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Re-Examining the Role of Patents in Appropriating the Value of DNA Sequences

Rebecca S. Eisenberg
University of Michigan Law School, rse@umich.edu

RE-EXAMINING THE ROLE OF PATENTS IN APPROPRIATING THE VALUE OF DNA SEQUENCES†

*Rebecca S. Eisenberg**

As public and private sector initiatives race to complete the sequence of the human genome,[1] patent issues have played a prominent role in speculations about the significance of this achievement.[2] How much of the genome will be subject to the control of patent holders, and what will this mean for future research and the development of products for the improvement of human health?[3] Is a patent system developed to establish rights in mechanical inventions of an earlier era up to the task of resolving competing claims to the genome[4] on behalf of the many sequential innovators who elucidate its sequence and function,[5] with due regard to the interests of the scientific community[6] and the broader public?[7]

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* Robert & Barbara Luciano Professor of Law, University of Michigan Law School. A.B., Stanford University (1975); J.D., University of California, Berkeley School of Law (Boalt Hall) (1979). I am grateful to Robert Cook-Deegan, Ronald Mann, Margaret Parr, and workshop participants at Haifa University, the University of Washington, Harvard University, Lewis & Clark University, the University of Minnesota, Emory University, the University of Pennsylvania, Princeton University, Stanford University, and the University of California at Berkeley for helpful comments on earlier drafts of this Article.

1 *See* Paul Smaglik, *A Billion Base Pairs, Times Two*, THE SCIENTIST, Dec. 6, 1999, at 8; Justin Gillis & Rick Weiss, *Private Firm Aims to Beat Government to Gene Map*, WASH. POST, May 12, 1998, at A1; Philip E. Ross, *The Making of a Gene Machine*, FORBES, Feb. 21, 2000, at 98; Nicholas Wade, *2 Groups in DNA Race Differ on Fixing Project's Finish Line*, N.Y. TIMES, Apr. 11, 2000, at A27; Nicholas Wade, *Scientist's Plan: Map All DNA Within 3 Years*, N.Y. TIMES, May 10, 1998, at A1; Francis S. Collins, *The Sequence of the Human Genome: Coming a Lot Sooner Than You Think* (visited Jan. 10, 2000) <http://www.nhgri.nih.gov/NEWS>.

2 *See* Justin Gillis, *Md. Gene Researcher Draws Fire on Filings; Venter Defends Patent Requests*, WASH. POST, Oct. 26, 1999, at E1; Peter G. Gosselin, *Patent Office Now at Heart of Gene Debate*, L.A. TIMES, Feb. 7, 2000, at A1; Ralph T. King, Jr., *Code Green: Gene Quest Will Bring Glory to Some; Incyte Will Stick With Cash*, WALL ST. J., Feb. 10, 2000, at A1.

3 *See* Peter G. Gosselin, *Clinton Urges Public Access to Genetic Code*, L.A. TIMES, Feb. 11, 2000, at A1; Peter G. Gosselin & Paul Jacobs, *Clinton, Blair to Back Access to Genetic Code*, L.A. TIMES, Mar. 14, 2000, at C1.

4 *See, e.g.*, Philippe Ducor, *Recombinant Products and Nonobviousness: A Typology*, 13 COMPUTER & HIGH TECH. L.J. 1 (1997); Karen F. Lech, Ph.D., Note, *Human Genes Without Functions: Biotechnology Tests the Patent Utility Standard*, 27 SUFFOLK U. L. REV. 1631 (1993).

5 *See* Rebecca S. Eisenberg, *Structure and Function in Gene Patenting*, 15 NATURE GENETICS 125 (1997); Stanley Fields, *The Future is Function*, 15 NATURE GENETICS 325 (1997).

6 *See* Martin Enserink, *Patent Office May Raise the Bar on Gene Claims*, 287 SCIENCE 1196 (2000).

Given that applicants have been seeking and obtaining patent claims on DNA sequences for twenty years,[8] one might expect that the Patent and Trademark Office ("PTO") and courts would have resolved many of the legal issues surrounding this practice. The patent system has had many opportunities to apply traditional patent law principles to a broad range of issues involving genetic discoveries as the industry has pursued and litigated patent claims covering biotechnology products.[9] One might therefore expect that biotechnology patent law would now be entering a relatively mature phase in which fundamental questions have been resolved and the issues that remain to be addressed are incremental and interstitial. Instead, the patent system is struggling to clarify the ground rules for patenting DNA sequences, while years worth of patent applications accumulate in the PTO. What accounts for this persistent lack of clarity regarding how patent law applies to these discoveries?

A significant part of the problem is that new technologies are rapidly changing how discoveries are made in genetics and genomics research. The patent system, which inevitably requires years to resolve even routine matters,[10] has so far focused primarily on the discoveries of the 1980s. DNA sequences that were the subject of patent claims in that era typically consisted of cloned genes that enabled the production of proteins through recombinant DNA technology.[11] Patents on the genes encoding these proteins promised exclusivity in the market for the protein itself, equivalent to the protection that a pharmaceutical firm obtains by patenting a new chemical compound that can be used as a drug. From this perspective, patents on DNA sequences seemed analogous to patents on new chemical entities. The Court of Appeals for the Federal Circuit accordingly turned to prior cases considering patents on chemicals in resolving disputed issues about how patent law should apply to

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[7] *See* Jon F. Merz et al., *Disease Gene Patenting Is a Bad Innovation*, 2 MOLECULAR DIAGNOSIS 299-304 (1997).

[8] *See* Rebecca S. Eisenberg, *Patenting the Human Genome*, 39 EMORY L.J. 721 (1990).

[9] *See, e.g.*, Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362 (Fed. Cir. 1999) (FLAVR SAVR® tomato); Bio-Technology General Corp. v. Genentech, Inc., 80 F.3d 1553 (Fed. Cir. 1996) (human growth hormone); Novo Nordisk of North Amer., Inc. v. Genentech, Inc., 77 F.3d 1364 (Fed. Cir. 1996) (human growth hormone); Genentech, Inc. v. The Wellcome Found., Ltd., 29 F.3d 1555 (Fed. Cir. 1994) (tissue plasminogen activator); Genentech, Inc. v. Eli Lilly & Co., 998 F.2d 931 (Fed. Cir. 1993) (human growth hormone); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991) (erythropoietin); Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991) (Factor VIII:C); Hormone Research Found., Inc. v. Genentech, Inc., 904 F.2d 1558 (Fed. Cir. 1990) (human growth hormone).

[10] Mark A. Lemley, *An Empirical Study of the Twenty-Year Patent Term*, 22 AIPLA Q.J. 369 (1994).

[11] *See, e.g.*, U.S. Patent No. 4,703,008, October 27, 1987 (DNA sequences encoding erythropoietin).

DNA sequences.[12] Whatever the limitations of this analogy, it provided a relatively clear point of departure for analyzing patent law issues presented by the first generation of biotechnology products—therapeutic proteins produced through recombinant DNA technology.

As DNA sequence discovery has moved beyond targeted efforts to clone particular genes to large-scale, high-throughput sequencing of entire genomes, new questions have emerged. The DNA sequences identified by high-throughput sequencing look less like new chemical entities than they do like new scientific information. From the perspective of patent claimants, the chemical analogy is of little value as a strategic guide to exploiting this information as intellectual property. From the perspective of the PTO and courts, claims to these discoveries raise unresolved questions that strain the chemical analogy. The result is profound uncertainty concerning how to apply the doctrinal tools of patent law for determining what may be patented and for drawing boundaries between the rights of inventors and the rights of the public.

I. PATENT ELIGIBILITY

A threshold issue that one might expect to have been resolved long ago is whether DNA sequences are the sort of subject matter that the patent system protects. The U.S. patent statute defines patent-eligible subject matter as "any ... process, machine, manufacture, or composition of matter."[13] The U.S. Supreme Court has held that this language encompasses an expansive scope that includes "anything under the sun that is made by man."[14] Although cases have held that "products of nature" may not be patented, this exclusion has not presented an obstacle to patenting DNA sequences in forms that do not occur in nature as new "compositions of matter."[15] On the threshold issue of patent-eligible subject matter, as on other issues, the analogy to chemical patent practice has supplied an answer.

The standard patent lawyer's response to the "products of nature" limitation is to treat it as a technical, claim-drafting problem. From this perspective, the prohibition against patenting products of nature only prevents the patenting of DNA sequences in a naturally occurring form that requires no human

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[12] *See, e.g., Amgen*, 927 F.2d at 1200 ("A gene is a chemical compound, albeit a complex one.").

[13] 35 U.S.C. § 101 (1994).

[14] Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (citing S. REP. No. 82-1979, at 5 (1952); H.R. REP. No. 82-1923, at 6 (1952)).

[15] *See supra* note 11.

intervention. One cannot get a patent on a DNA sequence with claim language that would be infringed by someone whose DNA continues to do what it has done for generations in nature. But one *can* get a patent on the same DNA sequence with more limited claim language that could only be infringed through the intervention of modern biotechnology.

Patents have thus issued on "isolated and purified" DNA sequences, separate from the chromosomes in which they occur in nature, or on DNA sequences that have been spliced into recombinant vectors or introduced into recombinant cells of a sort that do not exist in nature.[16] This is consistent with longstanding practice, even prior to the advent of modern biotechnology, of allowing patents to issue on isolated and purified chemical products that exist in nature only in an impure state, when human intervention has made them available in a new and useful form.[17] This is not simply a lawyer's trick, but a persuasive response to the intuition that patents should only issue for human inventions. It prevents the issuance of patents that take away from the public things that they were previously using (such as the DNA that resides in their cells), while allowing patents to issue on new human manipulations of nature. Those of us who simply use the DNA in our own cells, as our ancestors have been doing for generations, should not and need not worry about patent infringement liability. On the other hand, those of us who get injections of recombinant insulin or erythropoietin should in fairness expect to pay a patent premium to the inventors who made these technological interventions possible.

The patentability of DNA molecules in forms that involve human intervention appears to be well settled. But recent advances in DNA sequencing raise the question of patent eligibility in a new way that courts have yet to address.

II. MOLECULES VS. INFORMATION

DNA sequences are not simply molecules, they are also information. Knowing the DNA sequence for the genome of an organism provides valuable

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[16] Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737, 1959 (D. Mass. 1990) ("The invention claimed in the '008 patent is not as plaintiff argues the DNA sequence encoding human EPO since that is a nonpatentable natural phenomenon 'free to all men and reserved exclusively to none.' . . . Rather, the invention as claimed in claim 2 of the patent is the "purified and isolated" DNA sequence encoding erythropoietin.") (quoting *Chakrabarty*, 447 U.S. at 309).

[17] *See, e.g.*, Merck & Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156 (4th Cir. 1958) (upholding the patentability of purified Vitamin B-12).

scientific information that can open the door to future discoveries. Can the value of this information be captured through patents? Can information about the natural world, as distinguished from tangible human interventions that make use of that information, be patented?

The traditional statutory categories of patent-eligible subject matter—processes, machines, manufactures, and compositions of matter—seem to be limited to tangible products and processes, as distinguished from information as such. Although many cases have used the word "tangible" in defining the boundaries of patentable subject matter, neither the language of the statute nor judicial decisions elaborating its meaning have explicitly excluded "information" from patent protection. Arguably, such a limitation is implicit in prior judicial decisions stating that the patent system protects practical applications rather than fundamental new insights about the natural world[18] and in cases holding that "printed matter" is ineligible for patent protection.[19]

The exclusion of information itself from patent protection is also at least implicit in the statutory requirement that patent applicants make full disclosures of information about their inventions, with no restrictions upon public access to the disclosures once the patents issue.[20] One important function of patent disclosures is to enable the public to use inventions freely as soon as the patents expire, but this function alone cannot explain why patent law requires that disclosures become freely accessible to the public at the beginning of the patent term. The timing of the disclosure requirement suggests another function that is inconsistent with patent claims that cover the disclosed information itself. In the words of a leading commentator, "full

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[18] *See, e.g., Chakrabarty*, 447 U.S. at 309 ("Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'") (citing Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948)); Dickey-John Corp. v. International Tapetronics Corp., 710 F.2d 329, 348 n.9 (7th Cir. 1983) ("Yet patent law has never been the domain of the abstract—one cannot patent the very discoveries which make the greatest contributions to human knowledge, such as Einstein's discovery of the photoelectric effect nor has it ever been considered that the lure of commercial reward provided by a patent was needed to encourage such contributions. Patent law's domain has always been the application of the great discoveries of the human intellect to the mundane problems of everyday existence.").

[19] *See, e.g., In re* Russell, 48 F.2d 668 (C.C.P.A. 1931); Guthrie v. Curlett, 10 F.2d 725 (2d Cir. 1926). More recent decisions, while not explicitly overruling these prior cases, seem to limit the vitality of the printed matter exclusion from patentability. *See, e.g., In re* Lowry, 32 F.3d 1579 (Fed. Cir. 1994) (reversing PTO "printed matter" rejection of patent claims to a data structure for storing, using and managing data in a computer memory).

[20] 35 U.S.C. §§ 112, 154(a)(4) (1994). *See In re* Argoudelis, 434 F.2d 1390 (C.C.P.A. 1970).

disclosure . . . on issuance of the patent immediately increases the storehouse of public information available for further research and innovation."[21]

Patent claims on DNA sequences as "compositions of matter" give patent owners exclusionary rights over tangible DNA molecules and constructs, but do not prevent anyone from perceiving, using, and analyzing information about what the DNA sequence is. Once the patent issues, this information becomes freely available, subject only to the inventor's right to exclude others from making using, and selling the claimed materials. For patents on genes that encode therapeutic proteins, the value of this exclusionary right over tangible compositions of matter has been sufficiently large relative to the value of the information that spills over to the public through the patent disclosure to motivate inventors to file patent applications rather than to keep the sequence secret.[22] The commercially significant aspect of these discoveries was not the informational value of knowing what the sequence was, but the tangible value of being able to use the DNA molecules in recombinant production facilities to make therapeutic proteins for sale. So long as patents permitted capture of this tangible, commercial value, there was no need to withhold the sequence information from the public.

In contrast, in the contemporary setting of high-throughput DNA sequencing, there is immediate commercial value in knowing what the sequence is, while the commercial value of using particular portions of the sequence as tangible templates for protein production is remote and speculative. There are two reasons why informational value looms large relative to tangible value in this context, in contrast to the targeted cloning projects of an earlier era that yielded sequences encoding products of known value. First, high-throughput DNA sequencing typically yields information about DNA sequences for which the corresponding biological functions are not yet understood. It is thus unclear at the time of sequencing whether a particular sequence will have tangible value. Second, high-throughput DNA sequencing typically yields considerable chaff (in the form of non-coding sequences and sequences that do not correspond to any apparent commercial products) along with the occasional bit of wheat (in the form of sequences encoding commercially valuable proteins or offering other uses in tangible form). What is most valuable about these research results, at least initially, is

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[21] 3 DONALD S. CHISUM, CHISUM ON PATENTS § 7.01, at 7-3 (1999).

[22] Indeed, the scientists who cloned the genes encoding the first generation of biotechnology products typically published the DNA sequences they identified long before the corresponding patents issued (although after filing patent applications to avoid loss of patent rights outside the U.S.).

that they provide an information base for future discovery. DNA molecules corresponding to some portions of the sequence, such as those portions that encode valuable proteins or that are the site of diagnostic markers, may ultimately prove valuable as tangible compositions of matter. But it might not be immediately apparent just where in the sequence these nuggets of tangible value lie.

It is not obvious how an inventor might use patents to capture the value of DNA sequence discoveries under these circumstances. It may be difficult to draft claim language[23] that covers the portions of the sequence that prove to have tangible value without claiming either too broadly (rendering the claim invalid because it covers similar sequences that have already been disclosed in the prior art),[24] or too narrowly (rendering the claim easy to evade through minor changes in the molecule).[25] More importantly, claim language that is directed to tangible molecules fails to capture the informational value of knowing the sequence itself. If this informational value is great relative to the speculative value of tangible molecules corresponding to portions of the sequence, the more sensible strategy may be to sell access to a proprietary database of sequence information. So far, database subscriptions have been the principle source of revenue for most private firms involved in high-throughput DNA sequencing, although the same firms have also filed patent applications.[26]

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[23] The language of patent claims defines the scope of the patent holder's exclusionary rights. *See* 35 U.S.C. § 112 (1994); *Ex parte* Fressola, 27 U.S.P.Q.2d (BNA) 1608 (Bd. Pat. App. & Interf. 1993).

[24] A broad claim is a claim that has few limitations. One might, for example, seek a claim that covers any molecule that includes (or "comprises," in the vernacular of patent law) at least ten consecutive nucleotides from the disclosed sequence. If allowed, such a claim would be very broad in that it would be likely to cover any portion of the sequence that later proves to encode a valuable protein. But the breadth of the claim makes it more likely that it will be held invalid. The claim would be invalid if any previously disclosed DNA sequence included any 10 consecutive nucleotides that were identical to any portion of the sequence disclosed in the patent appplication. The shorter the portion of the disclosed sequence that is necessary to establish infringement, the broader the claim. But the broader the claim, the easier it is to find "prior art" disclosures that would fall within the scope of the claim, rendering the claim invalid. *See, e.g.*, Titanium Metals Corp. v. Banner, 778 F.2d 775, 782 (Fed. Cir. 1985) (stating that when a "claim covers several compositions, the claim is [invalid] if *one* of them is in the prior art") (emphasis added).

[25] A narrow claim is a claim that has many limitations. One might, for example, claim the entire disclosed sequence as an isolated molecule. Because every element of the claim must be present in a competitor's product to establish infringement, a competitor who made a DNA molecule that included only a portion of the disclosed sequence corresponding to a particular protein would not be liable.

[26] *See* King, *supra* note 2.

III. CLAIMING COMPUTER-READABLE INFORMATION

Another strategy that the PTO is currently facing but courts have yet to consider seeks to capture the informational value of DNA sequences through patent claims directed toward DNA sequences stored in a computer-readable medium. An early example of this strategy is the patent application filed by Human Genome Sciences ("HGS") on the sequence of the *Haemophilus influenzae* Rd genome.[27] This patent application has not yet issued as a patent anywhere in the world, but it was published eighteen months after its filing date under the terms of the Patent Cooperation Treaty.[28] *Haemophilus influenzae* is a bacterial strain that causes ear and respiratory tract infections in humans, and was the first bacterium to have its genome fully sequenced.[29] The fate of the related patent applications may offer a preview of how the patent system will allocate patent rights in future genomic discoveries. HGS filed a patent application setting forth the complete nucleotide sequence of the genome, identified as "SEQ ID NO.1."[30] The application concluded with a series of claims representing the invention to which HGS sought exclusive rights. The first of these claims read as follows:

> Computer-readable medium having recorded thereon the nucleotide sequence depicted in SEQ ID NO:1, a representative fragment thereof or a nucleotide sequence at least 99.9% identical to the nucleotide sequence depicted in SEQ ID NO:1.[31]

It bears emphasizing that this is not yet an issued patent. The foregoing claim language, in effect, is the first item on the wish list of HGS for patent rights associated with the discovery of the *H. influenzae* genome.

This claiming strategy represents a fundamental departure from the previously sanctioned practice of claiming DNA sequences as tangible molecules. By claiming exclusionary rights in the sequence information itself,

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[27] Nucleotide Sequence of the *Haemophilus influenzae* Rd Genome, Fragments Thereof, and Uses Thereof, WO 96/33276, PCT/US96/05320 (international patent application published under the Patent Cooperation Treaty on October 24, 1996).

[28] Patent Cooperation Treaty, June 19, 1970, art. 21(2), 28 U.S.T. 7645 (197) (providing for the publication of international patent applications 18 months after their priority dates).

[29] *See* R.D. Fleischmann et al., *Whole-Genome Random Sequencing and Assembly of* Haemophilus influenzae *Rd.*, 269 SCIENCE 496 (1995).

[30] The sequencing was done at The Institute for Genomic Research ("TIGR"), a private, non-profit organization affiliated with HGS at the time. Pursuant to an agreement between TIGR and HGS, patent rights in the *H. influenzae* genome were assigned to HGS.

[31] *See supra* note 27.

if stored in a computer-readable medium,[32] HGS seeks patent rights that would be infringed by information storage, retrieval, and analysis rather than simply by making, using, or selling DNA molecules. It remains to be seen whether the PTO will issue such a claim, or whether a rejection would stand up on appeal to the Federal Circuit.[33]

IV. EXPANSIVE TREND OF CASE LAW

Recent decisions concerning the patentability of computer-implemented inventions may provide more guidance than prior decisions concerning the patentability of discoveries in the life sciences in predicting whether DNA sequence information stored in computer-readable medium may be patented. The overall trend of decisions in the Federal Circuit is toward expansive interpretation of the scope of patent eligible subject matter—even for categories of inventions that prior decisions seemed to exclude from the protection of the patent statute—in order to make the patent system "responsive to the needs of the modern world."[34] The most conspicuous recent example of this trend was the 1998 decision in *State Street Bank & Trust v. Signature Financial Group* upholding the patentability of a computer-implemented accounting system for managing the flow of funds in partnerships of mutual funds that pool their assets.[35] This invention arguably fell within previously apparent judicial limitations that excluded mathematical algorithms[36] and business methods[37] from patent protection. The Federal Circuit minimized the first of these limitations,[38] holding that it only excluded from patent protection "abstract ideas constituting disembodied concepts or truths that are not 'useful.'"[39] It then repudiated the second, insisting that "[t]he business method exception has never been invoked by this court, or [its

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[32] The meaning of this term could be quite broad. See *infra* text accompanying notes 49-50.

[33] An applicant whose claims have been rejected by a PTO examiner twice may appeal to the Board of Patent Appeals and Interferences. *See* 35 U.S.C. § 134 (1994). An applicant who is dissatisfied with the decision of the Board of Patent Appeals and Interferences may appeal to the United States Court of Appeals for the Federal Circuit. 35 U.S.C. § 141 (1994).

[34] AT&T Corp. v. Excel Communications, Inc., 172 F.3d 1352, 1356 (1999). For a critical examination of the recent expansion in patent eligibility, *see* John R. Thomas, *The Post-Industrial Patent System*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 3 (1999).

[35] 149 F.3d 1368 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999).

[36] *See* Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63 (1972).

[37] *See* Hotel Sec. Checking Co. v. Lorraine Co., 160 F. 467 (2d Cir. 1908).

[38] The exclusion of mathematical algorithms from patent protection had already been substantially restricted by prior decisions of the Federal Circuit. *See, e.g., In re* Alappat, 33 F.3d 1526 (Fed. Cir. 1994).

[39] *State Street Bank & Trust*, 149 F.3d at 1373.

predecessor], to deem an invention unpatentable," and that other courts that had appeared to apply the business method exception always had other independent grounds for arriving at the same decisions without needing to rely on a categorical exclusion of business methods from patent protection.[40]

Rather than seeing the language of section 101 of the Patent Act, which permits patents to issue for "any new and useful process, machine, manufacture, or composition of matter," as a significant limitation on the types of advances that might qualify for patent protection, the Federal Circuit characterizes this language as a "seemingly limitless expanse," subject only to three "specifically identified ... categories of unpatentable subject matter: 'laws of nature, natural phenomena, and abstract ideas.'"[41] From this perspective, it is not obvious why DNA sequence information stored in computer-readable medium—a product that requires human intervention and serves human purposes—would be categorically excluded from patent protection.

V. PTO GUIDELINES

Of course, DNA sequence information stored in computer-readable medium is not the same thing as a computer-implemented business method, and it is certainly possible to define boundaries for the patent system that include the latter but not the former. Indeed, the PTO's Examination Guidelines for Computer-Related Inventions exclude data stored in computer-readable medium from patent protection.[42] The guidelines distinguish between "functional descriptive material" (such as "data structures and computer programs which impart functionality when encoded on a computer-readable medium"), and "non-functional descriptive material" (such as "music, literary works and a compilation or mere arrangement of data [which] is not structurally and functionally interrelated to the medium but is merely carried by the medium").[43] Although functional descriptive material generally will fall

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[40] *Id.* at 1375-76.

[41] *Excel Communications*, 172 F.3d at 1355 (citing Diamond v. Diehr, 450 U.S. 175, 185 (1981)).

[42] Examination Guidelines for Computer-Related Inventions, 61 Fed. Reg. 7478 (1996).

[43] *Id.* The focus on functional relationship between data and substrate echoes language from *In re Lowry*, 32 F.3d 1579 (Fed. Cir. 1994), in which the Federal Circuit upheld the patentability of a data structure for storing, using and managing data in a computer memory. In that case, the Board of Patent Appeals reversed the examiner's rejection of the claims under 35 U.S.C. § 101 as claiming non-statutory subject matter, and the issue of patentable subject matter was therefore not properly before the court on appeal. *Id.* Nonetheless, in its analysis of the remaining issues of patentability under 35 U.S.C. §§ 102 and 103, the court drew a

within the statutory categories of patent-eligible subject matter, the guidelines state that non-functional descriptive material generally will not meet the statutory limitations: "Merely claiming non-functional descriptive material stored in a computer-readable medium does not make it statutory. Such a result would exalt form over substance."[44] DNA sequence information stored in a computer-readable medium seems to fall squarely within the PTO's definition of "non-functional descriptive material" that is "merely carried by" the computer-readable medium and is not functionally interrelated to it.[45]

If the PTO continues to follow these four-year-old guidelines, it should reject claims to DNA sequence stored in computer-readable medium. But if a disgruntled patent applicant appeals to the Federal Circuit, that court might well reverse the rejection. The distinction between tangible molecules and intangible information may do little work today in delineating the boundaries of patent eligibility in the face of recent decisions de-emphasizing the importance of physical limitations in establishing the patentability of computer-implemented inventions. This shift in emphasis is particularly apparent in *AT&T v. Excel Communications*,[46] in which the Federal Circuit

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distinction between claiming information content and claiming a functional structure for managing information:

> Contrary to the PTO's assertion, Lowry does not claim merely the information content of a memory. Lowry's data structures, while including data resident in a database, depend only functionally on information content. While the information content affects the exact sequence of bits stored in accordance with Lowry's data structures, the claims require specific electronic structural elements which impart a physical organization on the information stored in memory. Lowry's invention manages information. As Lowry notes, the data structures provide increased computing efficiency.

Id. at 1583.

[44] Examination Guidelines for Computer-Related Inventions, 61 Fed. Reg. at 7478. This qualification in the Guidelines responds to a rhetorical question posed by Judge Archer in his dissenting opinion from the *en banc* decision of the Federal Circuit in *In re Alappat*, 33 F.3d 1526 (Fed. Cir. 1996). In that case, a majority of the court upheld the patentability of a claim to a computer-implemented mechanism for improving the quality of a picture in an oscilloscope. Judge Archer cautioned against the potential implications of allowing patent claims on mathematical algorithms stored in computer-readable medium in his dissenting opinion, asking rhetorically whether a piece of music recorded on a compact disc or player piano roll would be patentable:

> Through the expedient of putting his music on known structure, can a composer now claim as his invention the structure of a compact disc or player piano roll containing the melody he discovered and obtain a patent therefor? The answer must be no. The composer admittedly has invented or discovered nothing but music. The discovery of music does not become patentable subject matter simply because there is an arbitrary claim to some structure.

33 F.3d at 1554 (Archer, C.J., dissenting).

[45] Examination Guidelines for Computer-Related Inventions, 61 Fed. Reg. at 7478.

[46] 172 F.3d 1352, 1359-60 (Fed. Cir. 1999).

explicitly declined to focus on the "physical limitations inquiry" that had played a central role in distinguishing between unpatentable mathematical algorithms and patentable computer-implemented inventions in its prior decisions. Instead, the court asked "whether the mathematical algorithm is applied in a practical manner to produce a useful result."[47] This approach seems to merge the issue of patent eligibility with the issue of utility, opening the door to patent claims to information so long as it is "useful."

VI. TRADITIONAL PATENT BARGAIN

If the Federal Circuit steps back from the momentum of its recent decisions expanding the boundaries of the patent system, it should not be persuaded that information stored in computer-readable medium is patentable. Patent claims to information—even useful information—represent a fundamental departure from the traditional patent bargain. That bargain has always called for free disclosure of information to the public at the outset of the patent term in exchange for exclusionary rights in particular tangible applications until the patent expires.[48] Patent claims that are infringed by mere perception and analysis of the information set forth in the patent disclosure undermine the strong policy preventing patent applicants from restricting access to the disclosure once the patent has issued.[49] The limitation that the information be stored in computer-readable medium offers scant protection for the public interest in free access to the informational content of patent disclosures. Scanning technologies arguably bring paper printouts of DNA sequence information within the scope of the claim language, an interpretation that would make copying the patent document itself an act of infringement. Even if the claim language is more narrowly interpreted to cover only electronic media, numerous websites post the full text of issued patents, including a website maintained by the PTO.[50] Any claim that would count these postings as acts of infringement simply proves too much.

Patents on information surely represent a departure from tradition. But departure from tradition may not be a sufficient ground to reject them in light of the increasing importance of information products to technological progress.

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[47] *Id.* at 1360.

[48] *See supra* notes 20-21 and accompanying text.

[49] *See In re* Argoudelis, 434 F.2d 1340, 1394-96 (C.C.P.A. 1970) (Baldwin, J., concurring); Feldman v. Aunstrup, 517 F.2d 1351, 1355 (C.C.P.A. 1975).

[50] *See Patent Information and Searchable Database* (visited Sept. 8, 2000) <http://www.uspto.gov/web/menu/pats.html>.

Perhaps the traditional bargain of free disclosure of information in exchange for exclusionary rights that are limited to tangible applications makes no sense in this new environment. If the value of unprotectible information gained from high-throughput DNA sequencing is great relative to the value of tangible molecules that might be covered by established claiming strategies, patents that do not allow the inventor to capture the value of the information might not do enough to motivate investment in DNA sequencing. This may seem unlikely as an empirical matter, given the substantial investments that are being made in DNA sequencing efforts in both the public and private sectors with no clear precedent for capturing the informational value of this investment through the patent system,[51] but it is at least a logical possibility. A more plausible speculation is that inventors will forego the patent bargain if they are stuck with the traditional terms of that bargain, choosing instead to exploit their discoveries through restricted access to proprietary DNA sequence databases.[52]

Although the conventional wisdom in the patent community is that patent protection promotes the public interest in technological progress better than trade secrecy, it is by no means clear that the public interest in progress in genomics would be better served by issuing patents on DNA sequence information in computer-readable medium than by relying on trade secrecy to motivate investment in DNA sequence databases. If the terms of the traditional patent bargain are altered to allow patent holders to capture the informational value of their discoveries, the bargain becomes less attractive to the public. The public might be better off withholding patents and allowing others to derive the same information independently. Withholding patents makes particular sense if the efforts of the patent holder are not necessary to bring the information into the public domain. Much DNA sequence information is freely disclosed in the public domain, both by publicly funded researchers and by private firms. If a discovery is likely to be made and disclosed promptly even without patent incentives, there is little point in enduring the social costs of exclusionary rights.[53]

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[51] *See, e.g.*, Barry A. Palevitz, *Rice Genome Gets a Boost: Private Sequencing Effort Yields Rough Draft for the Public*, THE SCIENTIST, May 1, 2000, at 1.

[52] In fact, private firms that invest in DNA sequencing appear to be pursuing a dual strategy of licensing access to proprietary databases while pursuing traditional composition of matter patents on particular sequences within those databases that appear likely to correspond to valuable tangible products. *See* Ralph T. King, Jr., *supra* note 2.

[53] Normally the nonobviousness standard set forth at 35 U.S.C. § 103 prevents the issuance of patents on inventions that are highly likely to be made independently by another inventor by excluding from patent protection inventions that would have been "obvious" to persons of ordinary skill in the field of the invention given the state of the art. This standard fails to serve this important function in the context of DNA sequencing

VII. BRICKS AND MORTAR RULES FOR INFORMATION GOODS

There are sound policy reasons to be wary of permitting use of the patent system to capture the value of information itself. The traditional patent bargain ensures that patenting promptly enriches the information base, even as it slows down commercial imitation.[54] This balances the interests of inventors in earning a return on past research investments against the interests of the larger public in promoting future research. If patent claims could prevent the perception and analysis of information, this balance would tilt sharply in favor of patent owners.

Even if some form of intellectual property protection for information is necessary to promote investment in the creation of new information products, one might question whether the patent system is a suitable model. Compared to other forms of intellectual property protection, such as copyrights and trade secrets, there are few safety valves built into the patent system that constrain the rights of patent holders in favor of competing interests of the public. Unlike copyright law, patent law has no fair use defense that permits socially valuable uses without a license.[55] Contrary to the understanding of many scientists, patent law has only a "truly narrow" research exemption that offers no protection from infringement liability for research activities that are commercially threatening to the patent holder.[56] Nor is independent creation a defense to patent infringement, in contrast to both copyright law[57] and trade secret law.[58] Unlike trade secret law, patent law has no defense for reverse engineering.[59] The most important concession to the competing interests of the public that is built into a patent, apart from its finite term,[60] is the disclosure

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because of decisions of the Federal Circuit upholding the patentability of newly identified DNA sequences discovered through routine work, so long as the prior art did not permit prediction of the structure of the DNA molecule. *See In re* Deuel, 51 F.3d 1552 (Fed. Cir. 1995); *In re* Bell, 991 F.2d 781 (Fed. Cir. 1993).

[54] *See supra* notes 44-48 and accompanying text.

[55] 17 U.S.C. § 107 (1994). For an interesting analysis of whether a fair use defense would make sense for the patent system, *see* Maureen A. O'Rourke, *Towards a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

[56] Roche Prods., Inc. v. Bolar Pharmaceuticals, Inc., 733 F.2d 858, 863 (Fed. Cir. 1984). For a fuller discussion of the research exemption, see Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989).

[57] *See* 2 PAUL GOLDSTEIN, COPYRIGHT § 7.1.1, at 7:2 (2d ed. 1996) ("Infringement turns strictly on proof of copying and improper appropriation.").

[58] *See, e.g.*, Chicago Lock Co. v. Fanberg, 676 F.2d 400, 404 (9th Cir. 1982).

[59] *See* Kewanee Oil v. Bicron, 416 U.S. 470, 490 (1974); Rockwell Graphic Sys., Inc. v. DEV Indus., Inc., 925 F.2d 174, 178 (7th Cir. 1991).

[60] The rule for determining the expiration date of a U.S. patent was changed in 1995 by the Uruguay

requirement.[61] By requiring full disclosure of how to make and use the invention, and by mandating that this disclosure become freely available as soon as the patent issues, the patent system in effect permits unlicensed use of information about the invention, as distinguished from use of the tangible invention itself. But if patents issue that restrict the public from perceiving and analyzing information about the invention, the claim effectively defeats that safety valve.

If information is not appropriate subject matter for patent protection, does it follow that DNA sequences should not be patented at all? The foregoing discussion distinguishes between patent claims to DNA sequences stored in computer-readable medium, which are tantamount to patent claims on information itself, and traditional patent claims to DNA molecules and constructs. But perhaps any principle that excludes information from patent protection has broader implications for patents on DNA sequences. DNA molecules may be thought of as a tangible storage medium for information about the structure of proteins. Cells read the information stored in DNA molecules to make the proteins that they need to survive in their environments, and they copy that information when they divide and reproduce.[62] If DNA sequence information is not patentable when it is stored in an electronic medium that is readable by computers, how can it nonetheless be patented when stored in a molecular medium that is readable by living cells?

A quick answer is that information stored in a computer-readable medium is directed at the human observers who are the intended beneficiaries of the information spillovers that arise through patent disclosures. It is therefore *human*-readable information that must not be patented as such in order to maintain a balance between the exclusionary rights of patent holders and the rights of the public to use the disclosures that are the quid pro quo of those exclusionary rights. But humans can direct queries to DNA sequence information whether it is stored in molecular form or in electronic form. One might, for example, use DNA molecules as probes to detect the presence of a particular DNA sequence in a sample. This sort of molecular query has

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Round Amendments Act, Pub. L. No. 103-465, 108 Stat. 4809 (codified at 35 U.S.C. § 154(a)(2) (1994 & Supp. 2000)). Prior to passage of that Act, U.S. patents expired 17 years after the date that they were issued, regardless of their application filing dates. The new rule, applicable to U.S. patents issued on the basis of patent applications filed after June 8, 1995, provides for expiration 20 years after their filing dates. 35 U.S.C. § 154(a)(2) (1994).

[61] 35 U.S.C. § 112 (1994).

[62] *See* BENJAMIN LEWIN, GENES V 81-107 (1994).

diagnostic and forensic applications as well as research applications. Researchers seeking to learn more about the functional significance of DNA sequence information are likely to query the information in both computer-readable and molecular form.[63] The distinction between computer-readable and molecular versions of DNA sequence is particularly difficult to maintain in the context of DNA array technology. DNA array technology involves immobilizing thousands of short oligonucleotide molecules on a substrate to detect the presence of particular sequences in a sample using specialized robotics and imaging equipment.[64] In effect, this technology enables people to use computers to perceive information stored in DNA molecules in a sample. When contemporary technology blurs the boundaries between computer-readable and molecular forms of DNA, what logic is there to drawing this distinction in determining the patent rights of DNA sequencers?

A pragmatic reason for maintaining this distinction is that patent claims to DNA sequences in molecular form have been and will probably continue to be crucially important in motivating costly and risky investments in the commercial development of new therapeutic proteins, which must be proven safe and effective in human clinical trials before they can be brought to market. The arguments for free access to DNA sequences as a means of promoting scientific progress may have equal force whether the sequence is claimed in electronic or molecular form, but the countervailing arguments for exclusivity are far more powerful for DNA sequences in molecular form. The importance of patents in motivating drug development is well established;[65] the importance

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[63] After sequencing DNA, researchers might analyze the sequence in computer-readable form to identify similarities to known sequences, and then analyze the sequence in cell-readable form to observe the functional significance of different portions of the sequence in a living cell or organism. They might, for example, use DNA molecules as probes to determine when and where an organism expresses a particular portion of its DNA sequence, or they might induce a cell to express a particular DNA sequence in order to learn more about the protein that it encodes, or they might interrupt expression of a DNA sequence in an organism and observe the consequences in order to learn more about the functions of the corresponding protein. This sort of interaction between analysis of electronic information and observation of how cells use the information characterizes what in recent years has become known as "functional genomics" research. *See* Stanley Fields, *The Future is Function*, 15 NATURE GENETICS 325 (1997); Philip Hieter & Mark Boguski: *Functional Genomics: It's All How You Read It*, 278 SCIENCE 601 (1997).

[64] *See* Roger Ekins and Frederick W. Chu, *Microarrays: Their Origins and Applications*, 17 TRENDS IN BIOTECHNOLOGY 217 (1999); Bob Sinclair, *Everything's Great When It Sits on a Chip—A Bright Future for DNA Arrays*, THE SCIENTIST, May 24, 1999, at 18.

[65] *See generally* Richard C. Levin et al., *Appropriating the Returns From Industrial Research and Development*, 3 BROOKINGS PAPERS ON ECONOMIC ACTIVITY 783-820 (1987) (indicating that the importance of patents varies considerably across different industries and that patents are particularly important in the pharmaceutical industry).

of patents in motivating the development of information products is speculative.[66]

A final argument for maintaining a distinction between DNA sequence information and DNA molecules at this point is consistency with tradition and precedent. Any categorical exclusion of DNA molecules from eligibility for patent protection would contradict the practice of the PTO and courts for two decades and would undermine the precedent-based expectations of a patent-sensitive industry. On the other hand, issuing patent claims that cover DNA sequence information stored in computer-readable medium would extend patentable subject matter beyond what the PTO and courts have recognized thus far, and would depart from a long tradition of free access to the information disclosed in issued patents. Genomics investors might hope to receive such patents, but they can hardly claim to have relied on their availability.

This analysis may seem stubbornly "bricks and mortar" in its focus on tangibility as the touchstone for protection, and therefore out of step with the needs of the modern information economy. If a significant portion of the value of DNA sequencing resides in the information that it yields, rather than in the molecules that correspond to that information, then perhaps we should not assume that investments in creating that value will be forthcoming on the basis of an intellectual property system that limits exclusionary rights to tangible things and allows the information itself to spill over to the general public.[67] At some point, we may need intellectual property rights that permit the creators of information products to capture the value of the information itself in order to motivate socially valuable investments. But if we have arrived at that point, then we need to look beyond the patent system for a suitable model. The patent system was designed to serve the needs of a "bricks and mortar" world, and it would be foolish to assume that it can meet the changing needs of the

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[66] Proposals for special legislation to provide intellectual property protection for databases have provoked a lively debate concerning the costs and benefits of such protection. *See, e.g.*, NATIONAL RESEARCH COUNCIL, BITS OF POWER: ISSUES IN GLOBAL ACCESS TO SCIENTIFIC DATA (1997); NATIONAL RESEARCH COUNCIL, A QUESTION OF BALANCE: PRIVATE RIGHTS AND THE PUBLIC INTEREST IN SCIENTIFIC AND TECHNICAL DATABASES (1999).

[67] The classic argument for intellectual property is that exclusionary rights are necessary to motivate investments in the creation of goods that are costly to make initially, but cheap and easy to copy once someone else has made the initial investment. As growing volumes of information become freely available on the internet, this argument seems to be overlooking significant incentives to create and disseminate information outside the intellectual property system. *See generally* CARL SHAPIRO & HAL VARIAN, INFORMATION RULES (1999).

information economy simply by expanding the categories of subject matter that are eligible for patent protection.