries v. Air King Prods. Co., 183 F.2d 158, 162 (2d Cir. 1950).

### C. Utility

The way the Federal Circuit has treated the utility requirement raises similar issues. Under the current statutory provisions, a patentable invention must be "new and useful."[148] The utility requirement is explicit in the constitutional language that requires Congress to act "to promote the progress of . . . *useful* Arts"[149] and has been a component of patent law since the first Patent Act of 1793.[150] Utility dovetails with enablement: without utility, an invention cannot be enabled so that others can use it without undue experimentation. The utility requirement, however, is rarely invoked during prosecution or litigation[151] perhaps because the Federal Circuit has established a low standard for measuring utility.[152] However, this was not always the case.

Utility used to have a moral component. In 1817 Justice Story proscribed patents on inventions that were "injurious to the well-being, good policy, or sound morals of society," such as "a new invention to poison people, or to promote debauchery, or to facilitate private assassination."[153] This proposition continues to appear as precedent adopted and enforced by the Federal Circuit.[154] However, in the 1999 case *Juicy Whip, Inc., v. Orange Bang, Inc.*, citing on a decision from the Board of Patent Appeals, the Federal Circuit announced that morality was no longer a factor in a utility patenting determination.[155] Not only should the Federal Circuit not be relying on lower courts that have ignored Supreme Court precedent, but this ruling also fails to take into account the 1991

148. 35 U.S.C. § 101 (2000 & Supp. V.2005).

149. U.S. CONST. art. I, § 8, cl. 8 (emphasis added).

150. *See* Patent Act of 1793, ch. 11, § 1, 1 Stat. 318, 319 (requiring an invention to be sufficiently useful and important to warrant the issuance of a patent).

151. Brandon Baum, Partner, Mayer Brown Rowe & Maw, Remarks to the Patent Litigation Seminar at Hastings, College of the Law (Mar. 1, 2007).

152. *See* Juicy Whip, Inc., v. Orange Bang, Inc., 185 F.3d 1364, 1366 (Fed. Cir. 1999) (providing that "[t]he threshold of utility is not high: [a]n invention is 'useful' under section 101 if it is capable of providing some identifiable benefit").

153. Lowell v. Lewis, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (cited and incorporated into Brenner v. Manson, 383 U.S. 519, 532-33 (1966).

154. *See* Tol-O-Matic, Inc. v. Proma Produkt-Und Marketing Gesellschaft m.b.H., 945 F.2d 1546, 1552-53 (Fed. Cir. 1991); *In re Nelson*, 280 F.2d 172, 178-79 (C.C.P.A. 1960).

155. *Juicy Whip*, 185 F.3d at 1366-1367 ("the principle that inventions are invalid if they are principally designed to serve immoral or illegal purposes has not been applied broadly in recent years. For example, years ago courts invalidated patents on gambling devices on the ground that they were immoral . . . but that is no longer the law." (citing Brewer v. Lichtenstein, 278 F. 512 (7th Cir. 1922)); Schultze v. Holtz, 82 F. 448 (N.D. Cal. 1897); National Automatic Device Co. v. Lloyd, 40 F. 89 (N.D. Ill. 1889), but that is no longer the law, *see In re Murphy*, 200 U.S.P.Q. (BNA) 801 (PTO Bd. App. 1977)").

Federal Circuit decision relying on *Lowell v. Lewis*[156] (by citing a case[157] that incorporates it) stating that morality continues to be a consideration.[158]

The Supreme Court again spoke on utility in 1966 when it decided *Brenner v. Manson*.[159] In the context of an interference action[160] the Court characterized the actions of patentee Manson as an attempt to receive a patent on a novel chemical compound (for which he cited possible anti-tumor capabilities by analogizing its structure and composition to a known anti-tumor agent) so that he could proceed to determine useful applications for the novel compound without threats of competition and possible preemption.[161] The Court held that Manson's actions subverted the patent system, which seeks to award "compensation for [the search's] successful conclusion" rather than the search itself.[162] This analysis, as Justice Harlan pointed out, establishes a high standard for determining utility.[163]

Yet in 1995, the Federal Circuit reversed the lower courts' findings of patent invalidity for failure to satisfy the utility requirement in a case highly similar to *Brenner*.[164] In *In re Brana* the patentee disclosed that the newly discovered compound was useful in the "treatment of diseases" and as an "antitumor substance[]," but offered no other express utility such as against what diseases it was effective or how it would function as an anti-tumor agent.[165] Although it is unclear how a person having ordinary skill in the art would successfully use the chemical to "treat diseases," the Federal Circuit held that sufficient utility had been established to uphold the patent, even in light of the Supreme Court's treatment of Manson's "anti-tumor" utility disclosure.

*In re Brana* is, therefore, apparently in direct conflict with Supreme

156. *Lowell*, 15 F. Cas. at 1019.

157. *Nelson*, 280 F.2d at 178-79 (citing *Lowell*, 15 F. Cas. at 1019).

158. *See* Tol-O-Matic v. Proma Produkt-Und Mktg. Gesellschaft, 945 F.2d 1546, 1552-53 (1991).

159. Brenner v Manson, 383 U.S. 519, 534-36 (1966) (stating that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion").

160. *See* 35 U.S.C. § 102(g)(1) (2000 & Supp. V.2005). An inventor can request an "interference action" involving determination of inventorship when inventorship is disputed.

161. *See Brenner*, 383 U.S. at 522, 536 (1966). The chemical compound was exceedingly similar to a known anti-tumor agent. Manson alleged anti-tumor capabilities as the utility, although he had not proven if and how the chemical would function in this way except through analogy to similar known anti-tumor chemicals. Seeking to get a patent so he would have exclusive license to work on his newly discovered chemical, the Court responded that a patent is "not a hunting license." *Id.*

162. *Id.*

163. *Id.* at 536-37. (Harlan, J., concurring in part and dissenting in part).

164. *In re Brana*, 51 F.3d 1560, 1562 (Fed. Cir. 1995).

165. *Id.* at 1565.

Court precedent that holds a patent is not a "hunting license" that rewards patentees for the search, but not for the search's "successful conclusion."[166] Although the Supreme Court prevented Manson from performing such a search, the Federal Circuit essentially gave Brana free reign to search for myriad applications for his novel compound without the threat of competition or preemption. In both *Juicy Whip* and *In re Brana*, the Federal Circuit deviated from precedent and narrowed the utility requirement to which patentees must adhere. The result is that the courts now uphold patent claims that would not have satisfied previously required standards. This means that patentees are getting more for doing less, which is to society's detriment. This frustrates the *quid pro quo* of the patent system as well as the constitutional requirement to promote the progress of the useful arts.

### D. First-to-Invent Filing System

Currently the U.S. patent system follows a "first-to-invent" filing system.[167] First-to-invent filing allows only the first inventor to receive a patent, and therefore rewards the true inventor for his personal contribution.[168] By rewarding the person who in fact performed the inventive activity (the inventor himself), first-to-invent filing reinforces the incentives offered by the patent system by encouraging people to invent rather than copy, because the copier of an invention will not receive a patent.[169]

The first-to-invent system is generally considered to benefit small inventors.[170] Also, many of the previous inefficiencies[171] caused by the duplicative research efforts by researchers unaware of a pending patent on their research have been resolved by the practice of publishing pending

166. *Brenner*, 383 U.S. at 536.

167. *See* 35 U.S.C. §§ 102(a), (e), (g) (2000 & Supp. V. 2005) (stating the inventor can file for a patent). The patent system has always enforced first-to-invent filing. *See* Patent Act of 1793, ch. 11, § 1, 1 Stat. 318, 319 (providing patentability requirements for the inventor). Only the first inventor of a technology can obtain a patent, regardless of whether a later inventor filed an earlier application on the same technology. This implicates novelty requirements, which are a basic element of our "first to invent" patent system.

168. *See* 35 U.S.C. §§ 102(a), (e), (g) (2000 & Supp. V. 2005). Each of these provisions uses the word "inventor" such that only the inventor of a technology can obtain a patent, regardless of whether a later developer filed an earlier application on the same technology. *See supra* note 63.

169. MUELLER, *supra* note 75, at 26-29.

170. *See* Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

171. The major criticism of the first-to-invent system is that it is inefficient. *See* Charles R. B. Macedo, *First-to-File: Is American Adoption of the International Standard in Patent Law Worth the Price?*, 18 AIPLA Q.J. 193, 218 (1990).

patent applications.[172] Additionally Congress created interference proceedings[173] to correctly resolve disputes when two parties assert the same first-inventorship. The first-to-invent system is criticized for being inefficient because of interference proceedings, however, a first-to-invent system does not need to retain such proceedings in order to ensure the integrity of its first-to-invent system.[174]

Pending 2005 legislation in Congress proposes to change this system into a "first-to-file"[175] system, whereby the inventor who "races to the patent office" first receives the patent.[176] Switching to a first-to-file system would harmonize U.S. practices with international patent application practices.[177] However, if adopted, it may undermine the *quid pro quo* behind patenting and may create a system that less closely adheres to the constitutional mandate.[178]

For example, the first-to-file system does not reward the "first and true" inventor,[179] but rather the inventor who can file the soonest. Similarly, the first-to-file system has been characterized as unfair for prejudicing the independent inventor with fewer resources and limited capacity to win the race to the patent office.[180] Also, "[s]witching to a first-

172. The passage of the American Inventors Protection Act of 1999 established that patent applications would be published eighteen months after filing. *See* 35 U.S.C. § 122(b) (2000).

173. *See* 35 U.S.C. § 102(g)(1) (2000 & Supp. V. 2005).

174. *See* MUELLER, *supra* note 75, at 434-37. *See also* Edward Walterscheid, *Priority of Invention: How the United States Came to Have a "First-to-Invent" Patent System*, 23 AIPLA Q.J. 263 (1995) (noting that England had a first-to-invent patenting system and offered no such proceeding to determine inventorship but rather relied on the relative filing dates, among other things, as indications of the date of invention).

175. Technically it self-refers as a "first-inventor-to-file" system, but this is merely a difference of semantics: there is no qualitative difference between it and a "first-to-file" system. *See* Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

176. *Id.*

177. MUELLER, *supra* note 75, at 434-35.

178. In addition to frustrating the promotion of "the progress of science and the useful arts," some argue that adopting a first-to-file system would offend the Clause because it specifically refers to "inventor" rather than "first-filer." Macedo, *supra* note 171, at 210-15. However, the Supreme Court has broadly interpreted Congress' powers to act under the Clause, and only limits Congress' legislation to promoting "the progress of science and the useful arts." *Id.* at 215. Therefore, because of the Supreme Court's broad interpretation of Congress' power under the Act, a first-to-file system that grants patents to those other than the actual "inventor" as stated by the Clause will likely survive a direct constitutionality attack. *Id.* However, it is nevertheless possible that a first-to-file system would not "promote the progress of science and the useful arts" and therefore be unconstitutional.

179. To be an inventor according to patent law and the Constitution is "to discover or produce something not made before, i.e. *new*; and an invention [i]s something *new* that c[an] also be referred to as a discovery." Seidel, *supra* note 3, at 13 (emphasis in original).

180. MUELLER, *supra* note 75, at 435.

to-file system would result in a decline in the quality of applicants because of hasty filings, as well as the filing of the applications containing less experimental data[,]" and "would result in the filing of a large number of applications which would otherwise not be filed."[181]

Additionally, changing to a first-to-file system risks incentivizing duplicative research efforts, which introduces inefficiency; if researcher B learns about researcher A's novel and possibly lucrative project, B has an incentive to abandon his own work, copy A's research, and file the patent application before A so that B can get the patent.

A first-to-file system also creates an incentive for more secrecy during research and development; because conception, diligence and reduction to practice would no longer be sufficient to get a patent—because the only relevant date will become the filing date—researchers will be covert about their research. They will be unwilling to discuss ideas openly or share thoughts or results for fear someone will co-opt their work. Academic research depends on, and flourishes with, this exchange of ideas. Adopting the first-to-file system threatens this integral idea of sharing that promotes science and knowledge.

### E. Experimental Use

Patent law contains certain limitations on a patentee's right to exclude others from practicing his invention.[182] These limitations include the experimental use exception, which provides that a patentee cannot exclude someone from using his patent if the other is using the patent "solely for research, academic or experimental purposes."[183] The Framers did not contemplate the experimental use exception, and, unlike in other countries,[184] the exception is not codified.[185] The exception is judge-made doctrine established by Justice Story in an 1813 case.[186] Subsequent courts

181. Donald R. Dunner, *First to File: Should Our Interference System Be Abolished?*, 68 J. PAT. & TRADEMARK OFF. SOC'Y. 561, 563-64 (1986) (arguing additionally that interference proceedings as we currently have them are not necessary).

182. *See* 5 DONALD S. CHISUM, CHISUM ON PATENTS § 16.03 (2006).

183. Madey v. Duke Univ., 266 F. Supp. 2d 420, 425 (M.D.N.C. 2001); Deuterium Corp. v. United States, 19 Cl. Ct. 624, 630 (1990).

184. MUELLER, *supra* note 75, at 336 n. 37 (detailing codified experimental use exceptions in French, German, English, and Japanese patent systems).

185. *Id.* at 336-37 (noting that pursuant to preparing and filing an Abbreviated New Drug Application ("ANDA") there is a limited experimental use exception for drugs in U.S. patent law, but no other provision is codified).

186. Whittemore v. Cutter, 29 F. Cas. 1120, 1121 (C.C. Mass. 1813) (No. 17,600) (stating that "it could never have been the intention of the legislature to punish a man, who constructed such a machine merely for philosophical experiments, or for the purpose of ascertaining the sufficiency of the machine to produce its described effects").

have reiterated that it is "now well settled, that an experiment with a patented article for the sole purpose of gratifying a philosophical taste, or curiosity, or for mere amusement, is not an infringement of the rights of the patentee"[187] because it was not possible to show "injury and damage" required for infringement.[188]

Although there is significant scholarly discussion on the experimental use exception,[189] the Federal Circuit in *Madey v. Duke University*[190] altered general conception about the extent and application of the experimental use exception.[191]

Duke University hired plaintiff Madey away from Stanford to become the director of a nuclear physics lab.[192] Shortly thereafter, he was asked to step down as lab director and left Duke.[193] Madey practiced three of his patents in his research at Duke, and, after he left, researchers continued to practice his patents despite his objections.[194] Madey sued Duke for patent infringement, Duke sought refuge under the experimental use exception, and then moved for summary judgment.[195] The district court held that Duke's actions did not show "intent [to] benefit commercially" from the patents, and granted Duke's motion for summary judgment.[196] The Federal Circuit reversed, holding:

> Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's

187. Poppenhusen v. Falke, 19 F. Cas. 1048, 1049 (C.C.N.Y. 1861) (No. 11,279).

188. Byam v. Bullard, 4 F. Cas. 934, 935 (C.C. Mass. 1852) (No. 2,262); *see Whittemore*, 29 F. Cas. at 1121.

189. *See* CHISUM, *supra* note 182, § 16.03 (2006) (providing an extensive and comprehensive overview). *See generally* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017, 1018-20 (1989); Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 17 (2001).

190. Madey v. Duke Univ., 307 F.3d 1351, 1352, 1361-63, 1364 (Fed. Cir. 2002).

191. *See generally* Janice M. Mueller, *The Evanescent Experimental Use Exemption from the United States Patent Infringement Liability: Implications for University and Nonprofit Research and Development*, 56 BAYLOR L. REV. 917 (2004).

192. *Madey*, 307 F.3d at 1352.

193. *Id.*

194. *Id.* at 1353.

195. *Id.*

196. Madey v. Duke Univ., 266 F. Supp. 2d 420, 428 (M.D.N.C. 2001).

> legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.
>
> In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.[197]

This strict language from the Federal Circuit effectively debars any functional or large-scale application of the experimental use exception.[198]

Universities and non-profits require funding to exist, which, according to the logic of the Federal Circuit, means that everything that happens within these organizations is "business." However, a university's main "business" is the very progress in science and the useful arts that the Constitution sought to promote. Patents should serve as a supplement to the spontaneously engaged-upon research of university scientists, not as a competition device or as an impediment to research. The Federal Circuit has unnecessarily restricted the experimental use exception, and the court seemed to indicate that no feasible use of any patent could ever be characterized as experimental, not even in a research university setting. Yet again, this shows the Federal Court's unwillingness to question patent scope for the purpose of facilitating research and knowledge. This is perhaps the most blatant example of the Federal Circuit ruling so as not to promote the progress of science.

197. *Madey*, 307 F.3d at 1362.

198. This decision by the Federal Circuit could be considered the logical extension of the Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-214 (2000 & Supp. V. 2005), which authorizes and encourages federally funded institutions and research projects to seek patents and participate in "patent commerce." Given that researchers performing basic science research (as opposed to applied science research) are participating in this "patent commerce," it would be difficult for the Federal Circuit to decide the other way and protect basic science research institutions from attaining licenses or paying royalties when they could eventually parlay that knowledge into a patent. Also, to establish a procedure for post-grant compulsory licensing when research with others' patents yields a patentable invention would be prohibitively complicated, messy and difficult to enforce. Certain scientists and researchers could sign agreements binding them to never seek a patent regardless of the fruits of their research efforts, which would therefore sufficiently distance them from "patent commerce." However, the Federal Circuit did not limit its decision to "patent commerce" but rather found a commercial value in contributing to the image of a university. Therefore, while the argument can be made that this decision is the logical fallout of the Bayh-Dole Act over which the Federal Circuit had no control, the Federal Circuit could have used a finer tool to draw these lines.

**F. Summary**

Each of these elements of patent law (disclosure, obviousness, utility, first-to-invent filing, experimental use) has one thing in common: each represents a focus on the economics of patenting rather than a focus on the science, research and knowledge that patenting is supposed to encourage. The proposed removal of best mode and change from first-to-invent to first-to-file are efforts to harmonize the United States patent system with international systems. Harmonization means that it will be easier for foreign applicants to avail themselves of the U.S. patent system and for U.S. patentees to exploit their inventions in foreign markets. Yet both of these changes fail to consider the implications for promoting the progress of science. Obviousness can be discounted if the invention has economic success. Similarly, utility is turning into an economic analysis: if a patent can be exploited, the Federal Circuit seems to assume utility.[199] While economic desirability undoubtedly establishes utility of a sort, the Framers did not intend mere economic utility to be the measure for patentability. Finally, experimental use is essentially no longer available to academia, because universities are considered too involved in commerce to receive protection for activities that occur in their research laboratories.

Economic concerns are a part of the incentive inherent in the patent right. Economic incentives make the patenting system function by making the procurement of a patent a goal and a palpable reward of research efforts. However, economic considerations currently seem to play too significant a role in the patent system; they are eclipsing the constitutional aims of promoting the progress of the useful arts. Patenting may be too focused on promoting economic benefits and not enough on the progress of science.

These examples, although merely vignettes within the complex patenting process, illustrate shifts away from the constitutional idea of patentability. There is a noticeable trend away from considering patents in terms of the constitutional objectives of the Clause. Whether this is merely Congress and the courts nibbling around the edges of the constitutional directive, or whether it represents a movement toward fiercely aligning scientific research and economics in contravention of concerns for promoting knowledge, is unknown. However, there appears a need for awareness, if not concern, for how the patent system is performing today.

199. *See, e.g.*, *In re Brana*, 51 F.3d 1560, 1565 (Fed. Cir. 1995). (applicant's favorable comparison of the functioning of its anti-tumor agent to other anti-tumor agents currently in-use is sufficient to satisfy the utility requirement).

## V. Effects and Solutions

Patent law is drifting from its constitutional anchor, which results in an out-of-balance patent system. The net benefit to society is diminished, patents are upheld that have been over-issued and under-deserved, and patents have become exceedingly robust, making it nearly impossible to invalidate their claims.[200] While the recent trend might turn out to be just that, simply reflecting the ebb and flow of the governmental interface with commercial enterprise, the recent proliferation of suggested reforms in light of the shifting role of the patent system suggests otherwise.

Many critics have written extensively suggesting reforms to the patent system. Similarly, congresspersons have introduced legislation to change the system, and several agencies have conducted studies assessing whether action is necessary.[201] Nevertheless, the U.S. patent system is a complex and integrated body of judicial, statutory, and constitutional law and impacts governmental agencies, industry, and millions of patentees. Proposed changes, several of which are surveyed below, must therefore be measured and thoughtful.

Authors Heller and Eisenberg published an article asking whether patents can deter innovation, specifically warning of the "tragedy of the anticommons" occurring in patent law.[202] The "tragedy of the anticommons" is the antithesis of the social and evolutionary phenomenon "the tragedy of the commons."[203] It results from having too many patents

200. This is both good and bad: it permits stability in the patent system, which means that more people will rely on it, and it may foster innovation and development. However, many patents issue that are not deserved. Because of this, a stronger patent right means that patents that never should have issued are filling up research space and contributing to the "patent thicket." This ultimately discourages research and innovation—the tragedy of the anticommons—and they do not necessarily fulfill to society the benefit of the bargain. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCIENCE 698, 701 (1998), *available at* http://www.sciencemag.org/cgi/reprint/280/5364/698.pdf.

201. *See, e.g.*, H.R. 34, 110th Cong. (2007); H.R. 977, 110th Cong. (2007); FTC Report, *supra* note 46; Committee on Intellectual Property Rights in the Knowledge-Based Economy, National Research Council, A Patent System for the 21st Century (Stephen A. Merrill, Richard C. Levin, & Mark B. Myers, eds., 2004), *available at* http://books.nap.edu/html/patentsystem/0309089107.pdf [hereinafter NRC Report]; Stephen Hansen, et al., American Association for the Advancement of Science, The Effects of Patenting in the AAAS Scientific Community (2d ed. 2006), *available at* http://sippi.aaas.org/survey/AAAS_IP_Survey_Report.pdf [hereinafter AAAS Report].

202. Heller & Eisenberg, *supra* note 200, at 698.

203. The "tragedy of the commons" theory espouses that resources that are commonly owned and generally available will be overused, depleted and then exhausted. Observance of the social phenomenon, currently most often applied to evolutionary, developmental, and behavioral biology, can be traced to Aristotle, although Garret Hardin popularized the theory in 1968. Garret Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243 (1968) *available at*

issued on certain technologies so that everyone is prevented from using the new discovery or invention because of the overlapping rights to exclude. This results in the discoveries and innovations becoming "underused."[204] Heller and Eisenberg suggest that where previously a discoverer or inventor would have felt entitled to co-authorship or a citation in a paper, he or she now feels entitled to a patent.[205] Because research is an additive process where one's research builds on the research of others, the "result has been a spiral of overlapping patent claims in the hands of different owners reaching ever further upstream."[206] Due to the difficulty of navigating numerous patents and obtaining license agreements, "[b]y conferring monopolies in discoveries, patents necessarily increase prices and restrict use—a cost society pays to motivate invention and disclosure."[207] Therefore, "[u]nable to procure a complete set of licenses, firms choose between diverting resources to less promising projects with fewer licensing obstacles or proceeding . . . on the basis of incomplete information."[208] These options for researchers do not ensure the progress of the useful arts in the best possible way. In fact, they may serve to inhibit research, which "may lead paradoxically to fewer useful products."[209]

The Federal Trade Commission (FTC) also explored these issues. Recently, the FTC issued a report about competition and patents.[210] Justifying its focus, the report stated that "[c]ompetition and patents stand out among the federal policies that influence innovation[:] . . . both . . . can foster innovation, but each requires a proper balance with the other to do so. Errors or systematic biases in how one policy's rules are interpreted and applied can harm the other policy's effectiveness."[211] The FTC report endeavored to "discuss[] and make[] recommendations for the patent system to maintain a proper balance with competition law and policy."[212]

Patent law and antitrust concerns have been inexorably linked since the drafting of the Constitution.[213] However, recently their relationship to each other has changed: "[w]e have replaced the 1970s pattern of weak

http://www.sciencemag.org/cgi/reprint/162/3859/1243.pdf.

204. Heller & Eisenberg, *supra* note 200, at 698.

205. *Id.*

206. *Id.*

207. *Id.* at 699.

208. *Id.*

209. *Id.* at 701.

210. FTC Report, *supra* note 46, at I n. 1.

211. *Id.* at 1.

212. *Id.*

213. *See, e.g.*, Letters between Madison and Jefferson, *in* LETTERS, *supra* note 33, at 512, 545, 566, 630.

patent law and strong antitrust law with a 1990s pattern of strong patent law and weak antitrust law."[214] After surveying a representative sample group,[215] the FTC made several conclusions: (1) "although most of the patent system works well, some modifications are needed to maintain a proper balance of competition and patent law and policy[,]"[216] (2) "questionable patents are a significant competitive concern and can harm innovation" by "rais[ing] the costs[,]" "increase[ing] 'defensive patenting' and licensing complications[,]"[217] (3) certain patenting laws and procedures raise competitive concerns,[218] and (4) more communication between the antitrust agencies and patent institutions is necessary.[219]

In recognition of these conclusions, the report made several recommendations on how to remedy the problem.[220] Most interestingly, the FTC report suggested creating "a new administrative procedure to allow post-grant review of and opposition to patents," to lower the presumed validity standard from "clear and convincing" to "preponderance of the evidence," to tighten the "obviousness" determination standard so that more patents can be considered obvious, to increase funding to the PTO (which receives money from the Federal Government but currently is self-funded by fees from patent prosecutors[221]), and to consider the consequences of extending[222] the scope of patentable subject matter before doing so. Interestingly, each recommendation involves either weakening the patent right or tightening the standards according to which patents are granted.

The FTC report's recommendations are stellar and, if enacted, would aid the enforcement of the constitutional aims of patent protection.

214. John H. Barton, *Patents and Antitrust: A Rethinking in Light of Patent Breadth and Sequential Innovation*, 65 ANTITRUST L.J. 449, 449 (1997).

215. The sample group included "business representatives from large and small firms, and the independent inventor community; leading patent and antitrust organizations; leading antitrust and patent practitioners; [] leading scholars in economics and antitrust and patent law[; and,] business representatives from mostly high-tech industries." FTC Report, *supra* note 46, at 3-4.

216. *Id.* at 4.

217. *Id.* at 5-7.

218. *Id.* at 15.

219. *Id.* at 17.

220. *Id.* at 7-17. The report makes ten recommendations total.

221. MUELLER, *supra* note 75, at 23 ("USPTO has been fully 'user fee-funded' for several years").

222. Note that two times recently the Federal Circuit has extended the scope of patentable subject matter. In 1980 the Federal Circuit extended it to living organisms. *Chakrabarty*, 447 U.S. at 316-17. In 1994 the extension was to programmed computers (encompassing business methods, too). *In re* Alappat, 33 F.3d 1526, 1544 (Fed. Cir. 1994).

Congress has already adopted the FTC's recommendation[223] to publish patent applications 18 months after the filing date.[224] However, most of the recommendations remain unobserved in our patent laws or even in the proposed 2005 legislation. Instead, the focus of the proposed legislation is on harmonizing the patent system internationally rather than ensuring it abides by its constitutional dictate.[225]

Similarly, the National Academies' National Research Council Committee on Intellectual Property Rights in the Knowledge-Based Economy, Board on Science, Technology, and Economic Policy, Policy and Global Affairs Division issued a report detailing the state of the patent system and reforms necessary to improve its functioning, entitled *A Patent System for the 21st Century*.[226] The report was issued in light of a realization that

> since 1980 a series of judicial, legislative, administrative, and diplomatic actions have extended patenting to new technology (biotechnology) and to technologies previously without or subject to other forms of intellectual property protection (software), encouraged the emergence of new players (universities and public research institutions), strengthened the position of patent holders vis-à-vis alleged infringers domestically and internationally, relaxed antitrust constraints on the use of patents, and extended the reach of patenting upstream from commercial products to scientific research tools, materials, and discoveries.[227]

The report also recognized that patent policy in the last 50 years had been influenced by those in the legal profession or the legislature, and endeavored to give the insights of businesspeople and scholars in the sciences and social sciences on the issue of patent reform.

After giving the reasons to issue the report[228] and the seven criteria used to evaluate the patent system,[229] the National Research Council recommended seven reforms to the patent system: (1) "preserve a flexible, unitary open-ended patent system,"[230] (2) "reinvigorate the non-

223. FTC Report, *supra* note 46, at 15.

224. The American Inventors Protection Act of 1999 established that most patent applications would be published 18 months after filing. *See* 35 U.S.C. § 122(b) (2000).

225. *See* Patent Reform Act of 2005, H.R. 2795, 109th Cong. (2005).

226. NRC Report, *supra* note 201, at 1-3.

227. *Id.* at 1.

228. *Id.* at 19-38.

229. *Id.* at 39-79.

230. *Id.* at 83.

obviousness standard,"[231] (3) "institute a post grant open review procedure,"[232] (4) "strengthen USPTO capabilities,"[233] (5) "shield some research uses of patented inventions from infringement liability."[234] (6) "limit the subjective elements of patent litigation,"[235] (7) "harmonize the U.S., European, and Japanese patent examination systems."[236] Several of these reforms, if enacted, would give proper balance to the patent system to prevent strain and keep it in congruence with the constitutional aims of patent protection.[237]

In 2005, the American Association for the Advancement of Science (AAAS) conducted a random survey of its membership's opinions regarding intellectual property patents.[238] The survey "provide[d] insights into the way scientists approach their own intellectual property, including their motivations to protect it."[239] The results of the survey suggest that "there may be some appreciable differences in the methods by which scientists in different fields and sectors protect and disseminate their intellectual property."[240] The study concluded that "it appears that academia has been less affected than industry by more restrictive formal licensing practices in the acquisition and distribution of patented technologies necessary for research" by a ratio of more than two to one.[241] However, respondents in industry also reported "creating and holding" more intellectual property, and relying more on licensing than respondents in academia.[242] Therefore, the differences in opinion can be explained by industry's and academia's relative interactions with the patent system. This, however, may gradually change as a result of the holding in *Madey*[243] and the Bayh-Dole Act,[244] as academics participate increasingly in the

231. *Id.* at 87.

232. *Id.* at 95.

233. *Id.* at 103.

234. *Id.* at 108.

235. NRC Report, *supra* note 201, at 117.

236. *Id.* at 123.

237. *Id.* at 1-8.

238. AAAS Report, *supra* note 201, at 5.

239. *Id.* at 6.

240. *Id.*

241. *Id.* at 8 (stating that industry is more than two times more affected than academia by patenting concerns).

242. *Id.* at 9.

243. Madey v. Duke Univ., 307 F.3d 1351, 1362 (Fed. Cir. 2002) (limiting the use of the experimental use exception so that it is unavailable to researchers in academia).

244. 35 U.S.C. §§ 200-214 (2000 & Supp. V.2005) (authorizes and encourages federally funded institutions and research projects to seek patents and participate in "patent commerce");

patent system.

There is also patent reform legislation pending before Congress that would alter patenting. Representatives Xavier Becerra (D-CA) and Dave Weldon (R-FL) co-sponsored the re-introduction of the Genomic Research and Accessibility Act which would remove human genetic material from the scope of patentable subject matter.[245] In a press release announcing the legislation, Reps. Becerra and Weldon highlighted the mounting evidence that DNA patents are impeding genetic and medical research. Rep. Weldon stated that

> the practice of gene patenting is preventing critical research from advancing because scientists are wary of trespassing patent laws, [which] not only violates the spirit of the Human Genome Project, [but also] hinders the discovery of medical breakthroughs that could save lives. [The] bill is a common sense measure to ensure that genes yet unpatented remain the province of science.[246]

Rep. Becerra supported the bill saying that "[they] seek simply to fix a regulatory mistake. Genes are a product of nature; they were not created by man, but instead are the very blueprint that creates man, and thus, are not patentable. Gene patenting would be the analogous equivalent to patenting water, air, birds or diamonds."[247] Although the representatives' statements in the press release are not entirely accurate, this legislation represents an attempt to cure a perceived problem, namely that the scope of patent issuing has become too broad.

Other legislation includes a bill introduced by Rep. Darrell Issa (R-CA) currently in the Senate that was passed by the house on January 12, 2007.[248] The bill proposes "to establish a pilot program in certain United States district courts to encourage enhancement of expertise in patent cases

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*see* comments at note 198, *supra*.

245. H.R. 977, 110th Cong. (2007) (introduced "to amend title 35, United States Code, to prohibit the patenting of human genetic material"). In 2002 a similar bill was sponsored by Rep. Lynn Rivers (D-MI) entitled the Genomic Research and Diagnostic Accessibility Act that was intended "to amend title 35, United States Code, to provide for noninfringing uses of patents on genetic sequence information for purposes of research and genetic diagnostic testing, and to require public disclosure of such information in certain patent applications," but it never became law. H.R. 3967, 107th Cong. (2002).

246. Reps. Becerra and Weldon Introduce Bill to Ban the Practice of Gene Patenting, http://weldon.house.gov/News/DocumentSingle.aspx?DocumentID=57930 (last visited March 6, 2007).

247. *Id.*

248. H.R. 34, 110th Cong. (2007). This bill has been passed by the House, received and read twice by the Senate, and referred to the Committee on the Judiciary. http://www.govtrack.us/congress/bill.xpd?bill=h110-34 (last visited November 20, 2007).

among district judges."[249] If passed, this bill would make at least five district courts into patent expert courts by providing them with additional education regarding patent cases and receiving extra money to pay for more law clerks who are ready to assist in patent cases.

This pending legislation presents a mixed blessing for ensuring the constitutionality of patent law. The creation of the Federal Circuit in 1982[250] has had a significant impact on patent law by strengthening the patent right and making litigation more predictable and streamlined.[251] It is logical to assume that the creation of specialized district courts would have similar effects on the patent right. The positive effects from this legislation will be that patent infringement cases will receive a more sophisticated analysis, patent litigation will be more predictable, and patent rights will be better and more strongly enforced. However, these phenomena will be negative if the current infirmities in the patent system continue to exist. Therefore, if this legislation passes, it will become more imperative for Congress and the courts to address the growing concerns about patents.

## VI. Conclusion

The patent system has transformed dramatically over the last several years, and Congress is prepared to institute more changes to the Patent Act. Overall these changes have promoted grating patents and have strengthened patent rights. Even though patent filing numbers have increased at nearly exponential rates,[252] it is not conclusive that grants of patents have encouraged research or incentivized innovation.[253] Instead, some argue that the patent right has led to less innovation because it is impeding research,[254] and the strength of the right has stifled competition,[255] which is the most efficient and trusted way to encourage innovation.[256] The Clause in the Constitution requires at a minimum all patent protection to promote the progress of the useful arts. Both Congress and the courts need to reassess current patent protection and institute reforms that will maintain the *quid*

249. *Id.*

250. *See* Federal Courts Improvement Act of 1982, Pub. L. No. 97-164, 96 Stat. 37, 37 (1982).

251. *See* Barton, *supra* note 214, at 1.

252. James, *supra* note 7, at 98-100.

253. *See* Heller & Eisenberg, *supra* note 200, at 698, 701.

254. *Id.* at 698.

255. *See* Barton, *supra* note 214, at 464, 466.

256. AREEDA , *supra* note 8, at 5. This source also notes that non-patent incentives are often sufficient to recoup research costs and to provide sufficient profit to inventors before competitors enter the market so that innovation is encouraged. *Id.* at 105.

*pro quo* of patenting and satisfy the constitutional aims. To achieve this, Congress and the courts should enact at least some of the above suggestions.

The presumption of patent validity, or the standard by which validity must be disproved, should be lowered. This would enable the courts to demand closer adherence to the best mode disclosure requirement, to dismiss patents without significant utility, and to ensure inventions are non-obvious in light of prior art. This way the public can be certain to receive the benefit of the bargain. Congress should not legislate to eliminate best mode disclosure or to create a first-to-invent system: although the incentives to create a uniform international system are great, they do not, and must not, supersede the Constitution's dictates. Congress should legislate to heighten the patent standards. Specifically, Congress should reformulate the standard for obviousness determinations, as per the detailed suggestions in the FTC and NRC reports,[257] and should strengthen the utility requirement.

Additionally, as the reports suggest, the scope of patentable subject matter should be reconsidered. Biotechnology presents significantly more patent concerns than do other technologies.[258] Before the field is

257. *See* FTC Report, *supra* note 46, at 7-17; NRC Report, *supra* note 201, at 1-8.

258. The field of biotechnology is fundamentally different and presents problems for patents not present in software, for example. Biotechnology is an "unpredictable art," where patented technologies are not only products of hard work, but also are the actual tools for research, the pathways of biological processes, and components of life. *See* Barton, *supra* note 214, at 449. Biotechnology patenting deals with particularly complex and mutating matter, morality, and large sums of money and for these reasons it is complex. It was only just over fifty years ago that Watson and Crick discovered the structure of DNA. J.D. Watson & F.H.C. Crick, *A Structure for Deoxyribose Nucleic Acid*, NATURE, April 25, 1953, at 737-38; *see generally* JAMES D. WATSON, THE DOUBLE HELIX: A PERSONAL ACCOUNT OF THE DISCOVERY OF THE STRUCTURE OF DNA 73-100 (Touchstone, 2001) (1968). Subsequent advances such as cell lines, animal models, and cell transfecting techniques have rapidly advanced the field. Peter Gwynne & Gary Heebner, *Advances in: Genomics*, SCIENCE, Oct. 14, 2005, at 349-351. Regardless of the recent changes, however, the nature of biotechnology introduces certain complications into the patenting process.

First of all, biotechnology involves elements and materials for encoding, creating, and mutating living organisms, including humans. For this reason alone, many believe that the field presents substantive and moral challenges not present in other fields. Substantively, because patent law prohibits granting patents on living organisms, because, as products of nature, ,they are naturally occurring and not man-made, and therefore they have not been "invented" but merely "discovered." *See* 35 U.S.C. § 101 (2000). There are moral issues as well, because some people find it threatening or offensive to think that life, or subcomponents of life, can be patented or owned—they worry it is one step closer to cloning humans.

For example, two researchers filed for a patent on a chimeric organism (part human part non-human, non-primate). *See* USPTO: Still No Patent on Life Containing Human Cells, http://patentlaw.typepad.com/patent/2005/02/uspto_still_no_.html (last visited March 7, 2007); Rick Weiss, *US Denies Patent for Part-Human Hybrid*, BOSTON GLOBE, Feb. 13, 2005, http://www.boston.com/news/nation/washington/articles/2005/02/13/us_denies_patent_for_part_

completely littered and obscured by patents, Congress must re-evaluate the wisdom of extending the protection. Perhaps biotechnology patents should be treated under a different patenting rubric entirely.

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human_hybrid/ (last visited March 7, 2007). Although this organism complied with every statutory requirement for patentability (based on the broad scope of patentable subject matter for life forms created by *Diamond v. Chakrabarty*, 447 U.S. 303, 316-17 (1980)), it was nevertheless rejected during prosecution. The reason cited was that humans are not patentable subject matter. The researchers have not appealed the decision. However, myriad patents exist on living mice and other animals, and the chimera patent was only for an animal containing some human DNA. Although the patent rejection was never appealed, it shows that there is something fundamentally different about patenting life, particularly when it approaches human life.

Also, pending legislation in the House proposes removing the human genome from the scope of patentable subject matter. Genomic Research and Accessibility Act, H.R. 977, 110th Cong. (2007). Although the Human Genome Project attempted to take human genetic material out of the scope of patentability by establishing it as prior art, human genes are already widely patented. The prospect of patented human material makes many uncomfortable. These patentability concerns highlight differences people perceive when patents encroach upon human biology. Patenting human life is different. Concerns about morality and ethics regarding the invention arise in the field of biotechnology, concerns not present when patenting software.

Additionally, the field is unique because the claimed material in biotech patents is exceedingly technical, which makes patent prosecution and claim construction during litigation challenging. Further, different labs that perform the same experiments with the same methods may yield varying or even contradictory results. Occasionally cell lines or bacteria strains mutate in unexpected ways, which furthers the difficulties of patenting inventions. Also, biological research is often unpredictable and seemingly random. There are issues "such as [] filing date, deposits of biological material, . . . [the] existence of company documents and published works," and varying discovery processes between "inventions developed through basic research as opposed to those developed through applied research" that significantly affect patenting. James, *supra* note 7, at 142.

Exploiting a biotechnology patent can generate billions of dollars of annual revenue for the assignee. In 1997, Amgen received profits of roughly $1.1 billion from its patent covering the anti-coagulant EPO. *See* Answers.com, Amgen, Inc. Company History, http://www.answers.com/topic/amgen-inc (last visited March 6, 2007). Litigation disputes can involve "millions of dollars in biotechnology research and investments, and billions of dollars in future revenue," James, *supra* note 7, at 141, and many biotech companies carry their worth in their patents. *Id.* at 97. *See* Council for Responsible Genetics, DNA Patents Create Monopolies on Living Organisms (April 2000), http://www.actionbioscience.org/genomic/crg.html (last visited March 6, 2007) (discussing the recent rapid developments in biotechnology and how these patents are used by scientists and corporations for commercial profit and for private exploitation). Biotechnology research is expensive, *see* e.g., B.U. Sch. Med. Dep't Genetics and Genomics, Microarray Resource: Pricing, http://gg.bu.edu/microarray/pricing.htm (last visited March 6, 2007) (stating that the cost of running a single microarray experiment can cost up to one thousand dollars), but nevertheless, biotech companies spend more of their revenue derived from patents on advertising than on continued research and development, or making up for costs associated with the drug approval process.

Finally, United States' patent practices are inextricably bound with the health care industry. Although far too complex a topic to explore here, increasing numbers of patents on pharmaceuticals and medical devices, as well as the increased costs of research in the biotechnology arena due to the high number of patents on research tools, inevitably increases the costs of health care and treatment. For this reason too, the biotech research area should be considered differently.

Finally, if patents continue to be issued for under-deserving inventions, and, especially in biotechnology where many research tools are patented, continue to impede the execution of research, the experimental use exception must be reinvigorated. Without it, it is foreseeable that academic institutions and scientific journals will begin to perish because the only thing driving researchers will be patents, rather than publishing and contributing to the pool of knowledge.

Most importantly, our patent laws and enforcement systems must place a greater emphasis on granting patents that will further constitutional objectives rather than further "patent commerce." As Justice Douglas noticed in 1950:

> The attempts through the years to get a broader, looser conception of patents than the Constitution contemplates have been persistent. The Patent Office, like most administrative agencies, has looked with favor on the opportunity which the exercise of discretion affords to expand its own jurisdiction. And so it has placed a host of gadgets under the armour of patents—gadgets that obviously have had no place in the constitutional scheme of advancing scientific knowledge. [There is] pressure to extend monopoly to the simplest of devices.[259]

In 2007, the phenomenon of which Justice Douglas warned has become widespread. The legislatures must pass laws, and the PTO and courts must strictly enforce those laws, to ensure that patent rights do not extend to the "simplest of devices" or the most basic tools of research.

259. Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp., 340 U.S. 147, 156 (1950) (Douglas, J., concurring).