

INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY: ADDRESSING NEW TECHNOLOGY

Arti K. Rai*

This Article argues that the Court of Appeals for the Federal Circuit ("CAFC") has applied patent doctrine to biotechnology in a manner that makes patent protection far too strong in some respects and too weak in other respects. One major reason for the CAFC's mistakes has been its limited comprehension of the new technologies that are central to the biotechnology industry. Moreover, a comparative analysis of the various institutions that could address the new genetic technologies reveals that the Patent and Trademark Office ("PTO") is best equipped for the task. Thus, the CAFC should show greater deference to the PTO's factual and legal determinations regarding patentability.

INTRODUCTION

In the last few years, various commentators have criticized the approach that the Court of Appeals for the Federal Circuit ("CAFC") has taken towards biotechnology patents. Some have argued that the CAFC has been too liberal in allowing such patents.¹ Others have claimed that the CAFC has applied patentability requirements too strictly.² By contrast, this Article embraces aspects of both arguments: it argues that, in the area of biotechnology, the CAFC has applied patent doctrine in a manner that makes patent protection far too strong in certain respects and too weak in other respects. The Article then identifies a fundamental structural reason for this disjunction between the manner in which the patent law has been applied and the policy goals of the patent system. This is the difficulty that courts as institutions, even specialized courts like the CAFC, have in dealing with new technology. Perhaps needless to

* Associate Professor of Law, University of San Diego. I thank Stuart Benjamin for helpful comments and Ronald Levin for several useful discussions.

1. See, e.g., Phillipe Ducor, *Recombinant Products and Nonobviousness: A Typology*, 13 SANTA CLARA COMPUTER & HIGH TECH. L.J. 1, 31-49 (1997).

2. See, e.g., Janice M. Mueller, *The Evolving Application of the Written Description Requirement to Biotechnological Inventions*, 13 BERKELEY TECH. L.J. 615, 617 (1998).

say, however, new technology is and will continue to be a pervasive feature of the biotechnology industry. Therefore the legal system will have to adapt to address technological change.³

Having identified the problem of new technology, the Article then undertakes a comparative analysis of the various possible institutional responses. Such comparative analysis reveals that the Patent and Trademark Office ("PTO") is probably the institution best equipped to address new technology, at least in the biotechnology industry. Greater deference to the PTO would improve the CAFC's biotechnology jurisprudence.

The Article's analysis divides into three sections. Section I summarizes the policy goals of the patent system as well as the manner in which the central doctrinal requirements for patentability aid in effecting these goals. Section II argues that the CAFC's application of these doctrinal requirements—in particular, nonobviousness and written description—to biotechnology has been faulty. It also develops the thesis that the faulty analysis put forward by the CAFC stems, at least in part, from the difficulty courts as institutions have in dealing with new technology. Finally, Section III employs comparative institutional analysis to argue that the technological challenges posed by biotechnology could, and should, be addressed through greater deference to the PTO.

I. THE GOALS OF PATENT LAW AND THE ELEMENTS OF PATENTABILITY

The Constitution states that patent rights are granted for "limited Times" in order "to promote the progress of . . . the useful Arts."⁴ Thus, as the constitutional text makes clear, patent law exists primarily to promote invention.⁵ Patents promote invention by giving

3. Rapid technological change is, of course, a feature not only of biotechnology but also of other high technology industries. The legal literature in telecommunications and cyberspace is particularly rich with discussions of the proper legal response to technological change. See, e.g., I. Trotter Hardy, *The Proper Legal Regime for Cyberspace*, 55 U. PITT. L. REV. 993 (1994) (discussing communications within cyberspace); Lawrence Lessig, *The Path of Cyberlaw*, 104 YALE L.J. 1743 (1995) (discussing cyberspace and the First Amendment); Lance Liebman, *Foreword: The New Estates*, 97 COLUM. L. REV. 819 (1997) (discussing the present and future of telecommunications law). New technology in biotechnology probably does not, however, require the same rethinking of basic legal concepts that technological change in telecommunications and cyberspace may require. See *infra* Section III.

4. U.S. CONST., art. I, § 8, cl. 8.

5. The Supreme Court has also repeatedly invoked the goal of invention. See, e.g., *Graham v. John Deere Co.*, 383 U.S. 1, 9 (1966) ("The patent monopoly was not designed to secure to the inventor his natural right in his discoveries. Rather, it was a reward, an inducement, to bring forth new knowledge."); *Mazer v. Stein*, 347 U.S. 201, 219 (1954) ("The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance

individuals a monetary incentive to devote resources to such invention. Without a patent right, the inventor might not be able to recoup her investment in a socially valuable, but cheaply copied, product.⁶

By the same token, in requiring that patent rights be granted only for "limited Times," and only for "useful Arts," the Constitution also mandates that the patent law maintain a balance between property rights and the public domain. Numerous legal and economic scholars have elucidated the policy rationale for such a balance. They have noted that, although the patent grant may stimulate the production of new inventions, it also limits the use of those inventions.⁷ Productive uses that may be limited include both direct use of the invention as an end product and use of the invention for further improvement and development.⁸ These uses may be inhibited if the patent holder can exert market power and charge a supracompetitive price or if there are significant transaction cost difficulties associated with licensing the patent.⁹

Similarly, the central statutory doctrines of patentability reflect a concern for balancing appropriately property rights and the public domain. For example, although the patentable subject matter requirement¹⁰ has a broad scope,¹¹ it does not include phenomena of nature or abstract scientific/mathematical principles and formulae.¹²

public welfare.").

6. Some patent scholars have argued that patent rights are granted in order to induce investment in the technological "prospects" that inventions represent. On this view, absent patent protection of invention early in the development process, no one will invest for fear that "the fruits of the invention will produce unpatentable information appropriable by competitors." Edmund Kitch, *Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 267-71 (1977). This view has many detractors, however. See Arti K. Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. (forthcoming Fall 1999) (discussing criticisms enunciated by various commentators).

7. See FREDERIC M. SCHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 450-53 (2d ed. 1980).

8. See Fritz Machlup, *An Economic Review of the Patent System*, Subcomm. on Patents, Trademarks, and Copyright of the Senate Comm. on the Judiciary 21, Study No. 15, 8th Cong., 2d Sess. (GPO 1958); see also SCHERER, *supra* note 7, at 450-53.

9. See SCHERER, *supra* note 7, at 450-53. Notably, because of problems in determining the value of an improvement *vis a vis* the original product, transaction cost difficulties may be particularly severe if the invention is being licensed not for direct use but, rather, for further improvement and development.

10. See 35 U.S.C. § 101 (1994). Under the statute, patentable subject matter is defined as "any new and useful process, machine, manufacture, or composition or matter, or any new and useful improvement thereof." *Id.*

11. In *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), for example, the Supreme Court held that patentable subject matter included "anything under the sun that is made by man." *Id.* at 309 (citing S. REP. NO. 82-1979, at 5 (1952); H.R. REP. NO. 82-1923, at 6 (1952)).

12. See *Gottschalk v. Benson*, 409 U.S. 63, 71-72 (1972).

As the Supreme Court has emphasized, the exclusion of scientific/mathematical principles and formulae from patentability allows these "basic tools" of science and technology to be available for all scientists to draw upon.¹³ Likewise, the utility requirement,¹⁴ which mandates that inventions have some practical application, serves to exclude abstract principles from patentability.¹⁵

A balancing role is also played by the doctrines of nonobviousness, written description, and enablement. Nonobviousness excludes 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."¹⁶ Nonobviousness is the most litigated issue relating to patent validity¹⁷ and has been called the "ultimate condition of patentability."¹⁸

The written description requirement¹⁹ limits the scope of private property rights by requiring that the applicant "convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention."²⁰ Traditionally, however, the written description requirement has had limited application. It has typically been used strictly as a means of ensuring that the patent applicant had actually invented *later-claimed* subject matter as of the earlier filing date of the application.²¹ By

13. See *id.* at 67.

14. See 35 U.S.C. §§ 101, 112.

15. See, e.g., *Brenner v. Manson*, 383 U.S. 519 (1966) (denying a process patent where applicant could not prove the utility of a compound produced by the chemical process). To some extent, the balancing role played by the doctrines of patentable subject matter and utility has been undermined by various CAFC decisions that render these requirements less stringent, particularly in the area of computer software. See *Rai*, *supra* note 6. However, the Supreme Court has never repudiated the *Gottschalk* and *Brenner* decisions.

16. 35 U.S.C. § 103 (1994). Under nonobviousness, the prior art must do more, however, than simply suggest the invention on which a patent is sought; it must indicate 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); see also *Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1584 (Fed. Cir. 1987); *In re Hedges*, 783 F.2d 1038, 1041 (Fed. Cir. 1985); *Orthopedic Equip. Co. v. United States*, 702 F.2d 1005, 1013 (Fed. Cir. 1983); *In re Rinehart*, 531 F.2d 1048, 1053-54 (C.C.P.A. 1976). In other words, showing that an invention is "obvious to try" does not defeat patentability. *In re O'Farrell*, 853 F.2d 894, 903 (Fed. Cir. 1988).

17. See 3 DONALD CHISUM, PATENTS § 11-102.

18. NONOBVIOUSNESS—THE ULTIMATE CONDITION OF PATENTABILITY (John F. Witherspoon ed., 1980).

19. See 35 U.S.C. § 112 ("The specification shall contain a written description of the invention.").

20. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991). In that case, the Federal Circuit emphasized that the written description requirement differs from the enablement requirement that is also embodied in 35 U.S.C. § 112. For discussion of the enablement requirement, see *infra* notes 22-23 and accompanying text.

21. See, e.g., *Mahurkar*, 935 F.2d at 1561 (stating that the written descrip-

contrast, the enablement requirement focuses not on later-claimed subject matter but, rather, on the subject matter claimed by the original patent application. The enablement requirement's restriction on property rights is quite significant. It mandates that the patentee disclose "the manner and process of making and using [her invention] 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."²² Thus, to cite a classic example, Samuel Morse, who invented the telegraph, was not allowed to claim all means of using electromagnetism to communicate at a distance.²³ Morse had, after all, only made and used one such means—the telegraph; he had not shown the person skilled in the art how to make any other means (e.g., microwave or other electronic communications).

Thus, the central doctrines of patentability allow a considerable range of invention to be the subject of property rights; at the same time, they retain within the public domain basic scientific and mathematical information as well as information that the inventor cannot legitimately claim as her own. Unfortunately, in the context of biotechnology, the CAFC has failed to apply patent doctrine in a manner that maintains the intended proper balance between property rights and the public domain. This failure is the subject of Section II.

II. THE CAFC'S APPLICATION OF PATENT LAW DOCTRINE TO BIOTECHNOLOGY: A CRITIQUE

Since the CAFC was formed in 1982, a significant part of its caseload has involved biotechnology.²⁴ As a consequence, a reasonably robust body of case law can elucidate the CAFC's view regarding how the doctrinal requirements that balance private property rights with the public domain apply in biotechnology. Understanding the patent case law in the area requires, however, a basic understanding of the underlying technology. In the following Section, I briefly address this technology.²⁵ I then criticize the CAFC's biotechnology jurisprudence for failing to apply patent doctrine in a manner that properly balances the public domain and private property rights.

tion requirement is intended to guard against "the inventor's overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation". An earlier filing date is advantageous because the later-filed claims are then judged, for purposes of novelty and nonobviousness, against the prior art available at the earlier filing date.

22. 35 U.S.C. § 112 (1994).

23. See *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 112-13 (1853).

24. See *infra* Section II.B.

25. This technical discussion is largely drawn from KENNETH J. BURCHFIELD, *BIOTECHNOLOGY AND THE FEDERAL CIRCUIT* 17-20 (1995); *In re O' Farrell*, 853 F.2d 894 (Fed. Cir. 1988); and BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 95-100 (2d. ed. 1989).

A. *Biotechnology: Some Basic Principles*

Biotechnology is primarily concerned with proteins, the structural and chemical building blocks of organisms, and genes, the DNA sequences located on chromosomes that code for these proteins.²⁶ Once the gene for a protein is isolated, the gene can be cloned by inserting it into a bacterial cell.²⁷ Cloning the gene for a given protein means that large quantities of the protein will then be produced. Producing large quantities of certain proteins, such as insulin or interferon, will often be immensely valuable as a therapeutic matter.²⁸

A significant part of the work of biotechnology involves characterizing proteins and their associated genes.²⁹ This work is aided by the biochemical link between proteins and genes (colloquially known as the "genetic code"). The biochemical link operates in the following manner. Proteins are made up of amino acids that are bonded together covalently.³⁰ There are a total of twenty possible amino acids that can form proteins.³¹ The particular amino acids that form any given protein and the sequence in which the amino acids are bonded together determine the function of the protein.³² In order to assemble a protein, an organism therefore needs information about which amino acids should be used and the order in which the amino acids must be assembled. The DNA sequence that is a gene stores this information in subunits called nucleotide bases.³³ The four nucleotide bases are adenine, guanine, cytosine, and thymine (usually abbreviated as A, G, C, and T respectively).³⁴ A gene is essentially a sequence of these bases.³⁵ Each three-base sequence, or codon, codes for an amino acid.³⁶ Given that there are four bases, there are a total of sixty-four possible three-base codons.³⁷ Moreover, because there are only twenty amino acids,³⁸ each amino acid is generally coded for by more than one codon.³⁹ Because the genetic code is "degenerate"—that is, because there is no one-to-one correspondence between codons and amino acids—the DNA sequence of a protein cannot directly be deduced from its amino acid sequence.

26. See BURCHFIEL, *supra* note 25, at 17-18.

27. See *id.* at 20.

28. See *id.* at 22.

29. See *id.* at 18.

30. See *id.* at 19.

31. See *id.*

32. See *id.*

33. See *id.*

34. See *id.* at 18.

35. See *id.*

36. See *id.* at 19.

37. Four to the third power ($4 \times 4 \times 4$) is 64.

38. See BURCHFIEL, *supra* note 25, at 19.

39. Thus, for example, the amino acid alanine can be coded for by any of the following codons: guanine-cytosine-adenine, guanine-cytosine-cytosine, guanine-cytosine-guanine, and guanine-cytosine-thymine.

Even though the DNA sequence of a protein cannot, as a straightforward matter of code, be deduced from its amino acid sequence, such a DNA sequence can nonetheless be obtained.⁴⁰ Obtaining the DNA sequence requires, first, constructing a "library" of DNA sequences that code for proteins actually expressed in a given cell (known as a "cDNA" library), and second, designing an appropriate nucleotide "probe" to screen the library. The first step is relatively straightforward: cDNA libraries have been available since the early 1980s. The second step, designing a probe that will bind, or "hybridize," with the desired cDNA sequence for a particular protein, can be done if part or all of the amino acid sequence of the protein in question is known. The specifics of how such a probe should be designed are discussed further in the next Section.

B. Applying Patent Doctrine to Biotechnology

In this Section, I discuss how the patent law doctrines of nonobviousness and written description have, in the context of biotechnology, been applied incorrectly by the Federal Circuit. I suggest that the CAFC's mistakes stem from its inability to deal adequately with new technology.

In considering DNA-based inventions, the CAFC has employed nonobviousness in a manner that dramatically lowers the bar for patentability and, therefore, significantly impoverishes the public domain. As noted earlier, nonobviousness precludes patentability if, given the prior available technology (known as the "prior art"), the invention would have been obvious to someone of "ordinary skill in the art."⁴¹ In two recent cases, *In re Deuel*⁴² and *In re Bell*,⁴³ the CAFC has, however, rejected arguments by PTO patent examiners, who are skilled in the art of biotechnology, that knowing a general method for identifying genes through the use of nucleotide probes, as well as the complete or partial amino acid sequence of a protein, renders the DNA base sequence for that protein obvious.⁴⁴ The CAFC has justified its decisions by arguing that, with respect to patent claims to DNA sequences, the nonobviousness determination must focus on the DNA molecules as chemical compounds rather than on the method for isolating DNA.⁴⁵ Thus, according to the

40. This information regarding DNA sequence isolation is largely taken from JAMES D. WATSON ET AL., RECOMBINANT DNA 100-11 (2d ed. 1992).

41. See *supra* note 16 and accompanying text.

42. 51 F.3d 1552 (Fed. Cir. 1995).

43. 991 F.2d 781 (Fed. Cir. 1993).

44. Indeed, the PTO patent examiners have gone so far as to say 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 of cloning techniques." *Ex Parte Deuel*, 33 U.S.P.Q.2d 1445, 1447 (Bd. Pat. App. & Int'f 1993) (citing the views of the PTO examiners).

45. See *id.* at 1559 ("The PTO's focus on known methods for potentially isolating the claimed DNA molecules is also misplaced because the claims at

CAFC, any given DNA sequence (whether a full DNA sequence that encodes a gene or a mere sequence fragment) is obvious only if the prior art actually recites a similar or identical sequence and not simply a method for isolating the sequence. Under this logic, DNA sequences can be nonobvious no matter how easy or routine it is to isolate the sequences.⁴⁶ This significant lowering of the patentability bar has resulted in a situation where many biotechnology companies are seeking patents on hundreds of thousands of DNA sequence fragments that they have been able to isolate quickly through routine, automated methods.⁴⁷

In contrast with its use of the nonobviousness requirement, the CAFC has used the written description requirement in a manner that somewhat raises the patentability bar.⁴⁸ Thus, in *Regents of the University of California v. Eli Lilly & Co.*,⁴⁹ a case involving the use of recombinant DNA technology to produce human insulin, the CAFC broke new ground by applying the written description requirement not only to later-filed claims but also to claims filed in the *original* patent. Specifically, the court scrutinized the University of California's original claim to a human insulin-encoding cDNA for compliance with the written description requirement.⁵⁰ It then used an unusually strict construction of the written description requirement to hold that the University of California had to actually isolate and sequence the cDNA in order to adequately describe it.⁵¹ Describing the amino acid sequences that make up human insulin, as well as a method for isolating the human cDNA gene (as the Univer-

issue define compounds, not methods.") (citing *In re Bell*, 991 F.2d 781, 785 (Fed. Cir. 1993)).

46. See Rebecca Eisenberg & Robert Merges, *Opinion Letter as to the Patentability of Certain Inventions Associated with the Identification of Partial CDNA Sequences*, 23 AIPLA Q.J. 1, 32 (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. This position collapses the novelty and nonobviousness requirements for DNA sequences.").

47. See generally Eliot Marshall, *Patent Office Faces 90-Year Backlog*, 272 SCIENCE 643 (1996) (noting that the biotechnology company Incyte claims to have filed applications on over 400,000 DNA sequences).

48. This raising of the patentability bar in the context of the written description requirement does not, however, by any means counterbalance the effect on the public domain of the CAFC's having virtually eliminated the nonobviousness bar with respect to DNA. The virtual elimination of the nonobviousness bar allows a vast proliferation of patents on relatively trivial inventions that are nonetheless essential for future research. By contrast, the raising of the written description bar typically 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 still exerts an inefficient level of control over future research. For further discussion of this issue, see generally Rai, *supra* note 6.

49. 119 F.3d 1559 (Fed. Cir. 1997).

50. See *id.* at 1567-68.

51. See *id.* at 1568-69.

sity of California had done), was not sufficient.⁵² In essence, the *Lilly* court used the written description requirement as a type of elevated enablement requirement.⁵³ An ordinary enablement challenge to the University of California's claim was not raised (and, if raised, probably would have failed) because it would have been relatively easy for a person of ordinary skill in the art to use the rat insulin cDNA that Lilly had already sequenced to "fish out" the human insulin cDNA from a cDNA library.⁵⁴

Notably, in arguing that describing a method for generating a DNA sequence was not sufficient to describe (and hence claim) the sequence itself, the *Lilly* court relied in part on the CAFC's nonobviousness jurisprudence, specifically the CAFC's argument that a DNA sequence for a protein is not obvious even if the amino acid sequence for the protein, as well as a method for isolating DNA sequences, is known.⁵⁵ The *Lilly* court asserted that "a description that does not render a claimed invention obvious does not sufficiently describe that invention for purposes of [the written description requirement.]"⁵⁶

The *Lilly* court's holding that describing a method for isolating a DNA sequence is not a sufficient basis for claiming the sequence itself is, of course, consistent with the *Deuel* court's refusal to consider methods as appropriate prior art to a DNA sequence claim. In both contexts, the CAFC's argument is based on its view that DNA-based technology is simply a subset of chemical technology generally. In the chemical context, the conventional test for obviousness of a chemical product is "structural similarity" to previous chemical products.⁵⁷ According to the Federal Circuit, the structural similarity test applies equally well to biotechnology⁵⁸ so as to preclude methods from serving as either appropriate prior art or sufficient written description.

For purposes of the patent law, the CAFC's categorization of DNA-based technology as just another species of chemistry is fundamentally misconceived. In ordinary chemistry, there are good reasons for requiring structurally similar prior art as a prerequisite for obviousness. The properties of chemical compounds are often difficult to predict, except to the extent that structurally similar compounds typically have similar properties. Thus, in order to make a

52. See *id.* at 1567.

53. See Mueller, *supra* note 2, at 638-39.

54. See *id.* at 630 (citing Eliot Marshall, *A Bitter Battle over Insulin Gene*, 277 SCIENCE 1028, 1029 (1997)).

55. *Lilly*, 119 F.3d at 1567.

56. *Id.*

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

58. See *In re Deuel*, 51 F.3d at 1557-58 ("Because Deuel claims new chemical entities in structural terms . . . a prima facie case of obviousness is based on structural similarity, i.e. an established structural relationship between a prior art compound and the claimed compound.").

compound with a particular set of useful properties, the chemist must generally start with a structurally similar prior art compound whose useful properties are known. Or, to put the point another way, the usefulness of the structurally similar prior art compound provides motivation to search for homologous compounds, in the expectation that they will have similar properties.⁵⁹

This reasoning does not, however, squarely apply to DNA-based technology. Although DNA is, obviously enough, a chemical compound, it is more fundamentally a carrier of *information*. Indeed, the informational link between DNA and amino acids has been well established for decades (and was clearly established before the inventions at issue in *Bell* and *Deuel* were formulated). As a consequence, the biotechnology researcher who knows the partial or complete amino acid sequence information for a particular protein can use that sequence information to design a nucleotide probe that will search for, and isolate, the target DNA sequence.⁶⁰ There is no need for the amino acid sequence to be structurally similar to the DNA sequence (and, indeed, it is not). The CAFC's failure to recognize DNA-based technologies as involving information first and foremost reveals its inability to adjust existing paradigms to address new technology.

Admittedly, to some limited extent, the CAFC has acknowledged the informational link between DNA and amino acids. However, to the extent that it has acknowledged this link, the CAFC appears to be well behind the technology. In rejecting arguments about the informational link between an amino acid sequence and its corresponding DNA sequence, the CAFC has emphasized the idea that, because most amino acids can, at least in theory, be specified by several different combinations of the four DNA bases (adenine, cytosine, guanine, and thymine), various different DNA base sequences can code for the same amino acid sequence.⁶¹ The longer the amino acid sequence is, the more possible DNA sequences there are. Thus, as the CAFC has emphasized, a typical protein, which generally includes many different amino acids, could conceivably be coded for by thousands of different DNA sequences.⁶²

What the CAFC has ignored, however, is that researchers do not attempt to deduce the DNA sequence for a protein directly from its amino acid sequence. Rather, the researcher designs a DNA probe based on a *small piece* of the amino acid sequence. She then uses the probe to screen a cDNA library for the desired full DNA sequence. Of course, in theory, even a small amino acid sequence

59. See *Dillon*, 919 F.2d at 693.

60. See Notice of Public Hearing and Request for Patent Protection of Biotechnological Inventions, 59 Fed. Reg. 45,267, 45,269 (1994) (describing the approach and noting that it has been used since the early 1980s).

61. See *In re Deuel*, at 1558-59; *Bell*, 991 F.2d at 784.

62. See *Bell*, 991 F.2d at 784.

could be coded for by a number of different DNA sequences. However, well before the time the inventions at issue in *Bell* and *Deuel* were being formulated, it was known that the effects of degeneracy could be minimized by selecting areas of the protein's amino acid sequence that contained amino acids coded for by one or two possible codons (and avoiding those areas with amino acids coded for by five or six codons).⁶³ The degeneracy problem could be further minimized by taking advantage of "codon catalogs" that listed the preferences various species had shown in codon selection.⁶⁴

The mistakes made by the CAFC stem in large part from institutional constraints. One major constraint is simply that of resources. Like appellate courts generally, the CAFC is an institution of limited resources.⁶⁵ It cannot expand its decisionmaking capacity to keep pace with the expansion of technology. Indeed, as Professor Neil Komesar, one of the most thoughtful commentators on comparative institutional analysis, has noted, "the central role of the independent judge makes it very doubtful that adjudicative capacity—the size or scale of courts—can be expanded as easily as the capacities of the market . . . without seriously changing the character of the adjudicative process."⁶⁶

Another institutional constraint generally faced by courts is technical competence.⁶⁷ To be sure, this may be less of a problem for

63. See *Ex Parte Deuel*, 33 U.S.P.Q.2d at 1450.

By focusing, however, on sequences that mainly contain the less common amino acids, it is usually possible to define a small collection of oligonucleotides, one of which should be exactly complementary to the segment of interest. Such a restricted collection can then be used as probes to identify the complementary cDNA clones by hybridization. Already this approach has been used to isolate a number of important cDNA clones, and while it is never as simple as described here, it nevertheless is a practical technique that is bound to be increasingly employed.

Id.

64. See Anita Varma & David Abraham, *DNA Is Different: Legal Obviousness and the Balance Between Biotech Inventors and the Market*, 9 HARV. J.L. & TECH. 53, 62 (1996).

65. The literature on comparative institutional analysis emphasizes that, of the various major institutions that influence social policy (e.g., the legislature, the executive branch, the market, and the courts), the courts have by far the most limited capacity. See, e.g., NEIL K. KOMESAR, *IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY* 142-145 (1994) (discussing limited scale of adjudicative process).

66. *Id.* at 144.

67. See, e.g., Howard S. Erlanger & Thomas W. Merrill, *Institutional Choice and Political Faith*, 22 L. & SOC. INQUIRY 959, 968 n.9 (1997).

If we choose courts as the institutions to pursue a goal, we are subjecting ourselves to the views of generalist judges and the cross-section of the community embodied in the jury. Both the political system (through legislative committees or administrative agencies) and the market (through specialized institutions) can call on greater specialized knowledge.

the CAFC than for other courts. After all, the CAFC was created as a response to the widely divergent approaches the various federal appeals courts of general jurisdiction had taken towards patents.⁶⁸ The CAFC was intended as a forum that would rationalize patent law by hearing all patent appeals, whether from a district court or directly from the PTO. Nonetheless, the CAFC may not be as competent as other institutional alternatives. As an initial matter, the CAFC is not particularly specialized—it has jurisdiction not only over the PTO but also over such varied agencies as the Board of Contract Appeals, the Merit Systems Protection Board, and the International Trade Commission.⁶⁹ Moreover, the majority of the judges on the CAFC do not have technical backgrounds.⁷⁰

III. HOW CAN NEW TECHNOLOGY BE ADDRESSED?

The CAFC's failure to address adequately the new technology created by the biotechnology industry raises the obvious question of how such new technology should be addressed. In assessing alternatives, it is important to avoid hoping for "Nirvana" solutions.⁷¹ All approaches to addressing new technology will have their advantages and their drawbacks. Indeed, in this regard, we already have the cautionary example of the CAFC itself. Although the CAFC has arguably brought greater consistency and stability to patent law, it has also been charged with favoritism towards patent owners.⁷² In

Id.

68. See S. REP. NO. 275, 97th Cong., 2d Sess., at 5 (1982) (noting Congressional desire to increase doctrinal stability in the area of the patent law); see also H.R. REP. NO. 312, 97th Cong., 1st Sess., at 20-22 (1981) (noting that some circuit courts are regarded as pro-patent and others as anti-patent and that much time and energy is expended shopping for a favorable venue).

69. The legislative history also suggests that Congress did not intend to create a narrowly specialized court. See H.R. REP. NO. 312, 97th Cong., 1st Sess. 19 (1981) (noting that the bill creates a new intermediate appellate court less specialized than either of its predecessors and provides the judges of the new court with a breadth of jurisdiction that rivals that of the regional courts of appeal).

70. Only Judges Gajarsa, Lourie, and Newman have an undergraduate or advanced degree in a natural science. See generally ALMANAC OF THE FEDERAL JUDICIARY, FEDERAL CIRCUIT (Christine Housen ed., 1999) (providing biographical information on Federal Circuit judges including their education).

71. See generally Harold Demsetz, *Information and Efficiency: Another Viewpoint*, 12 J.L. & ECON. 1 (1969) (cautioning against the Nirvana fallacy).

72. See, e.g., Donald R. Dunner, et al., *A Statistical Look at the Federal Circuit's Patent Decisions: 1982-84*, 5 FED. CIR. B.J. 151, 154 (1995) (noting that, in district court cases, the CAFC was "significantly more likely to affirm district court judgments in favor of patent owners than accused infringers"). Specifically, the CAFC affirmed that district court judgments that a patent was nonobvious (and hence valid) about 88% of the time while affirming judgments that it was obvious (and hence invalid) only 61% of the time. See *id.* Similarly, the affirmance rate for district court judgments of validity under § 102 was 85% as compared to only 62% for invalidity under that section. See *id.* at 154-55. As for § 112, the CAFC affirmed validity under that section 87% of the time while

addition, the CAFC has clearly failed to keep up with the new technologies of molecular biology.

As an institutional matter, there are a variety of ways that the CAFC's deficiencies in the biotechnological arena might be addressed. The various institutional options boil down, however, to three basic alternatives: the market; legislative action; and administrative agencies, in this case the Patent and Trademark Office.⁷³ I consider each of these alternatives in turn.

A. *Let the Market Sort It Out*

It could be argued that the CAFC's mistakes in assigning property rights are not that significant. Specifically, even if property rights have been accorded to inventions that are obvious to those of "ordinary skill in the art," the ultimate effect of such assignment is not dramatic. After all, Coase's theorem holds that, absent transaction costs, property rights will be licensed to those who can make the most productive use of these rights.⁷⁴ Thus, the initial allocation of rights does not matter.⁷⁵

There are, however, several problems with this assertion. As an initial matter, Coase's theorem does not apply in the situation where rights that should have been accorded have *not* been accorded. For example, if the written description requirement is interpreted as strictly as the CAFC seems bent on interpreting it, then inventors will not be able to lay claim to biotechnological inventions to which they should legitimately be able to lay claim. As a consequence, the traditional market failure that intellectual property rights are intended to cure (i.e., the underproduction of valuable but cheaply copied inventions) will reassert itself.

Moreover, even in the context of excessive property rights, market approaches do not necessarily provide a solution. In the biotechnology area, the Coasean assumption of zero transaction costs is inapplicable. Biotechnology researchers working in a given area often need access to a wide variety of prior research published in the field.⁷⁶ If each element of this prior research is patented by a differ-

affirming invalidity only 37% of the time. *See id.* at 155. It bears mention, however, that the problem of bias towards interest groups such as patent owners arises with other institutional alternatives as well.

73. I have argued elsewhere that scientific research norms can represent a powerful institutional mechanism for achieving the proper balance between property rights and the public domain. *See Rai, supra* note 6. These norms apply, however, only to basic scientific research. By contrast, this Article discusses all research in the biotechnology area, not simply basic research.

74. *See R. H. Coase, The Problem of Social Cost*, 3 J.L. & ECON. 1, 15 (1960).

75. *See id.*

76. For example, in order to develop a commercial treatment for a genetic disease, particularly a disease influenced by a variety of different genes, it might be necessary to have access to a large variety of genetic information. *See, e.g., Michael Heller & Rebecca Eisenberg, Can Patents Deter Innovation? The*

ent entity, a large number of different licenses will have to be negotiated.⁷⁷ In addition, because it is often very difficult to evaluate the monetary worth of scientific research (particularly basic research far removed from commercial development that could lead in a variety of different directions), the cost of each licensing transaction is likely to be high.

Some commentators have suggested that the transaction cost difficulties associated with a proliferation of intellectual property rights represent only a temporary problem. This is because owners of such rights who are repeat players in a given market will come up with market mechanisms for addressing these difficulties.⁷⁸ For example, patent pools, which aggregate patent rights for the purposes of joint package licensing, might emerge.⁷⁹ As the United States Department of Justice has recognized, patent pools can "provide competitive benefits by integrating complementary technologies, reducing transaction costs, clearing blocking positions and avoiding costly infringement litigation."⁸⁰ However, the historical record with respect to patent pools is not encouraging. The two most historically prominent and comprehensive patent pools, the pools that arose in the automobile and aircraft industries, emerged only after protracted litigation.⁸¹ Moreover, even when patent pools did emerge, they were sometimes anti-competitive. For example, the Association of Automobile Manufacturers, a patent pool that arose in the early days of the automobile industry, maintained strict restrictions on the group of auto manufacturers to whom the benefits of pool membership would be extended.⁸²

Moreover, patent pools that promote competition are even less likely to emerge in the biotechnology industry than in the aircraft and automobile industries. As economists who have studied cooperative institutions such as patent pools have demonstrated, these institutions typically emerge only where the parties involved have long-term relationships and are relatively homogenous.⁸³ The membership of two narrow patent pools that have recently emerged to facilitate licensing of patents necessary to implement certain multi-

Anticommons in Biomedical Research, 290 SCIENCE 698, 699 (1998); see also Rai, *supra* note 6.

77. See Rai, *supra* note 6.

78. See generally Robert Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293 (1996) (arguing that participants in industries with strong intellectual property rights will form institutions to address transaction costs associated with licensing such rights).

79. See *id.* at 1340-42.

80. Department of Justice-Federal Trade Commission, *Antitrust Guidelines for the Licensing of Intellectual Property* § 5.5.

81. See Rai, *supra* note 6.

82. See WILLIAM GREENLEAF, *MONOPOLY ON WHEELS: HENRY FORD AND THE SELDEN PATENT* 101-102, 106-108, 173-75 (1961).

83. See, e.g., ELINOR OSTROM, *GOVERNING THE COMMONS* 88-89, 188 (1990).

media technological standards bears this thesis out. One of these pools consists of various hi-tech companies that own patents essential for compliance with the MPEG-2 compression technology standard.⁸⁴ The other pool comprises electronics companies (e.g., Sony Corporation of Japan, Pioneer Electronic Corporation of Japan) that own patents essential to the manufacture of digital versatile discs (DVDs) and players in compliance with the DVD-ROM and DVD-Video formats.⁸⁵ By contrast, the relevant players in the biotechnology industry include institutions ranging from federal agencies and academic institutions to various different types of private companies, each of which has a different agenda.⁸⁶ In the context of a patent pool, these heterogeneous parties would probably have difficulty reaching agreement on the licensing policy the pool should adopt.⁸⁷

B. *The Legislature*

An institutional alternative to both the courts and the market might be the legislature. In the context of biotechnology, the legislature would, however, represent a peculiar choice. In contrast with other areas of technological change, such as telecommunications, cyberspace, or computer software,⁸⁸ current difficulties in biotechnol-

84. See Business Review Letter, MPEG-2 Patent Pool, from Joel I. Klein, Assistant Attorney General, to Garrard R. Beeney, Esq., Sullivan and Cromwell, June 26, 1997, reprinted in *Technology Licensing and Litigation 1998: Protecting Your Clients' Rights*, 514 PLI/PAT 729, 740 (1998). The limitation of the patent pool to complementary, technically essential patents ensures that the pool does not foreclose competition between patents that could be competitive with each other. It also ensures that a patent portfolio license does not foreclose implementation of alternative competitive standards. See *id.* at 740. Indeed, the MPEG-2 portfolio license explicitly leaves licensees free independently to make products that do not comply with the MPEG-2 standard. See *id.* at 742. In addition, the companies that control licensing of the patent pool (each of which has contributed at least one patent to the pool) have agreed to license the patent portfolio on a nondiscriminatory basis to all licensees who request a portfolio license. See *id.* at 734.

85. See Phillips, Sony and Pioneer Business Review Letter, from Joel I. Klein, Assistant Attorney General, to Garrard R. Beeney, Esq., December 16, 1998, reprinted in *Handling Intellectual Property Issues in Business Transactions*, 55 PLI/PAT 201, 219 (1999). Like the MPEG-2 patent portfolio, the DVD patent portfolio will be licensed to all interested parties. See *id.* at 209. In addition, the owners of the patents in the portfolio are free to license their essential patents independently of the portfolio license. See *id.*

86. See Heller & Eisenberg, *supra* note 76, at 700.

87. See *id.* (making a similar point).

88. Arguably, at least some of the questions raised by technological developments in telecommunications, cyberspace, and computer software require new law. For example, in telecommunications, where such previously disparate media such as cable, telephone, and the Internet are beginning to converge as a technological matter, it may be necessary to construct a novel legal regime. See Liebman, *supra* note 3, at 823 ("Notwithstanding the dogged persistence of category, categorical [legal] doctrines divorced from economic and technological reality cannot survive indefinitely."). Similarly, in cyberspace, scholars have

ogy emerge not from the legal standards themselves but, rather, from the CAFC's faulty *application* of these standards. Of course, we could ask the legislature to come up with a *sui generis* regime for biotechnology that specified in detail how particular standards such as nonobviousness or written description should apply. Such a *sui generis* regime would be subject to several problems, however. First, the possibility of special interest influence in a legislative regime of such specialized application would be quite significant. Economic and legal theorists prominent in the public choice movement have long lamented the undue susceptibility of the political process to small, politically active interest groups.⁸⁹ In addition, the administrative costs of developing and applying a *sui generis* approach would be quite significant. Finally, and perhaps most importantly, there is no reason to assume that even a *sui generis* approach would be flexible enough to accommodate future research developments in the biotechnology industry. For example, in the case of the *sui generis* approach taken in the Semiconductor Chip Protection Act, technological change has significantly diminished the relevance of the Act.⁹⁰

C. *The Patent and Trademark Office*

A final possible alternative would involve having the CAFC take seriously the PTO's role as a specialized administrative agency and accordingly show it greater deference. The issue of deference is important not only with respect to the PTO's legal determinations but also with respect to its factual determinations. This is because, even though questions of patent validity such as nonobviousness are ultimately legal questions,⁹¹ the factual findings of the PTO regarding what the prior art teaches the person of "ordinary skill in the art" are very important for the ultimate legal determination.⁹² In this

identified a variety of circumstances in which new law may be needed. See Hardy, *supra* note 3, at 1015 (noting that "new technologies may create opportunities for new kinds of behavior and that existing policies behind real space analogs to cyberspace behavior may simply not apply"). Finally, existing categories of intellectual property (e.g., patent, copyright) may not apply particularly well to computer software. See generally Pamela Samuelson et al., *A Manifesto Concerning the Legal Protection of Computer Programs*, 94 COLUM. L. REV. 2308 (1994) (concluding that existing laws are inadequate to protect some aspects of computer programs).

89. See, e.g., George Stigler, *A Theory of Economic Regulation*, 2 BELL J. ECON. & MGMT SCI. 3, 3 (1971). The tendency of legislation to favor the interest of politically active small groups over the interest of the politically dormant majority is, of course, inefficient.

90. See A. Samuel Oddi, *An Easier Case for Copyright than for Patent Protection of Computer Programs*, 72 NEB. L. REV. 351, 450-51 (1993).

91. See Craig Allen Nard, *Deference, Defiance, and the Useful Arts*, 57 OHIO ST. L.J. 1415, 1437 (1995) (discussing Supreme Court and CAFC cases characterizing nonobviousness as a legal question).

92. *Id.*

Section, I will, therefore, address the issue of deference with respect to determinations of both fact and law.

Under the Administrative Procedure Act ("APA"), agencies like the PTO are generally entitled to deference on factual questions. Specifically, the APA provides that agency factfinding shall only be set aside if it is "arbitrary, capricious, an abuse of discretion, or . . . unsupported by substantial evidence."⁹³ The institutional competence argument in favor of court deference to agency factfinding is straightforward: in technically complex areas, specialized agencies are much more likely to know the relevant facts than are courts.⁹⁴ This institutional competence argument has merit even with respect to a relatively specialized court like the CAFC. While most CAFC judges do not have technical backgrounds, PTO examiners are required to have such backgrounds: a biotechnology patent examiner must, for example, have a bachelor's degree in biology, chemistry, biochemical engineering, or biomedical engineering.⁹⁵ Indeed, in the area of biotechnology, the PTO has over 150 Ph.Ds.⁹⁶ Moreover, the examiners-in-chief, who sit on the PTO's appellate body, the Board of Patent Appeals and Interferences ("BPAI"), are required by statute to be both technically and legally proficient.⁹⁷ Finally, unlike the CAFC, the PTO can conduct public hearings to familiarize itself with the technology in a particular industry.⁹⁸

Thus far, however, the CAFC has not been inclined to show APA-level deference to the PTO's factual findings. Rather, it has employed the "clearly erroneous" standard of review set forth in Federal Rule of Civil Procedure 52(a).⁹⁹ The clearly erroneous standard of review, which governs appellate court review of findings of fact made by a district court judge, is less deferential than the APA standard.¹⁰⁰

With respect to factual findings, the Federal Circuit's practice of refusing to show APA-level deference is at an end. A recent decision

93. 5 U.S.C. § 706(2)(A),(E) (1994). Although the "arbitrary, capricious, abuse of discretion" standard technically applies to agency factfinding in the context of informal adjudications, and the "substantial evidence" standard to agency factfinding "on the record," the two standards are substantively quite similar. *Dickinson v. Zurko*, 119 S. Ct. 1816, 1821 (1999).

94. See, e.g., *Consolo v. Federal Maritime Comm'n*, 387 U.S. 607, 620 (1966) (noting that deference to agency factfinding respects agency expertise).

95. See *USOPM-Job Details* (visited June 15, 1999) <<http://www.usajobs.com.opm.gov/wfjic/jobs/BG1809.HTM>>.

96. See Nard, *supra* note 91, at 1506 n.352.

97. See 35 U.S.C. § 7(a) (1994) ("The examiners-in-chief shall be persons of competent legal knowledge and scientific ability.").

98. See Nard, *supra* note 91, at 1501 & n.341 (discussing the PTO's public hearings with the biotechnology and computer software industries).

99. See, e.g., *In re Zurko*, 142 F.3d 1447, 1459 (Fed. Cir. 1998).

100. See *Dickinson*, 119 S. Ct. at 1818 (citing 2 K. DAVIS & R. PIERCE, *ADMINISTRATIVE LAW TREATISE* § 11.2, 174 (3d ed. 1994)). The difference between the standards is not large, however. See *id.*

by the Supreme Court, *Dickinson v. Zurko*,¹⁰¹ mandates that the Federal Circuit must, with respect to factual findings made by the PTO, use the APA standard of review. The Supreme Court decision makes sense not only on doctrinal grounds—the PTO is an agency and the terms of the APA indicate it applies to PTO decisions¹⁰²—but also from the standpoint of policy. As was discussed above, the PTO is well-equipped to deal with specialized knowledge. Indeed, as the *Zurko* decision emphasizes, the CAFC's predecessor body, the Court of Customs and Patent Appeals ("CCPA"), deferred to the PTO on factual findings precisely because the PTO was "an expert body" that could "better deal with the technically complex subject matter."¹⁰³

In addition, with respect to legal questions, a strong argument can be made that the PTO deserves deference. To a significant extent, legal decisions regarding patentability represent determinations of how best to balance property rights and the public domain in any given industry. Such determinations require both technical and economic expertise. As an agency that already has a substantial background in biotechnology and can further its knowledge by holding hearings with the biotechnology industry, the PTO has begun to accumulate that expertise. Moreover, the Supreme Court has recognized that agency expertise is a good reason for deference not only on factual questions but also on legal questions.¹⁰⁴

There are, however, significant arguments against unqualified deference to the PTO. As an initial matter, PTO expertise in technology is hardly uniform. In the computer software area, for example, the PTO is quite inexperienced.¹⁰⁵ In addition, the PTO's ability to maintain close contact with the various industries that seek patents is a double-edged sword. Although the PTO's interactions with industry may lead to greater expertise, they may also lead to a pro-patent bias.

Given these considerations, how should the law of deference apply to PTO determinations of patentability? Although a full discussion of this complicated question is well beyond the scope of this paper,¹⁰⁶ a few thoughts are in order.

101. 119 S. Ct. 1816 (1999).

102. *See id.* at 1819-22.

103. *Id.* at 1822.

104. *See, e.g., Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 661-52 (1990) ("[A]gency expertise is one of the principal justifications behind *Chevron* deference."). As explained further below, *Chevron* deference is the main analytical framework for deference used by the Supreme Court. *See infra* notes 107-16 and accompanying text.

105. *See* Raymond Van Dyke, *Software Patents Offer Opportunities and Obstacles*, THE NAT'L L.J., May 24, 1999, C19, C20 (noting that PTO has limited experience with software patents and that some of the software patents that the PTO has allowed have involved technologies that were widely known and used before the patent's filing date).

106. For example, I make no attempt to address whether deference on legal

The Supreme Court's dominant analytical framework for deference was enunciated by the Court in *Chevron v. National Resources Defense Council*.¹⁰⁷ Under *Chevron*, the deference analysis proceeds in two steps. The first step requires that the court determine whether the statutory language addresses the precise question at issue. If it does, "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."¹⁰⁸ If the court determines that Congress has not addressed the precise question at issue, it proceeds to step two, which requires that the court defer to the agency's construction of the statute, so long as that construction is reasonable.¹⁰⁹

Although the precise scope of *Chevron*'s application to agency decisionmaking is not entirely clear, the Supreme Court has suggested that *Chevron* is limited to rulemaking by agencies to which Congress has delegated substantive rulemaking authority.¹¹⁰ In a recent case, *Merck & Co. v. Kessler*,¹¹¹ the CAFC applied this limitation to hold that, because the PTO had not been given substantive rulemaking authority by the Patent Act, the *Chevron* framework did not apply an interpretive "Final Determination" by the PTO.¹¹² With respect to PTO interpretive rules, the CAFC's interpretation of Su-

determinations would contravene either the constitutional role of the court "to say what the law is," *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803), or the language of the APA, which states that "the reviewing court shall decide all relevant questions of law," 5 U.S.C. § 706 (1994). For discussions of these issues, see, for example, Cynthia Farina, *Statutory Interpretation and the Balance of Power in the Administrative State*, 89 COLUM. L. REV. 452 (1989) (arguing that deference violates traditional separation-of-powers principles); Cass Sunstein, *Law and Administration after Chevron*, 90 COLUM. L. REV. 2071 (attempting to reconcile deference and *Marbury* by suggesting that many agency interpretations of ambiguous statutes involve questions of policy as well as law); John Duffy, *Administrative Common Law in Judicial review*, 77 TEX. L. REV. 113, 193-207 (1998) (arguing that certain uses of deference violate the language of the APA). I discuss the issue of deference to the PTO's legal determinations further in Arti K. Rai, *Deference and the PTO*, WASH. U. L. & POL'Y (forthcoming spring 2000).

107. 487 U.S. 835 (1984).

108. *Id.* at 842.

109. *See id.* at 843.

110. *See* EEOC v. *Aramco*, 499 U.S. 244, 257 (1991) (arguing that interpretation of Title VII statutory language by EEOC did not deserve deference because EEOC did not have authority to promulgate rules or regulations under Title VII); *Adams Fruit Co. v. Barrett*, 494 U.S. 638, 650 (1990) ("Although agency determinations within the scope of delegated authority are entitled to deference, it is fundamental 'that an agency may not bootstrap itself in to an area in which it has no jurisdiction.'" (citations omitted)). Some commentators have also suggested this limitation. *See* Sunstein, *supra* note 106, at 2093 (arguing that "*Chevron* might be taken to suggest that whenever an agency is entrusted with rulemaking 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").

111. 80 F.3d 1543, 1549-50 (1996).

112. *Id.* at 1550 (citing 35 U.S.C. § 6(a) (1994)).

preme Court precedent may well be accurate.¹¹³ However, because the *Merck* case involved deference in the context of rulemaking, its relevance for PTO *adjudications* of nonobviousness (and other factors that relate to patentability) is not entirely clear.¹¹⁴ Arguably, because the Patent Act gives the PTO authority to "perform all duties required by law respecting the granting and issuing of patents and trademarks,"¹¹⁵ Congress has delegated adjudicatory power to the PTO, and, therefore, application of the *Chevron* framework to PTO adjudications regarding patentability is merited. This is particularly the case because the CAFC has given deference to interpretations made by the PTO (or, more specifically, by the Trademark Trial and Appeal Board ("TTAB"), which is an arm of the PTO) in the context of trademark adjudication.¹¹⁶

On the other hand, it would be a mistake for the Federal Circuit to apply the Supreme Court's *Chevron* jurisprudence unqualifiedly to PTO determinations of patentability. Because patentability determinations generally involve application of statutory terms that are ambiguous (consider, for example, the nonobviousness standard), such determinations would almost always be reviewed under step two of *Chevron*. Moreover, because step two, as applied by the Supreme Court, has almost never been used to strike down an agency's interpretation,¹¹⁷ strict adherence to Supreme Court prece-

113. A few commentators have, however, argued that the PTO does have the power to make substantive rules. See Nard, *supra* note 91, at 1453 n.148.

114. See GARY LAWSON, *FEDERAL ADMINISTRATIVE LAW* 604 (1998) (noting that the *Merck* court did not have occasion to determine whether "nonrule-making agencies could receive *Chevron* deference for interpretations issued during adjudications"). Indeed, in various pre-*Merck* cases involving PTO adjudications, the CAFC invoked the *Chevron* framework. See, e.g., *Hoechst v. Quigg*, 917 F.2d 522, 526-29 (1990) (invoking *Chevron* but arguing that the issue of deference did not have to be reached because the intent of Congress was clear). Moreover, although the CAFC has, post-*Merck*, argued that *Chevron* does not apply even to interpretations issued during adjudications, see *In re Portola*, 110 F.3d 786, 788 (Fed. Cir. 1997), the Supreme Court has not decided the question of what deference is due the adjudicative decisions of nonrule-making agencies.

115. 35 U.S.C. § 6(a).

116. See *Eastman Kodak Co. v. Bell & Howell Document Management Prods. Co.*, 994 F.2d 1569 (Fed. Cir. 1993) (according *Chevron* deference to TTAB adjudication that trademark was merely descriptive and therefore not entitled to registration); see also Nard, *supra* note 91, at 1433 (noting that the Federal Circuit has applied *Chevron* deference to an appeal from the TTAB, "a close relative of the BPAI").

117. See Ronald Levin, *The Anatomy of Chevron: Step Two Reconsidered*, 72 CHI.-KENT L. REV. 1253, 1261 (1997) (noting that, as of 1997, the Supreme Court had "never once struck down an agency's interpretation by relying squarely on the second *Chevron* step"). In those cases in which it applies the *Chevron* framework, the Court usually avoids step two altogether by claiming that the plain language of the statute is unambiguous. See Richard J. Pierce, *The Supreme Court's New Hypertextualism: An Invitation to Cacophony and Incoherence in the Administrative State*, 95 COLUM. L. REV. 749, 750 (1995) (not-

dent would result in uniform deference to the PTO. Deference would be required even where PTO expertise was quite limited or where the PTO had shown evidence of bias.

The arguments against unqualified deference to the PTO suggest that it might be useful to limit *Chevron*. One way in which this could be done would be by giving some force to the step two reasonableness inquiry. Indeed, a number of administrative law scholars have recently issued calls for vigorous step two review.¹¹⁸ As a general matter, vigorous step two review would serve as an important check on agency behavior. In the specific case of the PTO, requiring it to "explain why its interpretation is good policy in light of the purposes and concerns underlying the statutory scheme"¹¹⁹ would help to guard against incomplete knowledge and bias.

CONCLUSION

New technologies in biotechnology do not require a fundamental rethinking of patent law principles. However, they do require the attention of an institution that has the resources to investigate and understand an expanding amount of complex, constantly changing information. A comparative analysis of the available institutions suggests that the PTO may be the institution best situated to address technological change in biotechnology. Given the PTO's comparative institutional advantage, the CAFC should clearly show greater deference to the factual findings of the PTO. Deference to the PTO's legal findings poses a more complicated question. On balance, however, an appropriately limited form of the *Chevron* deference framework should probably apply.

ing 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"). See also Thomas Merrill, *Judicial Deference to Executive Precedent*, 101 YALE L.J. 969, 977 (1991) (noting that Supreme Court's approach to *Chevron* "makes deference an all-or-nothing matter").

118. Articles that have urged vigorous review at the *Chevron* step two stage include Levin, *supra* note 117, at 1253-71 (discussing, and approving, use of such review by D.C. Circuit); Mark Seidenfeld, *A Syncopated Chevron: Emphasizing Reasoned Decisionmaking in Reviewing Agency Interpretations of Statutes*, 73 TEX. L. REV. 83, 125-29 (1994) (arguing for vigorous review on political theory grounds); and Gary Lawson, *Outcome, Procedure, and Process: Agency Duties of Explanation for Legal Conclusions*, 48 RUTGERS L. REV. 313, 314 (1996) (arguing that vigorous review is required by "[w]ell-settled principles of administrative review").

119. Seidenfeld, *supra* note 118, at 129.

