**Journal of Health Care Law and Policy**

Volume 6 | Issue 2 Article 4

# Public Access Versus Proprietary Rights in Genomic Information: What is the Proper Role of Intellectual Property Rights?

Janice M. Mueller

# PUBLIC ACCESS VERSUS PROPRIETARY RIGHTS IN GENOMIC INFORMATION: WHAT IS THE PROPER ROLE OF INTELLECTUAL PROPERTY RIGHTS?

JANICE M. MUELLER, J.D.*

## I. INTRODUCTION

Lauded as "the *sine qua non* of 21st-century biology,"[1] bioinformatics (formerly referred to as computational biology) is a burgeoning discipline at the intersection of information technology and the life sciences.[2] The February 2001 announcement of the complete sequencing of the human genome represents the signature event in the relatively short history of bioinformatics.[3] The central goal of bioinformatics is to organize, analyze, and generally make sense of the massive quantities of genetic data and information that resulted from this tremendous scientific achievement.[4]

This article examines the proper role of intellectual property rights (IPRs) in bioinformatics. IPRs are property rights in intangible "knowledge goods," such as inventions and discoveries, which convey to their owners the right to prevent unauthorized uses of the identified property. Just as the owner of a parcel of land has an exclusive possessory interest to prevent others from trespassing thereon, so too does the owner of an intellectual property right have the power to prevent unauthorized uses of her invention or discovery. For example, the owner of a patent on a newly-synthesized life-saving chemical composition may make and sell it herself, may exclude all manufacture, sale, or use of the drug by others, or may choose to permit any number of licensees to manufacture and sell the drug for a negotiated monetary fee.

Many have criticized the notion of establishing and enforcing *any* IPRs in the fruits of the human genome project, characterizing it as an endeavor intended to

---

* Professor of Law and U.S. Patent Attorney, John Marshall Law School, Chicago, Ill. The author welcomes comments and can be contacted at 312.427.2737 or by e-mail at 7mueller@jmls.edu.

1. Sylvia J. Spengler, *Bioinformatics in the Information Age*, 287 SCI. 1221, 1221 (2000).

2. *See generally* Brad Stone, *Wanted: Hot Industry Seeks Super Geeks*, NEWSWEEK, Apr. 30, 2001, at 54; David S. Roos, *Bioinformatics—Trying to Swim in a Sea of Data*, 291 SCI. 1260 (2001); Spengler, *supra* note 1; Teresa K. Atwood, *The Babel of Bioinformatics; Identifying, Counting Genes*, 290 SCI. 471 (2000); Nigel Williams, *How to Get Databases Talking the Same Language (Movement to Standardize and Coordinate Bioinformatics)*, 275 SCI. 301 (1997).

3. *See generally* J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCI. 1304 (2001); INT'L HUMAN GENOME SEQUENCING CONSORTIUM, *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE 860, 860-921 (2001).

4. An article published in 2001 reported that GenBank accommodates more than $10^{10}$ nucleotides of nucleic acid sequence data, a figure that is predicted to more than double in size every year. *See* Roos, *supra* note 2, at 1260.

benefit all mankind.[5] Regardless of one's philosophical and economic views on that larger question, which this article does not attempt to answer, many IPRs in genomic material such as genes and gene fragments have already been obtained or at least applied for by private sector firms.[6] This latter-day "gold rush" is ongoing despite the parallel movement to put as much genetic information into the public domain as possible.[7]

Given that IPRs already exist in genomic material and are likely to be enforced (at least if it is economically rational to do so), the inquiry should shift to consideration of the manner in which society can ensure unrestricted access and use of the genetic data and information, for purposes of research and development that leads to new innovation in health care—critically important therapeutics, diagnostics, methods of streamlined drug screening, and the like. Any proposed framework must balance the public health rationale for unrestricted access against the possibility of damaging powerful incentives for investment in the research and development leading to these innovations. This article does not purport to suggest a single answer to this complex balancing of interests, but rather proposes several different responses for further consideration.

Part II of this article provides an overview of the various forms of intellectual property protection that are potentially relevant to bioinformatics research and development. Part III specifically focuses on the issues of statutory subject matter and the utility requirement of patentability as relevant to bioinformatics-related inventions. Part IV surveys some of the possible responses to public access concerns raised by the ownership of patents in the life sciences. Part V considers how patent rights will intersect with the rise of industry standards in the life sciences, which will likely proliferate through advances in bioinformatics as has been the case in the electronics and computing industries.

## II. FORMS OF INTELLECTUAL PROPERTY PROTECTION IN BIOINFORMATICS

A patent is generally the exclusionary mechanism of choice in bioinformatics, by far the most powerful form of IPR. Patents are available in four broad categories of subject matter: processes (*e.g.*, methods), machines, manufactures, and compositions of matter.[8] For a discussion of bioinformatics, the two

5. Videotape: Dr. Francis S. Collins, Address at "At the Crossroads–Public/Private Priorities Concerning Access to Genetic Information" (Oct. 21, 2002) (on file with the University of Maryland School of Law, Thurgood Marshall Law Library).

6. *See* PriceWaterhouseCoopers, *DNA and Gene Sequence Patents* (2000) (table listing top 15 holders of U.S. patents on genes and DNA sequences), *at* http://www.pwcglobal.com/Extweb/industry.nsf/docid/5ACE2513FC2DC3C5852568E40051FB0E (last visited May 19, 2003).

7. *See, e.g.*, The SNP Consortium Ltd., *available at* http://snp.cshl.org (last visited May 19, 2003).

8. *See* 35 U.S.C.S. § 101 (2000).

categories of greatest relevance are probably methods and compositions of matter. The latter form of patent protects *products*, while method patents protect the *processes* for making and using products.

Patent protection is the most difficult form of protection to obtain because of the rigorous criteria that patentable inventions must satisfy: they must be new (*e.g.*, novel),[9] have utility (*e.g.*, some practical use),[10] and be considered "non-obvious" to a hypothetical "person having ordinary skill" in the technology in question at the time the inventions were made.[11] Moreover, patent applications must provide a written description of the invention in a manner that enables its manufacture and use without undue experimentation, and U.S. patents must further disclose the "best mode of carrying out the invention."[12]

Copyright protection is available for original (*e.g.*, minimally creative) works of authorship, such as literary works and compilations of data. Copyright protection is much "thinner" than patent protection, but more easily obtained. Copyright protects original works of authorship that are minimally creative. Bare data– facts– are not copyrightable, but compilations of data may obtain "thin" protection, insofar as the compilation reflects original selection, coordination, or arrangement of data.[13]

Because databases, as collections of fact arranged in some standard, non-creative order, such as numerical or alphabetical, generally do not qualify for copyright protection, some legal regimes such as the European Union (EU) have created a *sui generis* form of protection against copying of the contents of the database.[14] The European regulation provides a

> right for the maker of a database which shows that there has been qualitatively and/or quantitatively a substantial investment in the obtaining, verification, or presentation of the contents to prevent extraction and/or re-utilization of the whole or of a substantial part, evaluated qualitatively and/or quantitatively, of the contents of that database.[15]

---

9. *See* 35 U.S.C.S. § 102(a), (e) & (g) (2000).

10. *See* 35 U.S.C.S. § 101. n.77 (2000).

11. *See* 35 U.S.C.S. § 103(a) (2000).

12. *See* 35 U.S.C.S. § 112 (2000).

13. *See* Feist Pubs. v. Rural Tel. Serv. Co., 499 U.S. 340, 364 (1991). The Court rejected the "sweat of the brow," or "industrious collection" theory of copyright protection, and held that an alphabetically-arranged white pages telephone directory was not sufficiently original to be protected as a compilation. *Id.* at 359-60.

14. COUNCIL, EUROPEAN PARLIAMENT, DIRECTIVE 96/9/EC OF THE EUROPEAN PARLIAMENT OF THE COUNCIL OF 11 MARCH 1996 ON THE LEGAL PROTECTION OF DATABASES, at Chapter 3 (1996), *available at* http://eon.law.harvard.edu/ilaw/Contract/directive1 (last visited May 19, 2003).

15. *Id.*

The term of protection is fifteen years.[16] Exceptions are recognized for "private purpose" extractions and extraction for teaching or scientific research for non-commercial purposes. Those entitled to claim the European database rights must be EU nationals and companies/firms having a registered office or principal place of business in EU.

In the U.S., database vendors have sought to protect the contents of their databases from duplication by means of so-called "shrink wrap" or "click through" licenses. For example, the U.S. Court of Appeals for the Seventh Circuit in *ProCD, Inc. v. Zeidenberg* upheld a "shrink wrap" license that prohibited commercial use of the contents of a database.[17] Some bioinformatics firms such as Human Genome Sciences, Inc. (HGS), Incyte, and Celera are maintaining databases of genetic information as trade secrets and requiring users to enter into subscription agreements in order to access the data.[18] This form of Intellectual Propery (IP) protection depends on maintaining secrecy and limiting access, and does not protect against "reverse engineering" or independent development of the same information.[19] Trade secret rights also assume that the underlying information is economically valuable because of its secrecy and is the subject of reasonable efforts to preserve that secrecy.[20]

The remainder of this article focuses on patent protection, the area of greatest controversy within bioinformatics IPRs.

## III. PATENTABLE SUBJECT MATTER AND THE UTILITY REQUIREMENT

This section considers the categories of patentable subject matter that pertain to bioinformatics inventions, as well as the patentability requirement that these inventions must possess a practical utility. Patents are the leading form of protection for bioinformatics inventions. The prevailing view among the IP community is that "virtually all aspects" of bioinformatics qualify as potentially patentable subject matter,[21] assuming of course, the utility,[22] novelty,[23] and non-obviousness[24] of the invention.

---

16. *Id.*

17. 86 F.3d 1447 (7th Cir. 1996).

18. Information on these bioinformatics firms can be located *at* http://www.HGSI.com; http://www.incyte.com; http://www.celera.com, respectively (all last visited May 19, 2003).

19. *See, e.g.*, Pamela Samuleson & Suzanne Scotchmer, *The Law and Economics of Reverse Engineering*, 111 YALE L. J. 1575, *1577 (2002), WL 111 YLJ 1575.

20. *See* Diamond v. Chakrabarty, 447 U.S. 303, 318 (1980).

21. Teresa J. Welch, *Identifying and Protecting the Intellectual Property Value of Bioinformatics Inventions*, PATENT STRATEGY & MGMT., (American Lawyer, New York, N.Y.), July 2002, at 1.

22. *See* 35 U.S.C.A. § 101.

23. *Id.*

24. *Id.*

Nevertheless, patenting in bioinformatics is still in its infancy. The published literature indicates that since around 1990, approximately 125 bioinformatics patents have issued.[25] Approximately 900 bioinformatics patent applications are currently pending in United States Patent and Trademark Office (USPTO) "Art Unit" 1631, a special bioinformatics examining unit created in December 1999.[26]

What types of inventions are being patented in the bioinformatics realm? The traditional view is that one cannot patent genetic information *per* se,[27] but it is possible (and increasingly common) to obtain patent protection on the *tools* that manipulate, analyze, or apply such information. Many bioinformatics patents are directed to such "research tools," which are often claimed as processes or methods. These patents protect a method of performing a task by following a certain series of steps. For example, tool patents have issued on protein modeling systems, sequence alignment methods, combinatorial library systems, computer-aided sequence visualization and analysis systems, and methods of testing new drug candidates against diseases.[28]

Product patents are being obtained in genomic material in the form of nucleic acid molecules, cloning vectors, recombinant expression cassettes, host cells, proteins, and the like. It is axiomatic that one cannot patent "products of nature," such as a newly-discovered naturally-occurring mineral or a plant found in the wild, because these discoveries are considered the handiwork of nature, or basic building blocks of scientific progress that are free for all to study and use. Patents are intended to protect the results of human manipulation of nature's bounty. Thus, a naturally-occurring bacterium discovered in the root nodule of a tree is not patentable,[29] but a bacterium that has been genetically-engineered to digest

---

25. Welch, *supra* note 21, at 3. The accuracy of this figure depends, of course, on one's definition of "bioinformatics."

26. Welch, *supra* note 21, at 3; *see also* Douglas Steinberg, *New PTO Unit Examines Bioinformatics Applications*, SCIENTIST, Nov. 27, 2000, *available at* http://www.the-scientist.com/yr2000/nov/steinberg_p8_001127.html (last visited May 19, 2003); *see also* e-mail from John Doll, USPTO, to Janice Mueller, Associate Professor, The John Marshall Law School (Mar. 4, 2003, 04:36 EST) (on file with the author).

27. *See* Lawrence M. Sung, *The Unblazed Trail: Bioinformatics and the Protection of Genetic Knowledge*, 8 WASH. U. J. L. & POL'Y 261, 268 (2002).

28. Welch, *supra* note 21, at 2. For example, see U.S. Patent Application No. 20030005483 ("Data Processing of the Maize Prolifera Genetic Sequence") (filed Jan. 2, 2003), which claims, *inter alia*, a data processing system for altering prolifera levels in plants:

11. A data processing system, comprising: data representing at least one genetic sequence; a genetic identification, analysis, or modeling computer program designed to govern the processing of such data; a data processor having an output for storing or displaying data processing results, said data processor containing said data and said program and executing instructions according to said program to process said data or a contiguous subsequence thereof; and wherein said genetic sequence is: (i) at least 90% sequence identical to a polynucleotide sequence of SEQ ID NO: 1, or (ii) at least 95% sequence identical to a polypeptide sequence of SEQ ID NO: 2, and wherein sequence identity is determined by the GAP algorithm under default parameters.

29. *See* Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948).

multiple components of spilled crude oil is patentable.[30] Thus, the human genome *as it exists in the human body* is not patentable.

It is possible, however, to obtain patent protection on the products of isolation and purification of genomic material. For example, patents have issued on expressed sequence tags (ESTs),[31] single nucleotide polymorphisms (SNPs),[32] full-length genes such as the breast cancer genes BRCA1 and BRCA2,[33] x-ray crystallographic structures, and deoxyribonucleic acid (DNA) arrays on microchips. The theory is that the isolation, purification, manipulation, and so on of a natural product can result in an invention that is sufficiently changed as to be novel and non-obvious with respect to the natural product on which it was based.[34]

*Product* patents are considered the most economically valuable, because they protect against unauthorized use of the product for *any* purpose (in contrast with *process* patents, which protect only the recited use or method).[35] The controversy for product patents in the life sciences often centers on the *utility* requirement.[36] Only *one* "substantial, specific and credible" utility need be established in order to obtain a product patent.[37] If a single utility is established, then the product patent is granted and that product patent controls all later-discovered uses of the product, at least under existing precedent.[38]

Consider, for example, the controversial patent granted in February 2000 to HGS of Rockville, Maryland on the gene that encodes the "CCR5" cell surface receptor, now recognized as an entry point for the AIDS virus.[39] When HGS filed its patent application, it knew only that its discovery played a general role as a receptor, or entry point into cells for foreign attacking organisms; the company expected to exploit the patent primarily in the development of anti-inflammatory therapies.[40] About a year after filing the patent application, independent research, which was not the work of HGS, showed that the CCR5 receptor is a critical entry

30. *See* Diamond v. Chakrabarty, 447 U.S. 303, 317 (1980).

31. A fragment of DNA which may be used to identify a particular gene. Allan C. Nunnally, *Commercialized Genetic Testing: The Role of Corporate Biotechnology in The New Genetic Age*, 8 B.U. J. SCI. & TECH. L. 306, *364 n.92 (2002), WL 8 BUJSTL 306.

32. Variations of a single base pair from a normal genetic sequence. *Id.* at *315.

33. *Id.* at *307 n.5.

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

35. Sherizaan Minwalla, *A Modest Proposal to Amend the Patent Code 35 USC § 287(C) to Allow Health Care Providers to Examine Their Patients DNA*, 26 S. ILL. U. L.J. 471, 478 (2002).

36. Julian David Forman, *A Timing Perspective on the Utility Requirement in Biotechnological Patent Applications*, 12 ALB. L. J. SCI. & TECH. 647, *661 (2002), WL 12 ALBLJST 647.

37. Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (Jan. 5, 2001) [hereinafter Guidelines].

38. *Id.* at 1095.

39. *See* U.S. Pat. No. 6,025,154 ("Polynucleotides Encoding Human G-Protein Chemokine Receptor HDGNR10") (issued Feb. 15, 2000).

40. *See id.*

point into cells for the AIDS virus.[41] Thus, the receptor may be a critically important tool in researching treatments for AIDS/HIV. Since HGS owns the patent on the receptor itself, and a product patent is understood to cover any use of that product, it appears that HGS has the right to demand royalties from any AIDS researcher whose work makes use of the patented receptor.[42] The issue is whether HGS deserves this windfall for later-discovered utilities not recognized by HGS when it filed its patent application.

The assertion of utility is even more tenuous for the U.S. patents that have been granted on fragments of complimentary DNA (cDNA) called ESTs and SNPs.[43] Many patent applications were filed that claimed these sequences but asserted no specific utility for the genetic material.[44] In most cases, the sequence was part of an as-yet unidentified full-length gene that coded for an as-yet unidentified protein.[45] Preliminary signals from the USPTO indicated that the agency would set a very lenient standard for utility of ESTs and other genomic inventions.[46] Considerable public criticism ensued.[47]

The USPTO has since reversed its course and established much more stringent utility standards for patenting ESTs.[48] In January 2001 the agency issued final utility examination guidelines that require the applicant to establish a "specific, substantial, and credible" utility.[49] Thus, a claim to a purified and isolated cDNA sequence, without any asserted utility other than as a probe to find the corresponding full-length gene, would likely *not* satisfy this standard.[50]

DNA molecules, isolated and purified from their natural state, are thus potentially patentable as compositions of matter if the current "specific,

---

41. Donna M. Gitter, *International Conflicts Over Patenting Human DNA Sequences in United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exception*, 76 N.Y.U. L. REV. 1623, *1625-26 (2001), WL 76 NYULR 1623.

42. *See* Eliot Marshall, *HIV Experts vs. Sequencers in Patent Race*, 275 SCI. 1261, 1263 (1997). A related issue is whether HGS should be entitled to "reach-through royalties" based on the marketplace success of any commercial product, *e.g.*, new drug, therapeutic, or the like developed through use of the CCR5 research tool. In other words, if A is building a house and needs to use B's patented hammer, does A pay B an up-front royalty based on some perceived value of A's use of the tool– the hammer– or must A pay B an after-the-fact royalty based on some percentage of the economic value of the end product– the house– when A later sells or rents the house?

43. Rochelle K. Seide et al., *Drafting Claims For Biotechnology Inventions*, 682 PLI/PAT 285, *345-46 (2001), WL 682 PLI/PAT 285.

44. *See id.* at *304.

45. *See id.* at *303.

46. In February 1997, a USPTO official stated publicly that the agency had decided to allow claims to ESTs based on their utility as probes for larger DNA sequences. *See Gene Fragments Patentable, Official Says*, 275 SCI. 1055, 1055 (1997).

47. Guidelines, *supra* note 37 at 1092-97 ("Discussion of Public Comments.").

48. *See generally* Guidelines, *supra* note 37.

49. *Id.* at 1094.

50. *Id.*

substantial, and credible" utility standard is satisfied (and the molecule is novel and non-obvious). Another, much more controversial avenue being explored by some firms is an attempt to capture the *informational value* of the DNA sequence *data,* which lies chiefly in its potential use as a template for future protein production.[51] The data itself, as descriptive matter, is not patentable *per se*,[52] but recent attempts to capture the sequence data claim it in the form of a "data structure."[53] For example, a U.S. patent application of HGS published in June 2002, claims, *inter alia,* a computer readable medium having recorded thereon specified DNA sequences.[54]

Here we are reaching a gray area or transition between patents on tangible *molecules,* and patents that attempt to capture the *informational value* of DNA sequences; *e.g.,* patents that claim a DNA sequence stored in a computer-readable medium, such as a data structure.[55] It remains to be seen whether the USPTO will allow such claims. Extant Federal Circuit decisions in software cases such as *In re Lowry,*[56] and the USPTO's approval of *Beauregard* claims[57] suggest that patent

---

51. *See* Rebecca Eisenberg, *Molecules vs. Information: Should Patents Protect Both?*, 8 B.U. J. SCI. & TECH. L. 190, 196-97 (2002) (noting that "knowing what the [DNA] sequence is– is becoming more significant relative to the material value of having access to a molecule that embodies that information. That is, the value of making and using the DNA molecule as a template for protein production.").

52. *See* Sung, *supra* note 27, at 285 n.130 (noting that the sequence of base pairs making up a DNA molecule is simply a property of the molecule, and like any other descriptive property, is not itself patentable).

53. Symposium, *Panel One: Intellectual Property and Genetic Science: The Legal Dilemmas*, 51 AM. U. L. REV. 371, 388 (2002).

54. U.S. Patent Application No. 20020072595 ("Nucleotide Sequence of Escherichia coli Pathogenicity Islands") (published June 13, 2002), *available at* http://appft1.uspto.gov/netahtml/PTO/srchnum.html (last visited May 19, 2003). The representative claims are:

29. Computer readable medium having recorded thereon one or more nucleotide sequences depicted in SEQ ID NOs: 1 through 142, or nucleotide sequences at least 99.9% identical thereto.

30. Computer readable medium having recorded thereon a nucleotide sequence of at least one uropathogenic E. coli J96 pathogenicity island open reading frame depicted in Tables 1 through 4, or a complement thereof.

31. The computer readable medium of claim 29, wherein said medium is selected from the group consisting of a floppy disc, a hard disc, random access memory (RAM), read only memory (ROM), and CD-ROM.

32. The computer readable medium of claim 30, wherein said medium is selected from the group consisting of a floppy disc, a hard disc, random access memory (RAM), read only memory (ROM), and CD-ROM.

55. *See generally* Eisenberg, *supra* note 51.

56. 32 F.3d 1579 (Fed. Cir. 1994) (reversing USPTO rejection of claimed data structures as obvious under 35 U.S.C. 103 and noting that claimed data structures are "physical entities that provide increased efficiency in computer operation [, which] are not analogous to printed matter."). *But see* In re Warmerdam, 33 F.3d 1354, 1362 (Fed. Cir. 1994) (affirming USPTO rejection of claim to "data structure" as not statutory subject matter within 35 U.S.C. 101, where court interpreted "data structure" as "[a] physical or logical relationship among data elements, designed to support specific data manipulation functions," which did "not imply a physical arrangement of the contents of a memory.").

claims to DNA sequence data in the form of a tangible data structure might be allowable. However, initial indications from the USPTO are that the agency views claiming DNA sequence data *per se* as amounting to no more than "nonfunctional descriptive matter," and on this basis will refuse patentability. [58]

It is surely sensible to characterize the nucleotide sequence of a DNA molecule as *describing* a property of that molecule, just as the molecular weight of the molecule, because neither property can be the subject of a patent claim, standing in isolation. On the other hand, should not the nucleotide sequence of a DNA be viewed not merely as *descriptive* but rather as uniquely *functional*, to the extent that the sequence operates as a genetic "blueprint" for the production of proteins? By this logic, a claim to the DNA *molecule* reciting a particular nucleotide sequence that renders the molecule useful, novel and non-obvious over the prior art (including DNA as it exists in the human body) is potentially patentable. It is difficult to contend that that same sequence embodied as a novel and non-obvious data structure is not also patentable subject matter. In particular, there does not seem to be a rational distinction between permitting claims to data structures that help computers operate more efficiently, as in *Lowry*, and claims to data structures comprising nucleotide sequences that code for proteins having a medically-beneficial use. The courts will have to sort out these difficult questions.

## IV. ASSURING ACCESS TO PATENTED GENETIC MATERIAL

This section describes problems of access that have recently surfaced in the milieu of patents and other IPRs on genetic material and information. The need for unrestricted access to genetic materials and information that can be essential to the development of life-saving new drugs and therapies does not fit comfortably with the notion that patents convey an absolute right to exclude others from all uses of the patented material, no matter how altruistic the purpose of the use.

Patent infringement is essentially a strict liability scheme. The patent property right is very broad— a patent conveys to its owner the right to prohibit any unauthorized "use" (or making or selling or offering for sale or importing)[59] of the patented invention, without regard for the purpose of the use. It matters not if

---

57. In re Beauregard, 53 F.3d 1583, 1584 (Fed. Cir. 1995).

58. *See* Michael P. Woodward, USPTO Supervisory Examiner, *Bioinformatics & §101* (slide presentation) at 6-7 (asserting that "nonfunctional descriptive material," including but not limited to music, literary works, and compilations or mere arrangements of data, are not statutory subject matter), *available at* http://www.uspto.gov/web/patents/biochempharm/documents/woodward.pps (last visited May 19, 2003); *id.* at 17 (asserting that claims to computer readable media with sequence data on it are drawn to non-statutory descriptive matter). *See also* DEPARTMENT OF COMMERCE & UNITED STATES PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE (8th ed. 2001), *available at* http://www.uspto.gov/web/offices/pac/mpep/documents/2100_2106.htm (last visited May 19, 2003).

59. 35 U.S.C.S. § 271(a) (2000); 35 U.S.C.S. § 154 (LEXIS Supp. 2002).

the user was aware that the invention was protected by patent; no "copying" or intentional imitation is required to infringe a patent.[60] Similarly, it is not relevant whether the unauthorized use of the invention was for commercial or non-profit purposes.[61]

Consider the example of a patented "research tool," such as a combinatorial library or a receptor, used for the purpose of research and development of a new drug product. Even though the tool is not a physical part of that end product, it is an upstream input and therefore permission must be obtained from the patent owner to use it. This requires obtaining a license, or permission to use the patented invention without liability for infringement, assuming that the patent owner is willing to grant such a license upon acceptable terms.

The profusion of patents on multiple tools or inputs needed in life sciences research and development raises issues of cost, known variously as the "royalty stacking," "patent thicket," or "patent web" problem.[62] Such costs involve not only the licensing fees paid to a plurality of patent owners, but also the transaction costs incurred in having to obtain the needed permission from multiple sources of upstream tools.[63] Some observers have gone so far as to forecast a "tragedy of the anticommons"—such a profusion of patents on upstream inputs or research tools, that the downstream products will not be made, or that their development will be materially slowed or hindered.[64]

A number of potential approaches to ameliorate the problem of access to patented materials have been proposed, including the implementation of compulsory licensing, the federal governmental exercise of eminent domain and "march-in" rights, and a revitalization of the moribund "experimental use" defense to patent infringement.[65]

### *A. Compulsory Licensing*

For purposes of discussion, compulsory patent licensing should be contrasted to consensual or voluntary licensing. In a compulsory licensing regime, the

---

60. *See* 35 U.S.C.S. § 271 (2000).

61. *See id.*

62. Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools*, 76 WASH. L. REV. 1, 7 (2001); Paul F. Fehlner, *Biotech Research Tools*, NAT'L L.J., July 10, 2000 at B9; Gregory J. Glover, *Patents Thickets and Innovation Markets Reviewed Antitrust Concerns Over the Life Sciences Sparked Recent Public Hearings*, NAT'L L.J., Oct. 14, 2002 at C10; Gretel Schueller, *Researchers Establish Frequency of Use of Genetically Engineered Food*, ENVTL. NEWS NETWORK, March 4, 2001 at 2.

63. *See* Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 699 (1998).

64. *Id.* at 698.

65. *See also* Sung, *supra* note 27, at 268 n.17 (listing various remedies proposed to ameliorate the detrimental effects of the issuance of unreasonably broad patent claims to nucleic acids based solely on their chemical character).

government can be petitioned to compel a patent owner to grant licenses to third parties (*e.g.*, generic drug companies) to make, use, and/or sell the patented invention. Compulsory licensing generally contemplates some remuneration to the patentee as compensation for the government-compelled use of the invention by the licensee.[66] The considerable difficulty of quantifying the amount of such payment remains a leading argument against adoption of compulsory licensing, however. Critics decry the fundamental inability of monetary payment to remedy the loss of exclusivity that compelled patent licensing represents.

For these and other reasons, the U.S. historically has shunned compulsory licensing.[67] Opponents contend that the practice decimates the economic value of patents because it destroys the exclusivity that they represent; e.g., the right to exclude all others from use or manufacture of the invention.[68]

Nevertheless, the U.S. is a signatory to the TRIPS Agreement, the key IP treaty administered by the World Trade Organization (WTO).[69] TRIPS permits member states to implement compulsory licensing systems under certain prescribed conditions.[70] Thus, even though the U.S. has not enacted compulsory licensing legislation (other than in a few very narrow exceptions such as the Bayh-Dole "march-in" right described below), it must recognize that many other countries can and do.[71]

---

66. WTO, TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS (TRIPS) Art. 31(h), *available at* http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs (requiring that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization . . . .") [hereinafter TRIPS].

67. *E.g.*, Dawson Chem. Co. v. Rohm & Haas Co., 448 U.S. 176, 215 (1980) (describing compulsory licensing as "rarity" in U.S. patent system); *see also* EDITH TILTON PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM 172 (1951) (explaining that compulsory licensing has been "violently opposed" in the U.S. because it "can be such a serious derogation of the monopoly 'rights' of the patentee"); F.M. SCHERER, INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE 396 (1970) ("[E]very attempt to alter the U.S. law in this direction [of introducing general compulsory licensing provisions] has been beaten down as a result of determined opposition from industrial groups and the patent bar."); Irving N. Feit, *Biotechnology Research and the Experimental Use Exception to Patent Infringement*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 819, 840 n.102 (1989) (characterizing U.S. policy as "not favoring compulsory licenses."); Evelyn H. McConathy & Clifford K. Weber, *Committee Report: University and Government IP Issues*, 2000 AM. INTELL. PROP. L. ASS'N BULL. 177, 178 (describing compulsory licensing as "abhorrent to both academia and industry"); Robert P. Merges & Richard R. Nelson, *On the Complex Economics of Patent Scope*, 90 COLUM. L. REV. 839, 811 (1990) (describing compulsory licensing as "anathema" to U.S. patent law). Congress considered but ultimately dropped the idea of compulsory licensing as part of the 1952 Patent Act. *Dawson Chem. Co.*, 448 U.S. at 215 n.21.

68. Grace K. Avedissian, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing*, 18 AM. U. INT'L L. REV. 236, 244-47 (2002).

69. TRIPS, *supra* note 66.

70. *Id.* at Art. 31.

71. See 35 U.S.C.S. § 203 (2000).

For example, the implementation of compulsory licensing to provide access to patented medicines is very much at the forefront of the "north-south" debate.[72] The compulsory licensing provisions of TRIPS continue to provoke vocal debate between developed countries like the U.S., which generally oppose compulsory licensing as weakening the economic value of patents, and the developing world and least developed countries, which see the possibility of compulsory licensing as essential to public health and the eradication of disease and malnutrition. [73]

The most recent example of the compulsory licensing controversy is the continued fallout from the "Declaration on the TRIPS Agreement and Public Health," adopted in November 2001 at the WTO Ministerial Conference in Doha, Qatar.[74] The Declaration recognizes that least-developed member countries without significant domestic manufacturing capacity would have a difficult time making effective use of compulsory licensing under TRIPS.[75] TRIPS requires that the manufacture of generic medicines made under compulsory licensing be "primarily for the supply of the domestic market,"[76] which would appear to prohibit extensive exportation. Based on this TRIPS provision, the U.S. has strongly opposed the exportation of patented drugs made by generic manufacturers in developing countries such as India, China, and Brazil to the least developed countries.[77]

### *B. Eminent Domain*

Governmental exercise of eminent domain power to condemn patented property is closely related to compulsory licensing. In eminent domain, rather than

---

72. Avedissian, *supra* note 68, at 244-58.

73. *Id.*

74. The text of the Doha declaration on TRIPS and public health is available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited May 19, 2002).

75. *See id.* at ¶ 6.

76. TRIPS, *supra* note 66, at Art. 31(f).

77. *See* THE N.Y. TIMES, *A Global Medicine Deal* (Editorial) (Jan. 6, 2003), *available at* http://www.nytimes.com/2003/01/06/opinion/06MON2Y.html?pagewanted=print&position=top. *See also U.S. Holds Out Against Allowing Compulsory Licensing of Patented Drugs For Export and Announces Moratorium On TRIPS Enforcement*, DAILY NEWS (Dec. 23, 2002), *available at* http://www.IPO.org/2002/DailyNewsChron2002.:

On Friday at the World Trade Organization in Geneva, after months of negotiation, the United States maintained its position as the lone holdout to an agreement for compulsory licensing of patented drugs for export to developing countries. The current TRIPS agreement allows compulsory licensing only when it is predominantly for the domestic market. The U.S. insisted that compulsory licensing for export must be limited to drugs to treat infectious epidemics such as AIDS, malaria, and TB. A U.S. list covering 23 such diseases was not accepted. The impasse means the WTO will not meet its Dec. 31 deadline for agreement on implementing the 2001 Doha Public Health Declaration. Late Friday the U.S. Trade Representative announced (www.ustr.gov) that as an interim measure the U.S. will observe a moratorium on using WTO dispute settlement procedures to prevent compulsory licensing for export "to help poor countries get access to emergency life-saving drugs."

compelling the patentee to license a third party, the government itself is the licensee. When the U.S. government needs to procure technology that is the subject of another's patent (*e.g.*, a proprietary weapons system or an antibiotic or vaccine for the treatment or prevention of a disease), federal law provides that the government can manufacture and use the patented invention itself, or (more typically) the government can acquire and use the patented invention from a nonlicensed supplier, without being enjoined.[78]

The government's use of the patented invention is construed as a taking—*e.g.*, the condemnation of a patent license under Fifth Amendment principles.[79] As with all such takings, the government must pay "just compensation" for the property taken.[80] Historically this has meant awarding the patentee damages for the taking in the form of a reasonable royalty.[81]

Thus, the grant of a U.S. patent is always subject to a nonexclusive but royalty-bearing license in the federal government.[82] Having waived its sovereign immunity from patent infringement, the government assumes any potential patent infringement liability on the part of its suppliers through clauses in its procurement contracts.[83]

Under this framework the federal government would have the absolute power to make and use, or have manufactured for it, a bioinformatics invention patented by a private firm. It seems unlikely that the government would exercise this power, however, except in a public health crisis of severe proportions. During the anthrax scare of 2001, the U.S. government threatened, but ultimately declined to exercise, its eminent domain power to manufacture the antibiotic CIPRO, patented by Bayer Corporation.[84]

### *C. March-In Rights*

The Bayh-Dole Act,[85] enacted in 1980, created statutory authority for yet another form of compulsory licensing— the possibility of obtaining a compulsory license to practice patented inventions made with federal funds. The Bayh-Dole Act was intended to encourage non-profit entities such as universities and small

78. 28 U.S.C.S. § 1498 (LEXIS Supp. 2002) (providing a cause of action against the U.S. to the patent holder).

79. *See* Decca Ltd. v. U.S., 640 F.2d 1156, 1166 (Ct. Cl. 1980).

80. U.S. CONST. amend. V.

81. *Decca Ltd.*, 640 F.2d at 1167; Leesona Corp. v. U.S., 599 F.2d 958, 968 (Ct. Cl. 1979). Reasonable royalty awards are evaluated under the multiple factors of *Georgia-Pacific Corp. v. U.S. Plywood-Champion Papers, Inc.*, 446 F.2d 295 (2d Cir. 1971).

82. *See Leesona Corp.*, 599 F.2d 958; *Decca Ltd.*, 640 F.2d 1156.

83. *See* 28 U.S.C.S § 1498(a) (LEXIS Supp. 2002).

84. Avedissian, *supra* note 68, at 258-59 (2002); *A Global Medicine Deal*, supra note 77.

85. 35 U.S.C.S. §§ 200-212 (2000).

businesses to patent their "subject inventions" made with government funds.[86] These patents are often owned by non-profits such as universities and exclusively licensed to for-profit corporations, which bear the primary cost of commercialization and are unlikely to make the required investment without an exclusive license.[87]

The Bayh-Dole Act provided for the exercise by the government of so-called "march-in" rights in the event that this scheme does not provide for sufficient supply of a subject invention. [88] If the government determines that either the patentee or its licensee is not reasonably satisfying "health or safety needs," the government can compel the patentee to grant licenses to additional third-party applicants, or if patentee refuses to do so, the government itself can grant such licenses, eliminating the formerly exclusive nature of the licensee's access.[89]

Similar to the eminent domain strategy described above, it is unlikely that the government will exercise its march-in rights except in the case of a severe public health calamity. In fact, following the enactment of Bayh-Dole in 1980, the U.S. government has never exercised its march-in rights to compel the licensing of any federally funded invention.[90]

### *D. Revamping the Research Use Exemption to Patent Infringement*

Other proposals suggest that the U.S. recognize a meaningful research (or "experimental") use exemption from patent infringement liability.[91] With one very narrow exception,[92] no U.S. statute provides for an exception to utility patent infringement liability when the use in question is for experimental or research purposes. There is no "fair use" provision in the U.S. Patent Act, in contrast with the U.S. Copyright Act,[93] although many academic researchers appear to assume otherwise.[94] U.S. judicial decisions grudgingly recognize a common law

86. *See* 35 U.S.C.S. § 203 (2000). "Subject inventions" are those inventions conceived or reduced to practice under a government funding agreement. Under subsection (c)(4), the government retains a nonexclusive, nontransferable, irrevocable, paid-up license to practice or have practiced for/on behalf of the government the subject invention.

87. *See* M. Patricia Thayer & Richard A. De Liberty, *The Research Exemption to Patent Infringement: The Time Has Come for Legislation*, 4 J. BIOLAW & BUS. 1, 17 (2000).

88. *See* 35 U.S.C.S. § 203 (2000).

89. *Id.*

90. *See* Johns Hopkins v. Cellpro, 152 F.3d 1342 (Fed. Cir. 1998).

91. *See, e.g.*, Mueller, *supra* note 62; Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989).

92. 35 U.S.C.S. § 271(e)(1) (2000) (providing that use of a patented invention solely for purposes reasonably related to gathering data to support an FDA application for generic versions of previously approved drugs (*e.g.*, an Abbreviated New Drug Application) is not patent infringement).

93. 17 U.S.C.S. § 107 (2000), *amended by* 17 U.S.C.S. § 107 (LEXIS Supp. 2002).

94. Thayer & De Liberty, *supra* note 87, at 15 (stating that "[m]any research scientists never question that a patent infringement lawsuit could be brought to stop scientific experiments.").

experimental use exception but narrowly limit its applicability to research use that is strictly philosophical or for amusement or curiosity.[95]

The Federal Circuit's most recent pronouncement on the experimental use doctrine, *Madey v. Duke University*,[96] demonstrates just how "very narrow" and "strictly limited" the courts perceive the research use exemption to be. As a faculty member at Duke, Dr. Madey ran the University's Free Electron Laser research laboratory (FEL) from 1989 to 1997.[97] Dr. Madey was the sole named inventor and owner of two U.S. patents that were practiced by operation of some of the equipment in the FEL lab in ongoing research projects.[98] After Madey resigned over an employment dispute, Duke continued to operate the patented equipment.[99] When Madey subsequently sued the University for patent infringement, a federal district court granted partial summary judgment to Duke, which had asserted the defense of non-liability based on experimental use.[100]

The Federal Circuit reversed and remanded, concluding that the district court had "attached too great a weight to the non-profit, educational status of Duke, effectively suppressing the fact that Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives."[101] The appellate court recognized that major research universities like Duke often conduct basic research with arguably no commercial application.[102] However, the court concluded, "these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects [, which] also serve . . . to increase the status of the institution and lure lucrative research grants, students, and faculty."[103]

In sharp contrast with the American disfavor of an experimental use exception to patent infringement, foreign patent codes generally include statutory general exemptions for research. For example, the proposed European Community Patent Convention would exclude from the effects of a Community patent those acts "done privately and for non-commercial purposes," and those "acts done for experimental purposes relating to the subject-matter of the patented invention."[104]

---

95. Madey v. Duke Univ., 307 F.3d 1351 (Fed. Cir. 2002); Embrex, Inc. v. Serv. Eng'g Corp., 216 F.3d 1343 (Fed. Cir. 2000); Roche v. Bolar, 733 F.2d 858 (Fed. Cir. 1984).

96. 307 F.3d 1351 (Fed. Cir. 2002).

97. *Id.* at 1352-53.

98. *Id.* at 1352.

99. *Id.* at 1353.

100. *Id.* at 1355.

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

102. *Id.*

103. *Id.*

104. COMM'N EUROPEAN CMTYS, PROPOSAL FOR A COUNCIL REGULATION ON THE COMMUNITY PATENT (2000), *available at* http://europa.eu.int/comm/internal_market/en/indprop/patent/412en.pdf (last visited May 19, 2002). The proposed regulation provides for the grant of a unitary "Community patent" of equal effect throughout the European Community. *Id.* § 2.4.1, at 9 ("Explanatory

Domestic statutes of many European countries and Japan similarly contain research use exemptions. [105]

## V. INTERSECTION OF BIOINFORMATICS PATENT RIGHTS AND INDUSTRY STANDARDS

This part examines the implications of IPRs in the subject matter of "industry standards," and the manner in which the assertion of such rights may impact bioinformatics research and development.

Industry standards (both *de facto*[106] and *de jure*[107]) have proliferated in the computing, communications, and entertainment sectors, where they help to ensure product interoperability, connectivity, and safety. Consider, for example, the typical 3.5-inch floppy disk relied on by computer users as a data storage medium. Although manufactured by many different companies, these disks have standard dimensions and other physical specifications that permit them to be used in any manufacturer's computer.

---

Memorandum"). A newly-created, centralized "Community Intellectual Property Court" with Community-wide jurisdiction will determine enforcement and validity questions. *Id.* § 2.4.5.1, at 13. The proposed regulation on the Community patent is independent from the European Patent Convention (EPC), which was signed in 1973. *Id.* § 1.1, at 4. The EPC provides a single procedure for the examination of patent applications in the European Patent Office. *Id.* Once a European patent has been granted, however, it becomes a national patent in each member country designated by the applicant, and is subject to the patent laws of each such designated country. *Id.* The EPC does not provide any Community-wide enforcement forum; rather, any infringement of a European patent "shall be dealt with by national law." Convention on the Grant of European Patents, Art. 64(3), *available at* http://www.european-patent-office.org/legal/epc/e/ar64.html (last modified Nov. 8, 2000).

105. For example, French law provides that "[a]cts accomplished for personal or domestic purposes or for the purpose of testing the object of the patented invention shall not be considered as affecting the patentee's rights." *See* French Patent Law Including Modifications of 1978, Art. 29, *reprinted in* JOHN P. SINNOTT ET AL., WORLD PATENT LAW AND PRACTICE, PAT. STATUTES, REGS. AND TREATIES, 2D, at FRANCE-9 (LexisNexis, Mathew Bender 1999) [hereinafter WORLD PATENT LAW AND PRACTICE]. Germany provides that the "effects of the patent shall not extend to . . . acts done for experimental purposes relating to the subject matter of the patented invention." *See* German Patent Act of 16 December 1980, § 11.2, *reprinted in* WORLD PATENT LAW AND PRACTICE, *supra* at WEST GERMANY-78.22. Great Britain exempts from infringement liability those acts "done privately and for purposes which are not commercial" as well as those acts "done for experimental purposes relating to the subject-matter of the invention." *See* Patent Act 1977, § 60(5), *reprinted in* WORLD PATENT LAW AND PRACTICE, *supra* at GREAT BRITAIN-269. The Japanese patent laws provide that "[t]he effects of the patent right shall not extend to the working of the patent right for the purposes of experiment or research." *See* Japanese Patent Law of 1959, as amended through May 6, 1998, effective June 1, 1998, § 69(1), *reprinted in* WORLD PATENT LAW AND PRACTICE, *supra* at JAPAN-194.

106. *De facto* standards are not promulgated by any particular body, but rather arise spontaneously due to marketplace success. The Microsoft WINDOWS operating system is an example of a *de facto* industry standard for personal computers.

107. *De jure* standards are those promulgated by some official body, whether it be the government, an academic consortium, or an industry working group. Examples of the latter include the World Wide Web Consortium and the Internet Engineering Task Force.

In the life sciences, standards are much less evolved. They are beginning to be developed, however, in the context of attempts to standardize or harmonize different types of genetic data formats such as CORBA, the Common Object Request Broker Architecture.[108] Standards are also being developed for cDNA micro array analysis of gene expression (*e.g.*, gene chips).[109]

As industry standards are developed in the life sciences, the information generated by bioinformatics research and development is easier to access and use and thus much more valuable. But the assertion of proprietary rights in the subject matter of industry standards can generate an undesirable "lock-in."[110] Once numerous applications are developed that run on a particular standard and a certain "tipping point" of adoptions is reached, it is unlikely that the tide can be changed, and that particular standard will remain "locked in." The switching costs are simply too high to migrate to a new standard.

In the special case where an individual or firm possesses patent, copyright, or other IPR in the technology that has become an industry standard, the economic potential that the patent represents is greatly magnified. Anyone who wants to comply with the standard will have to pay tribute to the patent owner; *e.g.*, obtain a license (if available). Consider a hypothetical in which a private firm obtains patent protection in a computer-implemented system that utilizes proprietary algorithms for gene sequencing. Should this system be marketed and become the industry standard, any other firms desiring to exploit the same system (including the algorithms) would require a patent license.

As a threshold matter, it is not intuitively obvious that IPRs can exist in *de jure* industry-wide standards. How can any single entity have ownership in such a standard? It has happened in the electronics industry, where it led to litigation and Federal Trade Commission investigation.[111] Sometimes consortium members that consider and set standards are not aware of pre-existing IP rights in the technology they select or adopt. Sometimes the standard-setting participants themselves may actively attempt to steer a developing standard in a particular direction, while failing to disclose that they have underlying proprietary rights in that technology.

For these reasons it is imperative that all participants in bioinformatics-related standard-setting make full, up-front disclosure of IPRs, so that the standard-setting body can make a fully informed choice as to whether to base the standard on that proprietary technology.[112] This should include disclosure of pending patent applications as well as issued patents. Most electronics and Internet industry

108. *See* Spengler, *supra* note 1, at 1223.

109. *Id.* at 1221.

110. *See* Dan Burk, *Open Source Genomics*, 8 B.U. J. SCI. & TECH. L. 254, 257-58 (2001).

111. *See generally* Rambus Inc. v. Infineon Techs. AG, 318 F.3d 1081 (Fed Cir. 2003); Micron v. Rambus, 189 F. Supp. 2d 201 (D. Del. 2002); *In re Dell*, 121 F.T.C. 616 (1996).

112. *See generally* Janice M. Mueller, *Patent Misuse Through the Capture of Industry Standards*, 17 BERKELEY TECH. L.J. 623 (2002).

standard-setting organizations have adopted their own policies requiring disclosure of proprietary rights,[113] but no law mandates that they do so, and the disclosure rules are far from uniform.

More difficult to resolve is the case of an IP owner that does not participate in standard setting, but later comes forward to assert its patent against users of the standard. The IP owner arguably cannot be bound by contractual obligations of which it had no notice, and to which it was not a party, yet its refusal to license its patented technology on terms agreeable to standards users can result in a difficult "hold-up" problem. If challenged in litigation by standards users, the patent might be invalidated and/or held unenforceable, or if not, the patentee might be ordered to license at royalty-free, or "reasonable and nondiscriminatory," terms. Yet, none of these outcomes is by any means certain or inexpensive, as courts are just beginning to grapple with the impact of IPRs on industry standards.[114]

In some industries like electronics and aviation, patent owners have "pooled" their patents in a way that allows manufacturers to obtain a "package license" giving them permission to make and use all the patented inventions in the pool for a particular fee.[115] Pools were first created in the aviation and sewing machine industries, and have occurred more recently with DVD technology, with MPEG2 data compression technology, and with the patents needed to perform LASIK eye surgery.[116]

Patent pooling has not yet occurred to any reported extent in bioinformatics, but some commentators have predicted that it will.[117] Others disagree that patent pooling is a viable solution to the access concerns in life sciences patenting.[118]

## VI. CONCLUSION

Attempts to patent bioinformatics-generated inventions will likely continue and expand beyond current levels. The USPTO and the courts have not yet grappled with the unique aspects of this technology at the intersection of

---

113. *See* Mark A. Lemley, *Intellectual Property Rights and Standard- Setting Organizations*, 90 CAL. L. REV. 1889 (2002).

114. *See, e.g.*, Townshend v. Rockwell Int'l Corp., 2000 WL 433505 (N.D. Cal. 2000), 55 U.S.P.Q.2d (BNA) 1011; *In re Dell*, 121 F.T.C. 616 (1996).

115. *See, e.g.*, Lori B. Andrews, *Genes & Patent Policy: Rethink Intellectual Property Rights*, 3 NATURE 803 (2002); Robert P. Merges, *Contracting into Liability Rules: Intellectual Property Rights and Collective Rights Organizations*, 84 CAL. L. REV. 1293, *1340-43 (1996), WL 84 CALR 1293.

116. *See e.g.*, Steven C. Carlson, *Patent Pools and the Antitrust Dilemma*, 16 YALE J. ON REG. 359, *368-71 (1999), WL 16 YJR 359.

117. *See* JEANNE CLARK ET AL., USPTO, PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? (2000), *available at* http://www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf (last visited May 19, 2002).

118. *See generally* Bradley J. Levang, *Evaluating the Use of Patent Pools for Biotechnology: A Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools*, 19 SANTA CLARA COMPUTER & HIGH TECH. L.J. *229 (2002), WL 19 SCCHITLJ 229.

biotechnology and the information sciences. Private firms are beginning to shift from utilizing patents as a means of obtaining proprietary rights in particular *molecules,* to their use as a vehicle to capture the *informational* value of genetic sequence information. Attempts to apply existing patentability rules developed for precursor technologies such as computer software-implemented business methods or chemical compounds to these new methods and products may be problematic.

As innovative constructs of patent protection evolve for bioinformatics-generated inventions, the availability of such protection will help to guarantee continued investment in bioinformatics research and development. But in its incentivizing role the patent system must not ignore the need to ensure reasonable access to those products and methods. The public health and welfare promise held by bioinformatics is simply too great to permit the fruits of this technology to be effectively suppressed through the assertion of patent rights. This article has identified several "safety valves" or checks on the patent system, such as compulsory licensing and the research use exemption, that should be evaluated by policy-makers as possible means of ensuring that research and development in bioinformatics reaches its full potential without significant impediment.