

Addressing the Patent Gold Rush: The Role of Deference to PTO Patent Denials

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Patents have rarely captured the legal imagination. Patent law has been seen as an abstruse area, best left to a few specialists trained in the technical arcana of claim drafting and interpretation. With the advent of the information economy, however, one conventional wisdom with respect to patents is being overturned. Even for those who would rather do so, it is difficult to ignore the headlong rush to claim patent rights in the two dynamic, rapidly evolving industries that undergird the information economy—biotechnology and computer technology.¹ After all, inventions long thought “unpatentable”—everything from gene sequences of unknown

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1. See, e.g., Eliot Marshall, *Patent Office Faces 90-Year Backlog*, 272 SCI. 643 (1996) (discussing patent applications that have been filed on hundreds of thousands of DNA sequences); Rodney Ho, *Patents Hit Record in '98 as Tech Firms Rushed to Protect Intellectual Property*, WALL ST. J., Jan. 15, 1999, at A2 (noting that 151,024 patents were issued in 1998, a “staggering” 33% jump from 133,720 in 1997 and that much of the increase was due to growing acceptance of computer-related patents); Lori Valigra, *Genomics at Heart of Revolution in Corporations, Global Economy*, BIOTECHNOLOGY NEWSWATCH, Aug. 17, 1998 (reporting that the United States Patent and Trademark Office (PTO) received 4000 requests for patents on nucleic acid sequences in 1991 and 500,000 in 1996); Raymond Van Dyke, *Software Patents Offer Opportunities and Obstacles*, NAT'L L.J., May 24, 1999, at C19, C20 (observing that data processing and computer group of the PTO issued up to 40% more patents in 1998 than in 1997 and that Internet patents “exploded from a mere nine in 1991 to about 1600 in 1998”). Within the computer program category, one particularly controversial area where patent filings are mushrooming is business concepts and methods. See Robert P. Merges, *As Many As Six Impossible Patents Before Breakfast: Property Rights For Business Concepts and Patent System Reform*, 14 BERKELEY TECH. L.J. 577 (1999) (discussing growth in business method patents); Gregory J. Maeir et al., *Patent Protection Provides Long-Term Net Strategy*, NAT'L L.J., Oct. 18, 1999, at B11 (noting comment by PTO Commissioner Todd Dickinson that the PTO has, since 1998, experienced a 700% increase in the number of filings on software and business-method patents).

My claim that biotechnology is a central part of the information economy may, at first blush, appear anomalous. However, because biotechnology is founded on DNA and DNA is ultimately just information, biotechnology is clearly an information industry.

function to one-step purchasing over the Internet—are now being claimed as property. For many, the race to patent such products and processes raises the specter of tightly restricted information flow and retarded innovation and development, in these economically vital industries.²

The proliferation of high-technology patents directly implicates the two institutions that are primarily responsible for administering the patent system—the United States Patent and Trademark Office (PTO), which grants patents, and the Court of Appeals for the Federal Circuit (CAFC), which hears all patent appeals.³ Thus far, however, commentators have tended to focus not on the institutional actors but rather on change in the substantive patent law.⁴ Moreover, even those who have begun to address the role of institutions have concentrated on the PTO, largely to the exclusion of the CAFC and the relationship between the CAFC and the PTO.⁵ In failing to address

2. See *infra* notes 19-20, 47-49 and accompanying text. For a creative and wide-ranging critique of the growing “proprertization” of information, see generally JAMES BOYLE, SHAMANS, SPLEENS, AND SOFTWARE (1996).

3. The CAFC hears two different types of patent appeals: direct appeals from PTO patent denials and appeals from district court decisions regarding patent infringement. This Article focuses on appeals from PTO patent denials.

4. In the computer program context there has been a plethora of articles addressing how the terms of the patent statute should be applied and/or altered. See, e.g., Vincent Chiappetta, *Patentability of Computer Software Instruction as an “Article of Manufacture:” Software As Such as the Right Stuff*, 17 J. MARSHALL J. COMPUTER & INFO. L. 89, 95 (1998) (arguing that the test for whether a software invention constitutes patentable subject matter should turn on whether the software is being used for technological purposes); Julie Cohen, *Reverse Engineering and the Rise of Electronic Vigilantism: Intellectual Property Implications of “Lock-Out” Programs*, 68 S. CAL. L. REV. 1092, 1168 (1995) (arguing for an interpretation of the nonobviousness standard that excludes from consideration the mathematical algorithm component of the computer software); Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308 (1994) (calling for sui generis protection of computer programs); Pamela Samuelson, *Benson Revisited: The Case Against Patent Protection for Algorithms and Other Computer Program-Related Inventions*, 39 EMORY L.J. 1025 (1990). The biotechnology literature has not been as voluminous. Nonetheless, several commentators have criticized the interpretations of the patent statute rendered by the CAFC. Compare Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615 (1998) (arguing that the CAFC’s interpretation of patentability requirements has been too strict), with Philippe Ducor, *Recombinant Products and Nonobviousness: A Typology*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 31-49 (1997) (arguing that CAFC’s approach to patentability has been too lax).

5. See, e.g., Merges, *supra* note 1, at 611-15; Mark D. Janis, *Rethinking Reexamination: Toward a Viable Administrative Revocation System for U.S. Patent Law*, 11 HARV. J.L. &

the relationship between the CAFC and the PTO, particularly in the context of CAFC review of PTO patent denials, commentators ignore several important historical and institutional realities. First, the CAFC's reversal of PTO decisions denying patent protection to certain biotechnology and computer program inventions has been a major reason for the recent proliferation of patents. Second, given the CAFC's frequent exercise of its ability to reverse PTO patent denials, PTO reform will, on its own, likely be insufficient. Third, at least for the time being, the most prudent course for addressing patent proliferation may not be a significant change in substantive patent law.

The absence of attention to the proper role of the CAFC in reviewing PTO decisions denying patentability reflects a larger tendency among patent law scholars to ignore the application of administrative law principles to patent law. Similarly, the CAFC itself has refused to apply administrative law principles to its review of PTO decisions denying patentability. The recent explosion of patent filings in biotechnology and computer software highlights the importance of determining how administrative law principles such as deference should apply to the relationship between the CAFC and the PTO. Deference implicates considerations of institutional competence, and such considerations should figure prominently in any inquiry regarding how the law should engage technologically complex, rapidly expanding industries.

This Article analyzes the CAFC and PTO as an integrated institution.⁶ From that perspective, although the Article strongly

TECH. 1 (1997); Allan M. Soobert, *Breaking New Grounds in Administrative Revocation of U.S. Patents: A Proposition for Opposition—and Beyond*, 14 SANTA CLARA COMPUTER & HIGH TECH. L.J. 63 (1998). One notable exception is Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 56 OHIO ST. L.J. 1415 (1995). Professor Nard makes a general argument in favor of deference to the PTO's factual and legal determinations. His argument, however, does not focus on the role of the CAFC in reversing PTO patent denials or on the particular issues raised by patenting in rapidly evolving industries such as biotechnology or computer software.

6. A caveat on the scope of the Article should be noted at the outset. Although I propose modest institutional changes in the context of the CAFC's direct review of PTO patent denials. I take as given the basic institutional structure of the patent system. In other words, I do not, for the purposes of this Article, challenge the need for an expert administrative agency that grants patents and a specialized court that constructs a uniform body of appellate law regarding patents. For an early assessment of the Federal Circuit as an experiment in specialized courts, see Rochelle Cooper Dreyfuss, *The Federal Circuit: A Case Study in Specialized Courts*, 64

endorses recent proposals for significant PTO reform, it also argues that PTO reform will not be sufficient. In addition to PTO reform, a reexamination of the relationship between the CAFC and the PTO is needed. With respect to this relationship, considerations of institutional competence—particularly institutional resources and expertise—suggest that the CAFC should be wary of reviewing independently PTO's decisions denying patentability. The CAFC's review should be particularly deferential when the denial is based on a determination that the invention is "obvious"—that is, not truly new. Deference to patent denials is warranted moreover, even if the PTO continues to have skewed incentives as well as limitations on its own resources and expertise: these limitations will tend systematically to produce errors in patent *grants*, not patent denials. Indeed, as a consequence, PTO reform will be much more important for ensuring valid PTO patent grants than for ensuring valid PTO patent denials.

The Article proceeds in three parts. Part I identifies the factors that have led to the current state of patent filings, arguing that the evidence points squarely towards certain questionable CAFC decisions that reversed prior denials of patentability by the PTO. Part II discusses why the most effective approach to the patent problem will involve a combination of PTO reform and greater deference to PTO decisions denying patentability. This Part stresses the importance of deference with respect to the patentability requirement of nonobviousness, which is likely to play the central gatekeeping role in limiting excess patenting in both biotechnology and computer software. Part III then addresses the administrative law doctrines through which greater deference to the PTO patentability denials could, and should, be implemented.

I. EXPLAINING THE PATENT GOLD RUSH: THE CAFC'S ROLE

I begin by discussing how the CAFC's reversal of PTO decisions constraining patentability in the areas of biotechnology and computer technology has led to the current plethora of patents and patent filings. In biotechnology the patent proliferation is a result of the

CAFC's disagreement with the PTO over DNA-based inventions. Specifically, the CAFC's treatment of DNA-based inventions as just another species of chemical compound has substantially diminished the balance between property rights and the public domain achieved by various patentability requirements—most importantly the requirement of nonobviousness.

Nonobviousness balances patent rights and the public domain by excluding from patentability subject matter that “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.”⁷ Showing that an invention is “obvious to try” does not defeat patentability.⁸ Rather, there must be a “reasonable likelihood of success” that a workable invention will emerge.⁹ In the context of an ordinary chemical compound, the nonobviousness requirement is

7. 35 U.S.C. § 103 (1994). Nonobviousness is the most litigated issue related to patent validity. DONALD CHISUM, CHISUM ON PATENTS § 11-06 (1999). It has been called the “ultimate condition of patentability.” NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1980). A recent study by Paul Allison and Mark Lemley indicates that 42% of patents that are held invalid in litigation are invalidated on grounds of nonobviousness. John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 204 (1998). To a lesser but nonetheless important extent, the novelty requirement protects the public domain by excluding from patentability an invention that is already “known or used” or “described in a printed publication” at the time that the patent application is filed. See 35 U.S.C. § 102(a) (1994). The Allison and Lemley study indicates that 26.8% of patents that are held invalid in litigation are invalidated on novelty grounds. *Id.* In addition to novelty and nonobviousness, the requirements of patentable subject matter, utility, and enablement also play some role in balancing property rights and the public domain. *Id.* §§ 101, 112. The patentable subject matter requirement excludes from patentability abstract scientific and mathematical principles, thus allowing these “basic tools” of science and technology to be available for all scientists to draw upon. See *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972). *But see* *infra* 31-42 and accompanying text (discussing CAFC's virtual elimination of this requirement in the area of computer programs). The utility requirement also serves to exclude abstract principles from patentability. See *Brenner v. Manson*, 383 U.S. 519 (1966). Finally, the enablement requirement limits the patentee to the range of invention that she has disclosed “in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same” 35 U.S.C. § 112 (1994).

8. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

9. See, e.g., *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988). Allowing patentability when there is no “reasonable likelihood of success” that a workable invention will emerge can be particularly important in biotechnology, where the results of experimentation are often unpredictable or uncertain. For a discussion of the relationship between uncertainty and the nonobviousness standard, see Robert Merges, *Uncertainty and the Standard of Patentability*, 7 HIGH TECH. L.J. 1 (1992).

satisfied so long as there is no structurally similar compound in the prior art.¹⁰ In ordinary chemistry there are good scientific reasons for having a nonobviousness standard focused on structure: the properties of chemical compounds are notoriously difficult to predict, and one of the few rules of prediction available to the chemist is that structurally similar compounds have similar properties. Thus, as a general matter, a chemist is likely to be able to synthesize a chemical compound with a particular set of useful properties only if she is already aware of a structurally similar compound that has similar properties.¹¹ Conversely, a chemist who synthesizes a compound with a particular set of useful properties even though there is no prior available information regarding structurally similar compounds with similar properties is likely to have invented a nonobvious product.

This chemical compound-based logic does not apply, however, to DNA sequences. Although DNA sequences represent chemical compounds, they are more fundamentally carriers of information. For example, in order to isolate a particular DNA sequence that codes for a particular protein, there is no need to start with a structurally similar DNA sequence. Rather, as the PTO has pointed out, because of the informational link between proteins, amino acids, and DNA, knowledge of the protein's complete or partial amino acid sequence can be used to obtain the desired DNA sequence.¹² To put the point another way, the current state of scientific knowledge renders the DNA sequence for a given protein obvious once the protein's

10. See, e.g., *In re Dillon*, 919 F.2d 688, 692 (Fed. Cir. 1990).

11. *Id.* at 693. See also Robert Blackburn, *Evolving Patent Law in the New Age of Biomedical Science*, 4 TEX. REV. L. & POL. 87, 88 (1999) (noting that in traditional pharmaceutical chemistry, the chemist makes many derivatives of a given "lead compound" that has a desirable activity in the hope of finding a derivative that has similar activity but can be manufactured more efficiently).

12. The informational link between proteins, amino acids, and DNA operates as follows. Proteins comprise amino acids that are bonded together covalently. There are a total of twenty possible amino acids that can form proteins. The particular amino acids that form any given protein along with the sequence in which the amino acids are bonded together determine the function of the proteins. Therefore, in order to assemble a protein, an organism needs information about which amino acids should be used and the order in which the amino acids should be assembled. A gene stores this information in subunits called nucleotide bases. The four nucleotide bases are adenine, guanine, cytosine, and thymine (usually abbreviated as A, G, C, and T respectively). A gene is a sequence of these bases and each three-base component of the gene sequence codes for an amino acid. See generally KENNETH J. BURCHFIELD, *BIOTECHNOLOGY AND THE FEDERAL CIRCUIT* 17-20 (1995).

complete or partial amino acid sequence is known.¹³

Nonetheless, despite the PTO's arguments to the contrary, the CAFC has applied chemical compound-based logic wholesale to DNA inventions.¹⁴ In overturning PTO determinations regarding nonobviousness, the CAFC has said that DNA sequences are obvious only if there is a structurally similar DNA sequence in the prior art.¹⁵ Under the CAFC's contorted logic, a DNA sequence can be nonobvious even though the information necessary for isolating the sequence is publicly available.¹⁶ This very significant lowering of the standard for nonobviousness has resulted in a situation where many biotechnology companies are seeking patents on hundreds of thousands of DNA sequences of unknown or speculative function that they have been able to isolate quickly through routine, automated

13. See *Ex parte Deuel*, 33 U.S.P.Q. 2d 1445, 1447 (Bd. Pat. App. & Int'f 1993) (noting views of PTO patent examiners that "when the [amino acid] sequence of a protein is placed into the public domain, the gene is also placed into the public domain because of the routine nature of cloning techniques").

14. Perhaps not surprisingly, the author of the relevant opinions, Judge Lourie, holds a Ph.D. in chemistry (as contrasted with molecular biology or biochemistry). See *ALMANAC OF THE FEDERAL JUDICIARY* (Christine Houser ed., 1999). For a discussion of why the CAFC is not particularly well equipped to handle specific technical questions despite its concentration in the area of patents and the fact that some of its judges have technical backgrounds, see *infra* note 64 and accompanying text.

The CAFC's decisions expanding the scope of patentability in biotechnology and computer software may be the result not only of institutional competence limitations but also of a systematic bias in favor of patent applicants. See, e.g., Donald R. Dunner et al., *A Statistical Look at the Federal Circuit's Patent Decisions: 1982-1994*, 5 *FED. CIR. B.J.* 151, 154 (1995) (noting that the CAFC is "much more likely to affirm district court judgments in favor of patent owners than accused infringers"). Various commentators have discussed the danger of bias faced by specialized courts. See, e.g., Dreyfuss, *supra* note 6, at 3; RICHARD POSNER, *THE FEDERAL COURTS* 157 (1985). See also Thomas W. Merrill, *Capture Theory and the Courts: 1967-1983*, 72 *CHI.-KENT L. REV.* 1039, 1069 (1997) (noting that "modern public choice theory regards not just administrative agencies but also legislatures, the President, and to an increasing degree even the courts, as institutions that should be modeled on the assumption that they seek to maximize their self-interested ends . . .") (emphasis added).

15. See *In re Deuel*, 51 F.3d 1552, 1557-58, 1559 (Fed. Cir. 1995) ("Because *Deuel* claims new chemical entities in structural terms . . . a prima facie case of obviousness is based upon structural similarity, i.e. an established structural relationship between a prior art compound and the claimed compound. . . . The PTO's focus on known methods for potentially isolating the claimed DNA molecules is . . . misplaced because the claims at issue define compounds, not methods.") (citations omitted).

16. See Rebecca S. Eisenberg & Robert P. Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial cDNA Sequences*, 23 *AIPLA Q.J.* 1, 32 (1996) (noting that the CAFC's approach "would seem to make all novel DNA sequences patentable, however trivial the scientific advance that led to their identification").

methods.¹⁷ The CAFC's interpretation of nonobviousness has thus skewed the balance between property rights and the public domain quite significantly against the public domain.¹⁸ Moreover, there is reason to believe that forcing future researchers to navigate a thicket of property rights obstacles, particularly in the context of relatively basic scientific information, will impede scientific research and development.¹⁹ Notably, in overturning the PTO's denials of patentability, the CAFC has shown no deference; indeed, it has not even suggested that principles of deference might apply.²⁰

17. See, e.g., Marshall, *supra* note 1 (noting that the biotechnology company Incyte claims to have filed applications on over 400,000 DNA sequence fragments). Proposed guidelines on utility recently issued by the PTO indicate that gene fragments of unknown function will be denied patentability for failure to show utility. See REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS 50-53. The problematic position on nonobviousness enunciated by the CAFC is still the law, however, and would apply to any DNA sequences that met the utility standard.

18. In contrast with its use of the nonobviousness requirement, the CAFC has used the written description requirement (which requires that the patentee convey with "sufficient detail that one skilled in the art can clearly conclude that the 'inventor' invented the claimed invention") in a manner that somewhat raises patentability standards. Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997). The *Lilly* case is consistent with *Deuel* in that both cases view DNA-based technology as a subset of chemical technology. For further discussion of the *Regents* case, see Arti K. Rai, *Intellectual Property Rights in Biotechnology: Addressing New Technology*, 34 WAKE FOREST L. REV. 827, 834-35 (1999). It is important to note, however, that this raising of the patentability standard in the context of the written description requirement does not by any means counterbalance the effect on the public domain of the CAFC's having virtually eliminated the nonobviousness standard with respect to DNA. While the elimination of the nonobviousness standard allows for a vast proliferation of patents on relatively trivial inventions, the fortification of the written description requirement serves merely to narrow the scope of the claims that can be made for some of these inventions. Even with narrow claims the patent owner can still exert an inefficient level of control over future research. For further discussion of this issue, see Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 141 (1999).

19. For arguments that the proliferation of property rights in basic biomedical research will impede scientific progress, see Rai, *supra* note 18, at 120-35; Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

20. See *In re Deuel*, *supra*; *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993) (failing to mention deference in overturning PTO determination that DNA sequence in question was obvious). Moreover, in other nonobviousness cases the CAFC has specifically rejected deference to the PTO's final decisionmaking body, the Board of Patent Appeals and Interferences. According to the Federal Circuit, because nonobviousness is a question of law, there should be no deference. See, e.g., *In re Donaldson*, 16 F.3d 1189, 1192 (1994) ("Obviousness under section 103 is a question of law that this court reviews de novo."); *In re McCarthy*, 763 F.2d 411, 412 (Fed. Cir. 1985) ("Obviousness is a conclusion of law. It is our responsibility, as for all appellate courts,

The profusion of patent filings in the area of computer programs can also be traced (albeit somewhat less directly) to the CAFC's disagreements with the PTO. In order to understand these disagreements, one must examine the historical development of the area. Prior to the formation of the CAFC in 1982,²¹ the patent law's focus on applied technology—a focus embodied in the Constitutional requirement that patents are to be granted only on the “*useful Arts*” and in the Congressional definition of patentable subject matter as a “*useful process, machine, manufacture, or composition of matter*”²²—was applied by the courts to exclude most mathematical algorithms, and hence most computer programs,²³ from the domain of patentable subject matter. Algorithms/computer programs were seen as similar to abstract scientific principles or ideas—in other words as “basic tools” of science and technology that all researchers should be free to use. For example, in the 1972 case *Gottschalk v. Benson*,²⁴ the Supreme Court rejected a patent on a computerized method for converting decimal numbers to binary numbers on the grounds that patent principles did not apply to abstract scientific or mathematical principles, including mathematical principles embodied in computer software.²⁵ In the 1981 decision *Diamond v. Diehr*, the Court narrowed *Gottschalk* by upholding as patentable subject matter a rubber-curing process that centered around using software (specifically, software that implemented the Arrhenius equation) to

to apply the law correctly, without deference to Board determinations, which may be in error even if there is a rational basis therefor.”). In addition, the CAFC has argued that the Supreme Court's main analytical framework for deference to administrative agencies, found in *Chevron v. Natural Resources Defense Council*, 487 U.S. 835 (1984), should not apply to PTO decisionmaking, whether issued through rulemaking or adjudication. See *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (*Chevron* deference inapplicable to PTO rulemaking); *In re Portola Packaging, Inc.*, 110 F.3d 786, 788 (Fed. Cir. 1997) (*Chevron* deference inapplicable to PTO adjudication).

21. The legislation that created the CAFC, the Federal Courts Improvement Act of 1982, 28 U.S.C. §§ 41-144 (1994), was driven by Congress' desire to unify and strengthen the patent law in the face of the forum shopping and the uncertainty that resulted from the widely divergent patent decisions of the various regional federal courts of appeal. See generally Dreyfuss, *supra* note 6, at 6-7.

22. 35 U.S.C. § 101 (1994) (emphasis added).

23. Computer programs comprise the subset of mathematical algorithms that are implemented via a computer.

24. 409 U.S. 63 (1972).

25. *Id.* at 69-70.

calculate the appropriate cure time. The Court, however, was still concerned with excluding from patentability computer software that was abstract.²⁶ The *Diehr* Court equated physicality with lack of abstraction and thus limited patentability of processes containing software to those situations where the software was clearly involved in physically “transforming . . . an article into a different state or thing.”²⁷

In response to the Supreme Court’s emphasis on physicality in *Diehr*, the predecessor to the CAFC, the Court of Customs and Patent Appeals, formulated the so-called *Freeman-Walter-Abele* (“FWA”) test for assessing the patentability of mathematical algorithms, including algorithms implemented via computer software. Under the test, “it is first determined if a mathematical algorithm is recited directly or indirectly in the claim. If so, it is next determined if the claimed invention as a whole is no more than the algorithm itself—that is, whether or not the claim is directed to a mathematical algorithm that is not applied to or limited by *physical elements or process* steps. Such claims are nonstatutory [i.e., not patentable subject matter].”²⁸ Under the FWA test physical elements are the relevant limitations with respect to a product claim (i.e., a claim to a machine, manufacture, or composition of matter); process steps that produce a change in a tangible medium are the relevant limitations with respect to a process/method claim.²⁹

The physicality standard is hardly a perfect proxy for lack of abstraction. As discussed further below,³⁰ algorithms that are used for non-physical activities such as information processing may be quite concrete. Indeed, as the CAFC’s decisions have made clear, precisely what constitutes a “physical” product or process is a tricky question.

26. Like *Gottschalk, Diehr* stated explicitly that “abstract ideas” were not patentable subject matter. *Id.* at 185.

27. *Id.* at 192.

28. *Arrhythmia Research Technology, Inc. v. Corazonix Corp.*, 958 F.2d 1053, 1058 (Fed. Cir. 1992).

29. *See In re Walter*, 618 F.2d 758, 767 (C.C.P.A. 1980) (“Once a mathematical algorithm has been found, the claim *as a whole* must be further analyzed. If it appears that the mathematical algorithm is implemented in a specific manner to define structural relationships between the physical elements of the claim (in apparatus claims) or to refine or limit claim steps (in process claims), the claim being otherwise statutory, the claim passes muster under § 101.”).

30. *See infra* text following note 31.

Nonetheless, a reasonably strict interpretation of the FWA test would have served to exclude a substantial number of abstract computer programs from patentability. For example, under a strict interpretation of the FWA test, the computerized calculation of the Arrhenius equation at issue in *Diehr* would not have been patentable if it had been claimed on its own, rather than as part of a specific process for physically transforming rubber.

The CAFC soon began to interpret the test's "physical elements or process steps" restriction, however, in a manner that rendered it a nullity. For example, in the 1989 decision *In re Iwahashi*,³¹ the CAFC applied the FWA test to uphold as patentable subject matter an invention that was essentially a mathematical algorithm for pattern recognition. In reversing the PTO's determination that the invention was merely a mathematical algorithm, the CAFC held that the requirement of a limiting physical element was satisfied by the very electronic circuitry necessary to perform the mathematical steps.³² Following the logic of *Iwahashi*, any mathematical algorithm could be a patentable product, so long as it was performed by a computer (or other physical element). Consequently, the large number of mathematical algorithms that are sufficiently complicated that they can only be performed plausibly by a computer would inevitably be patentable subject matter. Similarly, in *Arrhythmia Research Technology, Inc. v. Corazonix Corporation*,³³ the CAFC determined that a mathematical process for detecting and analyzing electrocardiographic signals was patentable subject matter. According to the CAFC, the requirement that there be a physical transformation could be satisfied by the fact that the process transformed the analog heart signal to a filtered digital signal.³⁴ Under the reasoning of the *Arrhythmia* case, any algorithm that takes as its input data represented in electronic form and transforms the data in some way is patentable subject matter.

31. 888 F.2d 1370 (Fed. Cir. 1989).

32. *Id.* at 1375.

33. 958 F.2d 1053 (Fed. Cir. 1992).

34. *Id.* at 1059 ("These claimed steps of 'converting,' 'applying,' 'determining,' and 'comparing' are physical process steps that transform one physical, electrical signal into another.").

After it became clear that, under the CAFC's interpretation, the physical elements or process limitation of the FWA test could be fulfilled by virtually any algorithm implemented via a computer, patent applications on computer software became quite common.³⁵ Ultimately, even the CAFC recognized its interpretation of the physical element or process limitation for the fiction that it had become. *In re Alappat*,³⁶ decided in 1994, was the first step in the interment of the FWA test. *Alappat*, which was yet another appeal from a PTO rejection of patentability, involved a mathematical algorithm that transformed vector data into continuous lines for display. In holding that the apparatus that embodied the algorithm was patentable subject matter, the CAFC did not even attempt to argue that the apparatus provided the physical element limitation required by the FWA test. Rather, the CAFC relegated the test to a footnote and focused on the fact that the apparatus "produce[d] a useful, concrete, and tangible result."³⁷ Then, in *State Street & Trust Co. v. Signature Financial Group, Inc.*,³⁸ the Federal Circuit explicitly rejected the "physicality" limitations of the FWA test.³⁹ In holding that a computerized data processing apparatus for implementing a particular type of investment structure was patentable subject matter, the Federal Circuit emphasized that mathematical algorithms are patentable so long as they produce a "useful" result, including (in the case of the State Street patent) something as non-physical as a final share value.⁴⁰ Indeed, in emphasizing "practical utility" as the hallmark of whether a mathematical algorithm constitutes statutory subject matter,⁴¹ the CAFC essentially collapsed the patentable subject matter requirement into the utility requirement,

35. See, e.g., Lawrence M. Fisher, *The Executive Computer: Will Users to Be the Big Losers in Software Patent Battles?*, N.Y. TIMES, Mar. 6, 1994, at C3.

36. *In re Alappat*, 33 F.3d 1526 (1994).

37. *Id.* at 1544.

38. 149 F.3d 1368 (Fed. Cir. 1998).

39. *Id.* at 1374 (noting that "the Freeman-Walter-Abele test has little, if any, applicability to determining the presence of statutory subject matter").

40. *Id.* at 1373.

41. *Id.* at 1375 (noting that "[t]he question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to—process, machine, manufacture, or composition of matter—but rather on the essential characteristics of the subject matter, in particular, its practical utility") (emphasis omitted).

even though the latter is a separate condition of patentability under the patent statute. The *State Street* decision also rejected as “ill-conceived” the so-called “business methods” exception to patentability, holding that methods of doing business were patentable subject matter.⁴²

In the wake of *State Street*, the number of patents (and patent filings) on methods of doing business over the Internet has jumped dramatically.⁴³ The *State Street* decision has also brought new credibility to various business method patents issued before the decision.⁴⁴ Indeed, high-profile lawsuits have already been filed over two such patents. In one case, Amazon.com is accusing Barnesandnoble.com of willfully infringing Amazon’s patent on one-click ordering, which lets online shoppers buy items by clicking a single button on a Web site.⁴⁵ In the other case, Priceline.com is suing Microsoft for infringing upon a patent covering its “reverse auction” model. The Priceline patent claims a computer network-implemented business method that receives from a consumer a conditional purchase offer and a payment identifier, solicits the conditional purchase offer to a number of vendors, and completes the transaction if a vendor accepts the offer. Notably, neither the Amazon.com patent nor the Priceline.com patent is limited to any specific implementation in code. Rather, both patents broadly claim all computer network-implemented versions of their business concept.⁴⁶

42. *Id.* Under the language of the *State Street* decision, it appears that business methods and mathematical algorithms can be patentable irrespective of whether they are implemented via a computer. As a practical matter, however, most business methods and mathematical algorithms that have economic significance will likely be implemented electronically.

43. See discussion *supra* note 1.

44. See Scott M. Alter, ‘*State Street*’ Sets Stage for New Patents, Battles, NAT’L L.J., Oct. 25, 1999, at C8 (discussing Cybergold’s patent on a system of viewing an online advertisement as well as Open Market Inc.’s patent on an electronic payment system for ordering merchandise).

45. George Anders and Rebecca Quick, *Technology Journal: Amazon Sues Barnesandnoble.com*, WALL ST. J., Oct. 25, 1999; see also U.S. Patent No. 5,960,411 entitled “Method and System for Placing a Purchase Order Via a Communications Network.”

46. U.S. Patent No. 5,960,411, *supra* note 45. Barton E. Showalter & Jeffery D. Baxter, *Strategic Use of Software Patents*, 547 PLL/Pat 1057, 1070 (1999) (quoting claims of a Priceline patent). In addition to Amazon.com and Priceline.com, Sightsound.com, which owns patents that control “the sale of audio or video recordings in download fashion over the Internet” has been pursuing licensing from various companies that offer music over the Internet. See Alter, *supra* note 44.

Commentators have expressed concern that program patents, particularly business method patents, are being granted on inventions that are obvious.⁴⁷ More generally, they have criticized the law's lax standards with respect to patents on computer-implemented algorithms.⁴⁸ As in biotechnology, the worry is that expansive patenting will stifle future innovation and development, particularly in the context of the Internet. If the key methods of doing business online are patented, current and future startup companies will find themselves mired in navigating intellectual property obstacles. As Professor Robert Merges has observed, "if everyone had been doing a property grab in the early days [of the Internet], we wouldn't have gotten where we are now."⁴⁹ Even if obvious Internet patents are eventually struck down in litigation (because, for example, an alleged infringer brings forward prior art not considered by the PTO), such litigation is likely to be expensive and time-consuming. Indeed, because of the short time window associated with the Internet business cycle, Internet patents that are invalid pose a particular problem: even if the patent is eventually struck down in litigation, the short time period in which the patentee has a right to exclude others from using the patent may be sufficient to give the patentee a valuable first-mover advantage.

II. ADDRESSING THE RACE TO PATENT

As discussed in Part I, the biotechnology patent race differs in some important respects from the race in computer technology. Responsibility for the biotechnology race rests squarely with the

47. See generally Merges, *supra* note 1. With respect to certain patents, such as the Amazon.com and Priceline.com patents, there is also the worry that they are claimed too broadly.

48. See sources cited *supra* note 4.

49. Thomas E. Weber, *Battles Over Patents Threaten to Dampen Web's Innovative Spirit*, WALL ST. J., Nov. 8, 1999, at B1 (quoting Professor Merges). Even before the CAFC's recent decisions unequivocally allowed patenting of computer programs, such programs enjoyed copyright protection; however, copyright protection is considerably less powerful than patent protection. While a copyright protects only the "expression" in a computer program (i.e. the object code, the source code, and certain non-literal components), patent law protects the underlying idea. See *Computer Associates International, Inc. v. Altai, Inc.*, 982 F.2d 693 (2d Cir. 1992). Moreover, unlike patent law, copyright law does not protect against independent creation or reverse engineering.

CAFC. Despite its limited understanding of DNA-based technology, the CAFC has refused to defer to the technical expertise of the PTO. By contrast, in the context of computer programs, the differences between the PTO and CAFC have both technical and legal aspects. Moreover, the PTO's issuance of obvious business method patents has contributed to the race. In both cases, however, there is a serious concern that obvious patents are being issued. Thus, the key to addressing the race to patent will be developing and implementing a cost-effective sorting mechanism for segregating obvious material not worthy of a patent from other material.⁵⁰

One option would be a substantive legislative fix. There is, however, reason to be cautious about a legislative fix. In the area of biotechnology, the case against a legislative fix is quite strong. Here the problem is not the patent statute itself but rather the CAFC's erroneous application of the statute. If the CAFC had applied the nonobviousness standard correctly, in the manner suggested by the PTO, many of the DNA-based patent applications that have been filed could quickly have been rejected on nonobviousness grounds (or would not have been filed in the first place). Moreover, even if legislation clarifying the meaning of nonobviousness with respect to DNA sequences were passed, such legislation would not accommodate future technological developments in the biotechnology industry. With respect to those future developments, the CAFC might continue to misapprehend the relevant technology. Indeed, one reason for drafting the nonobviousness standard in general terms is precisely for the purpose of accommodating inevitable, but largely unforeseeable, technological change in a variety of different industries. Finally, because evaluation of the legislative approach should examine the approach not only in theory but also in practice, it bears mention that legislative intervention with such a narrow, industry-specific focus would be quite susceptible to pressure by industry groups interested in stronger property rights. The history of narrowly tailored legislation in the intellectual property area has one been of stronger, not weaker, property rights. For example, the major section of the current patent statute that

50. A sorting mechanism will be cost-effective only if the benefits it confers in terms of invalid patents avoided outweigh the costs of implementing the mechanism.

specifically addresses biotechnology provides greater protection for such technology.⁵¹ Similarly, the Digital Millennium Copyright Act and other recent legislation in the intellectual property area have been criticized as giving too much weight to the interests of property owners.⁵²

In the area of computer-implemented algorithms, the issue of whether a substantive legislative fix would be helpful is more complicated. Arguably, legislation that clarified how the patentable subject matter requirement applies to computer-implemented algorithms, or to algorithms more generally, would be useful. Although concerns about abstraction inform the Constitutional and statutory language that addresses subject matter, the language does not address how we should determine which algorithms are too abstract to be patentable. However, even if we put the likelihood of distorting interest group pressures aside, it is not immediately clear what a legislative fix would provide. Codifying the “physicality” requirement of the FWA test would be an imperfect solution, as the physicality test does an imprecise job of distinguishing abstract mathematical algorithms from those that are not abstract. In *State Street*, for example, the share value calculation performed by the patented invention may have been non-physical but it was hardly abstract.

By the same token, the CAFC’s decision to focus exclusively on usefulness has even more significant drawbacks. As interpreted by the CAFC, usefulness establishes *no* significant limits on patentability. In the *Alappat* case, for example, the CAFC held that the “smooth waveform” that resulted from performing a series of mathematical calculations on raw input data represented a useful result.⁵³ Moreover, even if we were to adopt a more stringent

51. See 35 U.S.C. § 103(b)(1) (1994) (allowing patent protection for biotechnology processes, even if they produce obvious products). The area of specialized intellectual property legislation thus provides an illustration of the central tenets of public choice theory. See generally George Stigler, *A Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT. SCI. 3 (1971); see also James Q. Wilson, *The Politics of Regulation*, in THE POLITICS OF REGULATION 357, 369 (James Q. Wilson ed., 1980) (discussing rent-seeking by small, politically active interest groups).

52. See Yochai Benkler, *Free as the Air to Common Use: First amendment Constraints on Enclosure of the Public Domain*, 74 N.Y.U. L. REV. 354 (1999).

53. See *supra* note 37 and accompanying text.

definition of usefulness, this definition might not serve as much of a barrier. Even the most abstract mathematical algorithm could, if used in particular contexts, produce useful results. For instance, the binary number results produced by the number conversion process at issue in *Gottschalk* could have been useful in many different industrial and commercial contexts. As the court in *Gottschalk* noted, the end uses of the binary numbers could have included everything from “the operation of a train to verification of drivers’ licenses to researching the law books for precedents.”⁵⁴

Thus, at least at this juncture, it is not clear that a substantive change in the patent law which cleanly separates abstract algorithms from non-abstract ones can be formulated. Even if we could come up with a bright-line rule for determining abstraction, it is by no means clear that abstraction should be the economically relevant dividing line. As a matter of first principles, we might want to do an economic analysis of the net costs and net benefits of allowing patents on algorithms. Such analysis might reveal that while patents on certain types of algorithms are economically appropriate, patents on other types are inappropriate. For example, given the impressive history of business concept/method development in the era before patents, there may be no need to set up a proprietary system to encourage the creation of such concepts and methods.

For these reasons any substantive change in the patent law governing algorithms is likely to be a difficult, contested undertaking. Indeed, the proposals commentators have suggested thus far vary widely.⁵⁵ Irrespective of whether an appropriate substantive change in the patent law can be formulated, it is clear that patents that are obvious given the prior art should not be allowed.⁵⁶ There is little reason, economic or otherwise, to allow property rights on information that is common knowledge within a field.⁵⁷ Indeed,

54. *Gottschalk*, *supra* note 24, at 68.

55. See sources cited *supra* note 4.

56. *Merges*, *supra* note 1, at 592. See also Dennis S. Karjala, *The Relative Roles of Patent and Copyright in the Protection of Computer Programs*, 17 J. MARSHALL J. COMPUTER & INFO. L. 41, 43 (1998) (noting that “[b]ecause the subject matter question has now been mooted, essentially by fiat, patent lawyers must now begin to deal with the real issues of program novelty and nonobviousness”).

57. A few patent scholars disagree. They suggest that patent protection might be granted

proper application of the nonobviousness⁵⁸ requirement has the potential to weed out a significant number of biotechnology and computer program patents. For example, as was argued above, the hundreds of thousands of patent applications that have been filed on gene sequences of unknown function should be denied on obviousness grounds. Similarly, commentators have argued that the majority of Internet business method patents—including the patents at issue in the Amazon.com and Priceline.com disputes—are obvious.⁵⁹

If nonobviousness is going to play a key role in both biotechnology and computer software patenting, then it is important to determine the best institutional mechanism for making the nonobviousness determination. Nonobviousness is similar to other patentability requirements in that it represents a mixed question of

even for an obvious invention in order to induce investment in developing the invention. *See generally* Edmund Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265 (1977). This view has been subject to much criticism. *See* Rai, *supra* note 18 (discussing criticisms put forward by various commentators).

58. The question of precisely what “obvious” should mean in the field of computer software merits some discussion. Julie Cohen has argued, for example, that nonobviousness should represent the main patentability hurdle for computer software claimants and that examiners reviewing such software claims should invoke an “innovative programmer” test. *See* Julie E. Cohen, *Reverse Engineering and the Rise of Electronic Vigilantism: Intellectual Property Implications of “Lock-Out” Programs*, 68 S. CAL. L. REV. 1091, 1169 (1995). Under this test both general purpose computing equipment and the mathematical algorithm at issue in the software would be considered to be part of the prior art. *Id.* The question would then become whether the software would have been obvious to a programmer of ordinary skill who knew the algorithm and desired to implement the algorithm via a computer. *Id.* For present purposes, the difficulty with this test is that in taking all mathematical algorithms to be a part of the prior art, it essentially assumes that mathematical algorithms are not patentable subject matter. Although such an assumption may ultimately be warranted, it would represent a significant departure from current law. In this Article, I use a nonobviousness standard that does not assume that mathematical algorithms are necessarily unpatentable. Under this standard the nonobviousness determination is made with respect to the component of the invention that is claimed to be novel. Thus, for example, in the case of the asset management system at issue in *State Street*, if the business method at issue were claimed to be novel, then the nonobviousness of the invention would be judged against the understanding of the person of ordinary skill in the development of business methods. On the other hand, if the programming method that translated the business method into a piece of computer software were claimed to be novel, then the nonobviousness of the invention would be judged against the understanding of the programmer with average skill in the art.

59. *See* Mike France, *Why We Don't Need Patent Reform—Yet*, BUS. WK., Dec. 20, 1999 (referring to expert views).

law and fact (or, equivalently, an application of law to fact).⁶⁰ Nonobviousness disputes are arguably unique, however, in that such disputes almost always turn on disputed factual questions. As the Supreme Court has emphasized, the statutory inquiry regarding whether an invention “would have been obvious at the time the invention was made to a person having ordinary skill in the art” is inextricably bound up with factual questions regarding the scope and content of the prior art in the particular field, differences between the prior art and the claims at issue, and the level of ordinary skill in the pertinent art.⁶¹ Indeed, the Court has analogized the determination of nonobviousness to such intensely factual determinations such as negligence and scienter.⁶² In the context of the hundreds of thousands of patent applications that are filed annually, only administrative agencies like the PTO, which can call upon thousands of highly specialized personnel, have the institutional resources to make the complex factual determinations underlying nonobviousness. In contrast, the CAFC (like appellate courts generally) operates under resource constraints that constrain its ability to see more than a small fraction of the technological innovations on which patents are sought.⁶³ Moreover, because of limited resources, the amount of technical knowledge that can be wielded by any appellate court—including a specialized court like the CAFC—is quite limited. While the CAFC has a number of judges who are technically trained, they are not (and, indeed, could not be) trained in every area of science in

60. As was noted above, see *supra* 20, the Federal Circuit has justified its *de novo* review of nonobviousness by arguing that it is simply a conclusion of law. For the reasons stated in the text, however, the Federal Circuit’s view is mistaken. The other patentability requirements—patentable subject matter, utility, novelty, and written description/enableness—also represent mixed questions of law and fact. The same analysis of institutional competence that applies to nonobviousness would, therefore, presumably also apply to these other requirements.

61. See *Graham v. John Deere*, 383 U.S. 1, 17 (1965). The factual underpinnings of the nonobviousness inquiry are so clear that one may, on first examination, wonder whether the inquiry has *any* legal component. Nonobviousness does have a legal component to the extent that it is central to the “ultimate question of patent validity, [which] is one of law.” On the other hand, because the legal questions surrounding obviousness have largely been resolved, facts generally represent the centerpiece of the nonobviousness determination. *Id.*

62. *Id.* at 18.

63. See NEIL K. KOMESAR, IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY 142-49 (1994) (observing that adjudicative capacity cannot be expanded as easily as the capacities of the market).

which any given patent dispute may arise.⁶⁴ As Professor Rochelle Dreyfuss has noted, in cases like nonobviousness “[w]here the law is clear but difficult to apply to complex factual situations,” expertise is most usefully deployed not at the appellate level but at the administrative or trial level.⁶⁵

For these reasons, those who have acknowledged the central role of nonobviousness, particularly in the context of computer programs, have argued for various reforms to make the PTO more capable of distinguishing obvious inventions from nonobvious ones. Although these reforms would necessarily cost money, such costs should be relatively small compared to the costs created by invalid patents. One relatively straightforward reform would involve an increase in the number and quality of patent examiners.⁶⁶ Another reform might involve changing the incentive structure of the PTO so that examiners are no longer encouraged to issue patents. Currently, examiners are compensated in part based on the number of final dispositions of patents that they accumulate. Because it is easier and faster to achieve a final disposition by allowing a patent than by denying one, there is an incentive to allow applications.⁶⁷

Finally, perhaps the most effective reform would involve instituting an opposition proceeding that allowed interested private parties to challenge the validity of particular patent applications.⁶⁸ These opposition proceedings could be similar to the opposition procedures currently in place for trademark grants. Under the U.S. system for trademarks, trademark applications that the PTO has tentatively approved are published. Those who object to the issue of the trademark can lodge their objections prior to final approval of the trademark. Pre-grant opposition proceedings could, at least in theory,

64. Notably, in certain cases no technical training may be better than training in an area that is inapplicable. For example, the cases that have misconstrued the application of the nonobviousness requirement to DNA were decided by a judge (Judge Lourie) who has a Ph.D. in chemistry (as contrasted with molecular biology or biochemistry). See ALMANAC OF THE FEDERAL JUDICIARY (Christine Houser, ed., 1999).

65. Dreyfuss, *supra* note 6, at 74.

66. Merges, *supra* note 1, at 607. Because the PTO is funded in part by the continuation fees it receives from patents that are maintained, there is an institutional incentive to grant patents.

67. *Id.*

68. See, e.g., Merges, *supra* note 1, at 611-15.

cohere well with recent changes in the patent law that will, effective November 29, 2000, require patent applications to be published 18 months after filing.⁶⁹ Prior to this recent legislation, the only prior art available to the examiner was that cited by the patent applicant or found by the examiner, because patents were granted in confidential *ex parte* proceedings. This pool of prior art was often quite limited. Recent empirical work by Professors John Allison and Mark Lemley has shown that patents subsequently invalidated in litigation were generally invalidated on the basis of prior art not considered by the PTO.⁷⁰ The confidential *ex parte* nature of the patent grant process has represented a particular problem in the context of computer programs. Because software patents (particularly patents on software-implemented business concepts) only began to be issued relatively recently, a large amount of the prior art in the software area is not in the area of prior patents. Thus, for purposes of the nonobviousness determination, the ordinary PTO process of searching patent databases will not yield much of the relevant prior art.⁷¹ In contrast, in an opposition proceeding, private parties who were knowledgeable about the industry in question could bring forward prior art. Indeed, competitors of patent applicants would have every incentive to call attention to such prior art.

PTO reform is clearly necessary. It is, however, by no means sufficient. After all, the patent gold rush has emerged from the confluence of two synergistic practices—not only the PTO's

69. American Inventors Protection Act of 1999, § 4502, to be codified at 35 U.S.C. § 122. As a practical matter, however, the current version of the disclosure provision mandates that the PTO "establish appropriate procedures to ensure that no protest or other form of pre-issuance opposition to the grant of a patent on an application . . . be initiated after publication of the application without the express written consent of the applicant." *Id.*

70. See John R. Allison & Mark A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 204 (1998).

71. Merges, *supra* note 1, at 589-90. See also OFFICE OF TECHNOLOGY ASSESSMENT, U.S. CONG., FINDING A BALANCE: COMPUTER SOFTWARE, INTELLECTUAL PROPERTY, AND THE CHALLENGE OF TECHNOLOGICAL CHANGE 24 (1992) (arguing that improving software patent quality will involve "filling in" information about prior art). The PTO has, however, started taking steps to address its deficiencies in the software area. For example, in 1995 it started hiring examiners trained in computer science. Van Dyke, *supra* note 1, at C20. Moreover, the PTO recently announced that it would take steps to improve the process of checking prior art for computerized business method patents. See Anna Wilde Matthews, *U.S. Will Give Web Patents More Scrutiny*, WALL ST. J., Mar. 29, 2000, at B1.

tendency to grant obvious or otherwise invalid patents but also the CAFC's reversal of POTO patentability denials. PTO reform will be for naught if the CAFC continues its current practice of refusing to defer. Indeed, even absent PTO reform (or with incomplete PTO reform), deference to PTO *denials* of patentability is merited. This is because the PTO's deficiencies, in terms of incentive structure and lack of expertise will lead it systematically to err on the side of granting patents. These deficiencies show that there is no institutional reason for the PTO to err when it denies patents. Similarly, any agency bias in favor of industries that regularly seek patents before the PTO will lead in the direction of erroneous patent grants, not erroneous patent denials.⁷²

PTO reform, particularly in the form of opposition proceedings, is more important in the context of granted patents. Absent PTO reform much invalid patents will impose costs in terms of costly infringement litigation and the chilling of future inventions will continue to be granted. A full discussion of the standard of review that should apply to *granted* patents is beyond the scope of this Article. It bears mention, however, that if reforms that enabled the PTO to review fully and accurately the prior art were implemented, the statutory presumption of validity that attaches to granted patents⁷³ would be well justified. In that case, "deference . . . [would be] due a qualified government agency presumed to have properly done its job, which includes one or more examiners who are assumed to have some expertise in interpreting the references and to be familiar from their work with the level of skill in the art and whose duty it is to issue only valid patents."⁷⁴ In the context of patent denials, however, the PTO can, even under our current patent system, be "presumed to have properly done its job." The next Part, therefore, sketches the

72. See Richard B. Stewart, *The Reformation of American Administrative Law*, 88 HARV. L. REV. 1667, 1713 (1975) (noting, in a seminal article on agency capture theory, that "the comparative overrepresentation of regulated or client interests in the process of agency decision results in a persistent policy bias in favor of these interests" will lead in the direction of error of patents grants not patent denials).

73. See 35 U.S.C. § 282 (1994) ("A patent shall be presumed valid").

74. *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (1984) (arguing in favor of statutory prescription of validity for granted patents).

legal framework for immediate application of deference principles to PTO patent denials.

III. DEFERENCE TO PTO PATENT DENIALS: THE DOCTRINAL ANALYSIS

From an administrative law perspective, the issue of how much deference an agency decision should receive turns on where the decision falls on the law/fact spectrum. As was discussed above, nonobviousness—the single key determinant of whether particular biotechnology or computer software will be patentable—represents a mixed question of law and fact. For mixed questions of law and fact (as for “pure” questions of law), the starting point for deference analysis is the Supreme Court’s seminal decision in *Chevron v. Natural Resources Defense Council*.⁷⁵

Chevron enunciated a two-step framework for deference analysis. Under the first step the court determines whether Congress has “directly spoken to the precise question at issue.”⁷⁶ If it has, “that is the end of the matter, for the court, as well as the agency, must give effect to the unambiguously expressed intent of Congress.”⁷⁷ On the other hand, if the court determines that Congress has not spoken directly to the question, it proceeds to step two, which requires the court to defer to any reasonable interpretation propounded by the agency that administers the statute.⁷⁸ *Chevron*’s applicability to the central patentability question of nonobviousness is relatively straightforward. Because nonobviousness is a mixed question of law and fact to which Congress could not have spoken directly, application of *Chevron* would require proceeding to step two and

75. 467 U.S. 837 (1984). In one post-*Chevron* case, *INS v. Cardoza-Fonseca*, 480 U.S. 421, 446 (1987), the Supreme Court suggested that *Chevron* might apply only in cases involving mixed questions of law and fact. In subsequent cases, however, the Court has made it clear that *Chevron* applies not only to mixed questions of law and fact but also to “pure” questions of law. The Court’s refusal to separate mixed questions of law and fact from pure questions of law is probably wise, as the line between what is a mixed question and what is a pure question is exceedingly difficult to draw. See Cass R. Sunstein, *Law and Administration after Chevron*, 90 COLUM. L. REV. 2071, 2095 (1990).

76. *Id.* at 842.

77. *Id.*

78. *Id.* at 843.

examining whether the PTO's determination regarding nonobviousness was a reasonable one.⁷⁹ For example, under the *Chevron* standard the PTO's determination that DNA sequences could be rendered obvious through the existence of prior art methods (and not simply through the existence of structurally similar DNA) would probably have survived review.⁸⁰

Like prior case law on judicial deference to agency interpretations, *Chevron* emphasized the technical expertise of the agency as a reason for deference.⁸¹ It noted that the regulatory scheme at issue in the case (the Clean Air Act) was technical and complex and that judges were "not experts in the field."⁸² *Chevron*

79. To be sure, the Supreme Court has, in recent years, striven mightily to stop at the first step of *Chevron*. See Richard J. Pierce, Jr., *The Supreme Court's New Hypertextualism: An Invitation to Cacophony and Incoherence in the Administrative State*, 95 COLUM. L. REV. 749, 750 (1995) (noting that the court has gradually ceased to apply *Chevron* deference "to uphold an agency construction of ambiguous statutory language, because it rarely acknowledges the existence of ambiguity"). Nonetheless, because nonobviousness is so clearly a fact-based inquiry, it is difficult to imagine how a court could find that, in enacting the nonobviousness standard, Congress had unambiguously determined the question of whether any given invention was obvious.

80. Moreover, to the extent that step two review under *Chevron* can be considered similar to "arbitrary and capricious" review under § 706(2)(e) of the Administrative Procedure Act (APA), see Ronald Levin, *The Anatomy of Chevron: Step Two Reconsidered*, 72 CHI.-KENT L. REV. 1253, 1261 (1997) (arguing that the APA's arbitrary and capricious test can and should be used to provide content to the second step of the *Chevron* inquiry); Gary Lawson, *Reconceptualizing Chevron and Discretion: A Comment on Levin and Rubin*, 72 CHI.-KENT L. REV. 1377, 1379 (1997) (agreeing with Levin) the so-called "frontiers of science" branch of arbitrariness doctrine might be applicable. Under the latter doctrine the court's recognition of its limited capacity to make predictions in highly technical areas acts as a limitation on the scope of its review. See *Baltimore Gas & Elec. Co. v. NRDC*, 462 U.S. 87, 103 (1983) (noting that "a reviewing court must generally be at its most deferential" when an agency is "making predictions, within its area of special expertise, at the frontiers of science"). Nonobviousness can sometimes require an agency to make determinations that resemble predictions. For example, in order for the PTO to determine that prior art renders a given invention obvious, it must find that the prior art indicates a "reasonable likelihood of success" that a workable invention will emerge. See, e.g., *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988); *Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1584 (Fed. Cir. 1987).

81. Prior to *Chevron*'s two-step inquiry, the Supreme Court took a contextual, case-by-case approach towards deference. Under this older approach, the Court considered a variety of factors in determining not only whether to give deference but also the degree of deference that was due. Factors favoring deference included: evidence that the agency had particular expertise in the area of decisionmaking (or at least a longstanding and consistent interpretation in the area); Congressional delegation of interpretative authority to the agency; and indications that the agency interpretation had in some way been ratified by Congress. See, e.g., Thomas W. Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 973-75 (1992).

82. *Chevron*, 467 U.S. at 865.

also emphasized democratic accountability as another reason for favoring agency interpretation to court interpretation. The Court noted that agencies, unlike courts, are under the President's control and hence are directly accountable to the people.⁸³ The Court then relied on these dual pillars of technical expertise and democratic accountability to justify extending a blanket presumption of deference to agency interpretations of ambiguous statutes. The Court reasoned that, given agency expertise and accountability, where Congress had delegated to an agency the power to administer a statute, it had also implicitly delegated to the agency power to interpret gaps or ambiguities in the statute.

Chevron's emphasis on technical expertise and democratic accountability applies squarely to the PTO. As discussed in Part II, technical expertise is particularly relevant to nonobviousness determinations, which rely heavily on highly specialized fact-finding. Moreover, as a doctrinal matter, any argument that the technical competence of an agency becomes less important when its decisions are being reviewed by a specialized court has been laid to rest by the recent Supreme Court decision in *United States v. Haggart Apparel*.⁸⁴ *Haggart* makes it abundantly clear that *Chevron* analysis applies not only to courts of general jurisdiction that review agency decisions but also to specialized courts that conduct such review.

To be sure, the presumption of deference announced by *Chevron* has engendered great controversy. Some commentators have vigorously attacked *Chevron* as violating the separation of powers by undermining the ultimate authority of courts on questions of law.⁸⁵ They have also rejected the solution to the separation-of-powers problem advanced by the *Chevron* Court (and by some

83. *Id.* at 865-66 ("While agencies are not directly accountable to the people, the Chief Executive is . . ."). In defending agencies on grounds of expertise and democratic accountability, the Court followed the views of the New Deal reformers who created the administrative state. These reformers saw the administrative state as a necessary complement to the courts, which lacked the expertise, resources, and accountability necessary to address complex social problems. *See, e.g.,* Merrill, *supra* 81, at 1049; Sunstein, *supra* note 75, at 2079 (noting that New Dealers saw the administrative agency as uniquely situated to address complex problems).

84. 526 U.S. 380 (1999).

85. *See generally* Cynthia Farina, *Statutory Interpretation and the Balance of Power in the Administrative State*, 89 COLUM. L. REV. 452 (1989).

commentators⁸⁶)—that Congress delegates authority to interpret a statute whenever it delegates authority to administer the statute. For example, Thomas Merrill has argued that because Congress has not enacted a statute that contains a general delegation of interpretative authority to agencies, it contemplates that courts will typically apply independent judgment on questions of law, “reserving deference for administrative findings of fact or questions of policy.”⁸⁷ This critique of *Chevron* is bolstered by language in the Administrative Procedure Act that directs reviewing courts to “decide all relevant questions of law.”⁸⁸

Although critics of *Chevron* raise significant constitutional and statutory objections, these objections apply most squarely to “pure” questions of statutory construction, not mixed questions of law and fact. With respect to mixed questions, even pre-*Chevron* case law accorded a high level of deference to agency decisions. For example, in *NLRB v. Hearst Publications Inc.*,⁸⁹ the Supreme Court emphasized that “where the question is one of specific application of a broad statutory term in a proceeding in which the agency administering the statute must determine it initially, the reviewing court’s function is limited . . .”⁹⁰ Indeed, constitutional and statutory

86. See, e.g., Antonin Scalia, *Judicial Deference to Administrative Interpretations of Law*, 1989 DUKE L.J. 511, 516 (1989) (noting that if there is an ambiguity in a statute, and Congress expressed no particular intent on the subject, “what we have is a conferral of discretion upon the agency, and the only question of law presented to the courts is whether the agency has acted within the scope of its discretion—i.e., whether its resolution of the ambiguity is reasonable”).

87. Merrill, *supra* note 81, at 995.

88. 5 U.S.C. § 706 (1994). See also John F. Duffy, *Administrative Common Law in Judicial Review*, 77 TEX. L. REV. 113, 189-210 (arguing, on APA grounds, against a general delegation of interpretative authority to agencies).

89. 322 U.S. 111, 131 (1944).

90. Moreover, even with respect to so-called pure questions of law, resolving ambiguities in a statute is often a question of policy as much as it is one of law. Sunstein, *supra* note 75, at 2086 (noting that the *Chevron* approach might be defended on these grounds). See also Richard J. Pierce, Jr., *Chevron and Its Aftermath: Judicial Review of Agency Interpretations of Statutory Provisions*, 41 VAND. L. REV. 301, 305 (1988) (noting that Congress “typically leaves the vast majority of policy issues, including many of the most important issues, for resolution by some other institution of government”); Cass R. Sunstein, *Is Tobacco A Drug? Administrative Agencies as Common Law Courts*, 47 DUKE L.J. 1013, 1057 (1998) (“deciding how to read ambiguities in a law involves no brooding omnipresence in the sky but an emphatically human judgment about policy or principle”). The *Chevron* opinion itself indicates the Court thought that the EPA’s resolution of the legal ambiguity at issue in the case was a policy decision. See *Chevron*, 467 U.S. at 845 (noting that the EPA had made a “reasonable policy choice” and that

objections regarding the courts' duty to interpret the law are particularly inapplicable to nonobviousness determinations, as such determinations almost always turn on factual questions, not legal ones.

In addition, certain narrow interpretations of *Chevron* should pose less of a problem to those who are concerned about separation of powers and statutory language issues. For example, even some of those who attack applying *Chevron* liberally to all administrative agency interpretations note that deference to an agency's statutory interpretations is appropriate in the specific context where Congress has delegated substantive rulemaking power to the agency.⁹¹ Because the delegation to the agency is explicit, there is no need to rely on a flawed implicit delegation account.⁹² Somewhat more broadly, it could be argued that "whenever an agency is entrusted with implementing power—whether to be exercised through rulemaking or adjudication—agency interpretations in the course of exercising that power are entitled to respect so long as they are reasonable."⁹³

If *Chevron* were to be applied in this manner—and there is some evidence to suggest that the Supreme Court is so applying it⁹⁴—patentability interpretations made by the PTO in the course of adjudication would probably be entitled to deference. In the patent statute Congress has explicitly delegated to the PTO "all duties required by law respecting the granting and issuing of patents and trademarks."⁹⁵

it was "entirely appropriate for this political branch of the Government to make such policy choices").

91. Duffy, *supra* note 88, at 199-203; *see also* Atchison, Topeka, & Santa Fe Ry. Co. v Pena, 44 F.3d 437, 441-42 (7th Cir. 1994) ("[O]nly statutory interpretations by agencies with rule-making powers deserve substantial deference. . . . Congress develops the statutory framework and directs the agency to flesh out the operational details.").

92. Duffy, *supra* note 88, at 199.

93. Sunstein, *supra* note 75, at 2093.

94. *See, e.g.*, EEOC v. Arabian Am. Oil Co., 499 U.S. 244, 257 (1991) (arguing that EEOC regulations interpreting Title VII statutory language did not deserve deference because EEOC did not have authority to promulgate rules or regulations).

95. 35 U.S.C. § 6 (1994). Until recently, the Supreme Court had not specifically addressed the precise question of whether a nonrulemaking agency (e.g., the PTO) that has been delegated adjudicatory power should be entitled to deference for interpretations issued during adjudications. *See* GARY LAWSON, FEDERAL ADMINISTRATIVE LAW 604 (1998) (Perhaps not surprisingly, the CAFC had argued that *Chevron* did not apply to any PTO interpretations, whether issued during adjudication, *In re* Portola Packaging, Inc., 110 F.3d 786, 789 (Fed. Cir.

The Federal Circuit is unlikely, of its own accord, to apply *Chevron* deference to the PTO's decisions concerning patentability. It is likely, however, that the Supreme Court will mandate that it do so. Recent Supreme Court decision making at the intersection of administrative and patent law makes it clear that the Court considers the PTO an agency to which the ordinary terms of the APA apply. Specifically, the Court's decision in *Dickinson v. Zurko*⁹⁶ held that the APA, which provides that agency factfinding shall only be set aside if it is "arbitrary, capricious, an abuse of discretion or . . . unsupported by substantial evidence"⁹⁷ applies squarely to the PTO.⁹⁸ Thus, to the extent the CAFC is reviewing a nonobviousness decision in which the PTO made a specific factual determination (e.g., a determination regarding the difference between the invention at issue and the prior art), the CAFC is already required to show APA-level deference. Even more importantly, the *Zurko* case strongly suggests that the Supreme Court, if presented with a question regarding what level of deference the PTO should receive on mixed questions of law and fact, would mandate that *Chevron* apply.

CONCLUSION

This Article has argued that CAFC deference to PTO denials of patent protection, specifically those denials made on grounds on obviousness, represents an important mechanism for curtailing the patent gold rush in biotechnology and computer software. Ideally,

1997), or during rulemaking, *Merck & Co. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996)). A recent Supreme Court case suggests, however, that nonrulemaking agencies that are entrusted with adjudicatory power are entitled to deference with respect to interpretations issued during adjudications. See *INS v. Aquirre-Aquirre*, 526 U.S. 415, 424 (1999) (stating that *Chevron* deference applied to Board of Immigration Appeals interpretation issued during adjudication).

96. 119 S. Ct. 1816 (1999).

97. 5 U.S.C. § 706(2)(A),(E) (1994). Technically, the "arbitrary, capricious, an abuse of discretion" standard applies to informal factfinding while the "substantial evidence" standard applies to agency factfinding "on the record." The two standards are, however, quite similar substantively. *Zurko*, 119 S. Ct. at 1821.

98. *Id.* Prior to *Zurko* the CAFC had been using the "clearly erroneous" standard of review enunciated in F.R.C.P. 52(a). See, e.g., *In re Zurko*, 142 F.3d 1447, 1459 (Fed. Cir. 1998). The clearly erroneous standard is somewhat less deferential than the APA standard. See *Dickinson v. Zurko*, 119 S. Ct. 1816, 1818 (1999) (citing 2 KENNETH C. DAVIS & RICHARD J. PIERCE, ADMINISTRATIVE LAW TREATISE § 11.2, at 174 (3d ed. 1994)).

this implementation of deference to patent denial would be combined with reform that enabled the PTO to do a more expert job of distinguishing nonobvious inventions from obvious ones. Even absent such reform, however, implementation of deference with respect to PTO patent denials is warranted. In part, this is because the PTO's current structural problems make it likely to err in the direction of erroneous patent grants, not erroneous patent denials. Equally important, expeditious implementation of deference to patent denials would help to reconcile two fields of law—patent law and administrative law—whose estrangement has resulted in doctrinal confusion and substantively bad results.