COPYRIGHTABILITY OF RECOMBINANT DNA SEQUENCES*

Dan L. Burk†

ABSTRACT

The recent emergence and rapid growth of biotechnology as a commercial industry has raised serious questions concerning the role of patent law as the industry's dominant form of intellectual property protection. Several commentators, drawing on an analogy to computer software protection, have suggested copyright law as an alternative method of protecting recombinant DNA innovation. This article reviews these arguments in light of recent court decisions and scholarly commentary concerning copyright of computer software. The article argues that copyright law is not sacrosanct, but rather represents a particular scope of proprietary interests that may be used to accommodate the needs of new technologies such as biotechnology. The article asserts, however, that the decision to apply copyright protection to such a technology should be based on policy rather than on analogy. The article reviews the basic characteristics of both the science of molecular biology and of the biotechnology industry, and, by contrasting these characteristics to those of the software industry, concludes that, as a matter of policy, copyright is not the most appropriate form of intellectual property protection for biotechnology.

INTRODUCTION

Biotechnology has captured the attention of modern society.¹ Our rapidly advancing ability to manipulate genetic material at the molecular level has prompted serious debate over the legal and moral implications of this technol-

*© 1989 by Dan L. Burk.

†B.S., Microbiology, Brigham Young University, 1985; M.S., Molecular Biology, Northwestern University, 1987. Mr. Burk is a J.D. candidate for 1990 at the Arizona State University College of Law and an Editorial Assistant for *Jurimetrics Journal*. The author wishes to thank Rex Anderson, Gary Dukarich, Professor Dennis Karjala, Shirley Kaufmann, Dr. Kathy Matt, Professor Laurence Winer, and Milton R. Wessel for helpful discussion and advice on previous drafts of this article.

¹"Biotechnology" may refer to a wide range of technologies, but for purposes of this article the term will be employed to designate those reliant upon modern techniques of molecular and cell biology, particularly recombinant DNA techniques. This is the sense in which biotechnology has been employed in recent U.S. government surveys. See UNITED STATES CONGRESS OFFICE OF

ogy.² It has also prompted substantial financial investment in basic research, as the products of biotechnology show ever greater promise of substantial commercial worth.³ This latter development, leading to the growth of a commercial biotechnology industry, generally has been viewed as a desirable step in maintaining U.S. competitiveness in high technology, advancing our knowledge of basic science, and improving the overall quality of life on our planet.⁴

The advent of such market forces into an area of basic science has not, however, occurred without generating controversy. Central to many of the concerns raised by the development of commercial biotechnology has been the question of intellectual property protection for new and valuable discoveries.⁵ The continued growth of this industry will undoubtedly be shaped by the presence and scope of such protection.⁶ Patent law has been employed to protect many innovations in this field, but the standards required for patent protection are not necessarily well suited to the needs of commercial biotechnology.⁷ Additionally, as Eisenberg has recently documented, certain characteristics of patent law may foster conflict between society's interest in a strong biotechnology industry and society's interest in pursuing basic science.⁸

Because of these difficulties with current options for intellectual property protection in biotechnology, copyright law has been proposed as an alternative

---

TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: U.S. INVESTMENT IN BIOTECHNOLOGY 1 (1988) [hereinafter U.S. INVESTMENT]; UNITED STATES CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS 3 (1984) [hereinafter COMMERCIAL BIOTECHNOLOGY]. The example of a recombinant DNA vector is used throughout this article, but the principles elucidated by this example apply to many related biotechnology tools and products.

²A useful outline for considering both the favorable and unfavorable aspects of biotechnology brought out in this debate is provided by Stephen Crane, *The Snark, the Bellman, and the Biohazard Debate*, 3 YALE L. & POLICY REV., 358 (1985). Crane's conclusions are criticized by Lewis Thomas, *Introduction*, 3 YALE L. & POLICY REV. 309,310 (1985). See also Grobstein, *Manipulating Life: The God/Satan Ratio* in THE MANIPULATION OF LIFE: NOBEL CONFERENCE XIX, (1984).

³Scientists tend to distinguish basic research, which is designed purely to advance knowledge, from applied science, which produces new uses for knowledge. See D. NELKIN, SCIENCE AS INTELLECTUAL PROPERTY: WHO CONTROLS RESEARCH? 2 (1984). The dividing line demarcating these areas has never been pristine. However, one fundamental contention of this article is that the present state of the market for molecular genetics research has virtually collapsed the two areas into one another.

⁴The myriad benefits of commercial biotechnology products include human disease therapies, bacteria that will digest oil spills, and increased food production. See generally Gore and Owens, *The Challenge of Biotechnology*, 3 YALE L. & POLICY REV., 336,341 (1985); U.S. DEPARTMENT OF COMMERCE INTERNATIONAL TRADE ADMINISTRATION, HIGH PROFILE INDUSTRIES: PROFILES AND OUTLOOKS, BIOTECHNOLOGY, 53-55, 58-64 (1984) [hereinafter PROFILES AND OUTLOOKS] (listing present and anticipated products of biotechnology).

⁵See U.S. INVESTMENT, *supra* note 1, at 101-03.

⁶*Id.* at 11.

⁷See generally, Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177 (1987); Dresser, *Ethical and Legal Issues in Patenting New Animal Life*, 28 JURIMETRICS J.399 (1988); UNITED STATES CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: PATENTING LIFE (1989) [hereinafter PATENTING LIFE].

⁸See Eisenberg, *supra* note 7, at 214-16.

to protect at least some areas that patent law neglects.⁹ This suggestion is counterintuitive at best. The body of law that traditionally has protected works of art seems, at least initially, a strange vehicle by which to protect commercial interests in the newest and most esoteric of sciences. Nonetheless, commentators such as Irving Kayton have advanced innovative and coherent accounts of how such protection is compatible with the current statutory scheme.¹⁰ The plausibility of these proposals has not gone unchallenged, however. Other commentators, notably Iver Cooper, have provided a vigorous dissent to providing biotechnology with this form of protection.¹¹

This debate has largely revolved around an analogy drawn between computers as electronic information processing systems and genetically engineered organisms as biological information processing systems. This discussion could benefit greatly from a deeper analysis of recent judicial decisions regarding copyright and computer software.¹² The discussion could benefit even more from an examination of the policy considerations relevant to making recombinant nucleotide sequences the subject of copyright, in light of the needs of the biotechnology industry as a whole. The concerns raised over the adequacy of intellectual property protection for biotechnology are real and pressing. Copyright could be conscripted as an alternate form of protection. But in addition to a discussion of whether Congress has included recombinant nucleotide sequences within the ambit of copyright, and a discussion of whether Congress intended to place such sequences under the protection of copyright, some discussion is needed on whether Congress ought to put this emerging technology within the subject matter of copyright. Such a discussion requires an examina-

⁹See Kiley, *Learning to Live With the Living Invention*, 7 AM. PAT. L. ASS'N. Q.J. 220, 233-34 (1979); Kayton, *Copyright in Living Genetically Engineered Works*, GEO. WASH. L. REV. 191 (1982); Goldstein, *Copyrightability of Genetic Works*, BIO/TECHNOLOGY, Feb. 1984, at 138; Comment, *Copyright Protection for the Intellectual Property Rights to Recombinant Deoxyribonucleic Acid: A Proposal*, 19 ST. MARY'S L.J. 1083 (1988) (authored by Donna Smith). See also Davidson, *Common Law, Uncommon Software*, 47 U. PITT. L. REV. 1037, 1104-5 (1986); Stern, *The Bundle of Rights Suited to New Technology*, 47 U. PITT. L. REV. 1229 (1986); Karjala, *United States Adherence to the Berne Convention and Copyright Protection of Information Based Technologies*, 28 JURIMETRICS J. 147, 152 (1988).

¹⁰See Kayton, *supra* note 9.

¹¹I. COOPER, *BIOTECHNOLOGY AND LAW* § 11.02 (1985); Whale, *Patents and Genetic Engineering* in INTELL. PROP. L. REV. 1982 at 93, 110 (1982). See also PATENTING LIFE, *supra* note 7, at 43 (unofficial position of Copyright Office is that nucleic acid sequences are not copyrightable).

¹²This is not to say that these cases have been overlooked entirely. Jorge Goldstein recognized early on the importance of the *Franklin* case to this analysis. See Goldstein, *supra* note 9, at 138-39. Although most of the relevant cases were decided after his seminal article, Irving Kayton does briefly discuss *Tandy v. Personal Microcomputers*, 524 F. Supp. 171 (N.D. Cal. 1981), Kayton, *supra* note 9, at 209-10. Cooper acknowledges the existence of *Apple v. Franklin*, 714 F.2d 1240 (3d Cir. 1983) I. COOPER *supra* note 11, at 11-20.1. The most recent commentary on this matter also touches on these decisions. See Comment, *supra* note 9, at 1101-3. See also Comment, *Enemies to Innovation: Protecting Biotechnology Inventions*, 5 SANTA CLARA COMPUTER. & HIGH TECH. L. REV. 437, 455-57 (1989) (authored by Elizabeth F. Enayati) (arguing that recent software copyright "look and feel" cases may expand the scope of copyright sufficiently to include nucleotide sequences).

tion of both the underlying purposes of intellectual property law and its proper application to a new technology.

Happily, the recent literature on copyright law is particularly rich in just this type of examination, most of which has arisen in the context of the debate over protection of computer software.¹³ Because advocates on both sides of the DNA copyright debate have discussed the analogy between computer software and recombinant DNA, it seems particularly appropriate that analysis of protection for the former provide a starting point for discussion of protection for the latter. The results of such analysis may be very different when applied to the relevant characteristics of recombinant DNA technology, but may nonetheless initiate valuable discussion concerning the intellectual property needs of the industry that is growing up around that technology.

Consequently, this article is intended to begin addressing the question of intellectual property in the biotechnology industry, using copyrightability as a vehicle for discussion. **Part I** of this article supplies a simple introduction to the basic science and application of molecular biology, stressing several unique features of this field relevant to this inquiry. **Part II** outlines the legal protection presently available for recombinant DNA technologies, then discusses the perceived shortcomings of the current scheme. **Part III** introduces the arguments for and against copyright protection in this area: first the superficial arguments from statutory construction, then the arguments from statutory purpose. **Part IV** attempts to analyze these arguments on a more fundamental level, by discussing first the policies behind intellectual property protection and, second, how well those policies match the character of the emerging biotechnology industry. Finally, several other alternatives to the current scheme are briefly addressed to illustrate both the benefits and disadvantages of applying copyright protection to biotechnology.

I. A BIOTECHNOLOGY PRIMER

In order to intelligently discuss intellectual property protection for a given technology, we must first consider the nature of that technology. Accordingly, this section gives an overview of biotechnology and the science of molecular biology that lies behind it. The first part of this section offers a brief survey of the basic principles and terminology of molecular biology. The second part outlines the basic technology employing these principles. Finally, this background is used to draw some general conclusions regarding

---

¹³See, e.g., Samuelson, *CONTU Revisited: The Case Against Copyright Protection for Computer Programs in Machine-Readable Form*, 1984 DUKE L.J. 663; Raskind, *The Uncertain Case for Special Legislation Protecting Computer Software*, 47 U. PITT. L. REV. 1131 (1986); Karjala, *Copyright, Computer Software, and the New Protectionism*, 28 JURIMETRICS J. 33 (1987); Menell, *Tailoring Legal Protection for Computer Software*, 39 STAN. L. REV. 1329 (1987). See also Palmer, *Copyright and Computer Software* in RESEARCH ON LAW AND ECONOMICS, Vol. 8, at 205 (J. Palmer & R.O. Zerbo eds. 1986) (analyzing economic benefits of adopting United States' form of copyright protection).

the pertinent characteristics of biotechnology. These conclusions will form an essential consideration in discussing the propriety of copyright protection for this technology.

A. The Molecular Basis of Life

Living creatures are composed of tiny units called *cells*.¹⁴ All organisms, from the single-celled bacterium to the multi-cellular elephant, carry in their cells genetic information packaged as deoxyribonucleic acid, or *DNA*.¹⁵ DNA carries in coded form the blueprint for constructing and operating the organism. Thus, DNA is the genetic and hereditary molecule for all living creatures.¹⁶

1. *The Physical Structure of DNA*

DNA is an enormously long molecule, composed of subunits called nucleotides.¹⁷ Each nucleotide is composed of a sugar-phosphate backbone and an associated base.¹⁸ DNA contains four different bases, designated A, G, T, and C.¹⁹ These bases comprise the code containing genetic information. When the sugar-phosphate backbones are linked together, a long strand with bases projecting outward, like spikes on a chain, is formed. The *sequence* of bases in this *polynucleotide chain* contains the coded genetic information.²⁰

The physical structure of DNA is a double helix configuration, which may be imagined as a twisted ladder: two parallel strands with base pairs forming rungs in the middle.²¹ This structure is formed by two polynucleotide strands, brought together by the pairing of the projecting bases. Base pairing is very specific: G always pairs with C, and A always pairs with T.²² Thus, like a zipper, each strand of DNA will pair up only with a strand that has the matching complementary base sequence.

DNA in a cell is contained in tightly coiled packages called *chromosomes*.²³ A single celled organism such as a bacterium has a single, circular chromosome; a more complex organism, such as a human being, may have

---

¹⁴B. LEWIN, GENES II, 4 (1985).

¹⁵*Id.* at 13.

¹⁶Certain viruses carry their genetic information in the form of a different nucleic acid, RNA. Joklik, *The Virus Multiplication Cycle* in ZINSSER MICROBIOLOGY 857, 879-87 (18th ed., W.K. Joklik, H.P. Willett, & D.B. Amos eds., 1984). This, however, need not violate the general rule given here, because viruses are not exactly alive. Joklik, *The Nature, Isolation, and Measurement of Animal Viruses*, *id.* at 801, 803.

¹⁷B. LEWIN, *supra* note 14, at 17; D. FREIFELDER, MOLECULAR BIOLOGY: A COMPREHENSIVE INTRODUCTION TO PROKARYOTES AND EUKARYOTES, 80-82 (1983).

¹⁸B. LEWIN, *supra* note 14, at 17.

¹⁹*Id.*

²⁰*Id.*; D. FREIFELDER, *supra* note 17, at 101-3.

²¹This structure was elucidated by Nobel prize recipients James Watson and Francis Crick in 1953. See B. LEWIN, *supra* note 14, at 17; D. FREIFELDER, *supra* note 17, at 103. See also generally J. WATSON, THE DOUBLE HELIX (1968).

²²B. LEWIN, *supra* note 14, at 19.

²³*Id.* at 13.

several chromosomes.²⁴ The combined information encoded in the base sequences of an organism's chromosomes is called the *genome*.²⁵ Generally, each of the organism's cells will contain a complete set of chromosomes, a complete "blueprint" for the organism.²⁶ The entire genome is not used all the time, however. At any given time in a bacterium, only those portions of the genome necessary for cellular operations are active. Similarly, in multicellular organisms, each cell uses only the genetic information required to fulfill its specialized function.

2. *Expression of Genetic Information*

DNA is the genetic material because the DNA code embodies coded instructions for the assembly of cellular *proteins*.²⁷ Within the chromosomes are stretches of DNA called *genes*. Genes contain sequences that code for specific proteins, as well as associated control sequences that activate and regulate the gene.²⁸ Proteins are the primary mediators of an organism's characteristics; they comprise the bulk of an organism's cellular "machinery." For example, proteins called *enzymes* control chemical reactions within the cell.²⁹ The DNA code contains information that the cell may use to construct a protein with a certain property, which gives rise to a certain cellular activity or characteristic.

DNA does not directly mediate the construction of proteins. Rather, DNA is *transcribed* into another nucleic acid, *RNA*.³⁰ Although RNA uses a different set of bases than DNA, RNA nucleotide sequences will pair with DNA sequences. Thus, through pairing, the DNA sequence may serve as a template for construction of a complementary RNA sequence. RNA sequences, in turn, mediate the construction of proteins. The cellular machinery accomplishes this by "reading" the RNA base sequences in groups of three.³¹ Each RNA base triplet, or *codon*, corresponds to a particular *amino acid*. Proteins are amino acid chains.³² Consequently, the RNA base sequence corresponds to the amino acid sequence used to construct a particular protein. The sequence of amino acids in a protein chain determines the protein's shape which, as discussed below, determines the protein's characteristics.³³

²⁴*Id.* at 452-55.

²⁵*Id.* at 51.

²⁶The exceptions to this rule are certain anuclear cells, such as human red blood cells, and haploid sex gametes.

²⁷B. LEWIN, *supra* note 14, at 38.

²⁸*Id.*; D. FREIFELDER, *supra* note 17, at 375-80.

²⁹B. LEWIN, *supra* note 14, at 4; D. FREIFELDER, *supra* note 17, at 65, 169-74, 181-86.

³⁰D. FREIFELDER, *supra* note 17, at 381-85.

³¹B. LEWIN, *supra* note 14, at 94; D. FREIFELDER, *supra* note 17, at 232-33.

³²B. LEWIN, *supra* note 14, at 5; D. FREIFELDER, *supra* note 17, at 438-40. The correspondence between codons and amino acids is not precisely one to one. The genetic code consists of four bases arranged in groups of three, which yields more codons, or groups of three, than there are amino acids. Consequently, there is some *redundancy* in the code; an amino acid may be represented by more than one codon. See D. FREIFELDER, *supra*, at 438.

³³D. FREIFELDER, *supra* note 17, at 152-63.

3. Information and Molecular Structure

In a living cell, the shape of a molecule determines its structure and function. This is the fundamental precept of molecular biology. The polynucleotide sequence called DNA is able to carry information because of the physical configuration the sequence creates.³⁴ Certain proteins have physical configurations that will recognize the physical configuration of particular stretches of DNA, much the way a key will recognize the physical configuration of a lock, or the way a gear will recognize the physical configuration of another gear in a machine.³⁵ The physical configuration presented by the interaction of a particular protein, or enzyme, and a particular DNA base is in turn recognized by RNA bases.³⁶ This base by base recognition process allows the DNA sequence to serve as a template for RNA base chain formation. Similarly, cellular "machinery" physically interacts with triplets of RNA bases to form amino acid chains, or proteins.³⁷ The sequence of amino acids in the chain determines the folding and overall structure of the protein; the protein's structure in turn will recognize and complement the structure of other bits of cellular machinery—DNA strands, for example.³⁸

Consequently, the flow of information in a cell occurs because of the physical configuration of complex molecules. These configurations are determined by the sequence of units in the molecules: DNA bases, RNA bases, or amino acids. The configurations also ultimately determine the gross morphological characteristics of organisms composed of these complex molecules. In this manner, the sequence of nucleotides in a DNA molecule carries information for the physical characteristics of living creatures.

B. A Hypothetical Experiment

The information contained in the DNA molecule may be manipulated in the laboratory through *recombinant DNA* techniques, or as this is popularly called, *genetic engineering*.³⁹ These techniques have become the stock research tools of the molecular biologist, and the basis for biotechnology. They are perhaps best illustrated by following an imaginary line of scientific research.

1. Some Techniques in Molecular Biology

Let us suppose that certain scientists have decided to isolate and study the human gene that codes for the enzyme litiginase.⁴⁰ The search for this gene is in many senses an enormous undertaking. On a molecular scale, the gene the re-

---

³⁴B. LEWIN, *supra* note 14, at 189–90, 266–71.

³⁵D. FREIFELDER, *supra* note 17, at 206–10, 375.

³⁶B. LEWIN, *supra* note 14, at 176–79.

³⁷*Id.* at 138–40.

³⁸*Id.* at 5.

³⁹*See id.* at 281.

⁴⁰This fictional protein is found abundantly in the brains of jurists and attorneys, and is believed to mediate a genetic predisposition toward a career in law.

searchers are interested in finding comprises only a short stretch of nucleotides amid the millions of base pairs in the human genome.⁴¹ It will be difficult to find and separate this short stretch of nucleotides from all the unwanted surrounding material. At the same time, on a real world scale, the researchers cannot see what they are doing. The amounts of material they must work with are infinitesimally small, often contained in volumes smaller than a fraction of a drop of water. They cannot view the individual molecules, so they must find the gene by gauging the physical characteristics of multiple copies of each molecule.

a. Gene splicing

The search begins by extracting the DNA from many human cells. This yields many copies of the same molecule to work with. The extracted DNA is cut into fragments by the action of an enzyme called a *restrictive endonuclease*.⁴² The endonuclease recognizes sequences that occur randomly throughout the genome, and cuts one side of the DNA strand at each end of that sequence.⁴³ Different enzymes recognize different sequences. The particular sequence recognized is *palindromic*; that is, as shown in Figure 1, it forms base pairs in the same way whether it is read forward or backwards.⁴⁴ Because of this base pairing peculiarity and the mirror cuts made by the enzyme, the resulting fragments have "sticky ends": they will pair with the end of any other fragment cut by the same enzyme.⁴⁵

Next, the researcher chooses a *vector*, such as a *plasmid*, that will convey the human fragments into bacterial cells.⁴⁶ Plasmids are small circular pieces of bacterial DNA that exist and replicate independently of the bacterial chromosome.⁴⁷ Plasmids often code for their own particular proteins, in addition to whatever proteins the bacterial cell normally produces. The researcher will select a plasmid that contains one instance of the sequence recognized by the enzyme previously used to cut the human DNA. Multiple copies of the plasmid may be extracted from dividing bacterial cells, then cut with the restrictive endonuclease. This opens the circular plasmid molecules, leaving "sticky ends." When these cut vectors are mixed with the human DNA fragments, the ends of some of the fragments will randomly pair up with the open ends of some of the plasmids, forming once again circular molecules with a human DNA addition.⁴⁸ When these additions are sealed into place by addition of the enzyme *ligase*, the resulting recombinant DNA, or *rDNA*, vectors are ready to convey their respective fragments of human DNA into a bacterial host⁴⁹ as shown in Figure 2.

⁴¹B. LEWIN, *supra* note 14, at 287.

⁴²*Id.* at 283-85.

⁴³D. FREIFELDER, *supra* note 17, at 800-1.

⁴⁴*Id.*

⁴⁵B. LEWIN, *supra* note 14, at 284.

⁴⁶*Id.* at 282.

⁴⁷*Id.* at 224.

⁴⁸*Id.* at 285.

⁴⁹D. FREIFELDER, *supra* note 17, at 798-99.

Figure 1

The Palindromic DNA Sequence Cut by the Restriction Enzyme *EcoRI*

The enzyme, represented by the shaded oval, cuts the molecule's sugar-phosphate backbone at the sites indicated by the arrows. Note that the base pairs in the site "mirror" one another across the dotted line of symmetry.

Figure 2

The Assembly of rDNA Vectors

DNA fragments, cut with a particular restriction enzyme, are mixed with bacterial plasmids that have been cut with the same enzymes. Some fragments randomly join with some plasmids. The plasmids are then introduced into bacterial hosts, where genes on the plasmids may be expressed.

b. Locating recombinant vectors

Through another random selection process, the plasmids are taken up by bacterial cells.⁵⁰ The researchers now face a triple identification problem: they must first determine which cells have randomly taken up plasmids. They must then determine if the plasmids absorbed into these cells were rDNA plasmids containing human DNA fragments. Finally, they must determine whether any of the cells containing the rDNA plasmids happen to contain the gene they are interested in. Because the selection process is random, they have some hope that, having used many copies of each molecule, they will find what they seek. However, they may well find that the gene they are looking for has found its way into none of the genetically altered cells. In that case, they will have to repeat the process up to this point all over again.

The identification process is facilitated by employing a plasmid that independently codes for a distinctive protein, such as a protein that gives a bacterial host resistance to the antibiotic penicillin. Thus, as shown in Figure 3, by using a bacterial strain that is susceptible to penicillin, the researcher knows that any cells that grow in the presence of penicillin must have acquired a plasmid.⁵¹ A clever researcher may also have selected a plasmid that gives resistance to a second antibiotic, such as tetracycline, but contains within the tetracycline resistance region the recognition site for the restriction enzyme.⁵² Insertion of a fragment of human DNA at such a site would inactivate the tetracycline resistance gene. Consequently, the researcher knows that cells showing resistance to penicillin, but not to tetracycline, must have absorbed a recombinant plasmid containing a human DNA fragment.⁵³

c. Identifying the desired gene

The researcher must now find whether any of the bacterial colonies that have grown in the presence of penicillin, but not tetracycline, are comprised of cells containing the litiginase gene in a recombinant vector. They may do this by capitalizing on the properties of the immune systems in higher animals. An animal's immune system defends against disease by manufacturing antibodies against foreign molecules. Antibodies bind to foreign molecules, and each type of antibody binds with great specificity to only the particular molecule against which it is directed. Thus, antibodies that will bind specifically to litiginase may be produced by purifying litiginase from human tissue, then injecting the purified protein into a laboratory animal, such as a rabbit. The rabbit will develop antibodies against this foreign protein.⁵⁴ The researcher may harvest

---

⁵⁰*Id.* at 799.

⁵¹*Id.* at 814–15.

⁵²*Id.*

⁵³*Id.*

⁵⁴See generally Amos, *Introduction to Immunity* in ZINSSER MICROBIOLOGY, *supra* note 16, 253 at 254–56.

Figure 3
Selection for Recombinant Plasmids

Bacteria that may have taken up plasmids are placed on media containing penicillin. Only those with the penicillin resistance gene from the plasmid will grow. Cells with plasmids that have incorporated new DNA fragments will not grow on tetracycline medium, because the new fragment disrupts the tetracycline resistance gene. Finally, bacterial colonies that grow on penicillin but not on tetracycline are tested with radioactively tagged antibody against the gene product.

these antibodies from the rabbit's blood serum, and expose likely bacterial colonies to the anti-litiginase antibodies. These antibodies will bind to litiginase if it is present in the colony cells.⁵⁵

This binding, if it occurs, must somehow be detected. One method of detection would be to "tag" the antibodies with a radioactive marker. However, tagging antibodies in this manner is time consuming, expensive, and even dangerous. The researchers would prefer to avoid producing radioactive antibody for every different protein they investigate. They may do this by using antibodies against rabbit antibodies. These anti-rabbit antibodies are raised in an animal such as a goat, and are readily available from commercial suppliers.⁵⁶ The commercial goat antibodies have been tagged with an easily detectable marker, such as a radioactive isotope.⁵⁷ These tagged goat antibodies are "generic"; they can be used in many different experiments to detect the presence of antibodies raised in a rabbit, such as, in this instance, antibodies against litiginase. If the goat antibodies bind to a colony, that signals the presence of rabbit antibodies, which in turn signals the presence of litiginase. Bacteria in colonies producing the human protein litiginase must contain the recombinant gene.

Of course, the litiginase gene may be detected in this way only if it is being expressed. The gene may be present, but oriented the wrong direction for transcription, or bereft of the necessary control elements, or otherwise inoperable. If no cells appear to be expressing the gene, the researcher may undertake the task of examining the DNA from likely bacterial colonies, trying to find the gene rather than its product. This would entail "reverse engineering" the purified litiginase protein; sequencing it to find its amino acid sequence.⁵⁸ From this, the nucleotide sequence of at least parts of the gene may be deduced.⁵⁹ A DNA probe, complementary to sections of the litiginase gene, may be synthetically prepared using this information. Under the proper conditions, the probe will pair up with the corresponding portion of single-stranded DNA taken from a bacterial cell containing the litiginase gene.⁶⁰ Such pairing may be readily detected if the probe is radioactively tagged, and so cells containing inactive copies of the gene of interest may be identified.⁶¹

---

⁵⁵D. FREIFELDER, *supra* note 17, at 823-24.

⁵⁶See generally Dawson & Crosswell, *Immunogens (Antigens) and Antibodies and Their Determination* in ZINSSER MICROBIOLOGY, *supra* note 16, 261 at 284-85.

⁵⁷*Id.*

⁵⁸See A. LEHNINGER, *BIOCHEMISTRY*, 98-104 (2nd ed. 1975) (techniques of amino acid sequencing); D. FREIFELDER, *supra* note 17, at 169.

⁵⁹In higher organisms, the correspondence between the DNA sequence and the protein sequence is not exact. Portions of the RNA transcript, called *introns*, are edited out before translation to a protein occurs. These edited portions may nonetheless be important to producing the end product. Consequently, sequencing of a protein may not reveal the entire sequence of the corresponding gene. See B. LEWIN, *supra* note 14, at 312-13.

⁶⁰B. LEWIN, *supra* note 14, at 289-90; D. FREIFELDER, *supra* note 17, at 123-24.

⁶¹D. FREIFELDER, *supra* note 17, at 141.

d. Manipulating the gene

Once a cell colony containing the correct plasmid is identified, manipulation of the litiginase gene becomes much simpler. As long as the cells reproduce, multiple copies of the gene are available. The plasmid may also be extracted and replicated in a test tube.⁶² These multiple copies may be used in a variety of techniques to characterize and express the gene of interest. Through a process called base sequencing, the exact sequence of nucleotides in the gene may be determined.⁶³ The gene may be placed into a vector that will convey it into the cells of a higher organism; it may be more efficiently expressed in such cells.⁶⁴ A variety of different control elements may be placed in the vector. For example, *promoter* sequences are recognized by cellular machinery as the place to begin transcription. Certain promoters have physical characteristics that create a greater affinity for transcription enzymes, causing the gene to be expressed more efficiently or more often. *Enhancer* sequences may have a similar effect. Promoters must be placed at the beginning of the coding region, but enhancers may be placed almost anywhere. *Repressors* may cause the gene to be expressed only in the presence of certain trigger substances.⁶⁵ Indeed, the coding region of the gene itself may be altered. By replacing the codons for certain key amino acids with those for other amino acids, the shape of the resulting protein may be altered.⁶⁶ This process of "protein engineering" allows the creation of proteins with specific characteristics, such as resistance to stomach acid.⁶⁷

If the litiginase gene and its product are of interest only to scientists, then the organism containing the recombinant gene will remain in the laboratory. If, however, there appears to be a commercial market for the gene product, the organism may find itself in an industrial setting. The organism may be grown in large quantities, and may be manipulated to secrete large quantities of the desired product.⁶⁸ Industrial processes are readily available to extract and purify the protein produced. Thus, in biotechnology, once the desired gene is active within a microorganism, the step from laboratory to factory is primarily one of scale.

2. The General Nature of Gene-Splicing Technology

We will turn presently to an examination of the biotechnology industry as a whole. For the present, this description of an imaginary line of biochemical research is intended to illustrate, at least anecdotally, the range of techniques available in rDNA manipulation. Several of the aspects of the technology sug-

---

⁶²B. LEWIN, *supra* note 14, at 541-42.

⁶³*Id.* at 77.

⁶⁴*See generally* D. FREIFELDER, *supra* note 17, at 824.

⁶⁵*See generally* B. LEWIN, *supra* note 14, at 279-333.

⁶⁶*See* Bernard, deSt. Groth, Steinberg, et. al., *Knowledge-based Prediction of Protein Structures and the Design of Novel Molecules*, 326 NATURE 347 (1987); Rath & Fletterick, *Protein Structure and Design*, 49 CELL 583 (1987).

⁶⁷*See* sources cited *supra* note 66.

⁶⁸*See generally* UNITED STATES CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, COMMERCIAL BIOTECHNOLOGY: AN INTERNATIONAL ANALYSIS (1984).

gested here may be relevant in discussing the appropriate mode and range of intellectual property protection.

First, this is an information technology. Molecular biology is the study of information-bearing macromolecules. The architecture of these molecules determines their function and interaction, which in turn determines the flow of information within the cell. Our understanding of this information flow now allows us to manipulate it to some degree. As a consequence, scientists can control the output of the cell's elaborate machinery, and hence the characteristics that cell displays.

Second, this type of genetic manipulation requires a high degree of technical skill. The line of research outlined here is a highly simplified example of the type of techniques that are now common in molecular biology laboratories. Many subtle and clever variations have been developed for each of these techniques, but considerable time may be required to develop facility with any of these protocols. Determining which techniques will be most effective on a given problem requires an odd blend of planning and serendipity. Thus, as a practical matter, several months or years will be required for the type of experiments described above.

Third, there is a substantial initial investment of time and effort in this type of research. This characteristic of the technology is closely tied to the requirement of technical expertise, but both of these stem from a more fundamental feature of recombinant DNA manipulations. The constraints under which the molecular biologist operates have been noted above; Francis Crick once remarked that "there's nothing there and you only want one millionth of it."⁶⁹ Despite their sophisticated science, molecular biologists must conduct a largely random sampling of an organism's genome, using indirect indicators such as bacterial growth and radioactive markers as their guide. The probabilities of this sampling usually dictate an exhausting search before the material of interest turns up.

Fourth, a genetic sequence, once isolated, may be manipulated and copied with relative ease. The great marvel of modern molecular biology is that science can locate genes and put them in a form where they may be easily copied and examined. Once the material of interest has been found, there is certainly still a great deal of work that may be done in characterization and investigation. This work is relatively straightforward, however, compared to the location process.⁷⁰ Even industrial production of a protein is relatively straightforward once the necessary gene is in hand. This feature of biotechnology has tended to

---

⁶⁹The author was treated to this example of Crick's wry British humor at a seminar presented at the University of Utah in December of 1984.

⁷⁰This is not to dismiss the difficulties involved in scaling up laboratory procedures for manufacture; such bioprocess engineering problems are formidable and involve a unique technology of their own. See *COMMERCIAL BIOTECHNOLOGY*, *supra* note 1, at 3, 44-57 (describing bioprocess engineering); *PROFILES AND OUTLOOKS*, *supra* note 4, at 69 (scale-up cost a major barrier to market entry). However, these are problems of size rather than kind. See *PROFILES AND OUTLOOKS*, *supra* note 4, at 75 (manufacturing involves scaling up laboratory growth and purification).

collapse the distance usually found between basic and commercially applied science.⁷¹

Finally, molecular biologists do not generally engineer nucleotide genetic sequences "from scratch." As discussed above, the sequence of a DNA molecule gives rise to sequences of amino acids; the folding of these amino acid chains gives rise to the structure and function of a protein. The relationship between amino acid sequence and protein structure is not yet well enough understood to permit the design of a functional protein *de novo*. Perhaps more important, science as yet knows too little of the many structures within a cell, with which a protein must interact, to begin engineering novel proteins. Although knowledge in these areas is progressing rapidly, for the foreseeable future science will be confined to finding, assembling, and modifying bits of existing genetic material.⁷²

II. CURRENT PROTECTION FOR BIOTECHNOLOGY

Recent discussion regarding copyright protection for rDNA creations stem primarily from real or perceived problems with current schemes of protection.⁷³ At present, protection for this biotechnology comes almost exclusively from federal patent law. This section briefly reviews the nature of patent law, then discusses some of its shortcomings in the context of biotechnology. Finally, the alternative of trade secret protection is briefly addressed.

A. Patent Law

Article I, section 8, clause 8 of the United States Constitution empowers Congress to offer an incentive to inventors in the form of a limited monopoly, or patent, over their creations.⁷⁴ This monopoly is granted to processes, machines, articles of manufacture, and compositions of matter that meet high standards of novelty, utility, and nonobviousness.⁷⁵ Before a patent is granted, an administrative review of the application is required to determine if it meets these standards.⁷⁶ Once granted, the patent gives the inventor very broad intellectual property protection: an exclusive right to use of the invention for seventeen years.⁷⁷ Independent discovery of the invention is not a defense for patent

---

⁷¹See *id.*; see also Eisenberg, *supra* note 7, at 195.

⁷²Even protein engineering techniques are at present confined to modifying existing cellular products.

⁷³See Friedman, *Law and the Innovative Process: Preliminary Reflections*, 1 COLUM. BUS. L. REV. 1, 13 (1986) (inadequacy of patent protection for biotechnology).

⁷⁴U.S. CONST. art. I, sec. 8, cl. 8.

⁷⁵35 U.S.C. §§ 101-3, 112 (1982). See also E. KINTNER & J. LAHR, AN INTELLECTUAL PROPERTY PRIMER 37-46 (1982).

⁷⁶35 U.S.C. § 112 (1982).

⁷⁷35 U.S.C. §§ 154, 271(a) (1982).

infringement.⁷⁸ In return for this broad monopoly, the inventor is required to plainly disclose to the public how the invention is made.⁷⁹ Thus, at the end of seventeen years, the disclosed invention becomes available for general use.

1. Patent Protection for rDNA Inventions

The availability of patent protection for the fruit of rDNA technologies has been and continues to be a source of controversy.⁸⁰ Microorganisms genetically altered by recombinant DNA manipulation were denied patent protection until the 1980 case of *Diamond v. Chakrabarty*,⁸¹ in which the Supreme Court held such an organism to be patentable subject matter. The application of this decision to similarly manipulated multicellular life forms has yet to be worked out; the Patent and Trademark Office (PTO) has issued at least one such patent, prompting legislative action attempting to block further patenting of higher life forms.⁸² Patent protection for living organisms, even if granted, is further complicated by doctrines such as the "exhaustion doctrine," which raises questions as to the protection of the offspring of patented creatures.⁸³

The situation is even less clear where the patentability of rDNA innovations at the molecular level, rather than entire organisms, is concerned. Case-law on the patentability of nucleotide sequences outside an animate host is virtually nonexistent.⁸⁴ Commentators discussing the application of current patent doctrines to rDNA suggest that the prospects for successful patent applications in this field are slender.⁸⁵ This is primarily due to the high standards necessary for patentability, relative to the nature of biotechnology.

For example, current patent practice suggests that rDNA inventions may fail to meet patent law's utility requirement. Patent law tends to be directed toward applied, rather than basic science, because of the requirement that a patentable invention be useful.⁸⁶ Patents have been denied both for compounds with no known use and for processes producing compounds with no known

---

⁷⁸This arises from the patent grant of an exclusive right in the invention. 35 U.S.C. §§ 101-3 (1982).

⁷⁹35 U.S.C. § 112 (1982).

⁸⁰See generally Dresser, *supra* note 7; Adler, *Controlling the Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium on Animal Patenting*, 1 HARV. J.L. & TECH. 1 (1988).

⁸¹447 U.S. 303 (1980).

⁸²U.S. Patent No. 4,736,866, issued for the "Harvard mouse," has been the source of this controversy. See PATENTING LIFE, *supra* note 7, at 99; Dresser, *supra* note 7, at 400-35, n.256.

⁸³The "exhaustion doctrine" in patent law, much like the "first sale doctrine" in copyright law, prevents the patent holder from claiming an interest in articles after their sale. It is not entirely clear how this should apply to patented inventions that reproduce themselves after being sold. See Bent, *Patent Protection for DNA Molecules*, 64 J. PAT. OFF. SOC. 60-62 (1982); see also Dresser, *supra* note 7, at 432-33.

⁸⁴See Rauth & Jaenichen, *Novelty and Inventive Step in Inventions Having Proteins or DNA Sequences as Their Subject Matter*, 1988 J. PAT. & TRADEMARK OFF. SOC. 313, 314.

⁸⁵See generally Bent, *supra* note 83, at 62-77; Comment, *supra* note 9 at 1089-95.

⁸⁶See Eisenberg, *supra* note 7, at 185-86.

use.⁸⁷ "Practical utility" is required to meet this standard; usefulness as a research tool has been held not to entail patentable utility.⁸⁸ Thus, no matter how interesting or significant it may be in the laboratory, an rDNA invention would presumably be unpatentable unless put to some practical application. Such an application may not be developed until long after the invention is discovered. Some commentators have also expressed concern that rDNA inventions might be viewed as having a practical use only in the milieu of a living cell; thus, by themselves, they would be ineligible for patent protection.⁸⁹

Numerous other ambiguities have been raised regarding patent doctrine as applied to DNA molecules.⁹⁰ For example, algorithms have been held to be unpatentable as natural laws or processes; one commentator has suggested that rDNA inventions, as the embodiment of such information, could be found unpatentable.⁹¹ Non-obviousness may also prove to be a barrier against patenting such inventions. Once an important protein or nucleotide sequence is found, it may now be an obvious advance to produce it through gene splicing techniques.⁹² Indeed, the rapid advance of knowledge in this area may create difficulty in determining what is obvious.⁹³ As has been discussed, the application of these techniques is a labor-intensive process. Nonetheless, the issues raised here might well preclude the results of such labor from being protected under patent law.

It might be argued that, despite the labor involved, such discoveries should not as a matter of policy be protected by patent. Patent doctrines have evolved in order to grant monopolies only where creation and disclosure of the invention will most benefit society. If an rDNA invention is unpatentable due to obviousness, a lack of practical utility, or similar defect, then perhaps all is as it should be. Perhaps society has no interest in prompting the discovery and disclosure of such inventions.

A moment's reflection should reveal that this argument may not work well in the case of discoveries in biotechnology. Although this line of reasoning may

⁸⁷Application of Brenner, 37 C.C.P.A. 1032, 182 F.2d 216 (1950) (new chemical compound with no known use unpatentable).

⁸⁸See COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 387; see also Brenner v. Manson, 383 U.S. 519 (1966) (patent denied to process producing compound that was the subject of research only).

⁸⁹Comment, *supra* note 9, at 1093. This appears to be the case for computer programs. Divorced from its hardware milieu, a program listing has no utility, whereas a programmed system may be patentable as a machine or process. See Manual of Patent Examining Procedure § 2106; Diamond v. Diehr, 450 U.S. 175 (1981).

⁹⁰Some of these difficulties peculiar to biotechnology have been resolved already at the administrative level. For example, a patent will issue only if the invention is described in a manner sufficient to allow someone with ordinary skill in the art to reproduce it. Because reproduction of a biological innovation generally requires access to the materials, this enablement requirement may be met by depositing samples of the necessary material. See COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 388.

⁹¹See Brent, *supra* note 83, at 67.

⁹²See Rauth & Jaenichen, *supra* note 84, at 325-26; see also Comment, *supra* note 9, at 1093-95.

⁹³COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 387.

justify denying these inventions patent protection, it may not justify denying the inventions protection in any form whatsoever. At present, lack of patent protection for developments in biotechnology is tantamount to a lack of substantial protection in any form.⁹⁴ The defects precluding patenting of these discoveries arise primarily because they are discoveries in basic science. Society certainly has an interest in the disclosure of such discoveries, and, if necessary, might need to provide an incentive for disclosure. Traditionally, the norms of science, rather than a legal monopoly, have provided the incentive for disclosure.⁹⁵ In biotechnology, however, these norms presently show some signs of breaking down.⁹⁶

2. Patent Protection and Scientific Norms

Patent law generally has been viewed as a means to generate incentives for inventors to create inventions and share these discoveries with the public. The limited monopoly created by patent law is by no means the only incentive that might prompt disclosure. In the scientific community, the opportunity for peer recognitions has traditionally provided such an incentive, quite apart from any possible financial reward held out by intellectual property law.⁹⁷ This has been especially true in basic science, which is usually far removed from applied technologies that might supply a profit. Indeed, some courts have observed that intellectual property incentives have not been aimed at the pure scientists, because they labor for other rewards.⁹⁸

This scientific norm of peer recognition interacts closely with other norms of the scientific community, and is closely tied to the function of the scientific method itself. Because recognition has been the primary reward for successful scientific research, scientists are motivated to publish new data at the earliest opportunity, and avoid the possibility that another researcher working in the same area might publish the discovery first.⁹⁹ This pressure to publish early speeds the progress of science and allows other researchers early access to data that may be important to their own projects. More important, the incentive to disclose and the opportunity to build on others' recent data allow for duplication of experiments. Thus, science traditionally has been perceived as self-regulating: access to and use of another's scientific protocols create an incentive to review earlier experiments and identify any errors.¹⁰⁰

⁹⁴See Eisenberg, *supra* note 7, at 196, 197.

⁹⁵See *id.* at 181-85.

⁹⁶*Id.* at 197-99. Much of Eisenberg's discussion of the norms of the scientific community is based upon the collected work of sociologist Robert Merton. See R. MERTON, *THE SOCIOLOGY OF SCIENCE* (1973).

⁹⁷Eisenberg, *supra* note 7, at 197.

⁹⁸See *Katz v. Horni Signal Manufacturing Corp.*, 145 F.2d 961 (2d Cir. 1944) (great scientists are not motivated by monetary rewards, so intellectual property incentives not aimed at them).

⁹⁹See Eisenberg, *supra* note 7, at 183.

¹⁰⁰Some recent scholarship, however, suggests that as a practical matter such verification of previous work never occurs: no grants or awards are given for repeating what has been done before. See W. BROAD & N. WADE, *BETRAYERS OF THE TRUTH: FRAUD AND DECEIT IN THE HALLS OF SCIENCE*, 60-87 (1982).

The incentive to disclose scientific information has also fostered another important norm in the scientific community: that of open access to materials.¹⁰¹ This norm is critical in the biological sciences, where research is almost impossible to duplicate without obtaining the original materials.¹⁰² The imaginary experiment described above illustrates the long process of random selection a molecular biologist often goes through to isolate the bit of genetic material he desires to work with. Unless this material is supplied freely to subsequent researchers, their ability to incorporate the new discovery into their own work or to check the veracity of the previous discovery becomes subject to the same long, random search.¹⁰³ Consequently, leading journals in molecular biology and biochemistry have often required that researchers make available to others the materials necessary to duplicate the work in papers published by the journal.¹⁰⁴ This requirement in some senses codified a long standing practice in the basic sciences.

The sudden advent of commercial incentives into the world of biotechnology appears to be altering these norms, particularly in the face of reduced governmental spending for basic research. In molecular biology, the same bit of genetic material that is the subject of a new scientific discovery will also be the bit of material needed if the discovery is to become a profitable commercial venture. Thus, the gap between basic science and commercial application narrows considerably.¹⁰⁵ Scientists may be understandably reluctant to share information, and even more reluctant to share materials, that may later prove to be of considerable worth.¹⁰⁶ This becomes particularly true where joint ventures between universities and commercial industry are undertaken—a situation that is occurring with greater frequency.¹⁰⁷ Academic researchers who are dependent on industry funds may even find themselves restrained by contractual agreements not to disclose data and discoveries.¹⁰⁸ However strong the incentive for peer recognition may be, it may well lose when it clashes with economic incentives, and the disclosure that has traditionally been expected in order to further the progress of knowledge may be willingly or unwillingly delayed in order to further financial gain.¹⁰⁹

Ironically, the patent system, far from providing an alternate financial in-

¹⁰¹ See Eisenberg, *supra* note 7, at 198.

¹⁰² *Id.*, COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 388 (access to materials required because biological inventions are too complex to reproduce from written description alone).

¹⁰³ See *supra* notes 42–61 and accompanying text.

¹⁰⁴ Eisenberg, *supra* note 7, at 199–206.

¹⁰⁵ See Grobstein, *Biotechnology and Open University Science*, 10 SCI. TECH. & HUM. VALUES 55, 55 (1985) (theory and application closely juxtaposed in rapidly expanding field of molecular genetics).

¹⁰⁶ Eisenberg, *supra* note 7, at 199–206; see also U.S. INVESTMENT, *supra* note 1, at 7.

¹⁰⁷ See U.S. INVESTMENT, *supra* note 2, at 120–25; Dresser, *supra* note 7, at 419–22.

¹⁰⁸ See Markle & Robin, *Biotechnology and the Social Reconstruction of Molecular Biology*, 10 SCI. TECH. & HUM. VALUES 70, 89 (1985); Rozenzweig, *Research as Intellectual Property: Influences Within the University*, 10 SCI. TECH. & HUM. VALUES 47, 47–48 (1985).

¹⁰⁹ See D. NELKIN, *supra* note 3, at 16, 25, 27.

centive to disclose, appears likely to encourage greater secrecy. The problem is greatly exacerbated by the administrative review required before a patent issues.¹¹⁰ Between 1984 and 1987, the number of biotechnology patent applications filed with the PTO more than doubled.¹¹¹ The resulting backlog has created a waiting period of two and a half years before such an application reaches an examiner; a final ruling on the application is generally not reached for another two years.¹¹² This situation appears likely to worsen due to the increasing number of biotechnology patent applications and the difficulty of hiring and retaining qualified examiners for such applications.¹¹³

During the four or five years required for a patent to issue, the researcher remains uncertain whether or not her discovery will be granted the intellectual property incentive that might motivate her to disclosure. We have already reviewed several characteristics of rDNA inventions that make it difficult to predict whether a particular invention will meet the high standards necessary for patent protection. Patent doctrines create yet other serious problems for the basic scientist. First, publication of a discovery more than one year before a patent application is filed precludes issuance of a patent.¹¹⁴ This seems to require either an early guess as to the commercial value of a discovery, or gratuitous filing of patent applications. Second, such publication becomes part of the prior art examined to determine the invention's nonobviousness.¹¹⁵ Thus scientists, through their publications, may make their own inventions ineligible for patent protection.¹¹⁶ Finally, if the invention is found ineligible for patent protection, prior publication will leave the invention unprotected in the public domain.

These and similar difficulties may make researchers reluctant to publish their findings or supply the invention to other scientists until they have a patent in hand—even if the inventor files promptly for patent protection, publication of the discovery will put it in the public domain if the patent is denied. Researchers may be inclined to keep discoveries secret until they are certain that protection will be exchanged for disclosure. In such situations, disclosure, if it occurs at all, may be delayed until years after the discovery.¹¹⁷ This scenario is not imaginary or speculative. In the biotechnology community, several recent, well-publicized instances of scientists' reluctance to share information and materials have been linked to concern over current patent law doctrines.¹¹⁸ Of

¹¹⁰See sources cited *supra* note 74.

¹¹¹Crawford, *Patent Claims Buildup Haunts Biotechnology* 238 SCIENCE 723 (1988).

¹¹²*Id.*

¹¹³*Id.* See also U.S. INVESTMENT, *supra* note 1, at 103.

¹¹⁴35 U.S.C. § 102(b) (1985).

¹¹⁵See *e.g.*, *Mass. Institute of Technology v. A.B. Fortia*, 227 U.S.P.Q. (BNA) 428, 431-32 (Fed. Cir. 1985) (cell culture patent held invalid because paper presented at scientific conference became prior art).

¹¹⁶See Eisenberg, *supra* note 7, at 216.

¹¹⁷*Id.* at 207; COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 385. See also *In re Argoudelis*, 434 F.2d 1390 (C.C.P.A. 1970) (Baldwin, J. concurring) (even in patent application, no obligation to disclose invention until protected).

¹¹⁸See Eisenberg, *supra* note 7, at 198-214, 226-29.

course, the problem is not limited to the confines of biotechnology. The recent controversy regarding "cold fusion" is widely believed to provide another example of data withheld because of a conflict between scientific norms and intellectual property laws.¹¹⁹

Nonetheless, molecular biology and related disciplines are clearly most strongly affected by this trend. A recent sociological survey indicated that scientists in this area often feared to share data because of possible financial loss.¹²⁰ This finding contrasted with those among other groups of scientists, such as social scientists, who also sometimes feared to share data, but because of the possibility of being preempted in publishing.¹²¹ The traditional reward for success in basic science may have been peer recognition. Nonetheless, by making uncertain the protection of possible financial rewards, patent law appears to be supplying a negative incentive to disclosure of advances in biotechnology. This result is contrary not only to the basic norms of science and to the overall welfare of society, but to the underlying purpose of patent law itself.

Finally, even where patent protection is available for rDNA products, the broad scope of patent protection may still hamper scientific exchange.¹²² Researchers who receive patent protection for a discovery may exclude other scientists from using the discovery, even for investigation. The theoretical exceptions to patent exclusivity, allowing use of a discovery for pure research, may not extend to many experimental situations.¹²³ Consequently, both in its presence and absence, the configuration of patent law seems to create friction for the creator of rDNA innovations.

3. Patent Protection and the Biotechnology Industry

In addition to any unfortunate consequences the current scheme of patent protection may create for basic science, the uncertainties discussed here have a

---

¹¹⁹Researchers at the University of Utah announced the success of an unconventional experiment alleged to produce nuclear fusion at room temperature, but the researchers declined to release their protocols or data sufficient to allow other scientists to reproduce the experiment. It appears that these actions, which have been loudly denounced, permitted a claim of discovery priority without compromising patentability. See Dye & Mausch, *Fusion Claim Sparks Rush to Duplicate Experiment*, The Los Angeles Times, Mar. 25, 1989, 1, col. 5 (announcement without details); Hudson, *Pons and Fleischman Withdraw Fusion Paper from U.K. Journal*, Wall Street Journal, Apr. 20, 1989, B4, col. 1 (data and protocols not published); Bishop, *Utah's Pons Says New Fusion Tests Will Be Convincing*, The Wall Street Journal, Apr. 25, 1989, B4, col. 11 (patenting and licensing before publication).

¹²⁰Ceci, *Scientists' Attitudes Toward Data Sharing*, 13 SCI. TECH. & HUM. VALUES 45, 51 (1988).

¹²¹*Id.* Naturally, as Grobstein points out, academics have always had some apprehension about sharing data, but in the past it has usually been for the reasons advanced by the social scientists in this study. Grobstein, *supra* note 105, at 57-59. For an argument that the newer attitude is not a departure from the norms of science, but the development of new norms since Merton's 1945 studies, see Chubin, *Open Science and Closed Science: Tradeoffs in a Democracy*, 10 SCI. TECH. & HUM. VALUES 73 (1985).

¹²²*Id.* at 206; U.S. INVESTMENT, *supra* note 1, at 181.

¹²³See Eisenberg, *supra* note 7, at 220-26; see also Dresser, *supra* note 7, at 443-44.

demonstrably negative effect on the fledgling biotechnology industry as a whole. The characteristics of this emerging industry will receive some attention below; for the present, it is worthwhile to note that many new biotechnology companies are dependent on the success of a single product produced by rDNA techniques.¹²⁴ For such companies, even the threat of a patent suit may adversely affect the company's ability to compete in the market.¹²⁵ A recent study by the Congressional Office of Technology Assessment (OTA) indicates that uncertainty over the scope and viability of patent protection for biotechnology inventions poses a major concern regarding the continued growth of commercial biotechnology.¹²⁶

B. Trade Secret

Researchers who are awaiting issue of a patent, or who are denied patent protection for their rDNA works, may turn to the alternative of legal trade secret protection.¹²⁷ Trade secret protection is based on state common law or state statute rather than on federal intellectual property law; as a result, its scope and application vary among jurisdictions.¹²⁸ Trade secret protection has its basis in the law of torts.¹²⁹ Persons relying on trade secret protection are generally required to show that the particular innovation has been misappropriated, after an effort has been made to keep it secret.¹³⁰ This latter requirement for secrecy would interfere substantially with a researcher's obligations to scientific norms, as well as defeat society's interest in disclosure of important knowledge.¹³¹

Eisenberg has observed that, in many cases, even trade secret law will be unavailable to protect innovations in biotechnology.¹³² For example, many states require that a protected trade secret be integral to an operating business; this requirement removes many research discoveries from the ambit of trade secret law.¹³³ Additionally, because of the requirement that the innovation be misappropriated, trade secret law provides little protection against practices

---

¹²⁴U.S. INVESTMENT, *supra* note 1, at 79–80.

¹²⁵*Id.* at 103, 181.

¹²⁶*Id.* at 103. See also *infra* notes 296–98 and accompanying text.

¹²⁷See Lipsey, Brezner, & Majofis, *Trade Secrets in Biotechnology*, 2 TRADE SECRET L. REP. 21, 22 (1986) (biotechnology trade secret cases reviewed); Lipsey, Brezner, & Majofis, *Trade Secrets in Biotechnology (Part Two)*, 2 TRADE SECRET L. REP. 41, 44 (1986) (patent and trade secret interface discussed).

¹²⁸See generally UNIFORM TRADE SECRETS ACT § 1, comment e, 14 U.L.A. 373–74 (Supp. 1989) (variations between states adopting statutory trade secret law).

¹²⁹See generally RESTATEMENT OF TORTS § 757 (1959).

¹³⁰See generally E. KINTNER & J. LAHR, *supra* note 75, at 133–36; see also generally Epstein and Neelman, *Trade Secrets: Novel Applications to Biotechnology*, J. PROPRIETARY RTS., Dec. 1988, at 16.

¹³¹See PROFILES AND OUTLOOKS, *supra* note 4, at 166; Eisenberg, *supra* note 7, at 194.

¹³²Eisenberg, *supra* note 7, at 191–92; Comment, *supra* note 9, at 1095.

¹³³*Id.*

such as reverse engineering.¹³⁴ In cases where even trade secret law provides no protection, researchers may be forced to resort to actual secrecy in guarding potentially valuable discoveries.¹³⁵ Again, maintaining such silence about important knowledge poses serious problems for the advancement of science and other societal interests. Some other form of intellectual property protection, more accommodating to the purposes of basic research, clearly would be desirable for the scientific community and for society as a whole.

III. THE COPYRIGHT ALTERNATIVE

Against the background of conflict between the norms of science and the law of patents, copyright has been suggested as a new possibility to encourage disclosure.¹³⁶ Copyright affords its holder a more limited monopoly than does patent; independent creation, for example, will not infringe a copyright.¹³⁷ However, the duration of a copyright monopoly is far longer than that of a patent monopoly: the lifetime of the author plus fifty years.¹³⁸ Copyright arises spontaneously when a protectable work is fixed in some tangible medium for more than momentary duration; thus, no formal review process is necessary.¹³⁹ Prior to the 1988 Copyright Act amendments, registration with the Copyright Office was required to challenge infringement of a copyright, but for works created after March 31, 1989, even formalities such as notice largely have been done away with.¹⁴⁰

¹³⁴*Id.* at 193.

¹³⁵*Id.* See also U.S. INVESTMENT, *supra* note 1, at 6-7; Kayton, *supra* note 9, at 196-97.

¹³⁶Because the federal copyright scheme preempts state laws that grant rights equivalent to those of copyright, trade secret protection might well become unavailable for rDNA products if they were included within copyrightable subject matter. See 15 U.S.C. § 301 (1982); Videotronics v. Bend Electronics, 564 F. Supp. 1471, 1476 (D. Nev. 1983) (federal copyright preempted state trade secret protection for video game). The demarcation between copyright and trade secret protection is unclear. Ideas are specifically excluded from the subject matter of copyright, but trade secret protection may extend to ideas, and so escape preemption. *Boeing v. Seirracin Corp.*, 108 Wash. 2d 38, 49, 738 P.2d 665, 674 (1982). In addition, state trade secret laws that include "elements . . . different in kind from copyright infringement" such as "breach of trust or confidentiality" are not preempted. H.R. REPORT no. 94-1476, 94th Cong., 2d Sess. 131-32 (1976) [hereinafter H.R. REPORT]. Courts are somewhat divided on the application of these principles. Compare *Bryce & Associates v. Gladstone*, 107 Wis. 2d 241, 319 N.W.2d 907-09 (Ct. App. 1982) (articulating several alternative theories as to why trade secret law is left undisturbed by 1976 copyright act) with *Avco Corp. v. Precision Air Parts, Inc.*, 210 U.S.P.Q. 894 (M.D. Ga. 1980), *aff'd* at 676 F.2d 494 (11th Cir. 1982) (trade secret claim preempted by federal copyright because court found state law required no additional elements).

¹³⁷See *Arnstein v. Edward B. Marks Music Corp.*, 82 F.2d 275 (2d Cir. 1936); *Fred Fisher Music Co. Inc. v. Dillingham*, 289 F. 145, 159 (S.D.N.Y. 1924).

¹³⁸Or, copyright lasts for seventy-five years in works made for hire. 17 U.S.C. §§ 301(a), (c) (1985).

¹³⁹17 U.S.C. § 101 (1985).

¹⁴⁰However, registration and notice still confer benefits in an infringement suit, especially if the United States is the work's country of origin. See generally, *Berne Implementation Act of 1988*, Pub. L. 100-568 §§ 7, 9, 102 Stat. 2853, 2857-59 (1988); see also *United States Copyright Office, Circular 93: Highlights of U.S. Adherence to the Berne Convention* (Feb. 1989).

A. Arguments of Statutory Construction

Copyright law is not an obvious candidate to protect rDNA innovations; indeed, the suggestion is somewhat counterintuitive. Copyright law generally has been used to protect the creations of artists and writers, rather than those of molecular biologists. Congress has given no explicit indication that it intended to protect the products of biotechnology research under copyright law. Nonetheless, the discussion regarding copyrightability of rDNA has thus far centered upon copyright under the language of the copyright laws as now constituted. Proponents of copyright protection for rDNA have expended a great deal of effort attempting to show that the relevant statutory language could plausibly be construed to include nucleotide sequences.¹⁴¹ Opponents of the proposition have similarly attempted to construe the same language so as to exclude rDNA works, or even to show that the constitutional language authorizing copyright could not include rDNA.¹⁴² This section reviews the arguments advanced by each side, criticizing those arguments in light of recent judicial interpretation of the statutory language. An examination of these claims regarding the scope of the copyright statute properly begins with a discussion of the scope of the constitutional basis for the statute.

1. *The Constitutional Language*

The United States Constitution grants Congress the power to "Promote the Progress of Science and useful Arts, by securing for limited times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."¹⁴³ This clause traditionally has been interpreted, in Eisenberg's language, "distributively,"¹⁴⁴ authorizing the enactment of two separate bodies of law: patent and copyright. Thus, patent has been viewed as a vehicle to promote the "useful arts," or applied technology, by granting a limited monopoly of a certain character to an "inventor" over her "discovery."¹⁴⁵ Copyright has been viewed as a vehicle to promote "science," or general knowledge, by granting a limited monopoly of somewhat different character to an "author" over her "writings."¹⁴⁶ However, new information technologies, particularly computer science, have blurred these traditionally clear distinctions.¹⁴⁷

A possible objection to protecting rDNA creations by copyright is the definition of the constitutional term "Writings." It is not immediately obvious that this word should apply to strings of chemical units, even if they do in some sense embody information. Neither, however, is it immediately obvious that works embodied in magnetic tape, phonograph records, or silicon chips should

---

¹⁴¹See Kayton, *supra* note 9, at 197-205; Goldstein, *supra* note 9, at 138-41.

¹⁴²See I. COOPER, *supra* note 11, §§ 11.02 [1]-11.02 [7].

¹⁴³U.S. CONST. art I, sec. 8, cl. 8.

¹⁴⁴Eisenberg, *supra* note 7, at 185.

¹⁴⁵See *Graham v. John Deere Co.*, 383 U.S. 1, 5 (1966).

¹⁴⁶See *Alfred Bell & Co. Ltd. v. Catadala Fine Arts Inc.*, 191 F.2d 99 (2d Cir. 1951).

¹⁴⁷R.P. BENKO, *PROTECTING INTELLECTUAL PROPERTY RIGHTS*, 22-24 (1987).

fall within the meaning of the term.¹⁴⁸ Certainly, none of these media of expression were envisioned by those who drafted the Constitution. Yet works embodied in each of these media have been protected by Congress under copyright law.¹⁴⁹ In each instance, protection has been found to fall within the scope of this constitutional grant of authority.

Presumably, nucleotide sequences are just as eligible for classification as "writings" as any other medium found to fall within the term's ambit.¹⁵⁰ In short, protection under this constitutional grant has been found to depend less upon the medium of expression than upon the type of expression it embodies. To determine whether rDNA embodies the type of expression granted copyright protection, this article examines the language of the copyright statute.

2. *The Statutory Language*

Under section 102(b) of the recently amended Copyright Act of 1976, copyright protection extends to "original works of authorship fixed in any tangible medium of expression now known or later developed from which they can be perceived, reproduced, or otherwise communicated either directly or indirectly or with the aid of a machine or device."¹⁵¹ The most controversial questions regarding copyright protection for rDNA revolve around judicial interpretation of the statutory term "original works of authorship," and whether such works can be embodied in nucleotide sequences.

a. Works of authorship

A nucleotide sequence is not an obvious candidate for categorization as a work of "authorship." However, like the constitutional term "writings," authorship is by no means restricted to literature for purposes of copyright law. Section 102 of the Copyright Statute states that such works "include the following categories: (1) literary works; (2) musical works, including any accompanying words; (3) dramatic works, including any accompanying music; (4) pantomimes and choreographic works; (5) pictorial, graphic, and sculptural works; (6) motion pictures and other audiovisual works; and (7) sound recordings."¹⁵²

In developing their arguments, proponents of rDNA copyright have stressed the statutory language "include."¹⁵³ Presumably, rDNA works need not fit into any of the seven enumerated categories to qualify as works of authorship according to the legislative history and the definition of "including" in section 101, the list of works in the statute was intended to be "illustrative and not limitative."¹⁵⁴ Those opposing rDNA copyright object to this argu-

¹⁴⁸ See Goldstein, *supra* note 9, at 138.

¹⁴⁹ 17 U.S.C. § 101 (1985) (defining literary work).

¹⁵⁰ See Kayton, *supra* note 9, at 204.

¹⁵¹ 17 U.S.C. § 102(a) (1985).

¹⁵² *Id.*

¹⁵³ Kayton, *supra* note 9, at 200.

¹⁵⁴ 17 U.S.C. § 101 (1985); H.R. REPORT, *supra* note 136, at 53.

ment, relying on the legislative history to show that this language should not allow unlimited expansion of copyright protection beyond the scope of congressional intent.¹⁵⁵ From this they argue that inclusion of rDNA under copyright expands the scope of protection beyond Congress' intent.¹⁵⁶

This analysis, however, begs the question of what in fact was the scope of Congress' intent. The intent may very well have been to protect creativity in new technologies such as rDNA. These arguments properly stress the importance of intent in analyzing the statutory language. This question of intent permeates much of the discussion in this section, which looks to the language of the statute and judicial interpretation of that language to determine Congress' intent. In addition, both those commentators favoring rDNA copyright and those opposing it concede that, with regard to the inclusion of a new category of works under the statute, intent may be determined by analogy to the enumerated categories.¹⁵⁷ Naturally, they disagree as to a proper analogy in the case of rDNA, but the question they identify, that of analogy and the proper level of analogy, also permeates much of the discussion below.

b. Literary works

Even if the adoption of rDNA "works" as a new category of authorship is improper, nucleotide sequences may nonetheless fall within the ambit of the Copyright Act by inclusion within one of the stated categories. Proponents of rDNA copyright suggest that an rDNA creation may properly be granted copyright protection as a literary work.¹⁵⁸ As might be expected, the term "literary work" has a different meaning for purposes of the statute than it might have in everyday parlance. Section 101 of the Act defines literary works as "works, other than audiovisual works, expressed in words, numbers, or other verbal or numerical symbols or indicia. . . ."¹⁵⁹ This definition also states that literary works may be embodied in a variety of media that would commonly be considered non-literary, such as film, tapes, or disks.¹⁶⁰ It might be argued that DNA bases constitute "indicia," thus placing works expressed in nucleotide media within this category.¹⁶¹

Opponents of rDNA copyright object to this reading of the statute, claiming that the term "indicia" is modified by the words "verbal or numerical."¹⁶² This latter reading would limit the scope of indicia to those representing words or numbers, thus excluding DNA bases. Consequently, written representations of nucleotide sequences would certainly be protectable under copyright, but the sequences themselves would not.¹⁶³

¹⁵⁵I. COOPER, *supra* note 11, at § 11.02 [1].

¹⁵⁶*Id.*

¹⁵⁷*Id.* at 11-19; Kayton, *supra* note 9, at 201.

¹⁵⁸Kayton, *supra* note 9, at 199.

¹⁵⁹17 U.S.C. § 101 (1985).

¹⁶⁰*Id.*

¹⁶¹Kayton, *supra* note 9, at 199.

¹⁶²I. COOPER, *supra* note 11, at 11-20.1.

¹⁶³*Id.* at 11-26.

This reading of the statute's language, however, conflicts with current copyright practice by excluding computer programs in their machine-readable form. Computer software exists in the machine as a particular configuration of open or closed electronic circuits.¹⁶⁴ Software may also exist as a particular pattern of magnetic flux on a disk or tape.¹⁶⁵ These configurations, like the sequence of bases in a DNA molecule, may be represented by written verbal or numerical symbols. They are not *themselves* verbal or numerical symbols, however. They are simply particular arrangements of physical or electromagnetic media.

Not surprisingly, then, the defendants in several software copyright infringement suits have advanced arguments similar to those now advanced against copyright for rDNA. In *Apple Computer, Inc. v. Franklin Computer Corp.*,¹⁶⁶ the defendant claimed that the computer operating systems in question were unprotected by copyright because the programs were not in written form, but embedded in the silicon configuration of ROM chips. The defendants in *Tandy Corp. v. Personal Micro Computers, Inc.* and in *Williams Electronics v. Artic International, Inc.* made similar claims, all arguing that the Congressional mandate to protect computer software under copyright law did not extend past representation as verbal or numerical symbols.¹⁶⁷ Courts have categorically rejected this line of reasoning, holding rather that even in their machine-readable form, the programs were protected as literary works.¹⁶⁸

Thus, this limited reading of the Copyright Act, embraced by those arguing against rDNA copyright, conflicts with present interpretations of the Act evolving out of computer software protection. Several other arguments that have been raised against protection of rDNA under copyright also fail to take into account judicial doctrines evolving out of questions of software protection; these arguments are discussed in detail below. For the present it is enough to note that the language defining literary works appears adequate to encompass both sequences of nucleotide bases and their written representation.

c. Fixation

Works to be protected under copyright law must be fixed for more than momentary duration in a tangible medium of expression.¹⁶⁹ The medium may be one known at the time of the copyright statute's enactment, or one developed at a later date; in either case it must be perceivable either directly or by use of some device.¹⁷⁰ Proponents of rDNA copyright argue that rDNA meets these

¹⁶⁴See Karjala, *supra* note 13, at 37.

¹⁶⁵See Dukarich, *Patentability of Dedicated Information Processors and Infringement Protection of Inventions That Use Them*, 29 JURIMETRICS J. 135, 195 n.225, 201 n.258 (1989).

¹⁶⁶714 F.2d 1240 (3d Cir. 1983), *cert. dismissed* 464 U.S. 1033 (1984).

¹⁶⁷*Tandy*, 524 F. Supp. 171 (N.D. Cal. 1982); *Artic*, 685 F.2d 870 (3d Cir. 1982).

¹⁶⁸524 F. Supp. at 175; 685 F.2d at 877; 714 F.2d at 1249.

¹⁶⁹17 U.S.C. § 102(a) (1985).

¹⁷⁰*Id.*

requirements.¹⁷¹ Nucleic acids are tangible and unusually stable molecules. As noted previously, their sequences may be perceived by nucleotide sequencing or similar laboratory techniques.¹⁷² Although nucleic acids may not have been contemplated as a medium of expression in drafting the Copyright Act, the language of section 102 demonstrates that they need not have been. According to the legislative history, it “makes no difference what the form, manner, or medium of fixation may be . . . whether embodied in written, printed, photographic sculptural, punched, magnetic, or any other stable form.”¹⁷³

The argument favoring rDNA copyright relies on the fact that this language displays clear legislative intent to include works embodied in new media beyond the traditional or even foreseeable subjects of copyright.¹⁷⁴ Indeed, Congress intended this language to allow “sufficient flexibility to free the courts from rigid or outmoded concepts of the scope of particular categories.”¹⁷⁵ Arguably, therefore, the Copyright Act contemplates protection of new media such as rDNA that lie beyond the traditional concept of what copyright might embrace.

d. Originality in copyright

To qualify for copyright, a work must also be “original.”¹⁷⁶ We have already seen that molecular biologists assemble existing bits of genetic matter, rather than creating them *de novo*. Some question may therefore arise as to whether recombinant nucleotide sequences are “original” within the meaning of the statute. Some courts have indicated that some minimal level of creativity is necessary for copyright protection; although this standard is far less than the patent requirement of “novelty,” short phrases or expressions dictated by functional considerations have sometimes been found uncopyrightable on these grounds.¹⁷⁷ Under this sort of standard, it might be argued that rDNA creations are uncopyrightable for lack of originality.

This approach to originality in copyright is, however, atypical and possibly misguided. Originality under the copyright statute does not require any particular modicum of “novelty, ingenuity, or esthetic merit.”¹⁷⁸ Rather, the work must simply originate with the author; it cannot have been copied from other works.¹⁷⁹ Much like the organism at issue in the *Chakrabarty* patent case, recombinant DNA molecules do not exist in nature, they must be assembled by an author, an originator. Thus, to the extent that an rDNA work originates with its author, it is copyrightable.

¹⁷¹Kayton, *supra* note 9, at 202.

¹⁷²See *supra* note 63 and accompanying text.

¹⁷³H.R. REPORT, *supra* note 136, at 53.

¹⁷⁴Kayton, *supra* note 9, at 200.

¹⁷⁵H.R. REPORT, *supra* note 136, at 53.

¹⁷⁶17 U.S.C. § 102(a) (1985).

¹⁷⁷See *e.g.*, *Alberto-Culver Co. v. Andrea Dumaon, Inc.*, 466 F.2d 705, 711 (7th Cir. 1972) (simple advertisement phrase not entitled to copyright).

¹⁷⁸H.R. REPORT, *supra* note 136, at 51.

¹⁷⁹See *Alfred Bell*, 191 F.2d at 102.

e. Compilations

In considering originality under the Copyright Act, though, it would seem that if molecular biologists assemble or modify existing nucleotide sequences, those sequences cannot have originated with them. If an rDNA sequence, composed of sequences that did not originate with the author, qualifies for copyright only to the extent that it is original, then to what extent *can* the work be original? This question is not unique to the copyrightability of rDNA sequences. The copyright statute permits copyrighting of maps, directories, and similar collections of facts as a particular type of literary work called a compilation.¹⁸⁰ In such compilations, the facts themselves may not be copyrightable, but their collection, selection, and arrangement is.¹⁸¹ Consequently, those favoring rDNA copyright have suggested that rDNA sequences should be copyrightable as compilations; when a molecular biologist selects and arranges existing sequences into an rDNA plasmid, the original selection and arrangement are the protected features of the work.¹⁸²

This type of protection is, of course, extremely narrow, extending only to the selection and arrangement of material in the compilation and not to the material itself. Courts have held that where the order and arrangement of materials is dictated by external considerations, the organization is not original and is not protected.¹⁸³ In DNA, for example, the placement of promoter control elements, designating the beginning of gene transcription, is largely predetermined, and so would be uncopyrightable. For the placement of sequences whose positions are not predetermined, protection probably would not extend beyond very small variations on the particular arrangement. Those objecting to rDNA copyright argue that this narrow measure of protection would make rDNA copyright, even if granted, worthless.¹⁸⁴ The worth of a particular measure of protection is a broader policy consideration examined further in Part IV. For the present, it is enough that protection under this analysis seems plausible, however broad or narrow the protection's scope may be.

Indeed, a rather broad scope of protection could result for rDNA sequences if their proper scope of protection were determined under a different line of compilation cases. These decisions, dealing primarily with directories and catalogs, have relied on the labor involved in collecting and arranging material as the protectable element of a compilation.¹⁸⁵ Under this approach, use of

¹⁸⁰ 17 U.S.C. § 101 (1985) (compilation defined).

¹⁸¹ *Id.*

¹⁸² Kayton, *supra* note 9, at 202.

¹⁸³ See e.g., *Plains Cotton Cooperative Association v. Goodpasture Computer Service*, 807 F.2d 1256 (5th Cir. 1981) (software organization not protectible because predetermined by market); *Whelan Associates, Inc. v. Jaslow Dental Laboratory, Inc.*, 797 F.2d 1222 (3rd Cir. 1986) (software organization protectible if structure not predetermined).

¹⁸⁴ I. COOPER, *supra* note 11, at 11-25.

¹⁸⁵ See, e.g., *Schroeder v. William Morrow & Co.*, 566 F.2d 3 (7th Cir. 1977); *National Business Lists v. Dun & Bradstreet, Inc.*, 552 F. Supp. 89 (N.D. Ill. 1982). But see *Financial Information v. Moody's Investors Service*, 231 U.S.P.Q. 803 (S.D.N.Y. 1986) (abandoning "sweat of the brow" criteria).

the material collected, even in an entirely revised arrangement aimed at a different market, is considered an infringement.¹⁸⁶ The person producing a new compilation is thus obliged to repeat the work of the previous compiler. This economic approach to the scope of protection for this category seems at odds with the wording of the copyright statute, leading at least one court to suggest that the directory cases are a unique law unto themselves.¹⁸⁷

In the case of rDNA, this type of protection would prevent unauthorized use of even the unoriginal, "public domain" sequences arranged within a compilation such as a plasmid. Those who wished to use even an unoriginal sequence would be obliged to re-isolate the sequence independently or to negotiate some agreement with the prior investigator. Interestingly, neither of these options appears to be at odds with the scientific norms discussed above. One court has suggested that the "sweat of the brow" cases support the proposition that considerations of policy take precedence even over the wording of a statute when the scope of protection is at issue.¹⁸⁸ Thus, these cases simply lay bare the fact that courts decide as a matter of policy how far the scope of copyright protection should extend.¹⁸⁹ The factors that might influence such a determination for rDNA are discussed in greater detail in Part IV below.

f. Derivative works

Nucleotide sequences periodically recombine without the assistance of human intervention; such changes, or *mutations*, are fairly common if the sequences are within a living cell. One commentator on rDNA copyright has asked who would hold the copyright to mutations arising spontaneously out of rDNA works, particularly if the new work proved to be valuable.¹⁹⁰ The new work would be "based upon one or more preexisting works," thus fitting the Copyright Act's definition of a derivative work.¹⁹¹ The owner of a work on which a derivative work is based holds the rights to the derivative work to the extent it embodies original protected elements from his work.¹⁹² The author of the derivative work holds the rights to any original protectable additions.

¹⁸⁶See *Leon v. Pacific Telephone and Telegraph Co.*, 91 F.2d 484 (9th Cir. 1937).

¹⁸⁷*Miller v. Universal Studios*, 650 F.2d 1365, 1369-70 (5th Cir. 1981).

¹⁸⁸*Merritt Forbes & Co., Inc. v. Newman Investment Securities, Inc.*, 604 F. Supp. 943, 950-51 (S.D.N.Y. 1985).

¹⁸⁹A similar policy problem has presented itself in regard to the proposed human genome mapping project. One entrepreneur has proposed compiling a database of the human genome sequences, and some have expressed fear that this would allow a monopoly on this information. See Roberts, *Who Owns the Human Genome?*, 237 Sci. 358 (1987). Databases are protected as compilations under copyright law. The human genome sequences would not originate with the author, and even the arrangement, selection and ordering would be largely dictated by what exists in nature. Thus, such a data base would receive little protection under this theory, and might not be produced because the investment would not be worthwhile. If, however, such a compilation would benefit society, it might be necessary to adopt the "sweat of the brow" theory, providing an adequate incentive for production of the database.

¹⁹⁰See Davidson, *supra* note 9.

¹⁹¹17 U.S.C. § 101 (1985).

¹⁹²*Id.* at § 103.

Thus, the author of an rDNA work would continue to hold the copyright in the selection and arrangement of DNA sequences in the derivative work, to the extent that that selection and arrangement was derived from her original work. A spontaneously arising mutation, however, would originate with no one—thus, that feature of the derivative rDNA work would lie in the public domain. This would be true even under the “sweat of the brow” approach; no one invested labor in a spontaneously appearing recombination. By way of illustration, a similar situation would arise if an author compiled a collection of Elizabethan poetry, the pages of which were then rearranged by an errant wind. The poems lie in the public domain. The author’s selection and arrangement of them, however, is original and protected. The wind’s rearrangement originates with no one, and so the new features of the naturally produced derivative work would lie in the public domain.

As a practical matter, however, the compiler of the original plasmid would probably retain control of the valuable mutant derivative work. Someone attempting to discover the mutated sequence, which would lie in the public domain, would doubtless have to reproduce portions of the protected original arrangement. This would infringe the copyright in the original compilation. This situation would not arise with the poetry collection, which need not be reproduced to be examined. The situation might arise in the case of computer programs, which has engendered discussion of whether limited reproduction of computer programs should be permitted for the purpose of examining their code. As a policy matter, it is equally important to ask whether such “reverse engineering” of copyrighted rDNA sequences might similarly be allowed. This policy determination will rest largely on whether such practices legitimately contribute to advances in this field, a subject taken up again in Part IV below.

g. Merger

Closely related to matters regarding originality and the scope of protection in compilations are arguments surrounding the copyright doctrine of merger. Copyright protection extends only to the expression of a work, and not to the idea expressed.¹⁹³ Courts have held that where the number of ways an idea may be expressed is highly constrained, idea and expression merge.¹⁹⁴ Copyright has been denied in such situations, not for lack of creativity, but because “a party or parties, by copyrighting a mere handful of forms, could exhaust all possibilities of future use of the substance.”¹⁹⁵

Consequently, to the extent that expression in rDNA is limited to only a few possibilities, that expression may be uncopyrightable. This, however, does not bar nucleotide sequences from protection; this constraint affects any

---

¹⁹³The seminal case is *Baker v. Selden*, 101 U.S. 99 (1879).

¹⁹⁴See *Herbert Rosenthal Jewelry Corp. v. Kalpakian*, 446 F.2d 738 (9th Cir. 1971); *Morrissey v. Procter & Gamble Company*, 379 F.2d 675 (1st Cir. 1967).

¹⁹⁵*Morrissey*, 379 F.2d at 678.

work of authorship, and can be decided only on specific facts. For example, although redundancy in the genetic code allows some amino acids to be signified in more than one way, the number of ways is still highly constrained. Thus, the nucleotide sequence for a particular amino acid should be uncopyrightable. With regard to the arrangement of larger sequences, the placement of a promoter sequence in an rDNA creation is highly constrained, and so perhaps uncopyrightable. On the other hand, the placement of an enhancer control sequence is not constrained in this fashion. In the case of enhancers, the same function may be achieved through many arrangements, and thus a particular arrangement may be copyrightable.¹⁹⁶

h. Pictorial, graphic, or sculptural works

In asserting that nucleotide sequences may not be protected under any of the seven categories listed in section 102, one commentator compares rDNA to a work of sculpture.¹⁹⁷ This analogy appears to have been raised primarily for the purpose of knocking it down; the constraints placed upon copyright in the appropriate category are bound to exclude rDNA. The scope of copyright over physical form has been carefully limited with the intent of excluding the shape of purely functional objects from the protection of copyright law.¹⁹⁸ Nonetheless, this analogy raises several important issues and serves as a useful vehicle for discussing the utilitarian nature of rDNA.

The Copyright Act specifically provides for the inclusion of pictorial, graphic, and sculptural works (PGS works). This category includes applied art and utilitarian articles such as maps, globes, and models.¹⁹⁹ The latter are protected only as to their form, but not as to their mechanical or utilitarian aspects.²⁰⁰ Furthermore, the statute states that the design of a useful article, as

¹⁹⁶See B. LEWIN, *supra* note 14 at 201-2; see also Comment, *supra* note 12, at 456 (doctrine of merger may hamper application of copyright to rDNA). A closer question may be presented where elements are not absolutely constrained by functional considerations, but simply arranged for the sake of efficiency. If only one or a few arrangements are most efficient, merger may again prevent their copyrightability. Naturally, these would be the arrangements innovators would most want to protect.

¹⁹⁷I. COOPER, *supra* note 11, at 11-26.

¹⁹⁸Successful introduction of rDNA into this category would in any event lead to some strange results. It seems absurd, for example to obtain the 17 U.S.C. § 106 (5) right of public display for a molecule. In a similar vein, it should be noted that Ohno and Ohno have observed that the base sequences of DNA can be assigned to a musical scale. Ohno & Ohno, *The All Pervasive Principle of Repetitious Recurrence Governs Not Only Coding Sequence Construction But Also Human Endeavor in Musical Composition*, 24 IMMUNOGENETICS 71 (1986). The DNA sequences of certain mouse genes, when so transposed to musical notation and played, bear an uncanny resemblance to compositions by Chopin. *Id.* at 76-7. This analogy has also arisen in recent commentary regarding rDNA copyright. See Comment, *supra* note 12 at 453, n.90. Presumably, one could in this manner copyright DNA sequences as musical compositions, but it is unclear what use, for example, the right to publicly perform an rDNA sequence would be in protecting its commercial value. See 17 U.S.C. § 106 (4). This measure of protection is obviously not well suited to rDNA; as indicated by the discussion in Part IV below, these are not the types of protection one would presumably want for biotechnology innovations.

¹⁹⁹17 U.S.C. § 101 (1985).

²⁰⁰*Id.*

defined in section 101, is considered copyrightable work only with regard to its independently existing features that can be separately identified from the article's utilitarian aspects.²⁰¹

As noted in the discussion of basic molecular biology above, rDNA has a particular three-dimensional structure that is perhaps analogous to a sculpture or model.²⁰² However, an rDNA sequence clearly entails at least some utilitarian features. The statutory prohibitions against protecting the utilitarian aspects of this category would seem to severely restrict the scope of protection for rDNA molecules under this section, if not eliminate the possibility of protection altogether. This seems particularly true if such molecules are viewed as useful articles.

The definition of "useful articles" in section 101 is somewhat problematic when applied to nucleotide sequences. The definition encompasses articles "having an intrinsic utilitarian function that is not merely to portray the appearance of the article or to convey information."²⁰³ This exception to the useful article definition might be applied to information-bearing DNA molecules. However, the exception might also be dismissed by arguing that such molecules do not "merely" convey information.²⁰⁴ The exception should perhaps not be dismissed so lightly. First, one might question whether the construction of the statutory language indicates that the adverb "merely" is intended to modify only the verb "to portray," or also the verb "to convey," which is stated in the disjunctive.²⁰⁵ Even if it is granted that "merely" modifies everything that follows it, the question becomes one of determining what it means to "merely convey information." The DNA molecule has no purpose besides conveying information; the molecule's physical shape interacts with its surroundings to convey information on how a particular gene product is constructed. It might be argued that the molecule does not convey information to a *human being*.²⁰⁶ In the category of literary works, this has been held not to bar copyrightability, but this question as such has never been posed in the realm of PGS works.²⁰⁷

Classification of rDNA molecules as useful articles could raise certain interesting and unforeseen difficulties. For example, a map of the molecule's

---

²⁰¹ *Id.*

²⁰² I. COOPER, *supra* note 11, at 11-27.

²⁰³ 17 U.S.C. § 102 (b) (1985).

²⁰⁴ I. COOPER, *supra* note 11, at 11-28.

²⁰⁵ The author is grateful to Professor Rebecca White Berch of Arizona State University for helpful discussion on this point of grammar and construction.

²⁰⁶ The question of communication to a human audience is taken up again below. See *infra* notes 252-58 and accompanying text.

²⁰⁷ See *supra* note 198. Whether posed under the category of literary works, under the category of pictorial, graphic or sculptural works, or under some entirely new category, the question is largely the same: what as a matter of policy should society choose to protect? The policy choices that have been made under this category seem clearly intended to limit the scope of copyright where the dividing line between a work and the physical shape of embodiment is indistinct. See H.R. REPORT, *supra* note 136, at 54-55. The appropriateness of this or another measure of protection for rDNA is discussed in Part IV below.

structure would then become classified as "a work that portrays a useful article," much like an architectural diagram.²⁰⁸ Under section 113(b) of the Copyright Act, such works are accorded the same modicum of protection given to them by state and federal law prior to December 31, 1978.²⁰⁹ The cases delineating the bounds of such protection are less than clear. With regard to architectural plans, some courts prior to the determinative date enjoined construction of the building depicted by the plans, particularly if construction appeared to constitute unearned profit from another's labor.²¹⁰ Other courts held that copyright in the plans conferred no right to enjoin construction.²¹¹ The former line of cases might support an argument preventing assembly of rDNA molecules depicted by genetic maps, but the cases are mixed.

Section 113(b) is also unclear as to when pre-1979 state law applies to works depicting useful articles, and when pre-1979 federal law applies. Nimmer suggests that this choice of state or federal law should be made as though the present copyright laws had never been enacted.²¹² The rights flowing from architectural diagrams before the enactment of the present copyright laws turned in large part upon "common law" copyright, which was lost upon general publication. Construction of a building depicted in architectural plans was sometimes held to constitute general publication, often depending on the number of people who viewed it.²¹³ If this standard were applied to rDNA molecules depicted by gene maps, protection might hinge on preserving common law copyright by avoiding "general publication;" that is, allowing as few people as possible access to the diagram or to the molecule itself. This would raise con-

²⁰⁸ 17 U.S.C. § 113(b) (1985).

²⁰⁹ *Id.*

²¹⁰ In these cases, the language regarding reaping the benefit of another's labor is strongly reminiscent of that in the "sweat of the brow" compilation cases. *See, e.g.,* Nucor Corp. v. Tennessee Forging Steel Service, Inc., 476 F.2d 386 (8th Cir. 1973); Herman Frankel Organization v. Wolfe, 184 U.S.P.Q. (BNA) 819 (E.D. Mich. 1974).

²¹¹ *See* Imperial Homes Corp. v. LaMont, 485 F.2d 895 (5th Cir. 1972). *See also* Combustion Engineering, Inc. v. Murray Tube Works, 222 U.S.P.Q. 239 (E.D. Tenn. 1984) (producing parts from copyrighted technical drawings held not to infringe); Russell v. Trimfit, Inc., 568 F. Supp. 91 (E.D. Pa. 1977), *aff'd* 568 F.2d 770 (3d Cir. 1978) (registered drawing of socks gave no right over manufacture of article depicted); Jack Adelman, Inc. v. Sonners & Gordon, Inc., 112 F. Supp. 187 (S.D.N.Y. 1934) (copyright in a drawing of a dress gives no monopoly over dress itself). *But see also*, Jones Brothers Co. v. Underkoffler, 16 F. Supp. 729 (M.D. Pa. 1936) (drawing of cemetery monument infringed by construction of monument itself); King Features Syndicate v. Fleischer, 299 F. 533 (2d Cir. 1924) (unauthorized manufacture of three-dimensional figures depicting two-dimensional cartoon characters held to infringe). Note, however, that cemetery monuments and cartoon figurines appear to fit the exception to the useful article definition, the former conveying only information and the latter depicting only themselves.

²¹² M. NIMMER & D. NIMMER, NIMMER ON COPYRIGHT § 2.08[d] (1988). For most works under the present system, federal copyright subsists upon fixation, and the question of common law copyright is done away with. *See* Schuchart & Associates v. Solo Serve, 220 U.S.P.Q. 170 (W.D. Tex. 1983) (examining question of general publication of architectural plans in terms of 1976 Copyright Act).

²¹³ *See* Edgar H. Wood Associates v. Skene, 347 Mass. 351, 197 N.E.2d 886 (1976) (filing plans with building officials held not to constitute general publication); Shanahan v. Macco Construction Co., 224 Cal. App. 2d 327, 36 Cal. Rptr. 584 (1964) (number of people permitted to view building determined publication of plans).

flicts with the norms of science similar to those discussed for protection through trade secret.

Returning to the question of copyrighting rDNA molecules themselves, however, the end result under the category of PGS works will be much the same whether or not rDNA falls under the definition of a useful article. Assume that the three dimensional form of a nucleotide sequence may be copyrighted as a pictorial, graphic, or sculptural work except as to its utilitarian aspects. Even if the restrictions on useful articles are set aside, rDNA will be excluded from copyright as a PGS work. PGS works that do not qualify as useful articles are still uncopyrightable as to their utilitarian features. The DNA molecule *has* no physical structure that is not dictated by function: like a cog in a machine, the form of rDNA exists only to interact with cellular proteins. The exclusion of rDNA from this category raises a question as to how copyright law's antipathy to the utilitarian features of any work affects the copyrightability of features of rDNA other than its physical form.

i. Utilitarian works

Even outside the category of pictorial, graphic, or sculptural works, the prohibition against copyrighting utilitarian items, as embodied in section 102 and the doctrine of *Baker v. Selden*, is considered nearly axiomatic.²¹⁴ Section 102(b) of the Copyright Act states clearly that "[i]n no case does copyright protection for an original work of authorship extend to any idea, procedure, process, system, method of operation, concept, principle, or discovery. . . ."²¹⁵ Those who argue against rDNA copyright rely heavily on this language, observing that the discovery of a nucleotide sequence's operation is uncopyrightable, the process by which a gene expresses itself is uncopyrightable, and sequences themselves, as sets of instructions, are uncopyrightable.²¹⁶

Although much of this criticism as to the aspects of rDNA that are not copyrightable is quite valid, it underestimates the strength of the copyrightability argument by ignoring those aspects of rDNA that *are* copyrightable. This reading of the Copyright Act's language fails altogether to take into account recent judicial interpretations of section 102, especially those interpretations arising from cases involving computer software. The losing parties in several copyright infringement suits have, as mentioned above, suggested that computer operating systems fall outside the scope of copyright, particularly if the programs are embodied in semiconductor chips.²¹⁷ These arguments, which failed to persuade the courts, were based in part upon the contention that ROM chips are utilitarian objects; that operating system programs are processes, systems, or methods of operation; and that the programs themselves are purely utilitarian objects.²¹⁸

²¹⁴See 101 U.S. 99.

²¹⁵17 U.S.C. § 102 (b) (1982).

²¹⁶I. COOPER, *supra* note 11, at 11.02[3]–11.02[4].

²¹⁷See *supra* notes 166–69 and accompanying text.

²¹⁸See *Franklin*, 714 F.2d at 1250; *Tandy*, 524 F. Supp. at 175; *Artic*, 685 F.2d at 874–76.

The courts found that these arguments mischaracterized the issue. In *Williams v. Artic*, the court corrected the defendant by pointing out that the ROM chips themselves were not the subject of copyright; rather, the program embodied in them was.²¹⁹ According to the *Artic* court, the semiconductor chips may indeed have been utilitarian objects, and so not appropriable to any owner by means of copyright.²²⁰ Nonetheless, a program expressed in the medium of a chip was copyrightable.²²¹ The court in *Apple v. Franklin* found through similar reasoning that instructions to a computer, written as an operating program, were the proper subject of copyright protection, and quite distinct from the uncopyrightable method of instruction.²²² Finally, with regard to the utilitarian nature of operating systems, the *Franklin* court held that a utilitarian use to which a copyrightable work may be put is not itself a bar to copyright protection.²²³

These holdings seem to answer many of the concerns regarding utility that might surround copyrightability of rDNA. No one can lay claim to the medium of DNA through copyright, nor to the methods of translation or transcription by which the cell carries out the instructions embodied in a nucleotide sequence.²²⁴ These are not the proper subject of copyright, but this does not preclude the expression fixed in rDNA from being so protected. The DNA molecule, as a useful object, is not copyrightable, just as the physical form of a book or ROM chip is not. Nonetheless, the work embodied in any of these physical forms may be. The proponents of rDNA copyright may well have a tenable argument that the rDNA molecule embodies original selection and arrangement of sequences that may be protectable to the extent that it is not dictated by function or barred by merger. Finally, employment of an rDNA work for utilitarian purposes has of itself no effect on the protectability of the underlying expression.

B. Arguments of Legislative Purpose

Thus far, the arguments examined regarding copyrightability of rDNA have centered upon the actual language of the Copyright Act. From the statutory language and its judicial interpretation, some indication may be gained of whether the scope of copyright protection may properly include nucleotide sequences. These indicators draw upon information explicit in the statute. However, some insight into copyrightability may also be gained by information *implicit* in the statute. We might, for example, ask whether rDNA is the *type* of

²¹⁹685 F.2d at 874-76. *But see* Data Cash Systems, Inc. v. JS & A Group, Inc., 480 F. Supp. 1063 (N.D. Ill. 1979), *aff'd on other grounds*, 628 F.2d 1083 (7th Cir. 1980) (holding that ROM chips are utilitarian and so uncopyrightable).

²²⁰685 F.2d at 874-75.

²²¹*Id.*

²²²714 F.2d at 1251.

²²³*Id.*

²²⁴I. COOPER, *supra* note 11, at 11-20.2; 11-24.

subject matter that fits the overall statutory scheme. The proponents of rDNA copyright have in fact done this, by invoking an analogy to computer software.

1. *The Software Analogy*

In discussing the scope of the Copyright Act's language, judicial decisions regarding protection for computer software have clarified matters relating to copyright protection for rDNA in several areas.²²⁵ This type of precedent has not gone unnoticed by proponents of rDNA copyright. They have drawn heavily on analogies between computer software and nucleotide sequences to argue that the latter may be copyrightable.²²⁶ Even those who are not in favor of rDNA copyright admit that certain similarities do exist, but argue that the similarities are insubstantial.²²⁷ In order to discuss these similarities, it will be necessary to briefly outline the workings of computer software.

a. Electronic data processing

Computers are universal machines; they are designed to perform a variety of tasks based on their instructions.²²⁸ Computer programs, or software, comprise the instructions that direct these machines to perform specific tasks.²²⁹ Different types of programs are designed to meet different data processing needs. Application programs interact to some degree with the computer user; these programs perform real-world tasks, such as word processing, that require human direction.²³⁰ Operating systems relieve the user of tedious tasks regarding computer function; these programs automatically control the internal functions of the machine.²³¹ Microcode performs functions very far removed from the computer user's input; it directs the configuration of electronic pathways within a silicon chip.²³² Each type of program fulfills functions that could be accomplished by permanent wiring.²³³ However, a machine so wired would no longer be universal; it could no longer perform a variety of tasks without being rewired each time.

Computer programs of each type may exist in a variety of forms. They may, as noted above, be embedded in the circuits of a semiconductor chip.²³⁴ They may also exist as magnetic flux on a tape or disk.²³⁵ They may be represented on paper as abstract symbols of a high level programming language.²³⁶ These abstract symbols are used by human programmers for ease in manipulat-

²²⁵See *supra* notes 166-69, 216-20 and accompanying text.

²²⁶Kayton, *supra* note 9, at 199; Comment, *supra* note 9, at 1104-8.

²²⁷I. COOPER, *supra* note 11, at 11-19.

²²⁸Myrick & Sprowl, *Patent Law for Programmed Computers and Programmed Life Forms*, 68 ABA J. 920 (1982).

²²⁹See Karjala, *supra* note 13, at 37.

²³⁰See Menell, *supra* note 13, at 1334.

²³¹See Karjala, *supra* note 13, at 37; Menell, *supra* note 13, at 1334.

²³²See *NEC v. Intel*, No. C-84-20799-WPG slip op. at 3 (N.D. Cal. 1989).

²³³See Myrick & Sprowl, *supra* note 228.

²³⁴See *supra* notes 166, 217, and accompanying text.

²³⁵See sources cited *supra* note 165.

²³⁶See Karjala, *supra* note 13, at 37.

ing complex computer instructions; the symbols are in fact a kind of notation for binary digit code.²³⁷ Consequently, the program may also be expressed in binary code as a string of ones and zeros.²³⁸ These ones and zeros themselves represent a series of temporary physical configurations within the machine; it is in this machine-readable form that the program actually functions.²³⁹

b. The rDNA parallel

When the operation of computer software is compared to that of nucleotide sequences, several gross similarities at once stand out. In general, nucleotide sequences seem to be sets of instructions to a biological machine, much as computer programs are sets of instructions to an electronic machine. With the advent of gene splicing techniques, the cell has become more and more a universal machine, capable of being programmed for a variety of tasks.²⁴⁰

Software and rDNA also appear to share the concept of hierarchy in the flow of information. The information encoded in the DNA sequence, much like that in a computer program, must pass through multiple levels of translation before it is expressed: from DNA to RNA to protein.²⁴¹ Also like a computer program, a nucleotide sequence may exist in a variety of forms: as an abstract, high level genetic map, as a string of written base symbols, as an actual DNA chain, or as an actual RNA chain. Admittedly, computer programmers appear to write code freely, whereas the molecular biologists are constrained by the sequences they can find in nature. This constraint on molecular biology, however, appears simply to be an instance of the hardware constraints under which all programmers operate. A universal machine can only be instructed to execute the functions for which it was designed; programming creativity subsists in the ordering and arrangement of these basic steps to achieve a desired result. Consequently, at some level of consideration, the operation of nucleotide sequences may be said to resemble the operation of computer programs.

It is well to bear in mind, though, that all analogies break down at some point. For example, one commentator has suggested that genetic information embodied as messenger RNA resembles the operating system of an electronic computer.²⁴² It may be equally appropriate, however, to compare the control elements within a nucleotide sequence to an operating system; both serve the function of managing the respective machine's internal functions. In addition, it is not immediately obvious what parallel the concepts of programming or machine languages have in the context of the cell; molecular biologists cannot simply type high level code into their universal machines and have the

---

²³⁷*Id.*

²³⁸*Id.*

²³⁹*Id.*

²⁴⁰See Myrick & Sprowl, *supra* note 228.

²⁴¹See *supra* notes 30-7 and accompanying text.

²⁴²See Comment, *supra* note 9, at 1105.

instructions executed.²⁴³ The additional steps molecular biologists go through to instruct cellular machinery suggest that, at least for the present, they do not "program" cells in the same sense that computer scientists program computers.²⁴⁴

Thus, even at this most superficial level of comparison, the operations of a computer cannot be mapped perfectly onto a biological cell.²⁴⁵ Increasingly sophisticated scrutiny of this analogy between the two systems may reveal other, more serious differences. Because several commentators have suggested that an inappropriate analogy between computer programs and works of literature led to protection of software under copyright law,²⁴⁶ this more sophisticated type of scrutiny seems appropriate before endorsing similar protection for biotechnology.

c. The communication criterion

Opponents of rDNA copyright have attempted a more sophisticated scrutiny, arguing that the superficial analogy between nucleotide sequences and computer software is insufficient to support a claim upon copyright protection.²⁴⁷ Iver Cooper agrees that at some level of abstraction, a DNA sequence, like a computer program, may be considered a set of instructions for a machine.²⁴⁸ However, when he attempts to examine this analogy at a more detailed level, he suggests that the analogy quickly becomes inappropriate:

---

²⁴³The fact that molecular biologists must find and assemble the physical material embodying their coded instructions suggests that their endeavor is in some ways closer to "hardwiring" a computer to perform a task than it is to programming through software. Although hardwiring of computers has traditionally been the province of patent protection, it has become increasingly apparent that unless copyright protects the sequence of functions performed by a computer program, that program could be duplicated by hardwiring. See Siegel, *A First Look at Copyright Protection of Computer Hardware*, Computer Lawyer, Dec. 1987 at 1, 6-7. The first step toward recognizing such a copyright was taken by the *Franklin* court in recognizing copyright protection of programs unalterably embedded in ROM chips. See 714 F.2d at 1250. This almost inescapable line of reasoning has led several commentators to criticize Congress' choice of copyright as a vehicle for software protection. See sources cited *supra* at note 13.

²⁴⁴This point is stressed by Cooper as an important difference between the creation of software and rDNA, and is for the present a point to consider. Note, however, that protein engineering might well lead to *de novo* protein design, vastly expanding the freedom of molecular biologists to "write code" for cellular execution. It may well be possible for biotechnologists of the future to design recombinant nucleotide sequences by specifying in some high level notation the cellular functions they desire to have executed and have these parameters translated into DNA code. Thus, in analyzing the needs of a particular endeavor, society should be wary of relying upon short-sighted distinctions drawn from the characteristics of a technology still in its infancy.

²⁴⁵For an insightful and entertaining discussion of the dangers inherent in attempting to isomorph one information system onto another, see D. HOFSTADTER, GÖDEL, ESCHER, BACH, AN ETERNAL GOLDEN BRAID 376-88 (1978).

²⁴⁶See Karjala, *supra* note 13, at 38; Samuelson, *supra* note 13, at 727.

²⁴⁷I. COOPER, *supra* note 11, at 11-20, 11-24.

²⁴⁸*Id.* at 11-19. The importance of this observation lies in the fact that, at some level of abstraction, almost any human artifact may be considered a set of instructions for a machine. Nonetheless, we do not choose to protect them all under copyright. Such protection must, then, be based on policy rather than on analogy.

DNA molecules are not analogous to computer programs because they do not express ideas by means of words or numbers, however symbolized or indicated, as do computer programs (and other literary works.)²⁴⁹

Cooper then dismisses the question, discussed above, of embodiment in silicon chips, concluding:

There is no doubt that a DNA molecule could be used as a medium of expressing a sequence of words or numbers, provided there was some accepted convention for deciphering the DNA sequence in that manner. But what would be protected would be the message thus perceived, not the DNA sequence itself.²⁵⁰

This conclusion again fails to take into account the language of judicial opinions considering computer software copyright. Although such criticism succeeds in moving the discussion to a more sophisticated level of analysis, the result makes little sense in terms of copyright law. In a literary work such as a book, the actual sequence of words and sentences is protected by copyright, whereas the "message thus perceived" may not be. Similarly, in terms of the software analogy, these arguments are tantamount to asserting that in a computer program the message "conveyed" by the code is protected, while the literal code is not. The scope of protection for computer programs is the subject of considerable debate, but if anything at all in this area is clear it is that literal copying of protected code constitutes infringement.²⁵¹

The problem here lies in the underlying assumption that, in order to qualify for copyright, a work must communicate a message to a *human* audience. This was also the contention of the losing party in *Apple Computer v. Formula International Inc.*²⁵² The defendant in that case asserted that computer operating systems were ineligible for copyright because they do not communicate with human beings.²⁵³ This assertion is, of course, true to a greater or lesser extent of all computer software. Even in application programs, the "user interface" features that interact with the human operator comprise only a small portion of the program; the majority of a program's code is never perceived by the user.²⁵⁴ Computer operating systems, which manage the machine's internal functions, generally do not communicate to the user.²⁵⁵

This aspect of computer software makes its protection through copyright, admittedly, something of an anomaly. Commissioner John Hersey noted in the

---

²⁴⁹*Id.* at 11-20.

²⁵⁰*Id.* at 11-20.2.

²⁵¹See ARIZONA STATE UNIVERSITY CENTER FOR THE STUDY OF LAW, SCIENCE AND TECHNOLOGY, CONFERENCE REPORT: COMPUTER SOFTWARE AND COPYRIGHT PROTECTION 3 (1989) (forthcoming in 30 JURIMETRICS J. No. 1 (1989)) (consensus statement of intellectual property scholars that literal copying of code is prohibited); see also *Whelan*, 793 F.2d 1222; *Franklin Mint Corp. v. National Wildlife Art Exchange*, 575 F.2d 62 (3rd Cir. 1978).

²⁵²725 F.2d 525 (9th Cir. 1984) (affirming the district court's grant of a preliminary injunction).

²⁵³*Id.* at 524.

²⁵⁴See Menell, *supra* note 13, at 1334.

²⁵⁵*Id.*

report to Congress by the National Commission on New Technological Uses of Copyrighted Works (CONTU), "[A]dmitting these [computer software] devices [to copyright protection] would mark the first time copyright had ever covered a means of communication, not with the mind and senses, but with machines."²⁵⁶ Given, however, that Congress *has* protected software under copyright, the defendants in *Apple v. Formula*, like those opposing rDNA copyright, hoped to show that some measure of interaction with a human user was required for copyright protection.

The court rejected this argument, stated that "never has the Copyright Act required that the expression be communicated to a particular audience."²⁵⁷ Other courts have come to similar conclusions; as noted above, the embodiment of a computer program in a silicon chip, unperceived by human beings as words or numbers, has been found not to preclude its protection under copyright.²⁵⁸

The question of communication to humans is not a new one; it was first considered by the Supreme Court in *White-Smith v. Apollo Publishing Co.*²⁵⁹ This case might in some ways be considered the first computer software case, and the issues it dealt with have resurfaced in cases such as *Apple v. Franklin*. The *White-Smith* court was faced with deciding whether a player piano roll that embodied as punched holes the music to a copyrighted song infringed the copyright. The Court ruled that the piano roll did not infringe because it did not communicate with a human being; even those familiar with piano rolls could not read the hole pattern as music.²⁶⁰ This reasoning seems to rely on a nonsensical distinction—clearly, someone who wished to read music as punched holes could learn how, just as a human can decipher the ones and zeros of binary digit code. This would be inconvenient, but not impossible. The oft-repeated distinction that such messages are composed for machines seems equally unhelpful. A human being reading the piano instructions, whether encoded as punched holes or as musical notation, could depress the keys of the piano in lieu of allowing the machine to do so. A human being could, laboriously following the instructions of a computer program, by hand change the states in a computer to produce the addition and subtraction of data that occurs within the machine.²⁶¹ And, similarly, a human could manually synthesize a protein,

²⁵⁶NATIONAL COMMISSION ON NEW TECHNOLOGICAL USES OF COPYRIGHTED WORKS, FINAL REPORT 27 (1978) [hereinafter FINAL REPORT].

²⁵⁷725 F.2d at 525.

²⁵⁸See *supra* notes 166–68 and accompanying text.

²⁵⁹209 U.S. 1 (1908).

²⁶⁰The Court in fact held that the piano roll was not a "copy" for purposes of the copyright statute because it was not read by humans. Much of the expansive language regarding fixation, quoted above, was intended to end the "artificial and largely unjustifiable distinctions" created by holdings such as *White-Smith*. H.R. REPORT, *supra* note 136, at 53.

²⁶¹As argued by Saltman, *Computer Science and Technology: Copyright in Computer Readable Works: Policy Impacts of Technological Change* (1977) (National Science Foundation study) reprinted in COPYRIGHT, CONGRESS, AND TECHNOLOGY: THE PUBLIC RECORD, VOL. III: THE FUTURE OF COPYRIGHT, 1973–77 365, 415 (H. Nichols ed. 1980).

amino acid by amino acid, rather than taking advantage of natural cellular machinery to do so.

These purported distinctions appear to stem from the difficulty in distinguishing instructions, outputs, and processes. In each of the cases above, the line between copyrightable and uncopyrightable material must be carefully drawn. In these examples, no one would be particularly interested in work in its initial form; the musician doesn't much care to read the song as a piano roll, just as the computer user doesn't much want to play a video game at the level of object code. The works are valued for their eventual output: the musician wants to hear the song, and the computer user wants to see the screen display. By following step by step the instructions encoded in the piano roll, or in binary digit code, a human being could go through a process of producing the desired output. Processes are not protected by copyright; they are subject matter of patent law alone. Instructions for producing the desired output may be copyrightable, and the eventual output may itself be copyrightable, but the intervening process itself is not.

Recombinant DNA works would seem to be problematic in this respect. The molecular biologist may have some intellectual interest in viewing the sequence of an rDNA work, but what he would really like to protect is the product, perhaps a protein, that arises out of that sequence. The rDNA instructions to produce the product may be the subject of copyright, but the process they direct certainly is not. What, though, of the protein produced? The output of a cellular gene, like that of a player piano or computer, is what is valued. The protein may not contain any protectable elements. The sequence of the protein reflects the sequences of only one of the elements selected and arranged in the plasmid. Only if significant, original, non-functional alterations have been made in the sequence of the underlying gene will the protein sequence be protectable. However, computers or player pianos may generate output that is not eligible for copyright, even though the underlying instructions remain protected. It may also be argued that a protein will never be perceived in the way that output such as a song or a computer screen will be. The protein, like the underlying DNA sequence itself, must be observed with the aid of machines and devices. However, the language in the computer cases above suggests that direct perception is not a necessary prerequisite to copyrightability; protected computer code gives rise to output that may never be perceived by humans.

Consequently, the assertion that certain information comprises instructions for a machine, rather than for the human senses, is of little help in determining the proper scope of copyright. Although this distinction may exist in practice, it breaks down under conceptual scrutiny. Rather more helpful is Iver Cooper's observation that many items may be said to convey information to humans, but we do not copyright them all.²⁶² Litmus paper, for example, conveys information about acidity to human beings, but society has not chosen to

---

²⁶²I. COOPER, *supra* note 11, at 11-27.

make litmus paper the subject of copyright. The choice, then, is less a question of tradition or analogy, than it is one of policy.

In the case of computer software, Congress has extended copyright protection to a technological device, and that protection includes even such devices that communicate no message to a human audience. Whether such devices *should* be protected under copyright may be the subject of debate, but clearly copyright *may* be extended so far by Congress. In short, there is nothing sacrosanct about copyright protection in terms of its subject matter—copyright merely represents a particular type of legal protection that society may or may not choose to apply to a particular medium of expression. This normative question, whether copyright ought to be applied to rDNA creations, is taken up in more detail below. It is certainly worth observing at this point, though, that piano rolls posed something of a problem for traditional copyright analysis, computer software posed even greater difficulties, and the analysis here demonstrates that rDNA would pose greater difficulty yet. Nonetheless, the failure of a nucleotide sequence to communicate a message to a human audience need not of itself bar the sequence from copyright protection.

2. *The Congressional Mandate*

The objections against superficial comparisons of software and rDNA are well founded. Simply because some features of information processing in each system appear analogous, it does not follow that rDNA is eligible for copyright protection. However, these objections may overlook the more subtle and perhaps more powerful implications of the computer software analogy. Computer software and recombinant nucleotide sequences share something of their essential nature: they are creative bits of technology. The inclusion of software technology within the ambit of copyright appears to have carved out doctrines that will accommodate a similarly utilitarian technology such as gene splicing. Thus, computer software provides a precedent indicating that such technology can be protected by copyright, and indicating how such protection fits the constraints of copyright.

However, even though Congress can extend copyright protection to technological devices, and has done so in the case of computer software, it might well be argued that Congress has not done so in the case of rDNA sequences. Computer programs are specifically mentioned in the Copyright Act, whereas nucleotide sequences are not.²⁶³ The protection of software by copyright may be argued to depart from traditional copyright subject matter both in terms of utility and communication of expression. This type of protection is clearly the exception rather than the rule. Such exceptions presumably should be made only when explicitly set out in the statute. The exception for software explicitly appears in the statute; an exception for rDNA does not.

Although this approach makes the most sense in terms of interpreting the

---

²⁶³I. COOPER, *supra* note 11, at 11-17.

copyright statute, one or two cautionary notes deserve consideration. The exception for software does not, in fact, appear all that explicitly in the statute. Computer programs are defined, somewhat ambiguously, in section 101 of the Copyright Act.²⁶⁴ They are discussed again in section 117, which allows the limited copying of copyrighted software for archival purposes.²⁶⁵ Computer programs are not mentioned elsewhere in the statute; they do not appear even in section 102, which defines the subject matter of copyright. The legislative history of the Act indicates that Congress intended to protect computer software as copyrightable literary works, but this is nowhere stated in the Act itself.²⁶⁶ As illustrated by the cases discussed above, courts have had to interpret the Act's language in order to find the proper subject matter of software copyright protection. Does the congressional mandate include programs in their machine readable form? Did Congress' intent extend to microcode? The courts continue to interpret the Act's language to find the proper scope of such protection. As illustrated by the cases taking an economic approach to protection of compilations, this interpretation is a decision of policy. In cases such as *Apple v. Franklin* or *NEC v. Intel*, the decision was cloaked in statutory language; in the telephone directory cases it was not. Thus, it is not utterly outrageous for the proponents of rDNA copyright protection to suggest that courts, by interpretation of the Act's language, could find nucleotide sequences within the scope of the congressional mandate.

At this point, however, the last and strongest obstacle to such an interpretation becomes salient: as a practical matter, courts probably will be reluctant to find rDNA within the subject matter of copyright unless they receive some clear sign from Congress to do so.²⁶⁷ The sort of policy decision made in the directory cases is a rarity; generally courts look to the legislature for some indication of the direction to take. Consequently, some discussion is necessary of the arguments that might either persuade Congress to give such a sign or dissuade it from doing so. The discussion of rDNA copyright to this point should suggest the difficulty of fitting biotechnology to the doctrines of traditional copyright. These difficulties appear to be even more pronounced than those of fitting computer software into the scheme of copyright protection. Both types of works are largely functional in nature, but rDNA would seem to be even farther removed from the traditional categories of copyrightable works than is software. Consequently, the doctrines concerning merger, functionality, originality, and so on may leave very little room for protection for rDNA work. Part IV examines the overall purposes of intellectual property law and the emerging needs of the biotechnology industry in an attempt to determine whether this type of constrained protection is really what is needed in this area.

---

²⁶⁴17 U.S.C. § 101 (1982).

²⁶⁵*Id.* at § 117.

²⁶⁶H.R. REPORT, *supra* note 136, at 54.

²⁶⁷I. COOPER, *supra* note 11, at 11.02[6].

IV. POLICIES AND PROTECTION

Advocates of copyright protection for rDNA have drawn on an analogy to computer programs to advance their arguments. This simple analogy will not, by itself, support protection of rDNA under copyright law. Although the judicial doctrines that have accommodated computer software under copyright law will similarly accommodate rDNA, the analogy itself offers no rationale for this second exception to general policies against protection of utilitarian articles under copyright. Recombinant DNA innovations may, however, resemble computer programs in other relevant ways. For example, the policy considerations relevant to the protection of each industry may be similar. Consequently, the recent discussion over software protection policies may shed light on protection for biotechnology. This section reviews several recent comments and criticisms regarding software protection, applying them to what is known of the needs of the biotechnology industry.

A. Policies of Intellectual Property Protection

Recent discussion over the proper nature and scope of protection for computer programs has attempted to look past the simple analogy to traditional literary works. Several commentators have approached this analysis by considering the purposes of intellectual property law in relation to the nature of the software industry. A model of intellectual property protection is then selected that appears to best match the needs of this industry. In order to look past the simple analogy of rDNA to software, society similarly must select an intellectual property model that best meets the needs of the biotechnology industry, by examining intellectual property law in light of that industry's nature. This article begins such an examination by reviewing intellectual property protection generally.

1. *Intellectual Property Protection Generally*

Intellectual property protection was at one time regarded as an equitable means of safeguarding the rights of artists and inventors in their personal creative expression.²⁶⁸ Although this theme continues to crop up from time to time in intellectual property jurisprudence,²⁶⁹ it has been almost entirely abandoned in favor of economic models justifying this area of law. Modern courts and commentators have, as suggested above, viewed intellectual property protection as an incentive for the creation and disclosure of ideas.²⁷⁰

This incentive is believed to be required due to the unique nature of ideas as

---

²⁶⁸R.P. BENKO, *supra* note 147, at 18.

²⁶⁹*See Mazer v. Stein*, 347 U.S. 201, 219 (1954) ("Sacrificial days devoted to such creative activities deserve rewards commensurate with the services rendered.").

²⁷⁰R.P. BENKO, *supra* note 147, at 18.

a public good.²⁷¹ Ideas are intangible “goods,” and unlike physical goods may be held by more than one person at a time.²⁷² The distribution costs for disseminating an idea are minimal or nonexistent; hence, once an idea is disclosed, there are no real barriers to its free appropriation.²⁷³ This difficulty of exclusion creates a significant “free rider” problem in the market for knowledge goods; the goods may be consumed by the receiver without recompense to the originator.²⁷⁴ The creation of knowledge goods may entail significant initial production costs of time and effort, yet the knowledge may be freely taken once disclosed. In addition, the “free riders” may themselves become secondary producers, disseminating the goods to other recipients who need not recompense the originator.²⁷⁵ Consequently, it has been argued, there is little commercial incentive to produce or disclose knowledge goods.²⁷⁶ The knowledge market may thus become undersupplied, requiring an incentive, such as a limited monopoly, to prompt creation and disclosure.²⁷⁷

Paradoxically, such a monopoly incentive may defeat its own purpose. The monopoly is designed to benefit society by stimulating activity in the market of creative and applied ideas. The monopoly, however, may actually stifle activity by preventing free use of the ideas generated.²⁷⁸ Thus, the scope of the protection must be crafted to optimize both the free exchange of information and protection of disclosed ideas. Much of the debate surrounding intellectual property law concerns finding and accommodating this balance, but it is generally conceded that patent law and copyright law have been fashioned to strike the appropriate balance in two differing areas of the market.²⁷⁹ However, the sharp distinction between the two has recently been blurred by emerging infor-

²⁷¹*Id.* at 17-18; Leibowitz, *Copyright Law, Photocopying, and Price Discrimination* in RESEARCH ON LAW AND ECONOMICS, *supra* note 13, at 181, 183-86. Although this is the commonly given rationale, some commentators have observed that no empirical study has ever actually shown that a limited monopoly incentive increases the production of intellectual goods. See Priest, *What Economists Can Tell Lawyers about Intellectual Property: Comment on Cheung* in RESEARCH ON LAW AND ECONOMICS, *supra*, at 19.

²⁷²*Id.* See also *International News Service v. Associated Press*, 248 U.S. 215 (1918) (Brandeis, J., dissenting) (ideas once articulated properly become free for common use).

²⁷³*Id.* See also Menell, *supra* note 13, at 1337. However, some commentators have suggested that intellectual goods differ from classic public goods, such as “national defense,” in two ways: the originator gives the intellectual good its initial value, and recipients gain no further benefit from the intellectual good after absorbing the first unit. Adelstein & Peretz, *The Competition of Technologies in Markets for Ideas: Copyright and Fair Use in Evolutionary Perspective*, 5 INT’L. REV. L. & ECON. 209, 218 (1985).

²⁷⁴R.P. BENKO, *supra* note 147, at 17; Gordon, *Fair Use as Market Failure: A Structural and Economic Analysis of the Betamax Case and Its Precedents*, 82 COL. L. REV. 1600, 1611 (1982).

²⁷⁵See Adelstein & Peretz, *supra* note 273, at 222.

²⁷⁶*Id.* Daniel Bell has noted that this is problematic in the scientific community, where information is a “collective good.” Science by its nature depends on transmission of information at minimal cost, yet this paradoxically creates little incentive for anyone to bear the cost for generating the information. See Bell, *The Social Framework of the Information Society* in THE COMPUTER AGE: A TWENTY-YEAR VIEW 163, 168 (M. Detorou & J. Moses eds. 1979).

²⁷⁷Menell, *supra* note 13, at 1337.

²⁷⁸R.P. BENKO, *supra* note 147, at 19.

²⁷⁹*Id.* at 21-22.

mation technologies such as computer science, and perhaps, genetic engineering.²⁸⁰

2. Patent Versus Copyright Protection

Patent law gives the holder an exclusive right to his innovation for the term of the patent.²⁸¹ In addition to protecting the actual innovation, patent law also generates a penumbra of additional protection: slight variations on the innovation are unprotected by patents due to the novelty and non-obviousness requirements.²⁸² This broad scope has made patent protection most appropriate where total control of the innovation is required as an incentive.²⁸³ Thus, patent law traditionally has been the vehicle for protecting technological inventions; development of such inventions requires substantial investment, which may only be recovered by total control of the invention produced.²⁸⁴

Copyright protection, on the other hand, offers relatively limited control over the results of creative effort; the underlying idea may be freely used in any way that does not appropriate protected expression.²⁸⁵ Consequently, copyright is generally deemed appropriate where the novelty of an idea is less important than its expression.²⁸⁶ Copyright protection appears also to be best employed where society gains little by restricting particular knowledge, but benefits most by its wide dissemination.²⁸⁷ This has made copyright primarily the domain of literary and artistic works. Yet, copyright has also embraced certain utilitarian items.²⁸⁸ These have nonetheless been items that require a narrow protection as an incentive, rather than the broad protection appropriate to patentable novelty.²⁸⁹

B. The Biotechnology Industry

Several aspects of the emerging biotechnology industry appear relevant in attempting to determine whether copyright, patent, or some other form of protection best suits the needs of the industry. The science of molecular biology

²⁸⁰*Id.* at 22; Palmer, *Editor's Introduction* in RESEARCH ON LAW AND ECONOMICS, *supra* note 13, at 133, 134 (patent and copyright blurring because manufacturing responds to same incentives in either case).

²⁸¹35 U.S.C. §§ 154, 271 (1982).

²⁸²This effect arises out of the requirements of novelty and nonobviousness. The Doctrine of Equivalents and similar judicial doctrines preclude protection of inventions that simply involve trivial variations on existing patents. See E. KINTNER & J. LAHR, *supra* note 75, at 84-87.

²⁸³R.P. BENKO, *supra* note 147, at 22.

²⁸⁴*Id.*

²⁸⁵*Id.* at 23.

²⁸⁶*Id.*

²⁸⁷*Id.*

²⁸⁸17 U.S.C. § 101 (1982) (definition of pictorial, graphic, or sculptural work).

²⁸⁹See *supra* notes 176-79 and accompanying text. The distinction between patent and copyright has also been conceptualized in terms of separability: in literature and art, the creative idea is separable from the embodiment, whereas in technology the two are inseparable because the creative idea is the invention itself. See Adelstein & Peretz, *supra* note 273, at 218-19. The analysis of copyright in Part III should demonstrate how elusive and arbitrary this distinction is, especially when blurred by the new information technologies.

has certain characteristics, outlined above, that manifest themselves as characteristics of the biotechnology industry generally. Those characteristics that appear to be most relevant in selecting a model of intellectual property protection include the recent and sudden emergence of the industry, the effort involved in developing biotechnology products, and the close ties the industry maintains with academic science.

1. *Recent and Vigorous Development*

The emergence of the biotechnology industry has been a sudden phenomenon. A recent survey by the OTA found 403 American firms dedicated entirely to biotechnology.²⁹⁰ Most of these firms are small and relatively new, having been formed since 1980.²⁹¹ For the most part, these dedicated biotechnology firms are competing in the human pharmaceuticals market; the success of most of these firms is dependent upon the success of a single product.²⁹² In addition to these companies, several larger corporations have recently turned their attention to the market for biotechnology products.²⁹³ The discussion of patent law above indicated that, as a result of this market configuration, any real or perceived threat to the status of a particular product may have profound effects on the dedicated biotechnology companies.²⁹⁴ As a consequence, there has appeared a growing concern in the industry that the patent requirements for biotechnology products be more clearly defined.²⁹⁵ Because of these ambiguities and the long, expensive process of administrative review, obtaining and protecting strong patent positions has become too costly for small biotechnology companies.²⁹⁶ Resolution of these and related problems involving intellectual property has been identified as an important factor in the continued growth of the industry.²⁹⁷

The confidence in biotechnology's future that has led to its growth in the commercial sector seems to be shared by government at all levels. Many states, believing that biotechnology may be important to their economic development, have initiated programs to foster the growth of such industry within their borders.²⁹⁸ These initiatives sometimes involve direct funding, but more often take the form of reduced taxes or similar incentives.²⁹⁹ The federal government has

---

²⁹⁰U.S. INVESTMENT, *supra* note 1, at 78.

²⁹¹*Id.* at 79; COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 91-98. The emergence of this type of entrepreneurial small firm appears to be a phenomenon unique to the United States. COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 97.

²⁹²U.S. INVESTMENT, *supra* note 1, at 79-80; COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 95.

²⁹³U.S. INVESTMENT, *supra* note 1, at 79.

²⁹⁴*See supra* notes 124-26 and accompanying text.

²⁹⁵PROFILES AND OUTLOOKS, *supra* note 4, at 4.

²⁹⁶*Id.* at 167.

²⁹⁷*See* COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 16. At the same time, it should be recognized that the American system of intellectual property, because of the different options it encompasses, in many ways already offers the best protection in the world. *Id.* at 17.

²⁹⁸*See* U.S. INVESTMENT, *supra* note 1, at 55.

²⁹⁹*See id.* at 68-69.

also sponsored both direct and indirect funding programs.³⁰⁰ Federal funding for biotechnology exceeded \$2.72 billion in fiscal 1987;³⁰¹ states with programs to foster biotechnology spent an additional \$147 million.³⁰²

Even at this early stage of development, the incentives in biotechnology generating this level of activity appear substantial and real. Worldwide sales of biotechnology products are expected to reach between \$15-100 billion annually by the year 2000.³⁰³ One product of rDNA technology, human growth hormone, is expected to generate \$150 million in profits annually.³⁰⁴ Out of twenty new approvals by the Food and Drug Administration (FDA) in 1986, four were produced through biotechnology.³⁰⁵ Such early indicators of success in this industry promise opportunities prompting further growth and investment.

2. High Initial Investment

Biotechnology, because it is an emerging high technology field, requires substantial investment before marketable products are produced. The high cost of developing new biotechnology products for market has forced biotechnology companies to be selective about which avenues of research and production to pursue.³⁰⁶ During 1987, the OTA found that dedicated biotechnology firms invested approximately \$1.2 billion in research.³⁰⁷ These investments averaged \$4 million per firm, or about 40 percent of the total revenue of such small firms.³⁰⁸ Major corporations in the biotechnology arena invested an additional \$800 million in research, or about 20 percent of their total research and development expenditures.³⁰⁹ Additional outside funding has been provided either directly or indirectly, by state and federal government.³¹⁰ Despite this level of investment, only seven products produced by biotechnology have received FDA approval for marketing.³¹¹

An independent survey conducted in 1988 indicates that the biotechnology industry as a whole has not reached the "break even" point, particularly in regard to research expenditures. Only one quarter of the firms surveyed reported a net profit.³¹² This is in part because of the growth pattern among start-

³⁰⁰*Id.* at 35, 150.

³⁰¹*Id.* at 37.

³⁰²*Id.* at 4.

³⁰³PROFILES AND OUTLOOKS, *supra* note 4, at 47.

³⁰⁴U.S. INVESTMENT, *supra* note 1, at 180.

³⁰⁵*Id.* at 12.

³⁰⁶PROFILES AND OUTLOOKS, *supra* note 4, at 72.

³⁰⁷U.S. INVESTMENT, *supra* note 1, at 80.

³⁰⁸*Id.*

³⁰⁹*Id.* An independent survey conducted in 1988 showed that the biotechnology industry as a whole averaged \$571,000 per month in research and development expenditures, which comprised about one third of the industry's total expenditures. See ARTHUR YOUNG HIGH TECHNOLOGY GROUP, BIOTECH '89: COMMERCIALIZATION 33, 74 (1988). Because these surveys sampled somewhat different groups, using somewhat different methods, their results cannot be compared too closely. However, they offer a rough overall view of the present state of the biotechnology industry.

³¹⁰See sources cited *supra* note 294-301.

³¹¹U.S. INVESTMENT, *supra* note 1, at 12.

³¹²BIOTECH '89, *supra* note 309, at 65.

up biotechnology companies: their costs tend to remain greater than their revenues until they survive to become larger companies.³¹³ Accordingly, large companies reported that their largest expenditures were for marketing, whereas midsize companies' largest expenditures were on research and development, and small firms' greatest expenditures were administrative.³¹⁴ This indicates that research is the critical factor to development in this young industry, and other business skills become more important as companies mature.³¹⁵ The expenditures of the companies surveyed, measured against their sales revenues, further reflect this growth pattern. Research and development costs, on the average, comprised 130 percent of the sales of midsize biotechnology companies, 126 percent of the sales of small companies, and 33 percent of the sales of large companies.³¹⁶ By comparison, R&D costs comprise 14 percent of sales revenues among traditional pharmaceutical companies.³¹⁷

The initial research and development necessary to bring biotechnology to the market is reflected in other areas. Highly trained personnel are necessary to the biotechnology industry. Of approximately 35,900 jobs available in the field, half are for scientists and engineers.³¹⁸ In 1983, 46 percent of the research and development personnel in this area held Ph.D.s. This percentage has fallen as rapid growth of the industry has necessitated that additional positions be filled by personnel at the master's or bachelor's degree level.³¹⁹ Personnel shortages are predicted in certain biotechnology specialties.³²⁰ Thus, in addition to financial commitment, the growth of the biotechnology industry represents a significant investment in human resources and training.

3. *Close Ties with Academe*

The biotechnology industry owes much of its growth to academic research.³²¹ Recombinant DNA technology and similar techniques were developed in an academic setting, and commercial biotechnology is in large measure an outgrowth of university research.³²² This blurring of the traditional roles of

³¹³*Id.* at 74-75.

³¹⁴*Id.* Unlike the OTA survey cited *supra* notes 299-302, which distinguished biotechnology companies as either large corporations or dedicated biotechnology firms, the Arthur Young survey assigned the companies surveyed to size categories based on the number of employees. *Id.*

³¹⁵*Id.* at 26.

³¹⁶*Id.* at 50, 52.

³¹⁷*Id.*

³¹⁸U.S. INVESTMENT, *supra* note 1, at 5.

³¹⁹*Id.*

³²⁰*Id.* at 5, 184.

³²¹*Id.* at 6; PROFILES AND OUTLOOKS, *supra* note 4, at 146-50. The lack of a strong academic research base is believed to be the major barrier to entry of competing Japanese firms into the biotechnology market. *Id.* at 99; see also *infra* note 369 and accompanying text.

³²²A geographic map of U.S. biotechnology firms shows them to be clustered around the universities that fostered them. See BIOTECH '89, *supra* note 309, at 105. The growth pattern of biotechnology, arising out of the universities, has been contrasted to that of the semiconductor industry, which first developed in industrial laboratories and then became the subject of academic research. See COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 540.

academia and industry has led one industry leader to observe that commercial biotechnology is driven by the availability of scientific advances rather than by the availability of finance.³²³ Indeed, much of the capital that is raised for commercial biotechnology ventures is channeled into university laboratories. Biotechnology research at the university level receives four to five times more in industrial funding than does research in other fields.³²⁴ About half of the biotechnology companies surveyed by the OTA report supported research at universities; in 1984 this amounted to \$120.7 million in grants and contracts.³²⁵ Many of these firms are involved in collaborative efforts that include consulting and contract research.³²⁶

These collaborative ventures bring with them a number of difficulties, some of which have been indicated above. Most of the difficulties that have arisen surround the new "publish or profit" dilemma that commercial funding entails.³²⁷ Aside from the issues of secrecy, delayed publication, and unwillingness to share research data, many have questioned whether university research agendas might be altered to meet commercial rather than academic criteria.³²⁸ In addition, although many are optimistic that commercial biotechnology will provide new funds to fuel basic research, others have asked whether commercial research might actually compete with academic research for limited funding resources.³²⁹ These problems are not different in *kind* from those experienced in other areas of research; but they are particularly serious in biotechnology because of the *frequency* of university-industry interaction.³³⁰

C. The Software Analogy Revisited

Having reviewed several relevant facts concerning the nature of the biotechnology industry and the purpose of intellectual property protection, we may consider whether the analogy of rDNA to computer programs extends to the level of social policy. Certainly, both biotechnology and computer software are emerging technologies with significant implications for our society. Software already has been protected under the rubric of copyright law; this in itself has been controversial because it appears to overstep the traditional limits of copyright. However, copyright has always been employed on the forefront of

³²³BIOTECH '89, *supra* note 309, at 116 (statement of Brook. H. Bryers, founding president of Hybritech, Inc.); *see also* COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 416.

³²⁴U.S. INVESTMENT, *supra* note 1, at 6.

³²⁵*Id.* at 113.

³²⁶*Id.* at 7; COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 103.

³²⁷*Id.* at 121. *See also generally* Eisenberg, *supra* note 7; Dresser, *supra* note 7, at 419-22.

³²⁸U.S. INVESTMENT, *supra* note 1, at 7.

³²⁹*See* Markle & Robins, *supra* note 108, at 88.

³³⁰U.S. INVESTMENT, *supra* note 1, at 6.

technology in a continual series of steps over its previous bounds.³³¹ If the nature of the biotechnology industry and market resembles that of software, then the policy considerations leading Congress to protect software under copyright law might suggest similar protection for rDNA. Compare and contrast the present characteristics of the biotechnology industry, as described above, with those of the computer software industry at the time CONTU recommended copyright protection for computer programs:

The typical responding software firm was independently owned, young, and small. Founded within the last ten years, it employed fewer than one hundred people, had annual sales of under \$5 million, and spent about \$100,000 a year on research and development. . . . These firms showed a certain tendency toward specialization in one sort of product or service. A typical firm developed internally ten to twenty-five computer programs a year and a similar number for specific customers. . . . [M]any of the firms surveyed were not greatly concerned with legal protection of software; many . . . displayed a strong preference for contractual restraint through trade secret over either patent or copyright.³³²

Although this suggests similarities between the two industries at a certain stage of development, certain features of biotechnology also appear to diverge from those of the software industry. In particular, the discussion above indicates that the success of commercial biotechnology is closely tied to that of basic scientific research, that the fruits of biotechnology are slow to reach the market, and that even a small biotechnology start-up venture is extremely capital intensive. In addition, the objections raised against protecting technology under copyright law in the context of computer programs may deserve consideration in the context of biotechnology. Consequently, consideration of the "computer program/rDNA analogy" at this level may suggest different solutions altogether.

1. *Appropriate Models*

Intellectual property protection is designed around a particular model of ideas in a knowledge "marketplace."³³³ The model assumes that innovation will give rise to consumer goods.³³⁴ This model may not always be appropriate. It may well be that in a particular milieu innovation should simply give rise to other innovations, for their own sake rather than for practical application.³³⁵ In

³³¹See H.R. REPORT, *supra* note 136, at 51 ("The history of copyright law has been one of gradual expansion of the types of works accorded protection"). See, e.g., *Universal City Studios, Inc. v. Sony Corp. of America*, 464 U.S. 417 (1984) (video recorder technology); *White-Smith Music Publishing Co. v. Apollo Co.*, 209 U.S. 1 (1908) (sound recording technology); *Burrows-Giles Lithographic Co. v. Sarony*, 111 U.S. 53 (1884) (photographic technology); *Williams & Wilkins Co. v. United States*, 487 F.2d 1345 (Ct. Cl. 1973), *aff'd by an equally divided court*, 420 U.S. 376 (1975) (photocopying technology). See also the legislative response to the *White-Smith* decision, discussed *supra* at note 260.

³³²FINAL REPORT, *supra* note 256, at 126 (Appendix G).

³³³See *supra* notes 268-80 and accompanying text.

³³⁴See Newell, *The Models are Broken, the Models are Broken*, 47 U. PITT. L. REV. 1023, 1033-34 (1986).

³³⁵*Id.*

such a setting, society's interest in the free flow of information may alter the intellectual property protection equation in unusual ways.

For example, the relationship between academic computer science and commercial software development is a factor that has been largely neglected in fashioning software copyright protection. Although the needs of the academic computer science community are not entirely clear, at least one commentator has suggested that they are very different from those in the commercial sector.³³⁶ Research in computer science, it has been argued, requires relatively free exchange of discoveries so that others may build on previous work.³³⁷ Thus, it may be that practices like reverse engineering should be permitted in this setting, where the question of wrongful commercial gain is not at issue.

This would seem to be the case in biotechnology, where the intimate relationship between basic science and commercial growth is clear. As this article emphasizes, many of the questions regarding intellectual property protection for biotechnology stem from this odd juxtaposition of commercial interests and research into the basis of life. Protection in this setting must be carefully balanced so as to prompt disclosure of scientific discoveries without prohibiting their employment in further research. Intellectual property laws for biotechnology might also reasonably be crafted to encourage scientific norms, such as duplication of effort, that would be viewed as counterproductive "reinventing the wheel" for a field such as the software industry.³³⁸ In this regard, the discussion in Part II above suggests that a relatively narrow scope of intellectual property protection, arising without formal administrative review, would best foster academic exchange without misappropriation. Copyright, particularly as afforded to compilations, may well meet these criteria.

Additionally, the proper term of protection for biotechnology may be very different than that for software, where the duration of copyright protection seems inordinately long to foster free exchange of ideas in a rapidly changing technological setting. The brief description of the biotechnology industry offered above indicates that its temporal characteristics are very different than those of the other high technology industries such as software or semiconductors. Knowledge is advancing rapidly in biotechnology, but the problems of extended research, of scale-up, and regulatory delays greatly increase the time to commercial marketing.³³⁹ Whereas the rapid market turnover in software and semiconductors makes technological obsolescence a serious problem for pat-

---

³³⁶*Id.*

³³⁷*Id.* This feeling seems to be shared by programmers generally, as evidenced by the recent unauthorized distribution of Apple Corporation's MacIntosh source code by an unidentified group of engineers. This action was claimed to be an attempt at free exchange. See Lowenstein & Zachary, *Mysterious Group is Pirating Apple's Super-Secret Code*, Wall Street Journal, June 9, 1989, at C5, col. 5.

³³⁸Such an incentive to duplicate experiments has been suggested to counter the influences discussed *supra* at note 100. See Jones, *Is There a Property Interest in Scientific Research Data?*, 1 HIGH TECH. L.J. 447, 457 (1987).

³³⁹See PROFILES AND OUTLOOKS, *supra* note 4, at 69-71.

ents in these areas, the biotechnology outlook must be more long-term.³⁴⁰ Indeed, restoration of patent terms lost during FDA and other administrative approval has become an important issue in the area of biotechnology pharmaceuticals.³⁴¹ Thus, the optimal protection period for biotechnology products may prove to be closer to that of copyright than to that of patent.

2. Market Configuration

Recent scholarship on the market for computer software, with regard to intellectual property protection for that industry, provides a useful starting point for considering similar questions in biotechnology. Menell has observed that questions of software protection have been drastically altered by the advent of personal microcomputers.³⁴² Twenty years ago, the computer market was thought of exclusively in terms of mainframe computers.³⁴³ Indeed, software was sold only together with the appropriate hardware as part of a system.³⁴⁴ As a consequence, the software market was dominated by low-volume sales of expensive programs to large institutions that owned mainframes.³⁴⁵ Illegitimate copying was not a great concern because relatively few copies of a program were in circulation, and software tended to be tailored to a specific institution's needs. In such a market, the first units sold realize the capital invested in development, and a fair return may be had on a product before competitors have the opportunity for reverse engineering.³⁴⁶ Moreover, competitors presumably had difficulty obtaining copies of a program to reverse engineer, and even greater difficulty marketing "knock-off" software derived from the reverse engineered program.

More recently, the growth of home computing has shifted the software market to one of high volume, low cost consumer sales.³⁴⁷ In this type of market, the return on development investments comes not from the first unit sold, but from sales over an extended period of time.³⁴⁸ In addition, the technology for quick and easy reproduction of software is widely available. Software producers can no longer keep track of who should and should not have copies of their product, and this together with the proliferation of companies now competing in this market, makes locating and identifying the source of illegitimate competition a monumental task. Licensing schemes or schemes that protect

---

³⁴⁰ See Comment, *Defining the Scope of Copyright Protection for Computer Software*, 48 STAN. L. REV. 497, 504 (1986) (authored by Susan A. Dunn) (technological obsolescence a problem for protection in rapidly advancing software industry); BIOTECH '89, *supra* note 309, at 65 (semiconductor patent obsolescence a problem, but biotechnology is more long-term).

³⁴¹ See PROFILES AND OUTLOOKS, *supra* note 4, at 69-71.

³⁴² Menell, *supra* note 13, at 1336.

³⁴³ *Id.* at 1335-36.

³⁴⁴ This "bundling" of software lay at the heart of the thirteen-year antitrust suit against IBM. See *In re International Business Machines Corporation*, 618 F.2d 923, 924-25 n. 1 (2d Cir. 1979) (recounting the history of and reasons for the suit).

³⁴⁵ Menell, *supra* note 13, at 1335-36.

³⁴⁶ See *id.*, at 1367-68.

³⁴⁷ *Id.*

³⁴⁸ *Id.*

software through trade secret alone are much more difficult to maintain in such an environment.³⁴⁹ Thus, illegal copying and reverse engineering become serious concerns.³⁵⁰ This type of market presents several of the conditions that might make copyright protection appropriate; although such protection does little to prevent unauthorized personal copying, it deters wholesale piracy using materials readily available on the consumer market.³⁵¹ Consequently, copyright has been employed to foster the software industry by curtailing practices such as unfair copying.

At first glance, the same conditions that now dominate the software market may seem to be present in biotechnology. The biotechnology industry requires substantial initial investment to develop products.³⁵² The return on investment in such products comes from many low-cost sales over an extended period, rather than from initial high-cost units. Once developed and available, nucleic acid sequences may be quickly and easily reproduced; proteins may be sequenced and reverse engineered.³⁵³ These factors, common to both the software and biotechnology industries, suggest that copyright might indeed be an appropriate vehicle for protection of rDNA innovations.

However, closer scrutiny of the relevant market belies this conclusion. There is not, nor is there likely to be, a "desktop genetic engineering" market comparable to the personal computer market.³⁵⁴ As a consequence, the copying technology is *not* widely available. In fact, the demographics of the present biotechnology market may more closely resemble those of the computer market twenty years ago: the technology is distributed among a relatively small number of conspicuous institutions. Copies of the recombinant vectors needed to produce particular proteins are not in widespread circulation, and, because of the time required to get biotechnology products to market, the topic of research in prog-

³⁴⁹Comment, *supra* note 340, at 505 (1986).

³⁵⁰Menell, *supra* note 13, at 1336. Some estimate that for popular commercial software, one pirated copy is in circulation for every legitimate copy. See Friedman, *supra* note 73, at 11-12.

³⁵¹See Palmer, *supra* note 13, at 230 (copyright deters wholesale piracy, not individual abuse). Interestingly enough, studies of home duplication of sound recordings fail to show that commercial sales are reduced by unauthorized copying; some have even suggested that home recording may serve to increase sales by whetting the listener's appetite for more recordings. See Deon, *Audio Home Recording: Canadian Copyright Implications* in RESEARCH ON LAW AND ECONOMICS, *supra* note 13, at 157; Dansby, *Comment: Liability and Compensations in the Sale of Quasi-Public Goods* in RESEARCH ON LAW AND ECONOMICS, *supra*, at 175. One cannot help but wonder what a similar study of home duplication of computer programs would reveal about the folk wisdom concerning the software market.

³⁵²See Hardy, *Biotechnology: Improvement of Competitive Position* in PROFILES AND OUTLOOKS, *supra* note 4, at 20 (protection necessary or capital-intensive biotechnology research will be deterred).

³⁵³See Friedman, *supra* note 73, at 13 (easy, inexpensive duplication is a problem common to software and genetic engineering).

³⁵⁴Or at least one would hope not. It might, of course, be argued that the boom in personal computers could not have been foreseen twenty years ago, and some similar jump in technology might create a consumer market in rDNA. However, given the debate over whether gene splicing should be allowed in any context, we might reasonably expect that a home genetic engineering market would be heavily regulated if not prohibited entirely. See *generally* sources cited *supra* at notes 2, 4.

ress at any given biotechnology company is generally well known.³⁵⁵ Although computer software companies can be and have been successfully started with a minimum of equipment in someone's garage, the expense and intricacy inherent in successful molecular biology precludes this approach to biotechnology start-ups. These factors suggest that any source of illegitimate competition from pirated nucleotide sequences could be readily pinpointed.³⁵⁶

Consequently, in the case of biological inventions, physical control of materials necessary to implementation of the idea may prove an inexpensive impediment to "free riders."³⁵⁷ Licensing schemes might be a viable option in keeping track of valuable biological materials a molecular biologist does allow out of the lab.³⁵⁸ Because the gene product, rather than the gene itself, is released into the market, the intellectual goods embodied in rDNA innovations may enjoy a "natural patent" against reverse engineering by virtue of being too deeply embedded in the product sold.³⁵⁹ For example, reverse engineering of biotechnology pharmaceutical products is likely to be as tedious as initial development.³⁶⁰ The time required for scaling up reverse engineered products may itself give the original developer a head start in the market, allowing a good return on the initial investment.³⁶¹ These considerations suggest that piracy and reverse engineering are not the same sort of concerns that they now are in the software industry. The difference between rDNA and software at this level of scrutiny suggests that copyright may not be the most appropriate form of protection.

3. *Networks and User Preference*

The scope of protection for computer software has also recently been discussed in terms of network externalities.³⁶² The economic analysis of protection

---

³⁵⁵In fact, most biotechnology companies at present have pinned their hopes on the development and success of a single product. See *supra* note 292 and accompanying text.

³⁵⁶Cf. COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 391 (because of their unique nature, patent infringement of pioneering biotech inventions easy to detect).

³⁵⁷See Adelstein & Peretz, *supra* note 273, at 218-19; Gordon, *supra* note 274, at 1611 (physical control curbs free-riding). Indeed, as a practical matter, the "software" and "hardware" of biological materials might be considered bundled as a system, much like computers in their early days. See *supra* note 344 and accompanying text.

³⁵⁸As they have been thus far; the many joint ventures between large and small biotechnology companies have involved licensing agreements to develop products from technology owned by one of the participants. See PROFILES AND OUTLOOKS, *supra* note 4, at 74; COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 11. Some universities are now using such agreements to limit the use of biological materials that are exchanged for research, but which might have commercial value. See COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 420. These examples represent a private contractual approach to problems that might be addressed by intellectual property legislation or litigation.

³⁵⁹See Adelstein & Peretz, *supra* note 273, at 221 (natural monopoly if intellectual goods cannot be extracted).

³⁶⁰Recall that sequencing a biotechnology product such as a protein will yield no information about introns, control elements, or other non-coding sequences. See *supra* notes 58-59 and accompanying text; COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 385 (complexity of biological processes precludes most reverse engineering).

³⁶¹See Leibowitz, *supra* note 271, at 186-88 (copyright monopoly may be detrimental where market headstart is sufficient).

³⁶²See Menell, *supra* note 13, at 1340-42; see also Karjala, *supra* note 13, at 43-6.

is radically altered in the milieu of a network, such as a telephone system. Those who are already part of such a network derive great benefit from addition of each new user to the network. In addition, creation of a competing network becomes difficult because of the benefits available in joining the established system. Menell has argued that this is an appropriate model for considering intellectual property problems relating to computer compatibility in the consumer market.³⁶³ Protection in such a setting must be carefully tailored to allow the benefits of widespread compatibility standards, while at the same time fostering worthwhile innovations outside the accepted standard. More than one commentator has argued that software copyright protection in its present form is not well suited to this task.³⁶⁴

In the field of biotechnology, certain parallels to this situation arise, but with important differences. Basic science, as this article repeatedly emphasizes, is closely tied to the commercial biotechnology industry. The progress of science depends upon research that builds upon previous research. There is therefore a strong bias toward research in a system that is already well characterized. In molecular biology, the classic example of such a system is the bacterium *Escherichia coli*; intensive study of this organism has made it the best characterized living system in science.³⁶⁵ This level of understanding invites further research using *E. coli* as a model. In higher organisms, the yeast *S. cerevisiae*, the fruit fly *D. melanogaster*, and the *Xenopus* tree toad have similarly been the subjects of intensive investigation.³⁶⁶ The resources already invested by the scientific community in familiarizing themselves with these models creates a sort of "user lock-in" similar to examples, such as the QWERTY typewriter keyboard, discussed by commentators on software protection. Once a user has made some investment in learning to manipulate a keyboard or a living system, there is a natural tendency not to expend new resources to learn a new system. Granting a long term monopoly over, for example, the *E. coli* genome would surely hamper the progress of both science and the biotechnology industry.

At the same time, science has a strong interest in investigating new systems that are less well understood. The discovery and study of new scientific models depends upon ventures into the unknown. This interest arguably goes beyond a societal desire to develop more efficient technologies. Consequently, any system of intellectual property that hopes to encourage investigation and disclosure of rDNA inventions must be carefully tailored to accommodate both of these interests. The growth of the biotechnology industry and the advancement of human knowledge in general depends upon scientists' ability to build upon one another's work; hence, such practices should not be discouraged by overbroad rDNA protection. At the same time, biotechnology research and indus-

---

³⁶³Menell, *supra* note 13, at 1342.

³⁶⁴See generally Karjala, *supra* note 13; Menell, *supra* note 13.

³⁶⁵D. FREIFELDER, *supra* note 17, at 12, 30.

³⁶⁶*Id.* at 24, 28, 923.

try have both experienced a measure of natural "user lock-in" with respect to models such as *E. coli*.³⁶⁷ It is therefore desirable that incentives for development outside the established models also should be reinforced. It may be that a narrowly circumscribed grant of copyright protection, such as that entailed in the protection of compilations, would serve these interests. However, given the recent controversies surrounding the scope of protection for computer software copyright, it may be preferable to consider whether these same parameters for protection might be implemented through other means.

D. Options for Recombinant DNA Protection

The discussion above suggests that, although certain features of copyright protection may not be well suited to biotechnology's needs, other features of copyright may meet those needs admirably. This conclusion may suggest adopting copyright as a vehicle for biotechnology protection if the benefits outweigh the costs. However, it may also be possible to capture the benefits without the costs by adopting some form of protection not yet considered. We have already considered the merits of patent, trade secret, and copyright protection; several other alternative approaches are considered below.

1. *Do Nothing*

Should the costs of rDNA copyrighting appear to outweigh the potential benefits, the most obvious alternative is for Congress and the courts to do nothing. Many industries are given no special consideration in intellectual property. Biotechnology might be considered just another industry that must rely on patent law, trade secret law, or nothing for such protection. This, obviously, has not been the current trend in considering new technologies; both computer software and semiconductor mask works have recently received special attention as emerging high technology industries.³⁶⁸ Biotechnology would appear to deserve the same sort of consideration; the concerns outlined above cannot be brushed lightly aside. In addition, biotechnology presents questions regarding the United States' competitiveness in an international setting. At present, the United States holds a clear lead over the rest of the world in biotechnology. Japan is expected to strongly challenge this lead, however, and cases of foreign misappropriation have already surfaced.³⁶⁹ Clearly, initiating intellectual property protection that will foster a strong American biotechnology industry, while deterring foreign and domestic misappropriation, is preferable to doing nothing.

---

³⁶⁷ See PROFILES AND OUTLOOKS, *supra* note 4, at 75-76 (*E. Coli* and *Saccharomyces* will remain "biotechnology workhorses" until other systems are developed).

³⁶⁸ See 17 U.S.C. §§ 101, 117 (1982); 17 U.S.C.A. § 901 et seq. (West Supp. 1989).

³⁶⁹ See COMMERCIAL BIOTECHNOLOGY, *supra* note 1, at 3, 7-8; PROFILES AND OUTLOOKS, *supra* note 4, at 8, 48; see also UNITED STATES CONGRESS OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS 4 (1987) (foreign misappropriation of valuable cell line).

2. Common Law

Davidson, in discussing computer software protection, has observed that new problems of protection will arise with each new technology, including rDNA.³⁷⁰ He argues that these problems would be best solved, not by legislative fiat, but by turning intellectual property determinations over to the courts.³⁷¹ Areas of law such as tort and contract have become well defined by common law application of broad legal principles. Davidson suggests that the courts may be able to similarly define intellectual property law by applying the broad principle of misappropriation of expression case by case.³⁷²

Several problems with this approach immediately suggest themselves. One concern is the ability of a court to understand the relevant technology. Several recent controversial opinions in the computer software area arguably stem from the court's inability to grasp relevant aspects of the technology under consideration. This may be generally true in matters of high technology. Legislatures may be better equipped to conduct the extensive investigations necessary to determining the proper mode and scope of protection for a new technology.³⁷³

A second, and perhaps more serious objection to this approach stems from the time element involved. Common law doctrines, much like a pointillist painting, resolve themselves bit by bit into a discernible pattern over time. Unfortunately, society may not have the leisure to allow such doctrinal development in the matter of new technologies.³⁷⁴ Considering the rapid pace of development in science and technology, as well as the pressures of international and domestic competition, it would seem desirable to have Congress set some definite policy in place at the earliest opportunity.³⁷⁵ Nonetheless, the type of flexibility judicial *review* lends to protection is also clearly desirable for new and developing technologies. Individual judicial opinions may serve to "update" statutes on an ongoing basis. Rather than evolving their own doctrines from scratch, courts may interpret legislative enactments so as to keep them from becoming obsolete in the face of rapidly changing technology.³⁷⁶

---

³⁷⁰Davidson, *supra* note 9.

³⁷¹*Id.* at 1067-68.

³⁷²*Id.* at 1109, 1115.

³⁷³For example, whatever one may think of the final recommendations of the CONTU report, that level of investigation into the needs of new technologies will generally be initiated by a legislature rather than by a court. See generally FINAL REPORT, *supra* note 256. Similarly, the exhaustive OTA reports cited throughout this article were prompted by Congress' need for information on biotechnology. See generally sources cited *supra* in notes 1, 68, 369.

³⁷⁴Rines, Bradford, et al., *Computer Software: A New Proposal for Intellectual Property Protection*, 29 IDEA 3, 18 (1988) (common law too slow and expensive).

³⁷⁵However, one commentator suggests with some justification that Congressional hearings and legislative action may be just as slow. Rosen, *A Common Law for the Ages for Intellectual Property*, 38 MIAMI L. REV. 769, 795 (1984).

³⁷⁶*Id.* at 785.

3. *Sui Generis* Legislation

If Congress should set the policy for fostering new technologies, the suggestion will undoubtedly be raised that novel statutes should be enacted, tailored to the specific needs of biotechnology. This idea has been discussed at length as an alternative to copyright for computer software protection.³⁷⁷ Such arguments have already been accepted in the field of semiconductor chip design; Congress passed the Semiconductor Chip Protection Act in response to the needs of a specific industry.³⁷⁸ This Act resembles the Copyright Act in many particulars, but makes provisions for specific concerns such as reverse engineering.³⁷⁹ Similarly, Congress has provided *sui generis* protection for sexually reproducing plants.³⁸⁰

This type of individual attention seems to be the optimal solution for any emerging technology. However, Stern has observed that Congress can be expected to take this type of action fairly infrequently.³⁸¹ Although Congress has adopted this approach for semiconductor mask works, a new area of intellectual property law cannot be created every time a new technology emerges. It therefore may be more reasonable as a practical matter to expect broader congressional action covering multiple technologies.

4. *Administrative Control*

One broad solution in intellectual property protection might be to delegate this area to the "fourth branch of government." Stern has suggested the formation of a new administrative agency, empowered by Congress to investigate each emerging technology and formulate intellectual property regulations tailored to the technology's particular needs.³⁸² This solution has much to commend it. It would allow each new technology to receive individual attention without requiring new congressional action for each field. At the same time, uncertainty in dealing with administrative agencies such as the Food and Drug Administration, the Environmental Protection Agency, and the Department of Agriculture has already become a serious concern in the biotechnology indus-

---

³⁷⁷See, e.g., Rines, Bradford et al., *supra* note 373, at 3 (model for proposed new legislation); Samuelson, *supra* note 13. Samuelson's arguments in favor of novel legislation for computer software are extensively critiqued by Raskind, *supra* note 13.

³⁷⁸Pub. L. 98-620, Title III, 98 Stat. 3347, (Nov. 8, 1984) (codified at 17 U.S.C.A. § 901 et seq. (West Supp. 1989)).

³⁷⁹*Id.* at § 906.

³⁸⁰7 U.S.C. 2321 et seq. (1983). This Plant Variety Protection Act (PVPA) is the counterpart of the Plant Protection Act (PPA) for asexually reproducing plants. See *infra* notes 386-89 and accompanying text. Unlike the PPA, the PVPA is not part of the patent system and does not afford the same measure of protection as either utility or plant patents. See PATENTING LIFE, *supra* note 4, at 11. Additionally, the language of the PVPA may exclude species of sexually reproducing plants created through rDNA techniques. See I. COOPER, *supra* note 11, at § 9.01; Comment, *Plants and Biotechnology—Policy and Law*, 14 WEST. STATE U.L. REV. 529, 530-31 (1987) (authored by Eileen M. Baker).

³⁸¹See Stern, *supra* note 9, at 1261; see also Davidson, *supra* note 9, at 1065-67.

³⁸²Stern, *supra* note 9, at 1261.

try.³⁸³ The discussion of patent law above illustrates the uncertainty biotechnology firms have undergone in dealing with the PTO, an administrative agency empowered to oversee one type of intellectual property law.³⁸⁴ Additionally, this approach may also raise questions regarding congressional oversight, legislative vetoes, and the like.³⁸⁵ Straightforward principles might be sacrificed for the arcana of a code of federal regulations. In short, careful consideration should be undertaken before placing the development of biotechnology at the mercy of the usual muddle associated with the federal bureaucracy.

5. *Modification of Existing Law*

Gene-splicing techniques are not the first technology mankind has employed in genetic manipulation; neither has this new technology presented the first question of intellectual property protection for living subject matter. In 1930, Congress enacted the Plant Patent Act, designed to protect new varieties of plants created through genetic manipulation.³⁸⁶ Although this statute requires novelty, utility, and non-obviousness required for any patent, these standards have been altered somewhat in their application to plants.³⁸⁷ Indeed, one commentator has suggested that, in some respects, the requirements for a plant patent approach the premises of copyright.³⁸⁸ Plant patents are issued without the same review required for other patents, and the case law suggests that infringement requires access to cuttings or seed of the plant patented.³⁸⁹

This type of statute appears to incorporate into patent law the features that make copyright an attractive alternative for biotechnology. Patent law, when cast in such a form, may serve the needs of biotechnology very well. A similar

³⁸³See PROFILES AND OUTLOOKS, *supra* note 4, at 71.

³⁸⁴See *supra* notes 86-93, 114-16 and accompanying text; see also *infra* note 386.

³⁸⁵For a taste of the administrative quagmire this approach could entail, see, e.g., *Immigration and Naturalization Service v. Chadha*, 462 U.S. 419 (1983) (legislative veto held unconstitutional); *Panama Refining Co. v. Ryan*, 293 U.S. 388 (1935) (delegation held to be unconstitutionally broad); *Mistretta v. United States*, _____ U.S. _____, 109 S. Ct. 647 (1989) (challenged delegation upheld); *Environmental Defense Fund v. Thomas*, 627 F. Supp. 566 (D.C. 1986) (interference between administrative agencies enjoined); *Industrial Union Department, AFL-CIO v. American Petroleum Institute*, 448 U.S. 607 (1980) (OSHA standard held to have exceeded delegated authority).

³⁸⁶35 U.S.C. § 161 et seq. (1982). The Plant Patent Act covers only asexually reproducing plants. See PATENTING LIFE, *supra* note 4, at 9. Oddly enough, the PTO resisted attempts to patent genetically recombinant plants under utility patents, much as it previously resisted patenting of recombinant microorganisms. See Kroisin, *Are Plants Patentable Under the Utility Patent Act?*, 67 J. PAT. & TRADEMARK OFF. SOC. 220, 227 (1985). This changed with the decision in *Ex Parte Hibbard*, 227 U.S.P.Q. 473 (B.P.A.I. 1985), which declared recombinant plant species to be proper subject matter for utility patents. See PATENTING LIFE, *supra* note 4, at 75-76; see also Kroisin, *supra*, at 234.

³⁸⁷See I. COOPER, *supra* note 11, at §§ 8.04-8.06. The enablement requirement for plant patents is modified because of the difficulty in precisely describing living organisms in writing. Compare 35 U.S.C. § 112 (1982) (enablement standard for utility patents) with 35 U.S.C. § 162; 37 C.F.R. § 1.163(a) (1987) (enablement standard for plant patents). Note that a similar approach might alleviate the enablement concerns discussed *supra* note 90.

³⁸⁸Bernstein, *Is a Plant Patent a Form of Copyright?*, 27 IDEA 31 (1985).

³⁸⁹*Id.* at 34-37.

addendum to existing patent statutes could meet biotechnology's particular requirements without attempting to carve out an entirely new area of intellectual property law. This solution also may be preferable to creating a new administrative agency, simply through its elegance of resource conservation: it employs an administrative agency, the PTO, already empowered by Congress to oversee the relevant area of intellectual property law. Consequently, protection of the biotechnology industry would be met by a system already largely established and operating.

CONCLUSION

The suggestion that rDNA innovation be protected under copyright law arises out of serious concerns over the adequacy of current schemes of intellectual property protection for the biotechnology industry. Many of these concerns stem from the unique ties between commercial biotechnology and basic science. An examination of the practices endogenous to both basic research and commercial biotechnology suggests that, under a statute ideally suited to fostering development and disclosure of biotechnology innovations, intellectual property protection would:

- arise automatically, without formal review
- encompass a fairly narrow scope of protection
- protect for a longer period than do utility patents
- allow and even encourage independent re-creation of innovations
- discourage taking previous work and profiting from it without adding to it
- permit reverse engineering for purposes of studying previous work.

Certain features of copyright protection do, in fact, fit these criteria for protection of rDNA innovations. These features include a narrow scope of protection, a lack of formal review, and an emphasis against illegitimate taking by copying. A careful examination of current copyright doctrines suggests that nucleotide sequences are not per se uncopyrightable; the interpretations of copyright law that have accommodated computer software could similarly accommodate rDNA.

However, traditional copyright doctrines have not evolved in response to the needs of innovation in largely functional creations such as recombinant nucleotide sequences. The difficulty that courts have had accommodating copyright law to the needs of computer software foreshadows the difficulty protection of rDNA under copyright would entail. Copyright protection of software, because of its uncertain balance of costs and benefits, has generated considerable controversy. Similar protection of a second information technology should not be undertaken lightly. The present configuration of the biotechnology market appears to differ significantly from the configuration that prompted protection of computer software under copyright laws. In particular, biotechnology exhibits a close interrelationship with basic science, high start-up costs, long development periods, and a product consumption pattern that is quite un-

like that of the software industry. In the case of computer software, Congress' decision has already been made, but the options are still open for protection of biotechnology innovation. There is no need to attempt stuffing biotechnology into the copyright box. The features of copyright law that seem amenable to protection of biotechnology may be captured under entirely novel legislation, or even under a modification of existing statutes.³⁹⁰ Such approaches seem preferable to miring the emerging biotechnology industry in the debate over applications of traditional copyright doctrines to largely utilitarian innovations.

---

³⁹⁰ As this article went to press, such a proposed amendment to the patent statutes was published. This proposal, tailored specifically to the needs of biotechnology, would create expedited review, lengthened duration, and narrowed scope for biotechnology patents. *See Comment, supra* note 12, at 465–67.