FROM MICROBES, TO CORN SEEDS, TO OYSTERS, TO MICE: PATENTABILITY OF NEW LIFE FORMS

*Edmund J. Sease**

If we could all agree where science was going, everything would be solved ....[1]

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* Partner in the Des Moines, Iowa, firm of Zarley, McKee, Thomte, Voorhees & Sease. B.A. 1964, Drake University; J.D. 1967, Drake University. Member of the Iowa, Ohio, and Patent Bars.

1. J.D. WATSON, THE DOUBLE HELIX 108 (1968).

I. INTRODUCTION

In 1953 J. D. Watson and Francis Crick discovered the structure of DNA. Undoubtedly, this was the most significant biological discovery since Darwin's theory of evolution. A personal account of this dramatic breakthrough appears in *The Double Helix* by James D. Watson.[2] For their work, Watson and Crick received the 1962 Nobel Prize for medicine. Today, scientists are increasingly involved in applying Watson and Crick's discovery to the development of commercially useful products.

The discovery of the structure of the DNA molecule, which might be thought of as the genetic code of life, has created new frontiers in the world of science. These frontiers include frontiers of fear, frontiers of fact, frontiers of fantasy, and frontiers of law. Today the test-tube embryo of George Orwell's *1984* is fact, not science fiction. Man can now genetically alter animals and create new animals, never before existent, such as the cross between the sheep and the goat known as the "geep." Applied biotechnology has already provided us with an economical way of producing insulin,[3] and will no doubt allow economical production of many other valuable industrial compounds. Applied biotechnology also offers such exciting opportunities as new life forms and altered life forms of benefit to man, new plants which may create high yield row crops, and improved varieties of known plants which will be resistant to traditional pathogens.

History teaches that advances in science are inevitably viewed with fear. Consider the fact that early scientists had to take a clandestine approach to the dissection of human cadavers. Consider the heresy trials of famous scientists such as Galileo. Consider the strong opposition of Jerry Rifkin and others to genetic alteration of *any* natural organisms. There are those who say that unleashing man's ability to create new, self-propagating forms of life, offers a potential for destruction greater than that of nuclear weapons. History has proven that most fears of new science are unwarranted; they are based upon scientific fantasy—worst-case scenarios—rather than reasonable apprehension. Nevertheless, it is fair to say that risks should not be ignored and they mandate caution.

The pace of the law has often been described as tortoise-like. However, it cannot adopt such a pace in dealing with scientific developments. If it is tortoise-like, it will only be left behind as the genius of man's intellect unfolds. History also teaches that if the law does not accommodate changes in society, society simply moves on, leaving the law behind.

The application of DNA technology to the creation of new life forms raises many controversial legal issues. Just now our legal system finds itself directly confronted with the repercussions of Watson and Crick's dramatic

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2. J.D. WATSON, THE DOUBLE HELIX (1968).

3. Details of development of new pharmaceutical products are outlined in CHEM. ENG'G & NEWS, July 20, 1987, at 11-32 [hereinafter CHEM. ENG'G & NEWS].

discovery. These fundamental legal, ethical, moral, and philosophical issues will inevitably find their way into our courts in the form of new legal theories—which will once again test our living Constitution.

Our Constitution provides numerous first amendment rights, among which are freedom of speech,[4] freedom of the press,[5] and freedom of inquiry without censorship.[6] These rights will be directly involved in the controversies generated by the new developments in biotechnology. For example, DNA technology could have a significant impact on both national security and national economical interests. The government can reasonably be expected to impose certain security restraints on scientific communications, both in published literature and in society meetings, regarding certain aspects of DNA technology. We can only await the court system's response to these diverse issues.

The concepts of species integrity and reverence for life, and the general ethical and moral issues which are raised by the possibilities of recombinant DNA technology, also directly confront society with first amendment controversies concerning freedom of religion. If objections to the use of recombinant DNA technology are in fact based on moral or religious grounds, can the use of such technology be restrained without running afoul of the first amendment right to freedom of religion?[7]

Other constitutional issues, such as the reserved police powers of the states as protected by the tenth amendment,[8] may also be raised by biotechnology. For example, could the states, in the exercise of their police power, prohibit scientists residing within their borders from developing genetically altered life forms on the theory that such a prohibition was necessary to protect their citizens from the inherent dangers of such life forms? These and many other questions remain to be answered.

The economic power of biotechnology cannot be denied. If there ever was any residual doubt, it vanished with the Supreme Court's decision in *Diamond v. Chakrabarty*,[9] which held that a genetically altered microorganism can be patented. Given the patentability of the products of biotechnology, coupled with the economic rewards which follow on patentability, our society will obviously be forced to deal with the legal repercussions of the unwinding of the double helix.

History has proven that we cannot stop the growth of knowledge. Consider the Scopes "monkey trial" of the 1920s,[10] in which two giants of the

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4. *See* Brandenburg v. Ohio, 395 U.S. 444 (1969) (landmark free speech case).
5. *See* New York Times Co. v. Sullivan, 376 U.S. 254 (1964) (landmark freedom of press case).
6. *See* Griswold v. Connecticut, 381 U.S. 479 (1965) (inquiry without censorship case).
7. *See* Wisconsin v. Yoder, 406 U.S. 205 (1972) (freedom of religion case).
8. *See* Hodel v. Virginia Surface Mining & Reclamation Ass'n, 452 U.S. 264 (1981).
9. Diamond v. Chakrabarty, 477 U.S. 303 (1980).
10. Scopes v. State, 155 Tenn. 105, 298 S.W. 363 (1927).

legal profession, Clarence Darrow and William Jennings Bryan, squared off to litigate Darwin's theory of evolution. Consider the medieval heresy trials of our great scientists.[11] Consider the science fiction movie *Fahrenheit 451*: books were prohibited; they burned at 451 Fahrenheit; but even by burning the books the government could not stop the spread of knowledge—a society of exiles painstakingly memorized the great books to prevent their loss. Clearly, the human thirst for knowledge knows no bounds. Our only choice is to move forward. We can move forward with reluctance or with enthusiasm. We can move forward with revolution or with evolution. In 1980 nine men with an average age of close to seventy dragged us forward when, twenty-seven years after the structure of DNA was unraveled, the law of patents finally caught up with the science of Watson and Crick in *Diamond v. Chakrabarty*.[12]

II. Historical Development of the Law

A. *Patentability of New Life Forms Before* Diamond v. Chakrabarty—*The Product of Nature Doctrine*

The prior cases leading to *Diamond v. Chakrabarty* require a fundamental appreciation of the "product of nature" doctrine. Only new, useful, and non-obvious things are patentable.[13] Something cannot be "new" or "novel" if it already exists naturally. Thus, products of nature cannot be patented.

If the product of nature distinction seems clear, its application has been anything but. In fact, the line between organisms which are products of nature and altered organisms which are not products of nature is no clearer than the legal line between life and death. The case law illustrates this proposition nicely.

1. *Blue Mold Decay Resistant Oranges*

The analysis begins with the 1931 orange rind case.[14] On March 10, 1925, Messrs. Brogden and Crowbridge received United States Letters Patent 1,529,461. Presumably, the patent issued without fanfare. It was predicated on the discovery that impregnation of the rind of oranges with very small amounts of borax rendered the orange resistant to blue mold decay. Patent claim 26 covered: "Fresh citrus fruit of which the rind or skins carries borax in amount that is very small, but sufficient to render the fruit resistant to blue mold decay."[15] Both the district court and the court of

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11. *E.g.*, Galileo.

12. Diamond v. Chakrabarty, 477 U.S. 303 (1980).

13. The basic criteria of patentability are novelty, usefulness, and non-obvious subject matter. *See* 35 U.S.C. §§ 101, 102 & 103 (1984).

14. American Fruit Growers, Inc. v. Brogdex, 283 U.S. 1 (1931).

15. *Id.* at 6. Claims of a patent are like the metes and bounds of property description, and

appeals held that this claim was valid and infringed. The defendant used the borax impregnation process but argued that claim 26 defined nothing more than a natural fruit. The patentee argued that, since the product was a combination of the natural fruit and the borax carried by the rind or skin, the complete article was not found in nature and was properly patentable. The United States Supreme Court reversed the court of appeals' and found the product not patentable.[16] The Court stated:

> Addition of Borax to the rind of natural fruit does not produce from the raw material an article for use which possesses a new or distinctive form, quality, or property. The added substance only protects the natural article against deterioration by inhibiting development of extraneous spores upon the rind. There is no change in the name, appearance, or general character of the fruit. It remains a fresh orange fit only for the same beneficial uses as theretofore.[17]

The Court seemed to hold that to avoid application of the product of nature doctrine, the product must possess a new and distinctive form, quality or property; it must exhibit a change in name, appearance, or general character. Though the Court's actual decision concluded that a borax impregnated orange was not a new article of manufacture but only a product of nature, there was little logic in the decision.[18] The court of appeals' view that such oranges were not found in nature in the patented form seemed unrefuted. Nevertheless, the principle of law that products of nature were not patentable remained firm and accepted.

2. *Deveined Shrimp*

In the next significant decision, *Ex parte Grayson*,[19] the patent application claim covered fresh shrimp from which the head and sand vein had been removed. The patent examiner rejected the claim on the ground that the product did not differ from ordinary shrimp of commerce. The patent applicant argued that the removal of the sand vein rendered his deveined shrimp different from those ordinarily available. Citing *American Fruit Growers*, the board of appeals stated:

> The claim has also been rejected as in substance defining a product of nature, under authority of the decision in the case of *American Fruit Growers, Inc. v. Brogdex Co.* Applicant is not claiming the whole shrimp. However, the part he is claiming is still in its natural state, which has been changed in no manner. We consider this ground of rejection to be

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are the measure of the patent grant. 35 U.S.C. § 112 (1984).

16. American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11-14 (1983).

17. *Id.* at 11-12.

18. It could be argued that the orange was not changed in "general character," but in reality it was since it was combined with borax, a non-natural substance.

19. *Ex parte* Grayson, 51 U.S.P.Q. (BNA) 413 (PTO Bd. App. 1941).

sound.[20]

Presumably, a shrimp with some parts removed still had all of its remaining parts intact as they existed in nature. Nothing which remained was unchanged in its general character from its natural state. This decision seems more defensible than the orange rind case because in the latter man intervened and added borax to the orange rind. Here, however, man intervened only to eliminate something from the shrimp carcass; the flesh of the shrimp remained natural. Thus, there was no novel combination.

B. *Justice Frankfurter's Foresight*

Funk Brothers Seed Co. v. Kalo Inoculant Co.[21] dealt with U.S. Patent No. 2,200,532, issued May 14, 1940. The patent concerned an inoculant for leguminous plants. The inoculant contained six non-inhibitive strains of bacteria of the genus *Rhizobium;* none of the six strains was affected by the others with respect to its ability to fix nitrogen in legumes. In its broadest sense the claim defined a mixture of six bacteria for use in fixing nitrogen in legumes. The patentee took all six strains which were known to aid in nitrogen fixation and combined them into a single inoculant, which he packaged and sold. The Seventh Circuit Court of Appeals,[22] in reversing the district court, held the claim valid. The Supreme Court reversed, reasoning that the inventor did no more than take six strains of *Rhizobium*, which existed in nature, and aggregate them.[23] The Court reasoned:

> Discovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect to the properties of either is a discovery of their qualities of non-inhibition. It is no more than the discovery of some of the handiwork of nature and hence is not patentable. The aggregation of select strains of the several species into one product is an application of that newly-discovered natural principle. But however ingenious the discovery of that natural principle may have been, the application of it is hardly more than an advance in the packaging of the inoculants. Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.[24]

20. *Id.* at 414 (citations omitted).
21. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).
22. Funk Bros. Seed Co. v. Kalo Inoculant Co., 161 F.2d 981 (7th Cir. 1947).
23. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. at 132.
24. *Id.* at 131.

In writing the majority opinion, Justice Douglas seemed to reaffirm the orange rind case *in toto*. Interestingly, however, he did not cite it.

Justice Frankfurter concurred in the result but chose to base his decision on something other than the product of nature doctrine. He criticized the doctrine as follows:

> It only confuses the issues, however, to introduce such terms as "the work of nature" and "the laws of nature." For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed "the work of nature," and any patentable composite exemplifies in its properties "the laws of nature." Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent.[25]

Had Frankfurter's concurring opinion been heeded, much confusion in the law could have been avoided. But alas, it was not, and confusion abounded for thirty years.

C. *The Exceptions to the Products of Nature Doctrine*

1. *Non-Living Subject Matter*

In the years following *Funk Brothers*, the courts gradually developed exceptions to the products of nature doctrine. If the products of nature were altered, from the standpoint of purity, crystalline phase, optical isomer, admixture with diluents, or critical percentage ranges needed for operability,[26] the courts would allow composition claims. Put another way, if any of the physical or chemical attributes of the naturally occurring compound, composition, or product of nature were changed in any way to provide a claim which pertained to novel subject matter and had new utility, the claims were allowed.[27]

Merck & Co. v. Chase Chemical[28] illustrates this point. In *Merck* the invention was crystalline vitamin B-12. Merck successfully convinced both the Patent Office and the courts that crystalline vitamin B-12 never existed before, albeit vitamin B-12 *per se* had existed previously. Essential to Merck's theory was the fact that crystalline vitamin B-12 had properties different from those of vitamin B-12 as it exists in nature.[29]

Neither the courts, nor the Patent Office, nor the public had any objection to creating exceptions to the products of nature doctrine as long as the patented subject matter was non-living. For example, even if chemical com-

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25. *Id.* at 134-35 (Frankfurter, J., concurring).

26. This aspect of the product of nature doctrine is discussed in detail in Sease, *Chemical Properties: Are They a Sensible Legal Yardstick of Patentability*, 26 DRAKE L. REV. 39 (1977).

27. *Id.* at 51.

28. Merck & Co. v. Chase Chem., 273 F. Supp. 68 (D.N.J. 1967).

29. *Id.* at 83-84.

pounds existed in nature, they nevertheless were routinely held patentable if they existed in a different form after man's intervention.[30] The leap in logic was easily made where non-living, modified natural products were concerned. But the courts refused to apply the same reasoning to living organisms. The point is illustrated by *In re Merat*.[31]

2. *The Dwarf Chicken Case*

In *Merat* the patent applicants discovered in chickens a gene for dwarfism which allowed production of dwarf breeding hens. These dwarf hens could be mated with normal roosters. The resulting eggs produced normal and desirable heavy meat offspring. Cost savings resulted, since the dwarf hens were used solely for breeding purposes and did not consume much feed. In the patent application, claim 1 covered the process for producing normal chickens from dwarf hens. Claim 2 related to the product of the process itself, *i.e.*, a normal chicken descended from a dwarf hen.[32] These claims were rejected because they lacked utility and they related to non-statutory subject matter. The Patent Office Board of Appeals and the patent examiner held that claim 1 did not cover a patentable process within the meaning of 35 U.S.C. § 101,[33] and that a thing occurring in nature (*i.e.*, a normal chicken produced by the process described in claim 2) was not an article of manufacture.[34]

In a classic case of sidestepping, the Court of Customs and Patent Appeals avoided the whole issue of patentability of a living organism, and rejected the patent application on the basis of defects in the claims under 35 U.S.C. § 112.[35]

The lesson of the chicken case was clear. Applications for patents which related to living organisms, whether simple or complex, would find it difficult to pass through the United States Patent Office. Because of the variability which is inevitable in the reproduction of organisms, attempts to patent the results of reproduction would be doomed to failure under 35 U.S.C. § 112.

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30. *See id.*

31. *In re* Merat, 519 F.2d 1390 (C.C.P.A. 1975).

32. *Id.* at 1392.

33. 35 U.S.C. § 101 (1984) defines the categories of patentable subject matter, which are: compositions of matter, machines, articles of manufacture, processes, and improvements of each.

34. *In re* Merat, 519 F.2d at 1392.

35. *Id.* at 1396. 35 U.S.C. § 112 requires that patent claims particularly point out and distinctly claim the subject matter which the applicant regards as his invention. However, since there is some inherent uncertainty in breeding practices, for some time the Patent Office used this "sidestep" to avoid more difficult substantive issues.

3. *The Strawberry Case*

In the movie *The Caine Mutiny*, Humphrey Bogart passionately pursued the thieves of his strawberry preserves. In a similar manner, inventors Kratz and Strasburger pursued a patent on the flavor ingredients of strawberries. They discovered that a compound known as 2-methyl-2-pentanoic acid was an active ingredient in natural strawberries. When extracted, purified, and added in small amounts to fresh fruit, the compound imparted strawberry flavor. The claimed invention was a process for imparting strawberry flavor. A reissue application was rejected on the basis of obviousness since the compound used in the flavor-imparting process was known to be a natural constituent of strawberries. Citing *In re Bergstrom*,[36] which allowed claims to purified prostaglandins, and *Merck*, which allowed claims to crystallized vitamin B-12, the court reversed the Patent Office's rejection of the claims. The court held that the claimed pure materials were novel by comparison with the less pure materials of the references.[37] The court explained:

> It should be clear that an anticipation rejection in such a case is necessarily based on a dual footing. First, the natural composition must inherently contain the naturally occurring compound. Secondly, the claim must be of sufficient breadth to encompass both the known natural composition and the naturally occurring compound.[38]

The court concluded that the claims before it (like the claims to the prostaglandin in *Bergstrom* and the claims to vitamin B-12 in *Merck*) did neither.[39] In short, in the area of non-living products of nature, the line was bright. *Any* modification from nature properly defined in the claims would avoid rejection on the ground of lack of novelty.

4. *Living Organisms—The CCPA View in 1979*

In an exhaustive opinion covering two cases, *In re Bergy* and *In re Chakrabarty*,[40] the Court of Customs and Patent Appeals (CCPA)[41] found itself playing Ping-Pong with decisions. The procedural background is outlined in the joint decision by Judge Rich.[42] The court's earlier decision, *In re Bergy*,[43] had reversed the Patent Office and held that a pure culture of a living organism was patentable. In *In re Chakrabarty* a similar claim had

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36. *In re* Bergstrom, 427 F.2d 1394 (C.C.P.A. 1970).
37. *In re* Kratz, 592 F.2d 1169, 1174 (C.C.P.A. 1979).
38. *Id.*
39. *Id.*
40. *In re* Chakrabarty, 596 F.2d 952 (C.C.P.A. 1979).
41. The Court of Customs and Patent Appeals was the predecessor of the Court of Appeals for the Federal Circuit, which now has jurisdiction of all patent appeals. 28 U.S.C.A. § 1295 (West Supp. 1988).
42. *In re* Chakrabarty, 596 F.2d at 956.
43. *In re* Bergy, 563 F.2d 1031 (C.C.P.A. 1977).

received the same treatment.[44] However, in the interval between these two decisions, the United States Supreme Court had handed down *Parker v. Flook*.[45] The Supreme Court had then granted certiorari in *In re Bergy* and remanded that case for reconsideration in view of its decision in *Parker v. Flook*.[46]

On remand the CCPA concluded that *Parker v. Flook* had nothing whatsoever to do with the issues before it.[47] The earlier *Bergy* and *Chakrabarty* opinions were withdrawn, and a new, very scholarly opinion was substituted for both.[48] That opinion held that the biologically pure culture of microorganisms involved in *In re Bergy* was patentable, and that the genetically engineered microbe involved in *Chakrabarty* was also patentable.[49] The CCPA found that living organisms were statutory subject matter within the meaning of 35 U.S.C. § 101, and that the fact that they were living was irrelevant to the issue of patentability.[50] The CCPA rejected the argument that the Plant Patent Act of 1930[51] demonstrated an intent that the only living organisms to be afforded patent protection were asexually produced plants. The CCPA reasoned that the legislative history of the Act indicated that Congress was concerned solely with plants and did not intend to legislate with respect to other things.[52] The CCPA rejected the Patent Office's argument that a decision that living organisms were patentable subject matter overextended the patent laws (citing Chicken Little's cry that the sky was falling).[53] The court also noted that prior patents had been routinely issued for bacteria, yeasts, and viruses in compositions which were arguably living subject matter.[54] The court even chastised the Patent Office for supporting its contentions "with bits and pieces from wholly unrelated plant-patent legislation from nearly half a century ago."[55] The Patent Office was reminded of the mandate set forth in *United States v. Dubilier Condensor Corp.*,[56] wherein the Supreme Court stated: "We should not read into the patent laws limitations and conditions which the legislature has not expressed."[57]

And so the stage was set. The CCPA, as everyone expected, wholeheart-

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44. *See In re* Chakrabarty, 571 F.2d 40 (C.C.P.A. 1978).
45. Parker v. Flook, 437 U.S. 584 (1978). The decision involved a series of computer program patentability cases, and mentioned in passing 35 U.S.C. § 101.
46. Parker v. Bergy, 438 U.S. 902 (1978).
47. *In re* Bergy, 596 F.2d at 965-66.
48. *Id.* at 957.
49. *Id.* at 987.
50. *Id.* at 975.
51. 35 U.S.C. § 161 (1984).
52. *In re* Bergy, 596 F.2d at 982-83.
53. *Id.* at 984.
54. *Id.* at 985-86.
55. *Id.* at 987.
56. United States v. Dubilier Condensor Corp., 289 U.S. 178 (1933).
57. *Id.* at 199.

edly endorsed the patentability of claims if they met the criteria of 35 U.S.C. §§ 101, 102, and 103, without regard to whether the claimed subject matter was alive.[58]

III. *Diamond v. Chakrabarty*[59]

In 1972, Chakrabarty, a microbiologist, filed a patent application based upon his discovery that a bacterium of the genus *Pseudomonas*, when genetically engineered, was capable of successfully "eating" oil spills. This property was possessed by no known naturally occurring bacteria. As part of his invention Chakrabarty claimed the genetically altered bacterium. The claims were initially rejected by the United States Patent Office. Chakrabarty appealed, and the Patent Office Board of Appeals affirmed.[60] The CCPA reversed[61] on the authority of its prior decision in *In re Bergy*,[62] which held that whether microorganisms are alive is without legal significance for purposes of the patent law.[63] After the Supreme Court vacated *Bergy*, the CCPA reaffirmed the patentability of the microorganism claims in *Chakrabarty*.[64] The Supreme Court granted certiorari in both cases.[65] At the time of the decision, only *Chakrabarty* was left. The Court distinguished *Funk Brothers*, stating: "Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature, and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly, it is patentable subject matter under § 101."[66] The Court summarily rejected the argument that the 1930 Plant Patent Act was the sole means of protection of discoveries concerning living organisms.[67] Social and public policy concerns militating against the patentability of living organisms were similarly rejected:

> The legislative process, the [government] argues, is best equipped to weigh the competing economic, social, and scientific considerations involved, and to determine whether living organisms produced by genetic engineering should receive patent protection. In support of this position the [government] relies on our recent holding in *Parker v. Flook* . . . and the statement that the judiciary "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress." . . .
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> It is, of course, correct that Congress, not the courts, must define the

58. *In re* Bergy, 596 F.2d at 986.
59. Diamond v. Chakrabarty, 447 U.S. 303 (1980).
60. *In re* Bergy, 596 F.2d at 956.
61. *In re* Chakrabarty, 571 F.2d 40 (C.C.P.A. 1978).
62. *In re* Bergy, 563 F.2d 1031 (C.C.P.A. 1978).
63. *Id.* at 1038.
64. *In re* Bergy, 596 F.2d 952 (C.C.P.A. 1979).
65. *In re* Chakrabarty, 444 U.S. 924 (1979).
66. Diamond v. Chakrabarty, 447 U.S. at 310.
67. *Id.* at 311.

> limits of patentability; but it is equally true that once Congress has spoken it is "the province and duty of the Judicial Department to say what the law is." . . . Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in construing the language Congress has employed. In so doing, our obligation is to take statutes as we find them, guided, if ambiguity appears, by the legislative history and the statutory purpose. Here, we perceive no ambiguity. The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting "the Progress of Science and the useful Arts" with all that means for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad terms.
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> It is argued that this Court should weigh [the] potential hazards in considering whether respondent's invention is patentable subject matter under § 101. We disagree. The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more that Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.[68]

In short, with elegance, style, and the stroke of a pen, Chief Justice Berger's opinion brought the patent law to the place where Watson and Crick found themselves in 1953.

IV. Post-*Chakabarty* Developments

A. *Plants*

The Supreme Court decision in *Diamond v. Chakrabarty,* coupled with *Ex parte Hibbard,*[69] gave plant patent applicants the option of seeking utility patents under 35 U.S.C. § 101 to protect a novel variety. The advantage of a utility patent is, of course, that it is broader than the protection afforded by the Plant Patent Act of 1930[70] and the Plant Variety Protection Act of 1970.[71] In short, *Hibbard* did for plants what *Diamond v.*

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68. *Id.* at 314.

69. *Ex parte* Hibbard, 227 U.S.P.Q. (BNA) 443 (PTO Bd. App. & Int. 1985).

70. 35 U.S.C. §§ 161-164 (1982). The Plant Patent Act of 1930 provides protection for asexually reproduced plants.

71. 7 U.S.C. §§ 2321-2582 (1982). The Plant Variety Protection Act of 1970 provides patent-like protection for new, distinct, uniform, and stable varieties of sexually reproduced plants, except for fungi, bacteria, tuber-propagated, or uncultivated plants, and first generation hybrids. The Plant Variety Protection Act is administered by the United States Department of

Chakrabarty did for microorganisms.

In *Hibbard* the Board of Patent Appeals and Interferences ruled that a corn plant which contained an abnormally high level of an amino acid was patentable subject matter.[72] The patent examiner had rejected the application on the basis that utility patent protection of plants was not available under 35 U.S.C. § 101 by reason of the existence of the Plant Patent Act and the Plant Variety Protection Act. Not surprisingly, in view of *Diamond v. Chakrabarty*, the Board of Patent Appeals and Interferences rejected this argument and held that the availability of one form of statutory protection does not preclude the availability of protection in another form.[73] Following *Hibbard*, the Patent Office now routinely grants utility patents on plants if they meet the requisite criteria of novelty, utility, and non-obviousness.[74] Since this protection is broader than that available under the Plant Variety Protection Act and the Plant Patent Act, prudence dictates that a developer should apply for a utility patent if possible.

B. *Oysters*

In *Ex parte Allen*[75] the inventor filed a patent application claiming the invention of polyploid oysters (oysters which have three sets of chromosomes rather than the normal two). Their advantage was that they were sterile and grew much larger than normal oysters. The examiner rejected the oyster claims on the basis that they were living organisms. The examiner reasoned that the oysters were living entities which did not fall within the statutory subject matter of 35 U.S.C. § 101, and cited *In re Merat*.[76] The Board of Appeals and Interferences reversed the examiner's decision and reminded the Patent Office that the expansive terms "manufacture" and "composition of matter" which appear in the patent statute are modified by the comprehensive word "any," which indicates that Congress plainly contemplated that the patent laws would be given wide scope.[77] Further, the Board noted that the legislative history of § 101 supported a broad construc-

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Agriculture. The protection provided by the Act is narrower than utility patents because, under the "research exemption," a breeder cannot exclude others from using the protected variety to develop varieties, and under the "farmer's exemption," it is not an infringement for individuals whose primary farming occupation is growing crops for sale (for other than reproductive purposes) to save protected seed and use the seed in production of crops on their farms. There are no such exemptions for plants if the developer obtains patent protection under 35 U.S.C. § 101 (a conventional utility patent).

72. *Ex parte* Hibbard, 227 U.S.P.Q. (BNA) at ____.

73. *Id.* at 446.

74. For example, see U.S. Patent No. 4,406,089, assigned to Pioneer Hi-Bred International, Inc., for a genetically altered wheat seed.

75. *Ex parte* Allen, 2 U.S.P.Q. (BNA) 1425 (PTO Bd. App. & Int. 1987).

76. *In re* Merat, 519 F.2d 1390 (Cust. Ct. 1975).

77. *Ex parte* Allen, 2 U.S.P.Q. (BNA) at ____ (citing Diamond v. Chakrabarty, 447 U.S. at 308).

tion of the patent laws.[78] The Board concluded that *Diamond v. Chakrabarty* made it clear that 35 U.S.C.§ 101 includes man-made life forms:

> The issue, in our view, in determining whether the claimed subject matter is patentable under § 101 is simply whether the subject matter is made by man. If the claimed subject matter occurs naturally it is not a patentable subject under § 101. The fact urged by the Examiner that oysters produced by the claimed method are "controlled by the laws of nature" does not address the issue of whether the subject matter is a non-naturally occurring manufacture or composition of matter. The Examiner has presented no evidence that the claimed polyploid oysters occur naturally without the intervention of man, nor has the Examiner urged that the polyploid oysters occur naturally. The record before us leads to no conclusion other than the claimed polyploid oysters are non-naturally occurring manufactures or compositions of matter within 35 U.S.C. § 101. Accordingly, their rejection under § 101 must be reversed.[79]

The Board went on to conclude that the particular claims before it were unpatentable for reasons other than the fact that the oysters were living.[80] At last, the Patent Office position was consistent with scientific reality with respect to multi-cellular animals, single-cell microorganisms, and plants. The surrender of the Patent Office was signified by a notice in the *Official Gazette*.[81] The notice said simply:

> The Patent and Trademark Office now considers non-naturally occurring non-human multi-cellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. § 101 . . . . A claim directed to or including within its scope a human being will not be considered to be patentable subject matter within 35 U.S.C. § 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multi-cellular organism which would include a human being within its scope include that limitation "non-human" to avoid this ground of rejection.[82]

Presumably the mandate limiting the claims to non-human organisms is necessary to avoid running afoul of the thirteenth amendment, which abolished slavery.[83]

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78. *Id.* (citing Diamond v. Chakrabarty, 447 U.S. at 308-09).

79. *Id.* at 1427.

80. *Id.* at ____.

81. The *Official Gazette of the United States Patent Office* is a weekly Patent and Trademark Office publication listing rule changes and describing new patents which have been issued.

82. 1077 OFFICIAL GAZETTE PAT. OFF. 24 (April 7, 1987).

83. U.S. CONST. amend. XIII § 1 provides: "Neither slavery nor involuntary servitude . . . shall exist within the United States . . . ."

C. *The Harvard Mouse*

With great fanfare, the United States Patent Office issued its first patent on a multi-cellular living organism on April 12, 1988.[84] The patent was assigned to Harvard, and the patented mouse has become "the Harvard mouse." The patent related to a genetically altered mouse which is highly susceptible to cancer. Because it develops cancers so rapidly, the Harvard mouse presumably can serve as a more effective model for studying how genes contribute to the development of cancer. Thus, the lowly Harvard mouse extended the frontiers of patentability to include multi-cellular organisms.

D. *Transgenic Animal Patent Reform Act of 1988*

Congress has responded to the high level of public interest and emotion surrounding the patenting of life forms with numerous bills[85] such as the Transgenic Animal Patent Reform Act (H.R. 4970).[86] The Act provides for an exemption which allows farmers to reproduce patented transgenic farm animals through breeding for use in the farming operation or for sale.[87] The farmer's exemption does not apply, however, if the germ cells, the semen, or the embryos of the patented transgenic animal are sold without the permission of the patent owner.[88] Farm animals are defined as animals used or intended for use as food or fiber.[89]

The granting of patents for transgenic animals by the Patent Office is unaffected by the proposed Act, but the rights which patent owners obtain are limited by the farmer's exemption. The farmer *is* allowed to breed farm animals and sell the offspring of that breeding, *but* the farmer becomes an infringer if he enters into direct competition with the patent holder by selling the embryos, germ cells, or semen of the patented animal.

None of the proposed bills were passed into law before Congress recessed in 1988, but it is reasonable to expect that strong lobbying will pro-

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84. U.S. Patent No. 4,736,866.

85. While Congress recessed without enacting any legislation concerning the patenting of animals, it was nevertheless active. After the Patent Office announced its intention to issue patents on non-human animals, Rep. Robert W. Kastenmeier (D. Wis.) requested an eight-month moratorium on animal patenting, to which the Patent Office agreed. On April 12, 1988, after the moratorium expired, the Harvard mouse patent issued. On June 30, 1988, Rep. Kastenmeier introduced H.R. 4970. On September 13, 1988, H.R. 4970 was passed by the house on a voice vote. The full text of H.R. 4970, as well as the floor remarks and legislative history, appears at H.R. 4970, 100th Cong., 2d Sess., 134 CONG. REC. H7436-39 (daily ed. Sept. 13, 1988). The legislative history contains the views of many private groups, from religious organizations to industrial associations. For those interested in the subject, it is essential reading.

86. H.R. 4970, 100th Cong., 2d Sess., 134 CONG. REC. H7436 (daily ed. Sept. 13, 1988) (proposed 35 U.S.C. § 271(g)).

87. *Id.* (proposed 35 U.S.C. § 271(g)(1)).

88. *Id.* (proposed 35 U.S.C. § 271(g)(2)).

89. *Id.* (proposed 35 U.S.C. § 271(g)(3)(B)).

duce a law similar to, if not identical with, H.R. 4970.

And so, the federal patent laws are about to be extended into uncharted territory. One wonders whether the excitement which Watson and Crick felt when they successfully unraveled the structure of DNA in 1953 could possibly have exceeded the excitement felt in 1988 when the incentives of the patent system were becoming fully applicable to the emerging possibilities of biotechnology.

V. Obvious Industries Impacted

It is likely that the immediate impact of biotechnology patents on multicellular organisms will be felt in three primary areas: agriculture, health care products, and the chemical industry. It is interesting to consider, without attempting to be exhaustive, some of the obvious economic and legal impacts which patentability of life-forms will have on these important industries.

A. *Agriculture*

The impact on agriculture can be logically divided into two major areas: livestock and crops. While most of the emotion-filled publicity has so far dealt with living animals, the long-range impact of utility patents on plants and crops is apt to be just as great, if not greater. However, the public press currently seems most interested in animal issues.

1. *Livestock*

Notable segments of the livestock market include the production of meat, poultry, and dairy products, as well as spinoff products such as wool and leather. It is conceivable that cattle and hogs will be significantly genetically altered to provide higher yields of meat which is more nutritional, *i.e.*, lower in fat and cholesterol. The precise form of such genetic alterations is unimportant for this discussion; the point is that they will occur. With this occurrence, patents will issue.

Similarly, poultry (*i.e.*, chickens, turkeys, ducks, etc.) will be genetically altered to maximize meat, egg, and even feather production. Likewise, one can realistically expect that dairy cows will be altered to produce maximum yields of milk. Finally, it is not unreasonable to expect that biotechnology experts will be successful in altering the genetic makeup of hide-producing animals to maximize production of the hides of animals such as cows and sheep. These changes will follow on the creation of new, genetically separate and distinct living organisms capable of self-propagation. These new organisms will be patented.

These inevitable changes have produced an emotional upsurge of public reaction. To some they are equivalent to tinkering with the very concept of

creation—an activity so frightening that it should be legislatively banned.[90] To others they have an exciting potential for fulfilling many of the needs of mankind. To still others they are nothing more than another form of environmental pollution.

Should there be constraints on scientific experimentation with, or industrial exploitation of, these developments? If so, who shall regulate them? Who shall decide? Some say that questions concerning the issuance of animal patents are ethical, rather than technical. Perhaps the most pessimistic view was expressed by Jerome Rifkin, President of the Foundation of Economic Trends, who stated that animal patents "could lead to the exploitation of all living things by corporations for commercial gain."[91] Rifkin forecast the development of a new era in tenant farming, in which farmers will lease their plants and animals as well as their land.[92]

Many stress the potentially negative impact of biotechnology on the family farm, and in doing so, combine two emotionally charged issues. It seems that this connection is more emotional than logical. It is just as logical to emphasize the potential benefits of this new technology, such as decreased use of expensive and polluting herbicides and insecticides, and increased yields at lower costs.

2. *Plants and Row Crops*

Interestingly, recent developments in living organism patents have emphasized animals as opposed to plants. Moreover, historical experience under the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act has largely been ignored in predicting future consequences. Since nurseries and seed companies have not extensively used either the Plant Patent Act or the Plant Variety Protection Act, judicial interpretations of those acts are rare. One reason for this may be the fact that limitations under the Plant Patent Act (which applies only to asexually reproduced and non-tuber-propagated plants) and the Plant Variety Protection Act (which allows a farmer's exemption and a research exemption) have made these forms of protection of little interest. However, since *Hibbard* allows general utility patents on plants (without any of these limitations), it can reasonably be expected that both seed companies and nurseries will now rely to a much greater extent on patent protection. It is certain that the emerging plant biotechnology industry will rely heavily upon utility patents. Predictably, as utility patents issue in the future for major row crops such as soybeans and

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90. *Id.* at H7438.

91. These views were expressed at hearings conducted by the Subcommittee on Courts, Civil Liberties, and the Administration of Justice, held in Madison, Wisconsin, on November 5, 1987. *Patents and the Constitution: Transgenic Animals: Hearings on H.R. 4970 Before the Subcomm. on Courts, Civil Liberties, and the Administration of Justice of the House Comm. on the Judiciary*, 100th Cong., 1st Sess. ___ (1987).

92. *Id.*

corn, increasingly aggressive intellectual property litigation will be used to protect new plant varieties. One can guess that genetic engineering will lead to the development of disease resistant crops, high yield crops, and crops which produce high yields of desirable chemical byproducts. The biotechnology companies will also be in the forefront of developing biological controls for plant pathogens. Genetically altered organisms which produce extracellular chemicals will be used for biological control of plant pathogens. Thus, the costs of herbicides and insecticides, as well as the pollution which they produce, could both be avoided.

Obviously, developments like these fit nicely into the conceptual framework of utility patents and are clearly protectable under *Diamond v. Chakrabarty*. As high risk venture capital biotechnology companies aggressively patent their research efforts, the more reluctant seed companies and nurseries will be forced to follow suit. Increasing awareness of and use of the patent system will probably make these industries more aggressively competitive and bring rapid, dramatic advances.

B. *Health Care Products*

The pharmaceutical industry has been one of the most patent-conscious industries, thanks to the high development costs of pharmaceuticals and the length and expense of the process of obtaining FDA approval. A simple check of the indices to patent cases reveals that the pharmaceutical companies have been very active in patent litigation. Moreover, since many of the emerging biotechnology companies are owned in part by pharmaceutical houses or engaged in joint ventures with pharmaceutical houses, one can expect increased aggressiveness in seeking and protecting discoveries via patents. These industries have already produced marketable products. For example, the insulin produced by fermentation of genetically altered *E. coli* bacteria is now a commercial product.

Litigation has already been reported in this area. In *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*,[93] the Court of Appeals for the Federal Circuit held that Hybritech's patent on a sandwich assay technique for using monoclonal antibodies for diagnostic purposes was valid and infringed.[94]

A bitter battle currently rages between Scripps Institute and Genentech over the Scripps Institute's patent on natural Factor VIII.[95] In that case, one issue is whether a product which results from genetic engineering infringes a patent on the isolated natural product. Products now under development include interleukin 2 (IL-2, an anti-cancer agent); tPA (an enzyme which dissolves blood clots, useful in treating heart attack patients); and EPO (er-

93. Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367 (Fed. Cir. 1986).

94. *Id.* at 1376-78.

95. Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379 (N.D. Cal. 1987).

thropoietin, useful in treating anemia associated with dialysis).[96]

Four protein products produced through recombinant DNA technology are already on the market: human growth hormone, human insulin, alpha interferon, and a hepetitis B vaccine. Many more products are on the way. *Chemical Engineering and News* reports that some of them will have annual sales in the range of hundreds of millions of dollars.[97] It is in this area—health care—that biotechnology seems to have moved most rapidly. Intellectual property litigation has kept pace: courts have had to decide difficult legal issues which have compelled judges and juries to attempt to comprehend recombitant DNA technology. The increase in capital investment in biotechnology has made names such as Genetech, Cetus, Amgen, Xoma, and Hybritech close to household words. The *Wall Street Journal* reports on the activities of these corporations frequently, and independent biotechnology publications, such as *Biotech Investor*, routinely spring forth. The stocks of these companies have fluctuated widely in price, and some, like Hybritech, have been swallowed by established pharmaceutical houses.

It is not unreasonable to predict that this expansion in biotechnology will continue. There will be increased infusions of capital, increased efforts to patent the results of scientific enterprise, and rapid development of new products. The industry will continue to lead the way for other segments of biotechnology in which market entry barriers are not nearly as great, *e.g.*, basic agriculture.

C. *The Chemical Industry*

Within the chemical industry, many manufacturers of applied products are totally dependent upon raw chemicals supplied by others. These raw chemical producers, such as Monsanto (famous for herbicides and insecticides), American Cyanamid, Union Carbide, Quantum Chemical, Dow, and 3M (to name a few), will undoubtedly double and redouble their efforts. It is reasonable to expect that companies like Monsanto will be on the forefront of development of biological controls for pathogens in order to protect the markets they have already established for herbicides and insecticides. It is also reasonable to expect that most raw chemical producers will necessarily invest in efforts to patent biological production of some products they are now producing, and of new products which will compete with raw chemicals they are currently producing. Will all of this be for the public good? Extrapolating from other maturing industries which have gone through such periods, one can answer with a resounding "yes."

At the same time that Watson and Crick were working in England to discover the structure of DNA, Dr. Karl Ziegler at the Max Planck Institute in Germany and Dr. Giulio Natta at Montedison in Italy were developing

96. CHEM. ENG'G & NEWS, *supra* note 3, at 11-12.
97. *Id.* at 12.

stereo regulated polymers of alpha-olefins.[98] For their efforts the duo shared the 1963 Nobel Prize for Chemistry. Their discovery has resulted in years of patent litigation, which still continues. But more to the point, what followed was the creation of new markets and new products, predicated on polymers of ethylene and propylene. The result was untold numbers of new plants and jobs and the development of multi-billion-dollar markets which did not previously exist. We stand today on the threshold of an advance in biotechnology similar to that which occurred in the field of polymerized plastics in the 1950s, 1960s, and 1970s. As before, patent system incentives will play an important role.

VI. Public Policy Considerations

A. *Ethics*

There are those who view the issuance of animal patents as an ethical—rather than a legal—issue. This group includes certain religious leaders, animal rights activists, certain farm organizations, and some educational organizations. Among them they include those who place a high value on the preservation of the integrity of species, those who object to tinkering with God's creation, those who fear that scientists will become Frankensteins, those who fear biological pollution of our environment, and those who fear that patents will restrict freedom of academic research. Representatives of many of these groups routinely testify in hearing before Congress.[99]

The courts have uniformly refused to use the patent laws to regulate morality. In *Ex parte Murphy*,[100] for example, the Board of Appeals rejected an argument that an invention lacked utility because it related to gambling devices (slot machines) which were illegal.[101] In rejecting this argument the Board of Appeals noted that Colt's famous revolver arguably lacked legal utility and was, therefore, not patentable.[102] Obviously, Colt's revolver was used for both good and evil. However, it was not the revolver, but what man chose to do with it, which resulted in evil. Similarly, the Patent Office has rejected attempts to use the patent law utility requirement to impose safety and efficacy regulations like those promulgated by the FDA.[103] In short, courts have held, and presumably will continue to hold, that tech-

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98. For an interesting account of these equally dramatic developments, see McMillan, The Chain Straighteners (1979).

99. Hearings on the proposed Transgenic Animal Patent Reform Act of 1988 were conducted in Madison, Wisconsin, on July 11, 1987, July 22, 1987, August 21, 1987, and November 5, 1987. The witnesses represented the administration, various business and farm organizations, patent lawyers, animal rights activists, ethicists, environmentalists, academics, researchers, and religious organizations.

100. *Ex parte* Murphy, 200 U.S.P.Q. (BNA) 801 (PTO Bd. App. & Int. 1977).

101. *Id.* at ____.

102. *Id.* at ____.

103. *See In re* Hartop, 311 F.2d 249 (Cust. Ct. 1962).

nology is neutral, not moral or immoral. To hold otherwise would represent a dangerous intrusion upon first amendment rights. Moreover, what is moral or immoral constantly changes as the norms of society change. Yesterday's immoral birth control devices are routinely accepted today. Yesterday's immoral and illegal abortion practices are today, not only accepted, but also constitutionally protected.[104]

The nuclear energy industry provides a useful lesson. While nuclear energy is neither moral or immoral, it has both destructive potential and beneficial potential. In fact, history shows that man has used nuclear energy both destructively and beneficially. Accordingly, nuclear energy patents have been regulated.[105] Specifically, the regulations prohibit patents whose usefulness is limited to the production of special nuclear material or atomic energy in an atomic weapon. While it would be naive to believe that this statute has diminished the worldwide nuclear threat, it *has* diminished the threat from private industry. In short, where knowledge exists, the threat of immoral use is ever-present. But the fault lies not with the knowledge, but with man. Proper legislation can provide incentives for beneficial use and reduce the risk of evil use.

B. *A Proper Perspective*

The public needs to be reminded that the recent developments in biotechnology are not as new as they seem. For example, viruses have been attenuated (through repetitive culture growth) and harvested for many years.[106] This process was the basis of the Salk polio vaccine.[107] Recombinant DNA technology merely offers an opportunity to attain the same result more quickly. Selective breeding of livestock has been practiced for years in order to emphasize desirable genetic characteristics and diminish undesirable genetic characteristics. Genetic engineering, again, simply offers the opportunity to do the same thing more rapidly. Likewise, plant breeding has allowed us to develop today's large ear hybrid seed corn—a vast improvement over the Indian maize of many years past. Hybrid seed corn exemplifies species alteration at its best. Furthermore, such hybridization is merely an extension of a process which has been occurring naturally since the beginning of time.

Species alteration cannot be stopped as long as there is life. The question is, therefore, not whether it will occur, but whether it should occur

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104. Roe v. Wade, 410 U.S. 113 (1973). *But see* Webster v. Reproductive Health Servs., 109 S. Ct.3040 (1989).

105. 42 U.S.C. § 2181 (1982).

106. *See* Diamond Scientific Co. v. Ambico, Inc., 848 F.2d 1220 (Fed. Cir. 1988) (patents for attenuated virus vaccines for swine were litigated based upon a patent application filed in 1964).

107. Jonas A. Salk received the Congressional Gold Medal for Great Achievement in Medicine for his 1954 work on the polio vaccine.

under regulatory controls? And if so, who should do the controlling? This is certainly not the role of the Patent and Trademark Office. It may be the role of other regulatory agencies such as the FDA, the USDA, and the states under their reserved police powers.[108] But the patent system should not be tinkered with to accomplish what Congress and the respective state legislatures should specifically address in the proper exercise of their powers and duties. Science is responsible, if man is.

VII. Conclusion

Our patent system has served us faithfully since the first patent law in 1790. Soon we will celebrate the two-hundredth anniversary of our United States patent system. At one point, in the 1800s it was suggested that the United States Patent Office should be closed because everything which was new and valuable had already been invented.[109] How wrong! History teaches that today's controversy is often tomorrow's forgotten fact. History further teaches that knowledge must be pursued for the benefit of all mankind, and that mankind will pursue knowledge regardless of inhibitory regulations. The landmark decision in *Diamond v. Chakrabarty* will not change the course of the rapid evolution of biotechnology.[110] But the failure of our courts to adequately protect these developments would have an impact upon the future economic well-being of our nation. Given the strong pro-patent positions currently taken by the Court of Appeals for the Federal Circuit, it is likely that the current trend will continue. To paraphrase Abraham Lincoln: the fuel of incentive provided by the patent system should continue to be added to the fire of biotechnology genius.[111]

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108. The legislative history of the Transgenic Animal Patent Reform Act, which has been passed by the House but not the Senate, reports: "We have not asked—nor should we ask the Patent Office—to act as a health and safety regulatory agency. Concerns about animal welfare can be—and are—addressed in a separate regulatory framework."

109. In 1833 Dr. John D. Craig, Superintendent of the U.S. Patent Office, concluded that "everything seems to have been done," and wanted to resign his post.

110. Even the U.S. Supreme Court recognized this in *Diamond v. Chakrabarty*, 447 U.S. at 317.

111. The author first saw these words over the door of the former U.S. Patent and Trademark Office in Washington, D.C. This language apparently comes from a speech delivered by Abraham Lincoln in Springfield, Illinois, in 1859.