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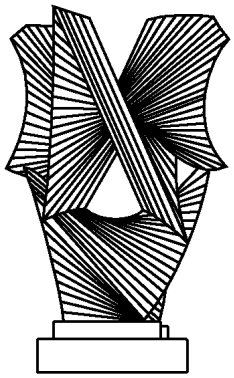

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THE LAW SCHOOL
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Intellectual Property in an Age of Software and Biotechnology

Kenneth W. Dam[‡]

The basic economic foundations of intellectual property are straightforward and increasingly recognized by the courts. The problems lie in applying those principles in particular situations. That theme can be highlighted by considering how intellectual property deals with new technologies. This essay will emphasize the two latest technologies to create major intellectual property problems for courts and legislatures—namely, software and biotechnology.

New technologies drive courts and legislatures back to basic principles. For example, new technologies frequently raise the question whether intellectual property rights should be accorded.

The way in which this question arises has traditionally been somewhat different in copyright from patent, largely for historical rather than analytical reasons. In the case of copyright the issue has usually been decided by the Congress, technology by technology. But even after Congress decides for copyright protection, the scope of that protection can be enlarged or cut back sharply by the way the courts apply traditional copyright doctrines. By finding, for example, that the "writing" in question is an idea[1] or a method of operation[2] or that copying constitutes fair use,[3] courts have it within their power to restrict drastically the scope of the property right.

In the case of patents in contrast, the Congress has played little role in the decision whether or not to protect the new technology.

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‡ Max Pam Professor of American and Foreign Law, University of Chicago Law School. This article is based on a Coase Lecture delivered at the University of Chicago Law School on May 16, 1995. This lecture series honors Ronald H. Coase, Senior Lecturer and Clifton R. Musser Professor Emeritus at the Law School and 1991 Nobel Laureate in economics, and is intended to explore how basic principles of economics can be applied to various fields of law. The author would like to thank Douglas Baird, Jack Brown, Mark Ramseyer, and Sandra Panem for their helpful comments.

[1] Computer Associates Int'l v. Altai, Inc., 982 F.2d 693 (2d Cir. 1992).

[2] Lotus Development Corp. v. Borland Int'l, Inc., 49 F.3d 807 (1995).

[3] Sega Enterprises, Ltd. v. Accolade, Inc., 977 F.2d 1510 (9th Cir. 1992).

Courts have normally made that determination. But here too the courts have the power to narrow patent protection by applying technical patent doctrines so as to leave the property right for a new technology more theoretical than real.[4]

Even where the societal consensus is that a new technology should be accorded legal protection, the question often arises whether protection should take the form not of traditional intellectual property—say copyright or patent—but rather some new sui generis form.

Sometimes, even after the decision has been reached to use a traditional form of protection, strong and persistent voices will be heard arguing for sui generis protection. For example, a recent massive "Manifesto" in the Columbia Law Review argued for abandoning both software and patent protection of computer software in favor of a new, specially tailored statutory scheme.[5]

This essay discusses the economic principles of intellectual property not just in the abstract but especially as they apply to the decision framework for new technologies. It is limited to patents and copyrights, leaving out of account trademarks, trade secrets and other forms of protection (where other considerations come into play).

I. THE ECONOMIC FOUNDATIONS OF INTELLECTUAL PROPERTY

What are the basic economic principles underlying intellectual property protection?

The first derives from the simple observation that innovation takes the form of information. To be sure, for innovators to profit from innovation and for consumers to benefit, it is often necessary for the innovation to be found in some physical form, if only as the

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[4] The Congress has, of course, the power to legislate to change any judicial decision narrowing, or for that matter broadening, the scope of protection. For example, a 1988 amendment to the Patent Code cut back substantially on prior judicial decisions rendering patents unenforceable for patent misuse. See 102 Stat. 4674, incorporated in 35 U.S.C. §271(d)(4) and (5). This kind of Congressional response is relatively rare in intellectual property scope-of-protection decisions.

[5] Pamela Samuelson, Randall Davis, Mitchell D. Kapor and J.H. Richman, A Manifesto Concerning the Legal Protection of Computer Programs, 94 Colum. L. Rev. 2308 (1994).

medium in which the innovation is transmitted. Still, the need for protection arises from the simple fact that the innovation itself is information and therefore creates a condition often called the public goods problem. Information is costly to produce, yet cheap to copy. Indeed, it is often said that my use of information does not exclude or place any costs on your use of the same information: hence, the notion of public goods.

Looked at from the standpoint of the innovator, we often describe the same phenomenon as the appropriability problem. If the information can be copied at little or no cost, then the price for using the innovation is likely to be driven down through competition to the costs of copying. As a result, the innovator will not be able to appropriate the benefits of the innovation and recoup his costs of generating the information in the first place.[6] And if this condition were generalized to innovation as an economy-wide process, then there would be a less than optimal economic incentive to innovate. We can, of course, imagine other motives than direct profit—prestige, other nonmonetary returns, monetary returns from being first to market, and the like—but still the need to protect innovators through according intellectual property rights is generally accepted and widely understood.

This incentive-to-innovate principle is quite general. It applies not only to inventions in the patent sense but also to a wide range of human activities including the writing and publishing of books, the traditional realm of copyright. Moreover, even businessmen and judges who have never heard of public goods or of the appropriation problem recognize the need to accord intellectual property protection to support research and development and to support investments necessary to commercialization of new technology.

So too, everyone—economist, lawyer, businessman—understands that intellectual property rights can be on balance harmful if they are too broad in scope or too rigidly applied. Here we come to a second well-recognized economic principle underlying intellectual property. Even conceding the need to accord intellectual property

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[6] William M. Landes & Richard A. Posner, An Economic Analysis of Copyright Law, 18 J. Legal Stud. 325, 328 (1989).

protection in order to give an incentive, innovation is not a once-for-all matter. We are interested in innovation over time.[7]

If giving too broad protection today arrests future innovation, then we will not have an optimum rate of innovation over time, and the economy will suffer. This is particularly the case because in the overwhelming majority of instances each innovation builds on past innovations. Each innovator stands on the shoulders of the innovators of the past, even where those past innovators were not giants but just a wee bit taller than the crowd. Hence, to obtain an appropriate balance between innovation today and innovation tomorrow, it is essential to allow access.

How much access, under what conditions, and when are major topics in the law of patents and copyrights, whatever the legal rubric used—whether it be, in the case of patents, disclosure, length of term, or the reverse doctrine of equivalents, or, in the case of copyrights, such doctrines as fair use.[8] Sometimes this access principle is so strongly valued by a society, especially in the case of new technologies, that it is allowed to overwhelm completely the incentive-to-innovate principle and no intellectual property right is accorded. In the case of patents, this judgment favoring access over incentives is expressed in the legal conclusion that the invention is non-patentable subject matter.

II. PROTECTING NEW TECHNOLOGIES

In considering the new technologies of software and biotechnology, it is useful to keep in mind that there are in principle three options for each new technology. First, do not protect at all. Second, protect in principle while applying the rules in such a way as to balance incentive and access. A variant of this second option is to

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[7] See Douglas G. Baird, Changing Technology and Unchanging Doctrine: Sony Corporation v. Universal Studios, Inc., 1984 Sup. Ct. Rev. 237, 239 (1985).

[8] See Kenneth W. Dam, The Economic Underpinnings of Patent Law, 23 J. Legal Stud. 247, 266-267 (1994). A third economic principle of intellectual property not specially relevant to new technologies is the need to reduce the incidence of rent seeking. Patent law, for example, needs to be constructed in such a way that it does not lead to undue investment in innovation in the race to obtain the governmentally-accorded privilege of excluding competitors. Id. at 251-153, 261-266.

protect in principle but, because of some societal judgment, to decide—often case by case—to emphasize access over incentive in particular situations.[9] Third, protect not through patent or copyright but through a tailored, sui generis system.

A related preliminary point is that new technology protection has evolved in somewhat different ways in the copyright and patent regimes. For the first century of the Republic, and even to some extent today, Congress has made a separate decision as to whether each new technology should be protected and, if so, how. This pattern was set in the very first copyright statute. In 1790 Congress accorded copyright protection to any "map, chart, book or books"[10] and to no other category of writings. In 1802 it added prints, clearly extending copyright into the realm of technology, albeit not a new technology.[11] In 1831 Congress added musical compositions[12] and in 1856 dramatic compositions.[13] In 1865 it added a new technology—photographs.[14]

Congress did not get around to covering paintings, drawings, sculpture and fine arts models and designs until 1870.[15] When one considers that Congress covered maps and charts in 1790 and added photography as soon as the Civil War revealed the power of that technology, while not even dealing with the fine arts until 1870, we can deduce that Congress had technology very much in mind in the first century of American copyright.[16]

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[9] A variant of this second option is to emphasize incentive over access. Although in the application of the second option, the balancing of incentive and access may have been done by some courts in such a way as to unduly emphasize incentive, no system appears to have explicitly downgraded the access principle.

[10] 1 Stat. 124 (1790).

[11] 2 Stat. 171 (1802). It is significant that in referring to prints, section 2 of the 1802 Act speaks of persons "who shall *invent* and design, engrave, etch or work" prints. (Emphasis supplied) See William F. Patry, Copyright Law and Practice, Vol. I, p. 36 n. 108 (1994) (hereafter "Patry").

[12] 4 Stat. 436 (1831).

[13] 11 Stat. 138 (1856).

[14] 13 Stat. 540 (1865).

[15] Section 86, 16 Stat. 198, 312 (1870).

[16] See the correlative point that Congress in the first century of American copyright was at least as concerned with protection of labor-intensive informational writings as with creative writings. Jane C. Ginsburg, Creation and

In the twentieth century Congress began to legislate more generically, presumably leaving to the courts a greater role in deciding to what extent new technologies were to be protected by copyright. For example, the 1976 comprehensive revision uses the format of protecting "works of authorship" (in the 1909 copyright revision called "writings of an author"[17]) which "include" certain stated categories. Examples are literary works and musical works.[18] Some of these categories are defined, other not. Thus, in principle a new technology could come into existence and be covered under one of the already listed categories.

But old habits die hard and when it came time to protect some new technologies, they were legislatively added to the list. Motion pictures were included in 1912.[19] Sound recordings, as opposed to long-protected musical compositions,[20] did not receive explicit protection until 1971.[21] When computer software came on the scene, Congress established a commission to study the problem, but even before the commission reported, Congress confirmed through legislative history that software would be covered under the existing category of "literary works," thereby resolving an already long-standing controversy on the protection issue.[22] Later legislation

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Commercial Value: Copyright Protection of Works of Information, 90 Colum. L. Rev. 1865, 1873-1881 (1990).

[17] Section 4, 35 Stat. 1075, 1077 (1909).

[18] 17 U.S.C. §102.

[19] 37 Stat. 488 (1912).

[20] Patry, Vol. I, 234-235.

[21] 85 Stat. 391. Sound recordings received state law protection earlier, and there was controversy and ambiguity about pre-1971 federal protection for sound recordings. Donald S. Chisum and Michael A. Jacobs, Understanding Intellectual Property Law §4C[1][c]. See Goldstein v. California, 412 U.S. 546 (1973). See Patry, Vol. I, 73-74, 294-297 and Vol. II, 830-831 (1994), concerning the history of protection of sound recordings as well as their indirect protection as derivative works.

[22] See discussion in Kenneth W. Dam, Some Economic Considerations in the Intellectual Property Protection of Software, 24 J. Legal Stud. 321, 322 n. 5 (hereafter Dam, Legal Protection of Software); and Arthur R. Miller, Copyright Protection for Computer Programs, Databases, and Computer-Generated Works: Is Anything New since CONTU?, 106 Harv. L. Rev. 977, 978-80 (1993).

nailed down copyright protection for software.[23] Indeed, the copyright tradition required special legislation in 1990 simply to include "architectural works," even though such works have been around much longer than any U.S. copyright statute.[24]

Since the 1976 Act the copyright statute has grown increasingly complex. Congress has attempted to deal with competitive fights between industries based on different technologies by adjusting rights and obligations. The names of some of the statutes tell the story: the Satellite Home Viewer Act,[25] the Audio Home Recording Act,[26] and the Cable Television Consumer Protection and Competition Act.[27] Without too much exaggeration, one could summarize the copyright approach as a separate statutory scheme for each new technology.

Congress has played other roles in deciding on protection. For example, when the question of protection for semiconductor mask works arose, Congress decided that, rather than establishing a new copyright category, a brand new property rights scheme—a sui generis scheme—should be used. We find it in the Semiconductor Chip Protection Act of 1984.[28]

The pattern in patent law was completely different. The first patent statute set out to give protection to inventions of every kind. The original 1790 statute broadly authorized patents on "any useful art, manufacture, engine, machine, or device."[29] Thanks to the draftsman Thomas Jefferson, something of an inventor himself, a 1793 amendment broadened the categories to "art, machine, manu-

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[23] 94 Stat. 3015 (1980).

[24] 104 Stat. 5089, 5133 (1991), now 17 U.S.C. §102(a)(8). For the background of this enactment, see Patry, Vol. I, 302-304.

[25] 102 Stat. 3949 (1988).

[26] 106 Stat. 4237 (1992).

[27] 106 Stat. 1460 (1992). New technologies have led to a large volume of statutory enactments to define narrow technology-specific rules with regard, for example, to limitations on rights. See examples in Patry, Vol. 1, pp. 89-115. For an extensive explanation of this copyright phenomenon, see Jessica Litman, Copyright Legislation and Technological Change, 68 Oregon L. Rev. 275 (1989).

[28] 98 Stat. 3347, now 17 U.S.C. §§901-914.

[29] 1 Stat. 109, 110 (1790).

facturer or composition of matter."[30] Today, the list of categories remains the same, substituting only "process" for "art" to reflect contemporary usage.[31]

To be sure, the form of the patent code is somewhat analogous to that of the copyright act in the sense that both list categories that are to be covered. In principle, an invention has to fall within one of the four patent categories or no patent will issue. However, the four patent categories are broader and more general than the eight copyright categories. For example, "machine" in the patent statute is an altogether broader concept than "sound recording" or "architectural works" in the copyright act. Hence, though the four patent categories could be thought to fail to exhaust the universe of things that ought to be patented, that view does not reflect that the history of patent law. Under the patent law in action, new technologies were automatically covered as they came along. There was no need for Congressional action.[32]

Perhaps the different pattern in patent from copyright is not a question so much of statutory drafting or of inherent differences in the two types of protection but rather of the very idea of invention, which presupposes technological change.[33] In any event, the patent law approach focuses attention not on the kind of technology, but rather on whether the particular invention is new, useful and, to use the neologism of the current statute, "non-obvious."[34]

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[30] 1 Stat. 318, 319 (1793). See Diamond v. Chakrabarty, 447 U.S. 303, 308-309 (1980); Graham v. John Deere Co., 383 U.S. 1, 7-10 (1966).

[31] 35 U.S.C. §101.

[32] A fuller discussion of the four patent categories would consider the definition of "process" in 35 U.S.C. §100(b), which includes in that term "a new use of a known process, machine, manufacture, composition of matter, or material."

[33] Diamond v. Chakrabarty, 447 U.S. 303, 316 (1980); and see U.S. Patent and Trademark Office, Revolutionary Ideas, Patents and Progress in America (1976).

[34] The statutory term "non-obvious" appears in the Patent Code in the title to Section 103. The section itself refers to whether the subject matter sought to be patented "would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. §103. This essay will use, in following the tradition of patent law commentary, the terms "obviousness" and "nonobviousness."

For example, when the question of patent protection for computer software arose, the Congress felt no need to confront the issue. Nor did the courts decide in principle whether patents could provide protection. It was assumed that in some cases software patents were possible, and the struggle was over the circumstances. Specifically, the courts, especially the Supreme Court, invoked a judge-made mathematical algorithm exception to patentable subject matter, thereby making it hard to sustain software-related patents.[35] But as discussed below, this objection has been largely overcome,[36] and, in any event, the courts have never ruled out software-related patents in principle but have considered only the particular circumstances of each software innovation so long as it fell within the statutory categories of "process, machine, manufacture, or composition of matter."[37]

A caveat is, however, in order. Despite this rather clear positive direction on coverage, the courts took it upon themselves to declare that certain kinds of inventions were not patentable subject matter. Although some courts had declared that a "product of nature" could not be patented because it was not in one of the patentable categories,[38] the courts later took to declaring certain things not patentable without too much attention to the categories.[39]

To summarize, patent protection for computer software and biotechnology did not require a go/no go decision by either legislature or courts. The only question was under what circumstances software and biotech patents met the standards of novelty, usefulness and nonobviousness. However, as we shall see, the courts did have to wrestle with some judicially created exceptions to patentable subject matter. In contrast, returning to copyright, we have seen that a legislative decision was necessary to assure protection for software.

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[35] See Gottschalk v. Benson, 409 U.S. 63 (1972); Parker v. Flook, 437 U.S. 584 (1978). But see Diamond v. Diehr, 450 U.S. 175 (1981).

[36] See discussion infra at notes 52-57 and accompanying text.

[37] 35 U.S.C. §101. See Diamond v. Diehr, 450 U.S. 175 (1981).

[38] Merck & Co. v. Olin Mathieson Chemical Corp., 253 F.2d 156, 162 (4th Cir. 1958); Parke-Davis & Co. v. H. K. Mulford Co., 189 Fed. 95, 103 (S.D.N.Y. 1911).

[39] See discussion of the mathematical algorithm exception infra at notes 52-57 and accompanying text.

This difference between the copyright and patent traditions is illustrated by biotechnology. Since Congress did not undertake to protect biotechnology by copyright, protection has been sought and accorded only by patent despite the fact that Congress also took no action under the patent code. This differential result of Congressional non-action in both fields is significant not just because there is a secondary literature suggesting copyright protection for biotechnology[40] but because at least some of the field would lend itself to copyright protection insofar as it has the equivalent of letters, words and sentences. The genetic code in DNA has only four letters, one for each of the building blocks (nucleotides) that comprised DNA. This is a remarkably efficient alphabet, indeed one in which all substantive "words" are only three letters long with each different three-letter "word" coding for an amino acid. With this language cells are able to express thousands, probably hundreds of thousands of proteins, and—equally remarkably—to do so with only twenty naturally occurring amino acids. These amino acids are, if you like, the "letters" of protein words and sentences. Be that as it may, patents, not copyrights, are the weapons of choice for biotechnology.

III. SOFTWARE AND COPYRIGHT

Copyright protection for software, though widely considered necessary for the incentive effect, clearly risks denying a desirable and even a necessary degree of access to follow-on innovators. And this is true even though independent creation is a complete defense to a charge of copyright infringement. In part this fear of denying access is based on the quite legitimate need of computer programs to attach to other programs and to computer hardware. But in part this fear has also been fed by economists and economics-oriented lawyers who, with a raft of arguments concerning compatibility, de facto standards, network externalities, switching costs and lock-in, have sought to argue that at least some outright copying, not just of soft-

[40] For suggestions in the secondary literature that copyright be used for biotechnology, see, e.g., Dan L. Burk, Copyrightability of Recombinant DNA Sequences, 29 Jurimetrics J. 469, 492-512 (1989); Irving Kayton, Copyright in Living Genetically Engineered Works, 50 George Washington L. Rev. 191, 216-218 (1982).

ware and hardware interfaces but of baseline programming itself, should be permitted.[41]

I have argued elsewhere that despite the extraordinary versatility of these economic constructs, which incidentally boil down to essentially the same argument, the basic case for copyright protection of software is quite strong, with only two possible exceptions: first, where attachment interfaces are involved and second, where the follow-on innovator substantially improves and adds value to the software.[42] Both of these two possible exceptions involve a special need for access and the latter is simply a copyright law analogue, via the "fair use" principle, for what in patent law is called an "improvement patent."

The courts have tended in recent years to concentrate on developing theories by which to deny copyright protection to certain features of particular software programs despite the presence, often conceded by infringement defendants, of outright wholesale copying. In arriving at these results, the courts in those software cases have sometimes downplayed the need to balance incentive and access, settling instead on two quite simple legal theories—one, that the copied programming involved ideas rather than expression[43] and two, that it involved a system or method of operation.[44] In short, those courts have simply applied the statute which denies copyright protection "to any idea, procedure, process, system, method of operation, concept, principle, or discovery,"[45] a litany that is hardly self-defining.

Most of those software cases fall in the first category, denying protection to an idea, which necessarily involves a continuum between unprotected "ideas" and protected "expression." As Judge Easterbrook said in *Nash v. CBS*, a case outside the software field, the courts must find where on that continuum to draw the line, yet

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[41] See the analysis of these economic arguments in Kenneth W. Dam, Some Economic Considerations in the Intellectual Property Protection of Software, 24 J. Leg. Studies 321 (hereafter "Protection of Software").

[42] See discussion in Protection of Software.

[43] See, e.g., Computer Associates Int'l v. Altai, Inc., 982 F.2d 693 (2d Cir. 1992).

[44] See, e.g., Lotus Development Corp. v. Borland International, Inc., 49 F.3d 807 (1st Cir. 1995).

[45] 17 U.S.C. §102(b).

"[n]either Congress nor the courts has the information" necessary to draw the line in particular cases.[46] What we do know, he said, is that "it is a mistake to hitch up at either pole of the continuum."[47] So the courts have been drawing the line using a variety of techniques and labels. Perhaps some courts have drawn the line too far in one direction, undercutting the incentive function of copyright protection. Perhaps some have undervalued the importance of access. On the whole the courts have done a reasonable job in approaching the balancing task, even though they have not usually recognized the two economic principles of incentive and access. Indeed, looking beyond the software cases to the general issue of incentive and access, the courts have long been aware, at least intuitively, of the need to balance these two principles.[48]

Some commentators argue that software so poorly fits the copyright paradigm that it would have been better to choose a sui generis approach more conducive to the technical nature of software.[49] When one looks at the results of the 1974 Semiconductor Chip Protection Act, one is left with doubts about a sui generis approach. There Congress set forth detailed rules but, by failing to consider amendments over time, Congress has failed to keep progress with rapidly changing technology and thereby has left the statute essentially irrelevant to present-day semiconductor technology. As the 1992 Patent Advisory Commission found, "[S]ome of the basic definitions [of the Act] are already obsolete, leaving important parts of mask work technology outside the protection of that legislation."[50]

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[46] Nash v. CBS, Inc., 899 F.2d 1537, 1541 (7th Cir. 1990).

[47] 899 F.2d at 1543.

[48] See Gerald Gunther, Learned Hand: The Man and the Judge 316 (1994); Paul Goldstein, The Competitive Mandate: From Sears to Lear, 59 Calif. L. Rev. 873 (1971). And see Benjamin Kaplan, An Unhurried View of Copyright 89-92 (1967).

[49] See the Columbia Manifesto, cited supra note 5, and citations to earlier articles along the same line therein.

[50] Advisory Commission on Patent Law Reform, A Report to the Secretary of Commerce 151 (August 1992). Moreover, according to Rauch, the rapid change in process technologies creates opportunity for piratical exploitation of the reverse engineering exception to the relatively narrow protection accorded by the statute. John G. Rauch, The Realities of Our Times: The

One can conclude that the general intellectual property law has a flexibility that sui generis statutes are unlikely to have where fast-moving technology is involved. This conclusion may be somewhat counter-intuitive, for one might suppose that a specialized statute should usually be better at dealing with a specialized field of endeavor, but that conclusion about the superiority of Congress over the courts is not obvious where rapidly advancing technology is concerned.[51]

IV. SOFTWARE AND PATENTS

As we have seen, software has also benefited from patent protection. But there too the courts have, on a case by case basis, tried to balance the incentive and access principles. They have done so, however, with less clarity of view than in the software copyright cases. In software patent cases the main field of battle has been a legal principle not to be found in the statute, namely the principle that mathematical algorithms are not patentable subject matter.

Several decades of time and vats of judicial ink have been spilled in deciding whether particular software-related inventions constitute patentable subject matter. The Supreme Court and the Federal Circuit have wrestled with the issue without bringing much clarity.[52] The issues have been how much physical interaction between software and hardware must be present and whether the software produces a physical change. To be sure, part of the problem has been that the Patent and Trademark Office until recently has fought a rearguard action against enlarging the sphere of software patent protection, leading to repeated appeals by patent applicants—frequently successful but not always with well-reasoned resulting opinions.[53] The practical effect of these decisions has been

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Semiconductor Chip Protection Act of 1984 and the Evolution of the Semiconductor Industry, 75 J. Pat. & Trademark Office Soc'y 93 (1993).

[51] See Protection of Software at 371-376. Several minor amendments have been made to the Chip Protection Act concerning procedural, rather than substantive, matters.

[52] See generally Robert Patrick Merges, Patent Law and Policy 45-100 (1992)

[53] See, however, the PTO's proposed guidelines for reviewing "computer-implemented inventions." 60 Fed. Reg. 28778 (1995), reprinted in 50 BNA

to cause many patent lawyers to draft software claims as so-called apparatus or machine claims. The applications say, in effect, that the invention is a machine, not software and certainly not a mathematical algorithm, and the software is simply a means by which the machine does its work.

In a recent case, *In re Allapat*,[54] the Federal Circuit—which has become de facto the Supreme Court of patent law—took a long step toward drastically restricting the mathematical algorithm exception by allowing, in an *en banc* decision, a patent on a software program whose instructions were executed by well-known computer components. Indeed, the *Allapat* court emphasized that when a general purpose computer is programmed, it becomes a special purpose computer and hence, if the claimed invention is new, useful and nonobvious, a patent is appropriate even if a mathematical algorithm is central to the software itself.[55]

Suggestive of what is actually at stake is Judge Newman's concurring opinion in which she argues that "mathematics is not a monster to be struck down or out of the patent system, but simply another resource whereby technological advance is achieved."[56] She went on to observe that modern technology such as software and electronics inevitably relies heavily on mathematics, that mathematics is "simply another resource whereby technological advance is achieved," that there has been "no major technological advance, no new industry or evolving technology, that has not participated in the patent system" and therefore the fact that a new technology relies

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Patent, Trademark & Copyright J. 164 (1995), and the supporting legal analysis, reprinted id. at 659. The proposed guidelines, while directed to patent examiners, not only promise a more receptive attitude toward software patents but also provide a blueprint for patent claim drafting.

[54] 33 F.3d 1526 (Fed. Cir. 1994).

[55] See also In re Lowry, 32 F.3d (1994), applying analogous reasoning in reversing a "printed matter" rejection concerning data structures in computer memory. On the issue of the relevance of a programmed computer as a statutory "machine" in software cases, see also In re Warmerdam, 33 F.3d 1354 (Fed Cir. 1994), and the Federal Circuit's vacation and remand (July 25, 1995) of In re Trovato, 42 F.3d 1376 (Fed. Cir. 1994).

[56] 33 F.3d at 1568, 1570.

heavily on mathematics should no more disqualify an innovation than if it relied on the principles of chemistry.[57]

The Federal Circuit rarely articulates what is really at stake in its decisions, but it seems apparent that the mathematical algorithm principle is an attempt to prevent a patent applicant from preempting an abstract principle of human knowledge. To allow such an abstract principle to be preempted would completely imbalance the trade-off between incentive and access and would gravely impede future innovation.

Under this analysis software-related patents can be seen to raise few access problems with regard to abstract mathematical principles because a patent on the application of particular software to a computer or to some specialized machine in no ways precludes others from applying the same mathematical principles to achieve some other result in a computer or specialized machine. It is the application of the mathematics for a narrow practical use, not the mathematics itself, from which the patentee can exclude the competitor.

Obviously the application of this concept of a balance between the two economic principles of incentive and access is not self-executing. All of the tools of legal process, including fact-finding and reasoning, are still required. But explicit attention to this balance would make patent law decisions more understandable and predictable.

V. BIOTECHNOLOGY AND PATENTS

Biotechnology is another new technology that has faced problems in achieving equal protection in the patent system. Nearly every principle of patent law has to be rethought and interpreted anew in biotechnology, which is a reason why so many leading patent law decisions of the last decade have been biotech cases.[58] For this reason and in order to explore more deeply the application of the incentive and access principles to contemporary patent law, it is worth reviewing not merely patentable subject matter but also how the

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[57] 33 F.3d at 1568, 1570-1571.

[58] See Diamond v. Chakrabarty, 447 U.S. 303 (1980) (patentable subject matter); In re Bell, 991 F.2d 781 (Fed. Cir. 1993)(obviousness); In re Vaeck, 947 F.2d 488 (Fed.Cir. 1991) (enablement); Fiers v. Revel, 984 F.2d 1164 (Fed Cir. 1993)(conception).

courts have handled other core patent issues, such as novelty, nonobviousness and utility in the biotechnology field.

With respect to the threshold issue of patentable subject matter, the underlying question is, as in the case of software, one of balancing the two grand economic principles of intellectual property—incentive and access. Under this economic approach, we should take care to assure that principles of the biological sciences not be preempted through patents but rather only specific technological applications, so that the basic scientific principles remain open to future innovators. Still the question whether biotech innovations are patentable subject matter has had to be fought out in the courts.

What has particularly bedeviled the courts and many opponents of biotechnological research has been the frightening notion that life itself might be patented. As usually argued, this is predominantly a religious or ethical concern, but it obviously relates to the question of what is being preempted if patents are granted.

In the United States the threshold issue was left to the courts and, as in the case of software, the issue was phrased as whether patentable subject matter was presented by the patent application. The breakthrough in the United States was the Supreme Court decision in the 1980 *Chakrabarty* case involving a patent on a living bacterium that could break crude oil down into its chemical components, a highly useful property in fighting crude oil spills.[59] The Court simply concluded that the bacterium was "not nature's handiwork," but the inventor's, and that Congress had got it right in the 1952 patent codification when it said that patentable subject matter "include[d] everything under the sun that is made by man."[60]

Converting this approach to my language, one can summarize by saying that since neither naturally occurring bacteria nor the principles of life but rather just a newly created bacterium was the subject matter from which the patentee could exclude others, the incentive principle clearly dominated any concerns about the access principle. It is thanks to this decision that we now have patents on such things as the famous Harvard mouse, an *onco*mouse that rather per-

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[59] Diamond v. Chakrabarty, 447 U.S. 303 (1980). See also In re Allen, 2 USPQ2d 1425 (Bd. Pat. App. & Int. 1987), aff'd, 846 F.2d 77 (Fed. Cir. 1988).

[60] 447 U.S. at 309-310.

versely had the highly useful property that it was particularly susceptible to carcinogens and therefore lent itself to cancer research.[61]

The problem in that patent has nothing to do with mice for one can invent any other kind of non-oncomouse one pleases and so access is not compromised. Rather an access problem lurks in its broadest claims, including the claim to all transgenic non-human mammals with increased susceptibilities to cancer. Not just mice but elephants and whales are excluded too, so long as they show the same susceptibility to carcinogens.[62] Of course, one can still invent a new elephant if it is made especially susceptible to say malaria rather than cancer.

More important than transgenic creatures has been the fact that biotechnology inventions now enjoy patent protection without unnecessary squabbles about threshold life-related subject matter issues. The situation has been fundamentally different in some foreign countries that impose major restrictions on biotechnology patents, just as indeed some still do on pharmaceuticals,[63] though the TRIPS agreement in the Uruguay Round should help because it is a violation of that agreement to exclude any "field of technology" from patent protection.[64]

One general point is that although Congress had previously enacted two sui generis plant patent statutes to protect innovations in

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[61] P. Leder and T. Stewart, Transgenic Non-Human Mammals, U.S. Pat. 4,736,866 (1988).

[62] The European Patent Office rejected the broader claims. See Robert P. Merges and Richard R. Nelson, On the Complex Economics of Patent Scope, 90 Colum. L. Rev. 839, 847 (1990).

[63] Harold C. Wegener, Patent Harmonization §§2311-2312 (1993); Gerald J. Mossinghoff, Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide, 2 J. of Law & Tech. 307 (1987); Michael L. Doane, TRIPS and Int'l Intellectual Property Protection in an Age of Advancing Technology, 9 Am. U. J. Int'l Law and Policy 465, 479 (1994).

[64] Agreement on Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, Art. 27(1). However, Article 27(3) has certain exceptions with regard to biotechnology. See also the transitional provisions of Article 65. See J.H. Reichman, Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement, 29 Int'l Lawyer 345, 352-353, 358-360 (1995).

plants,[65] in part to avoid lurking doubts about the "product of nature" exception to conventional patent coverage,[66] the courts have wisely found a sui generis approach unnecessary for biotechnology. Indeed, new man-made plants, whether or not created by biotech methods, have been held eligible for conventional patents—that is, eligible for what are called utility patents in order to distinguish them from plant and design patents.[67]

VI. BIOTECH PATENT DOCTRINE

In addition to the patentable subject matter issue, biotech product patent applications must face the three hurdles faced by all patents; the product must be novel, nonobvious and useful.[68] For commercial efforts in biotechnology, which at least initially were mostly concerned with using biotech methods to make what already existed in nature (say a human protein), one can readily see that these hurdles are not automatically cleared. The key in that context to meeting these three requirements lies in the fact that biotech provides the product in a form that is purer and easier to administer in the treatment of disease, while at the same time being cheaper to produce than through conventional pharmaceutical processes. As Sandra Panem has concisely summarized the early promise of

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[65] The two statutes are the Plant Patent Act of 1930, 35 U.S.C. §161, and the Plant Variety Protection Act of 1970, 7 U.S.C. §2402.

[66] This was a major motivation of the 1930 Act. Diamond v. Chakrabarty, 447 U.S. 303, 311-313 (1980). The 1970 Act extended coverage to sexually reproduced plants. 447 U.S. at 313-314.

[67] Ex parte Hibberd, 227 USPQ 443 (Bd. of Pat. App. 1985). See Animal Legal Defense Fund v. Quigg, 932 F.2d 920, 923 (Fed Cir. 1991).

[68] A further hurdle is the enablement requirement. 15 U.S.C. §112. See Amgen, Inc. v. Chugai Pharmaceutical Co., 13 USPQ2d 1737 (D. Mass. 1989), 927 F.2d 1200 (Fed. Cir. 1991). This requirement has the effect of narrowing the scope of biotech patents by limiting the ability of the applicant to make generic product claims covering more than the applicant has actually made, In re Vaeck, 947 F.2d 488 (Fed.Cir. 1991), and thereby balances the incentive and access principle by granting the first innovator a narrow patent while leaving room for follow-on innovators to make claims for other species within the genus, assuming that the obviousness hurdle can be overcome. For a discussion of the significance of the enablement requirement to the biotech industry, see Kenneth J. Burchfield, Biotechnology and the Federal Circuit 208-210 (1995).

biotechnology, "The power of this new technology lies in the ability to produce rare biological products in large quantity, with high purity, and at low cost."[69]

1. Novelty. The courts, particularly the Federal Circuit, have approached the biotech cases in the traditional patent law manner, which is to treat patent law as unitary and then to apply that law to the facts as if there were nothing extraordinary about the new technology. The novelty question, which is simply whether the naturally-occurring product is new, had already been answered in the pharmaceutical cases. Those cases held that if a protein is isolated and purified, then it is new for the purpose of the novelty test.[70] This result not only solves a riddle inherent in the nature of biotechnology but does so in a way that promotes the incentive principle.[71]

2. *Nonobviousness.* The novelty cases do not answer the obviousness question, the second hurdle to patentability. How, one might ask, can the isolated, purified form of a protein fail to be obvious if it is otherwise identical to a naturally occurring protein, which we already know about? This is a complicated question that the courts have struggled with.[72] But the courts have not tried to construct a separate biotechnology patent doctrine. Rather they have used the traditional approach of comparing what is claimed with the prior art. The crucial point is that the prior art is not what is known to nature but what is known to man. For example, if what is known to man is a protein and what is claimed is a gene and the gene has been isolated and purified so that it clears the novelty hurdle, then the obviousness question is not whether it is obvious that a particular

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[69] Sandra Panem, The Interferon Crusade, back cover (1984).

[70] Merck v. Olin Mathieson Chemical, 253 F.2d 156 (4th Cir. 1958); In re Bergstrom, 427 F.2d 1394 (CCPA 1970).

[71] To the extent that biotech innovation has expanded to include substances, not found in nature, the novelty requirement no longer presents a special barrier to patentability. See Burchfield, supra note 68 at 66.

[72] The pharmaceutical cases used a variant of the purification rationale to deal with the obviousness doctrine as well. See Merck v. Olin Mathieson Chemical, 253 F.2d 156, 164 (4th Cir. 1958) ("It did not exist in nature in *the form* in which the patentees produced it and it was produced by them only after lengthy experiments. Nothing in the prior art . . . suggested it." (emphasis supplied)).

gene having a particular nucleotide sequence exists in principle, but whether it would be obvious to one skilled in the art how to identify and isolate it.

The leading case of *In re Bell* held that while "[i]t may be true that knowing the structure of the protein, one can use the genetic code to hypothesize possible structures for the corresponding gene and that one thus has the potential for obtaining that gene," nevertheless the degeneracy of the genetic code is such that there are more than 10^{36} different possible nucleotide sequences in a gene that might code for that protein.[73] This recognition of the special nature of the genetic code does not involve, however, any separate doctrine favoring biotechnology patents but rather constitutes an application of the long-established principle applied across a wide range of technologies that simply because a new research approach is "obvious to try" does not mean that a resulting product would be obvious. Thus, unless there is something in the prior art that would suggest to a researcher a particular gene in question, as opposed to the thousands or millions of other possible nucleotide sequences that might possibly encode the particular protein, the resulting isolated and purified DNA molecules are not obvious and may be patented. While the processes for looking for the right nucleotide sequence might be known, it is not obvious how to pick the right one out of this human haystack.

This approach seems eminently good common sense in the protein-to-gene case, but it does not provide a rule for the protein-to-protein situation where biotech methods are used to produce a protein identical to a protein found in nature. Yes, the patent application may meet the novelty test if the protein is isolated and purified, but does it meet the obviousness test? One possible, but inadequate answer is that if the biotech *process* used to obtain the biotech form of the protein is new and nonobvious, then of course the patentability standard is met.[74] But the problem is that the inventor

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[73] 991 F.2d 781, 784 (Fed. Cir. 1993). See also In re Deuel, 51 F.3d 1552 (1995).

[74] Process (or "method") patents are of course also subject to the nonobviousness requirement. See In re O'Farrell, 853 F.2d 894 (Fed. Cir. 1988).

can obtain a process patent, not a product patent,[75] and as the courts have recognized in the pharmaceutical cases, process patents may be so hard to enforce that they do not provide a sufficient property rights basis to finance the risky development and clinical trials necessary to bring a new drug to market.[76]

The effort to emphasize the incentive function through the isolation-and-purification rationale has created a problem of deterring future innovation. In the *Scripps* case a patent involving a blood growth factor produced by a chemical purification process was held potentially infringed by the biotech version of the same product.[77]

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[75] The 1988 process patent amendments provide product protection in the sense that 35 U.S.C. §154 makes "sale or use" in the United States of a product made by a patent process an independent act of infringement. However, the use of the patent process must still be established. Although the amendment was aimed at imported goods, it was not so limited. See the legislative history cited in Burchfield, supra note 68 at 313 n. 10.

[76] See statement of Judge Rich, dissenting in Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1279, 1280-1281 (1992), that the cost in 1990 of moving a new chemical entity from laboratory to market was over $230 million and that only one of 5,000 to 10,000 compounds discovered ever make it to market. Some attempts to find a solution to this problem have involved so-called product-by-process claims. Such claims have sometimes sought to give product protection where the essence of the invention is in truth a nonobvious process. However, the justification for such claims, which are not mentioned in the patent code, is to permit a patent on "an otherwise patentable product that resists definition by other than the process by which it is made." In re Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985). Compare Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834 (Fed Cir. 1992), holding that the process is a limitation on a product-by-process claim so that making the product by a different process would not constitute infringement with Scripps Clinic & Research Foundation v. Genentech, Inc., 927 F.2d 1565 (Fed. Cir. 1991), and the dissents of Judges Rich and Newman in the Atlantic Thermoplastics case, supra.

[77] Scripps Clinic & Research Foundation v. Genentech, Inc., 666 F. Supp. 1379 (N.D. Cal. 1987), but see a later decision in same case holding many claims invalid, 707 F. Supp. 1547 (N.D. Cal. 1989), aff'd in part, rev'd in part, 927 F.2d 1565 (Fed. Cir. 1991). See discussion in Robert Patrick Merges, Patent Law and Policy 488-489 (1992), and Robert P. Merges and Richard R. Nelson, On the Complex Economics of Patent Scope, 90 Colum. L. Rev. 839, 914-915 (1990). The Federal Circuit pointed a way out of the dilemma thus created by the Scripps lower court holding by remanding the case to the trial court to determine whether the reverse doctrine of equivalents, a seldom applied doctrine,

The full impact of that decision on innovation over time becomes clearer when one considers that its doctrine could presumably preclude a subsequent biotech firm from producing the same growth factor through still newer and even more superior biotech processes.[78]

As biotechnology has progressed, the obviousness question tends not to arise in the simplistic way just discussed in which the applicant claims the biotech equivalent of the naturally occurring substance—for example, a protein or a gene—but rather claims some new biotechnological half-way house. To the extent that biotechnology today creates substances that do not exist in nature, the obviousness issue rather becomes the generic issue of what would have been obvious to one skilled in the art.[79]

3. *Utility*. The third hurdle to patentability, namely the utility doctrine, has become in some ways the front line in the biotech patent wars. The Constitution's reference to the "useful Arts" has led to the statutory requirement of utility. Put abstractly, the threshold utility issue is whether any utility has been shown if a substance simply does what the corresponding natural substance does. The essence of the issue is, however, that some major advances may not yet have a concrete use in medicine or agriculture or any other end use economic activity.

These R&D outputs, often the product of enormous R&D outlays, are more than basic research results but may not, without further R&D, result in something of immediate concrete value to mankind. Still, they may be sold in the marketplace, particularly to pharmaceutical firms. While an economist might say that whatever commands a price in the marketplace meets an economic utility test,

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avoided the dilemma by absolving the biotech firm from infringement liability. 927 F.2d 1565 (Fed. Cir. 1991).

[78] See, however, Genentech, Inc. v. Wellcome Foundation, 29 F.3d 1555 (Fed. Cir. 1994), a doctrine of equivalents case, implicitly distinguishing the situation where an allegedly infringing protein was superior in therapeutic application to the patented protein.

[79] See, e.g., In re Vaeck, 947 F.2d 488 (Fed Cir. 1991). A recent statute extends biotech patent protection for processes by prohibiting obviousness rejections for biotech processes "using or resulting in a composition of matter" that is novel and nonobvious. P.L. 104-41 (1995).

a conventional legal view has been that something that is useful only in further research does not meet the statutory utility requirement.

For the purposes of emphasizing the factors at play it suffices to take just one hotly contested, indeed highly emotional, question now being fought out in the patent system. Suppose I use biotech methods to isolate not previously known partial complementary DNA sequences.[80] Yes, partial cDNA sequences may be patentable subject matter, but is the utility requirement met if we do not know for sure what they are useful for? Put in the language of the current debate, should we not wait until we at least know the function of these sequences? Or, to use the jargon of patent law, do the sequences have practical utility?[81] In short, do they provide "some immediate benefit to the public"?[82]

One answer is to say that we should just wait until we have something truly useful—of "immediate benefit to the public"—before granting a patent.[83] Under this view we should wait, for example, until we have isolated a useful protein using that cDNA sequence before considering patentability or until we have at least identified and located the cellular DNA or perhaps synthetically generated the full DNA sequences required to produce a protein. The essence of the policy argument for this wait-and-see approach is that issuing such cDNA patents would inhibit research leading to truly useful discoveries.[84]

The problem with this wait-and-see solution is twofold: First, given the progress in biotech methods, the method of identifying

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[80] A complementary DNA sequence is one derived from messenger RNA, which may be thought of as a half-way house between cellular DNA and the protein expressed by that DNA within the cell. For an explanation, see In re Deuel, 51 F.3d 1552, 1554 (1995).

[81] On the patent law concept of utility, see Brenner v. Manson, 383 U.S. 519 (1966).

[82] Nelson v. Bowler, 626 F.2d 853, 856 (CCPA 1980).

[83] One can find an analogy in In re Joly, 376 F.2d 906 (CCPA 1962), which held that one cannot patent a chemical compound that is useful only because it is an intermediate in making another chemical compound in the absence of showing the utility of the latter compound.

[84] Bernice Wuetherich, All Rights Reserved: How the Gene-Patenting Race is Affecting Science, 144 Science News 154 (Sept. 4, 1993), offers an example.

and locating the entire gene may be obvious from knowledge of the partial cDNA sequence. Second, the protein may be obvious from the gene or even from a complete cDNA sequence.[85] And so if there is no patent on the partial sequence, there may be no patent available at a later stage because of the nonobviousness requirement.

Would such an outcome serve the incentive function of the patent system? As already mentioned, it is well-known that pharmaceutical companies are reluctant to engage in R&D and unwilling to go through the expensive Federal Drug Administration clinical trial process on new drugs unless patent protection can be relatively assured because otherwise commercialization will not be financially feasible.[86] Of course, if the firm that discovers the partial sequence neither publishes it nor sells it publicly, then it may later be able to patent the full gene. The result would, however, be later disclosure to the public and to that extent, perversely, serve neither the incentive nor the access function.[87]

No doubt recognizing this simple fact of business life, the Commissioner of Patents, reacting to criticism from the biotech industry, adopted guidelines in 1995 making clear that a patent examiner should not reject biotech applications where the asserted utility

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[85] "Like mRNA [messenger RNA], cDNA contains only the protein-encoding regions of DNA. Thus, once a cDNA's nucleotide sequence is known, the amino acid sequence of the protein for which it codes may be predicted using the genetic code relationship between codons and amino acids." In re Deuel, 51 F.3d 1552, 1554 (Fed. Cir. 1995).

[86] Bernadine Healey, Special Report on Gene Patenting, 327 New England J. of Medicine 664, 667 (1992); Reid G. Adler, Genome Research: Fulfilling the Public's Expectations for Knowledge and Commercialization, 257 Science 908 (1992); Gerald G. Mossinghoff, Research-Based Pharmaceutical Companies: The Need for Improved Patent Protection Worldwide, 2 J. of Law & Tech. 307 (1987).

[87] A recent development has been the effort of Merck to underwrite University laboratory sequencing of human cDNA followed by immediate deposit of the sequences in a public databank. This approach results in prompt disclosure to the public but also undercuts efforts by other to patent such sequences. See Columbia Shuns Profits from Gene Fragments, 268 Science 487 (April 28, 1995). Since Merck is primarily a pharmaceutical rather than a biotech firm, the question of its motivation has arisen. Eliot Marshall, HGS Opens its Databanks—for a Price, 266 Science 25 (Oct. 7, 1994); and Jerry B. Bishop, Plan May Blow Lid Off Secret Gene Research, Wall St. J. B1 (Sept. 28, 1994).

"would be considered credible by a person of ordinary skill."[88] Perhaps these guidelines will lead to patents being granted on cDNA sequences for their utility in construction of DNA probes or in new forensic applications or in tissue typing or in diagnostic applications.[89] Looking further ahead, cDNA sequences could be useful in some as yet unexploited ways based on the essential comparability of DNA in all of earth's creatures. Some of these utility theories, especially use in constructing cDNA probes to identify and locate the gene, have to confront the important principle of utility doctrine that frowns on any theory based on usefulness in further research.[90] This principle, which has its legal justification in the notion that an innovation useful only in further research is not of "immediate benefit to the public,"[91] is a somewhat dubious notion when biotech research itself has raised billions of dollars of capital from the public.

The legal memorandum accompanying the PTO's new utility guidelines casts doubt on the legal rationale for any research tool exception:

> Many research tools such as gas chromatographs, screening assays, and nucleotide sequencing techniques have a clear, specific and unquestionable utility (e.g., they are useful in analyzing compounds). An assessment that focuses on whether an invention is useful only in a research setting thus does not address whether the specific invention is in fact "useful" in a patent sense.[92]

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[88] 60 Fed. Reg. 97, 98 (1995) reprinted in BNA Patent, Trademark & Copyright Journal 234 (1995)

[89] Rebecca S. Eisenberg, Genes, Patents, and Product Development, 257 Science 903 (1992); Eliot Marshall, The Company that Genome Researchers Love to Hate, 266 Science 1800 (Dec. 16, 1994); John Carey, Untangling the Legal Strands of DNA, Business Week 78 (May 8, 1995). For a critical review of these utility theories, see Stephen B. Mabius, Novel DNA Sequences and the Utility Requirement: the Human Genome Initiative, 34 J. Pat. and Trademark Off. Soc. 651 (1992).

[90] See Burchfield, supra note 68 at 57-59; and Rebecca S. Eisenberg, Symposium: A Technology Policy Perspective on the NIH Gene Patenting Controversy, 55 U. Pitt. L. Rev. 633, 645-647 (1994);

[91] Nelson v. Bowler, 626 F.2d 853, 856 (CCPA 1980).

[92] 50 BNA Patent, Trademark & Copyright J. 297, 298 (1995).

If this view is sustained by the courts, the incentive function will be preserved in the biotech industry. But what about access for future innovation? We must recognize that the fight over partial cDNA sequences arises from the fear in academia, and also in some portions of the pharmaceutical industry, that access to the basic biological building blocks of the human body will be preempted by patents.[93] Here again the solution to this burning biotech patent issue lies in a clear recognition and discussion of the balance between the incentive and access principles.

The foregoing discussion of the utility issue in biotechnology is not an attempt to lay down rules for its resolution in the manifold factual situations presented by the onrushing progress of the field but rather is simply an illustration of an economic approach to intellectual property law that is by no means limited to threshold issues of whether or not to protect a new technology. This economic approach throws light on nearly all of the technical issues of patent and copyright law.

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[93] On the possibility that the experimental use defense to patent infringement will satisfy the academic concerns, see Rebecca S. Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental use, 56 U.Chi.L.Rev. 1017 (1989).

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