CASE NOTES

PATENTS—A LIVE, MAN-MADE MICRO-ORGANISM IS PATENTABLE SUBJECT MATTER UNDER 35 U.S.C. § 101.—*Diamond v. Chakrabarty* (U.S. Sup. Ct. 1980).

Ananda Chakrabarty, a microbiologist, filed a patent application in 1972 which described a process to create a new, genetically engineered strain of *Pseudomonas aeruginosa* capable of degrading liquid hydrocarbons.[1] Chakrabarty discovered that he could transfer and stably maintain, in a single *Pseudomonas aeruginosa* cell, four different plasmids[2] not originally found in this cell.[3] This new strain of bacteria, with a capacity to degrade four different crude oil components, has significant value in combating oil spills when inoculated into straw and deposited on the spill.[4] Such a capability to degrade multiple oil components is not present in any naturally occurring bacteria.[5]

The patent examiner approved Chakrabarty's claims for the method of producing the micro-organisms, as well as the claims for an inoculum consisting of the bacteria and a carrier material;[6] however, the examiner rejected the claims to the bacteria themselves.[7] Chakrabarty appealed the re-

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1. Diamond v. Chakrabarty, 100 S. Ct. 2204, 2205-06 (1980). The application was assigned to the General Electric Company. *Id.*

2. *Id.* Plasmids are autonomously replicating hereditary units physically distinct from a cell's chromosomes. *Id.* at 2205-06 n.1.

3. *Id.* at 2205-06 n.1.

4. *In re* Bergy, 596 F.2d 952, 970 (C.C.P.A. 1979).

5. *Id.* at 969. Microbial strains do exist that are capable of degrading individual elements of crude oil. *Pseudomonas* and other bacterial species have the capacity to decompose the aliphatic, aromatic and polynuclear aromatic hydocarbon compounds present in crude oil, but any natural strain of bacteria can break down only one individual component of the oil. Prior to Chakrabarty's invention, mixed bacterial strains were used to control oil spills. Each strain was able to degrade only one particular component of the crude oil complex. However, any given bacterial strain differs from others in its growth rate, nutritional, temperature and salt requirements. Therefore, only a small fraction of the initial mixture of bacterial strains survives when mixed cultures are used. As a result, the oil in the spill is not totally degraded. *Id.*

6. 100 S. Ct. at 2206. A beneficial method to disperse the micro-organism is to use straw as a carrier for the micro-organisms. The inoculated straw is dispersed on the oil spill and serves as an oil absorbent in addition to acting as a carrier for the bacteria. *In re* Bergy, 596 F.2d at 970.

7. 100 S. Ct. at 2206. Rejection was based upon grounds that micro-organisms are "products of nature" and that under 35 U.S.C. section 101 living organisms do not fall within the scope of patentable subject matter. *See generally* Guttag, *The Patentability of Microorganisms: Statutory Subject Matter and Other Living Things*, 13 U. RICH. L. REV. 247 (1979)

jection of these claims to the Patent Office Board of Appeals, which disagreed with the patent examiner's contention that the new bacteria were "products of nature"[8] but which affirmed the examiner's other ground of rejection that living things are not patentable subject matter under 35 U.S.C. section 101.[9]

The Court of Customs and Patent Appeals reversed, finding that the patent application claims were not outside the scope of patentable subject matter simply because the claims were for living organisms.[10] In reaching its decision, the court relied upon the authority of its prior decision, *In re Bergy*, in which the court held that it is not legally significant for purposes of the patent law that micro-organisms are alive.[11]

The Supreme Court subsequently granted the Government's petition for a writ of certiorari in the *Bergy* case, vacated the *Bergy* judgment and remanded the case[12] for further consideration in light of another recent patent case, *Parker v. Flook*.[13]

In view of the Supreme Court's order in *Bergy*, the Government petitioned the Court of Customs and Patent Appeals to "vacate the *Chakrabarty* decision, recall its mandate and enter a new decision."[14] The court granted the petition only to the extent of vacating the *Chakrabarty* judgment.[15]

Since both *Bergy* and *Chakrabarty* involved the same issue, the Court of Customs and Patent Appeals consolidated the cases for reconsideration.[16] Upon re-examination of both *Chakrabarty* and *Bergy*, the court reaffirmed its earlier judgments.[17]

The Government's petition for a writ of certiorari was granted.[18] *Bergy*, however, was subsequently dismissed as moot, leaving only *Chakrabarty* for

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(discussion of "products of nature"). A "product of nature" can be defined as a "naturally occurring element, composition of matter or substance that can be found in and extracted from minerals or living organisms." *Id.* at 252 n.27. *See also* Behringer, *Patenting Bacteria*, 31 HASTINGS L. J. 883 (1980) (discussion of "products of nature").

8. 100 S. Ct. at 2206 n.3. *Pseudomonas* bacteria including two or more plasmids with the capacity to degrade more than one component of the crude oil do not occur naturally. *Id.*

9. *Id.* at 2206. 35 U.S.C. section 101 (1976) reads: "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

10. *In re* Chakrabarty, 571 F.2d 40 (C.C.P.A. 1978).

11. 563 F.2d 1031 (C.C.P.A. 1977).

12. Parker v. Bergy, 438 U.S. 902 (1978).

13. 437 U.S. 584 (1978) (a method in which a mathematical algorithm was implemented by a computer program was unpatentable subject matter under 35 U.S.C. section 101).

14. *In re* Bergy, 596 F.2d at 957.

15. *Id.*

16. *Id.*

17. *Id.* at 955.

18. Parker v. Bergy, 444 U.S. 924 (1980).

consideration.[19] The United States Supreme Court *held*, affirmed. A live, man-made micro-organism is patentable subject matter under 35 U.S.C. section 101.[20] *Diamond v. Chakrabarty*, 100 S. Ct. 2204 (1980).

Pursuant to its express grant of power,[21] Congress provided statutory protection for new and useful inventions.[22] A patent is a federal right which excludes all others from making, using or selling a particular invention for seventeen years.[23] The goal of the Patent Act was to promote technological and scientific advances[24] by offering the inventor an incentive to risk the frequently tremendous cost involved in the development and production of an invention[25] through the means of granting the inventor a right of exclusive use for seventeen years.[26] This right of exclusion benefits society by encouraging the production of new inventions, which both enhance the lives of citizens and positively affect the economy.[27] In addition, as a result of the patent laws' requirement of disclosure,[28] after the expiration of the seventeen year period, society further benefits by acquiring access to the invention and its profitable use, thus stimulating further new ideas.[29]

The Supreme Court recently reiterated the purposes of the patent sys-

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19. Diamond v. Chakrabarty, 444 U.S. 1028 (1980).

20. Chief Justice Burger delivered the opinion of the Court, in which Justices Stewart, Blackmun, Rehnquist and Stevens joined. Justice Brennan, with whom Justices White, Marshall and Powell joined, dissented.

21. U.S. CONST. art. I, § 8, cl. 8. Congress has the power "[t]o 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." *Id.*

22. *See* note 9 *supra*.

23. 35 U.S.C. section 154 (1976) states:

> Every patent shall contain a short title of the invention and a grant to the patentee, his heirs or assigns, for the term of seventeen years, subject to the payment of issue fees as provided for in this title, of the right to exclude others from making, using, or selling the invention throughout the United States, referring to the specification for the particulars thereof. A copy of the specifications and drawings shall be annexed to the patent and be a part thereof.

Id.

24. Sinclair & Carroll Co. v. Interchemical Corp., 325 U.S. 327, 330-31 (1945).

25. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974).

26. *See* note 23 *supra*.

27. 416 U.S. at 480.

28. 35 U.S.C. section 112 (1976) reads in part:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
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> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Id.

29. 416 U.S. at 481.

tem in *Aronson v. Quick Point Pencil Co.*[30] The Court deemed the system beneficial because patent law encouraged and rewarded inventions, stimulated further ideas, enabled the public to use the invention after the patent expired and warranted that ideas in general circulation remained available for unencumbered public use.[31]

In *Chakrabarty*, the Government proposed two arguments to support its position that micro-organisms should not be patented.[32] It first argued that the passage of the 1930 Plant Patent Act[33] and the 1970 Plant Variety Protection Act[34] revealed the understanding of Congress that living organisms are excluded from the phrases "manufacture" or "composition of matter."[35] Secondly, the Government contended that Congress had not foreseen genetic engineering when section 101 was enacted and that until Congress expressly legislated patent law protection for micro-organisms, they remained outside the scope of patentable subject matter.[36] However, before addressing either Government argument, the Court construed the applicable statute, 35 U.S.C. section 101,[37] to resolve whether the terms "manufacture" or "composition of matter" in section 101 encompassed Chakrabarty's genetically engineered micro-organism.[38]

An analysis of the relevant legislative history and the definitions of the terms used to create categories of patentable subject matter was cited by the Court as evidence that section 101[39] provided patent coverage for living subject matter.[40] It was necessary to broadly define patentable subject matter

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30. 99 S. Ct. 1096 (1979).
31. *Id.* at 1099.
32. 100 S. Ct. at 2208-10.
33. 35 U.S.C. § 161 (1976). This section provides:

> Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor, subject to the conditions and requirements of this title.
>
> The provisions of this title relating to patents for inventions shall apply to patents for plants, except as otherwise provided.

Id.

34. 7 U.S.C. § 2402(a)(1970). The Act provides that "[t]he breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids). . .shall be entitled to plant variety protection therefor. . . ." *Id.*
35. 100 S. Ct. at 2208.
36. *Id.* at 2210-11.
37. *See* note 9 *supra*.
38. *Id.* at 2207.
39. *Id.*
40. 100 S. Ct. at 2207-08. The 1952 Act was accompanied by Committee Reports which indicated that Congress intended patentable subject matter encompassed by the statute to "include anything under the sun that is made by man." S. REP. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess., 6 (1952); *see* 100 S. Ct. at 2207.

It is interesting to note that the Court indicated that the 1970 Act, *see* note 34 *supra*, did not suggest in either language or history that it was "enacted because § 101 did not include

since the scope of future technological developments was unforeseeable.[41] Therefore, Congress defined patentable subject matter to include "any new and useful art, machine, manufacture or composition of matter, or any new and useful improvement thereof."[42]

In concluding that a live, man-made micro-organism was patentable subject matter under 35 U.S.C. section 101,[43] the Court determined that Chakrabarty's micro-organism constituted a "manufacture"[44] or "composition of matter"[45] within the meaning of the statute.[46] The Court observed that the phrases "manufacture" or "composition of matter," modified by the inclusive term "any" were expansive and it found a clear Congressional intent to give patent laws a broad construction.[47] The Court noted that Chakrabarty's micro-organism was not an unknown natural phenomenon,[48]

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living things." 100 S. Ct. at 2210. *See* notes 64-66 and accompanying text *infra*. However, the House Report on the Plant Variety Protection Act stated that "[u]nder patent law, protection is presently limited to those varieties of plants which reproduce asexually, that is, by such methods as grafting or budding." The report further stated that "[i]n the United States. . .legal protection for plant varieties is not now available. . . ." H.R. REP. No. 91-1605, 91st Cong., 2d Sess. ___, *reprinted in* [1970] U.S. CODE CONG. & AD. NEWS 5082-83. It is difficult to understand how a committee could represent in 1952 that patentable subject matter included anything made by man, yet in 1970 state that legal protection for plant varieties was not available. The Court also did not comment on the significance, if any, of the placement of the Plant Variety Protection Act under Title 7, Agriculture, when the Plant Patent Act was placed in Title 35, Patents.

41. 100 S. Ct. at 2211.

42. *Id.* at 2207. Act of Feb. 21, 1793, ch. 11, § 1, Stat. 318. The present patent law differs from the Patent Act of 1793 only slightly. The word "art" in the 1793 statute was replaced with the word "process" when the patent laws were recodified in 1952. The present law provides: "Whoever invents or discovers any new and useful *process*, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (1976) (emphasis added).

43. *See* note 9 *supra*.

44. 100 S. Ct. at 2207. "Manufacture" is defined as "the production of articles from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery." *Id.*

45. *Id.* "Composition of matter" is defined as "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids." *Id.*

46. Determination that patentable subject matter exists under section 101 precedes the determinations to be made under sections 102-103. Parker v. Flook, 437 U.S. at 593. 35 U.S.C. section 101 (1976) establishes the subject matter to be patented. 35 U.S.C. section 102 (1976) covers the conditions relating to novelty. 35 U.S.C. section 103 (1976) relates to the non-obviousness requirement. This case does not involve either section 102 or section 103. 100 S. Ct. at 2207 n.5.

47. *Id.* at 2207.

48. *Id.* at 2208. Phenomena of nature, and abstract concepts are excluded from the scope of patent protection. *See, e.g.*, Parker v. Flook, 437 U.S. 584 (1978)(mathematical formula denied patent); Funk Bros. Seed Co. v. Kalo Co., 333 U.S. 127 (1948)(a discovery that naturally occurring root nodule bacteria can be mixed without a mutually inhibitive effect is simply the discovery of a work of nature and not patentable). If a patent is to be granted, an invention

but rather, was a non-naturally occurring "manufacture" or "composition of matter" with characteristics unlike any existing in nature.[49]

The Court then addressed the Government's first argument that neither the Plant Patent Act nor the Plant Variety Protection Act would have been necessary if the terms "manufacture" or "composition of matter" included living things.[50] Prior to 1930, two obstacles existed which excluded plants from patent protection. First, plants were considered "products of nature,"[51] even if artificially bred, and second, it was not considered possible to render an adequate written description of plants in compliance with 35 U.S.C. section 112.[53] Congress directed its attention to both issues[53] without expressing the view that the terms "manufacture" or "composition of matter" excluded living things.[54] The passage of the Plant Patent Acts reflected the recognition of Congress that the distinction was between inventions produced by man and naturally occurring products, whether alive or not.[55]

The sole support for the Government's contention that the 1930 Act excluded living things was found in Secretary of Agriculture Hyde's letter[56] in response to a request for his views on the administration of the law.[57] The Court found Secretary Hyde's statement unpersuasive, since his comment concerning the scope of patentability was beyond his area of expertise.[58] The Court cited language in the house and senate committee reports which supported its position that Secretary Hyde's letter lacked

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from a previously undiscovered phenomenon of nature must arise from the "application of the law to a new and useful end." *Id.* at 130. The Court additionally cited Gottschalk v. Benson, 409 U.S. 63 (1973) (algorithms and mathematical formulas were determined to be analogous to unpatentable abstract ideas); O'Reilly v. Morse, 56 U.S. (15 How.) 61 (1853)(the category of electromagnetism claimed in specification eight was too broad and not patentable); LeRoy v. Tatham, 55 U.S. (14 How.) 156 (1852)(the discovery of a new principle can only be patented if it results in a new and useful end). 100 S. Ct. at 2208.

49. *Id.*

50. *Id.* at 2209.

51. *Id.* An 1889 Patent Office Decision, *Ex parte* Latimer, 1889 Dec. Com. Pat. 123, 46 Off. Gaz. Pat. Office 1638 (1889), was precedent for the position that plants were natural products not subject to patent protection.

52. 100 S. Ct. at 2209. *See* note 28 *supra.*

53. 100 S. Ct. at 2209. Congress determined that often the processes of nature can be directed and controlled by man and that plant cultivation can produce a unique result which nature cannot repeat. S. REP. No. 315, 71st Cong., 2d Sess., 6-8 (1930); H.R. REP. No. 1129, 71st Cong., 2d Sess., 7-9 (1930). Congress relaxed the written description requirement. Consequently, if a description is made "as complete as is reasonably possible" patents are not denied on grounds of noncompliance with section 162. 35 U.S.C. § 162 (1976).

54. 100 S. Ct. at 2209.

55. *Id.* at 2210.

56. *Id.* at 2209. Secretary Hyde's letter was written to the Chairmen of the House and Senate committees considering the 1930 Act.

57. *Id.* at 2209. Secretary Hyde's letter read in part: "[T]he patent laws . . . at the present time are understood to cover only inventions or discoveries in the field of inanimate nature." *Id.*

58. *Id.*

persuasiveness.[59]

Additional legislative history of the 1930 Plant Patent Act indicates that the enactment of the Act was not an expression of opinion by Congress on the patentability of living things. The purpose of the Act was to extend to agriculture the same opportunity to share in the benefits of the patent system that was available to industry, therefore enabling agriculture to compete economically with industry.[60] The Act was passed to eliminate the discrimination which then existed between plant breeders and industrial producers.[61] Prior to that time benefits of the patent system had been available only to established industry, whereas plant breeding had not then been considered an industrial endeavor.[62] Committee reports noted the newly developing state of plant breeding and research and its dependency on government subsidies to government research facilities or on the amateur breeder's limited endeavors.[63]

The *Chakrabarty* Court also rejected the Government's contention that the passage of the 1970 Plant Variety Protection Act further supported its position that the patent laws excluded living subject matter.[64] Nothing in the language or history of the 1970 Act suggested that it was passed because living objects were not within the scope of section 101.[65] The 1970 Act merely extended protection to sexually reproduced plants which could not be grown true-to-type at the time the 1930 Act was passed.[66]

The Court agreed with the Court of Customs and Patent Appeals' suggestion that the exclusion of bacteria from the 1970 Act may have merely reflected the agreement of Congress with the ruling in *In re Arzberger*.[67] Further, Congress may have taken into account the fact that patents had been previously granted which stated claims for living micro-organisms.[68]

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59. *Id.* at 2209-10 (citing S. Rep. No. 315, 71st Cong., 2d Sess., 6 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., 7 (1930)).

60. *In re* Bergy, 596 F.2d at 982 (citing H.R. Rep. No. 1129, 71st Cong., 2d Sess., 1 (1930); S. Rep. No. 315, 71st Cong., 2d Sess., 1 (1930)). Both house and senate reports accompanying the bill stated: "[I]t is hoped that the bill will afford a sound basis for investing capital in plant breeding and consequently stimulate plant development through private funds." H.R. Rep. No. 1129 at 2; S. Rep. No. 315 at 2.

61. 596 F.2d at 982 (citing H.R. Rep. No. 1129, 71st Cong., 2d Sess., 1 (1930); S. Rep. No. 315, 71st Cong., 2d Sess., 1 (1930)).

62. 596 F.2d at 982.

63. *Id.* (citing H.R. Rep. No. 1129, 71st Cong., 2d Sess., 1 (1930); S. Rep. No. 315, 71st Cong., 2d Sess., 1 (1930)).

64. 100 S. Ct. at 2210.

65. *Id. See* note 40 *supra*.

66. *Id.*

67. 112 F.2d 834 (C.C.P.A. 1940). In *Arzberger* the court recognized that bacteria may be considered plants in the scientific sense, but concluded that Congress did not use the strict, scientific meaning of the term "plant" but rather, used the word "plant" in its non-scientific "common" sense and thus, did not contemplate that the term "plant" should encompass bacteria. *See* 100 S. Ct. at 2210.

68. 100 S. Ct. at 2210. The Court referred to an 1873 patent granted to Louis Pasteur for

Without a clear indication that Congress addressed the issue of patentability of living subject matter, the Court was reluctant to attribute an intent concerning this issue to Congress. Consequently, the Court lacked any basis to infer that Congress meant to change the meaning of the language in section 101.[69]

The Government's second argument, that genetic engineering was not anticipated by Congress when section 101 was passed and that until Congress enacts such legislation, micro-organisms cannot be protected by the patent laws,[70] was based upon the Government's interpretation of the Court's holding in *Parker v. Flook*.[71] In *Flook* the Court stated that the courts "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress."[72]

The *Flook* applicant claimed a technique for calculating and updating the value of certain alarm limits during a catalytic conversion process.[73] The requisite feature of the procedure was a new mathematical formula for determining the values of the alarm limits from particular input variables.[74] The Court noted that a formula was similar to a principle or law of nature and that phenomena of nature, mental processes and abstract concepts could not be patented, since the patent laws were not passed to protect that type of "discovery."[75] The Court did note, however, that "[e]ven though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented."[76] Flook's claim was rejected since the only novel feature of the claimed method was the algorithm, which was regarded as a part of the prior art.[77] The process was not considered patentable subject matter under section 101 since the invention

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yeast. *Id.* at n.9. The Court also referred to a concession by the United States in its reply brief: "We have examined each of the listed patents, and only three of the 68 clearly claim a novel, living organism itself." Reply Brief for the Petitioner at 3, Diamond v. Chakrabarty, 100 S. Ct. 2204 (1980). Those patents were all issued after 1967, and include numbers 3,923,601; 3,356,574; and 3,364,117. *Id.* at 3 n.2. *See* 100 S. Ct. at 2210 n.9.

In response to the majority's treatment of the 1970 Act, see note 34 *supra*, the dissent noted the exception in the Act for bacteria and stated "[t]he Court's attempts to supply explanations for this explicit exclusion ring hollow." 100 S. Ct. at 2214.

69. *Id.* at 2210.

70. *Id.* at 2210-11.

71. 437 U.S. 584. *See* note 13 *supra*.

72. 100 S. Ct. at 2210 (citing Parker v. Flook, 437 U.S. at 596).

73. 437 U.S. at 584.

74. *Id.* at 585-86.

75. *Id.* at 589, 593.

76. *Id.* at 594.

77. *Id.* at 594. The term "prior art" is not defined in title 35, although section 103, which relates to the non-obviousness of the invention, requires that the differences between "the prior art" and the subject matter desired to be patented be determined. 35 U.S.C. § 103 (1976). The concept of "prior art," although a complex question of law, is basically that which is known to the public. *In re* Bergy, 596 F.2d at 965 n.7.

only provided an improved technique to calculate alarm limits.[78]

The *Chakrabarty* Court stated that the *Flook* analysis concentrated on whether the *Flook* claim was for an idea or for a phenomenon of nature.[79] The Court applied the same analysis in its examination of the Chakrabarty claim at issue.[80] The *Chakrabarty* majority stated that *Parker v. Flook* did not stand for the proposition that inventions are not patentable *per se* simply because they fall within an area unforeseen by Congress at the time the patent laws were legislated.[81] According to the majority, Congress used broad general terms to define patentable subject matter in order to achieve the broad objectives of the patent laws.[82] The Court reasoned that to insist upon specific Congressional foresight in construing section 101 would totally frustrate the Congressional purpose of stimulating the creation of new technologies, which by their very nature are unforeseeable.[83] The patent statutes have frequently been construed as including new technological developments unforeseen at the time of the enactment of the patent laws.[84]

The Government pointed out that granting patents on micro-organisms could result in genetic research that would pose grave risks to the human race.[85] In response, the Court stated that its job was statutory interpretation and that it was the responsibility of the legislative and executive branches to balance the competing values and interests at issue.[86] The majority's discussion indicated that the Court lacked the competence to fully examine the risks created by genetic research, whereas legislative bodies would have access to the kind of investigation, examination and scrutiny required for such an analysis.[87]

The dissent argued that particularly in the absence of legislation, pat-

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78. 437 U.S. at 594-95.
79. 100 S. Ct. at 2211.
80. *Id.*
81. *Id.*
82. *Id.*
83. *Id.* The patent laws were enacted " 'to promote the progress of sciences and the useful arts,' contemplating and necessarily implying their extension, and increasing adaption to the uses of society." Kendall v. Winsor, 62 U.S. (21 How.) 322, 328 (1859).
84. 100 S. Ct. at 2211 n.10.
85. *See* Brief for the Petitioner at 18-19, Diamond v. Chakrabarty, 100 S. Ct. 2204 (1980); Brief on Behalf of the Peoples Business Commission, Amicus Curiae at 18-19, *id.* The potential exists for the pollution of the earth's gene pool with novel organisms which may result in "pollution and disease disasters." Organisms "eating" oil slicks may not die as intended when their food supply of oil vanishes. Cancer causing agents can be formed as a result of recombinant DNA research. For an overview of potential dangers of genetic engineering research see Curtiss, *Genetic Manipulation of Microorganisms: Potential Benefits and Biohazards*, 30 ANN. REV. OF MICROBIOLOGY 507 (1976); Wade, *Dicing with Nature: Three Narrow Escapes*, 195 SCIENCE 378 (1977). For a general treatment of recombinant DNA research and its implications see Symposium, *Biotechnology and the Law: Recombinant DNA and the Control of Scientific Research*, 51 S. CAL. L. REV. 969, 969-1554 (1978).
86. 100 S. Ct. at 2211-12.
87. *Id.* at 2212.

ent protection should be extended no further than Congress has provided.[88] The dissent contended, however, that there was not a legislative vacuum, since the Plant Acts indicated an intent to exclude bacteria from patentable subject matter.[89] According to the dissent, if newly developed, non-naturally occurring organisms had been patentable under section 101, the passage of the 1930 and 1970 Acts would have been unnecessary.[90] The dissent found it unpersuasive that the 1930 Act was passed to eliminate descriptive problems with respect to identifying the plants[91] and theorized that the further limitation on asexually reproduced plants would have been unnecessary if the technical problem of description was truly the issue. Consequently, the dissent concluded there was no Congressional intent to make objects not within the scope of the limited legislation patentable.[92]

The *Chakrabarty* dissent failed to consider the impossibility of producing true-to-type seedlings from sexually reproduced plants, hence, the need to limit the 1930 Act to asexually reproduced plants. In addition, the dissent apparently did not consider prior case law which referred to plants as "products of nature" and which served as precedent for the proposition that plants were not patentable subject matter,[93] or the legislative history which demonstrated the intent to elevate plant breeding to a position of parity with established industry.[94]

The dissent acknowledged that the legislative history of the 1970 Act did not mention the exclusion of bacteria,[95] but further stated that explanations could not be invented for this exclusion.[96] The dissent concluded that Congress had assumed that animate objects for which there was no specific legislation were not patentable, and as a result, Congress excluded bacteria.[97]

A practical effect of the *Chakrabarty* decision will be additional protection for processes that utilize new strains of micro-organisms.[98] In the past, patents have repeatedly been granted for processes[99] which utilized bacteria

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88. *Id.* at 2213.

89. *Id. See* 7 U.S.C. § 2402(a) (1976). The Act excludes "fungi, bacteria or first generation hybrids . . . ." *Id. See* note 34 *supra.*

90. 100 S. Ct. at 2213.

91. *Id.* at 2213 n.4.

92. *Id.* at 2214.

93. *See* note 51 and accompanying text *supra.*

94. *See* note 60 and accompanying text *supra.*

95. 100 S. Ct. at 2214. *See* note 89 *supra.*

96. *Id.*

97. *Id.* The fact that this interpretation appealed to four members of the Court underscores the lack of guidance from Congress in this area. *See* note 40 *supra.*

98. Irons & Sears, *Patents in Relation to Microbiology*, 29 ANN. REV. OF MICROBIOLOGY 319, 320 (1975).

99. *See, e.g.*, Cameron Septic Tank Co. v. Village of Saratoga Springs, 159 F. 453, 462-63 (2d Cir.), *cert. denied*, 209 U.S. 548 (1908) (bacterial process claims held valid); *In re* Mancy, 499 F.2d 1289 (C.C.P.A. 1974) (process utilizing a previously unknown micro-organism to pro-

or other living organisms.[100] However, difficulties are encountered when only the process and not the organism itself is patentable. Considering the time, effort and expense involved in producing the invention,[101] and the inventor's desire to protect his investment, the inventor is afforded incomplete protection by being allowed to patent only the process and not the micro-organism developed expressly for the process.

When a patent is granted only on a process, the organism identified in the patent protecting the process can be obtained by any member of the public from the depository in which it has been placed.[102] A sample of an organism from a depository must be made available since the written description required by section 112[103] is often insufficient to enable a person to develop the patented micro-organism solely from the written words.[104] Deposit of the organism provides an adequate description and permits the inventor to meet the enabling disclosure requirement of section 112.[105]

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duce antibiotics); Guaranty Trust Co. v. Union Solvents Corp., 54 F. Supp. 400 (D. Del. 1931), *aff'd per curiam*, 61 F.2d 1041 (3d Cir. 1932), *cert. denied*, 288 U.S. 614 (1933)(process using micro-organisms to produce acetone and butyl alcohol).

100. *See* Dick v. Lederle Antitoxin Laboratories, 43 F.2d 628, 630 (S.D.N.Y. 1930) (process for the production of scarlet fever antitoxin by injecting the sterile toxin into an animal and obtaining antitoxin from the animal).

101. Kiley, *Learning to Live with the Living Invention*, 7 AM. PAT. LAW A.Q.J. 220, 228 (1979). The development of a "new" micro-organism is a time-consuming and expensive process. The process is described as follows:

> One by one by one, genetic letters in the hundreds are strung together to form a gene capable of expressing a useful substance. The new gene is then tediously inserted in a plasmid which, in particular cases, may contain other man-made sequences designated to permit optimal control of the product's expression, and maximal yields. The gene bearing plasmid is then placed within a single microbe, bringing to a successful culmination what may have been years of effort. After that, the microbe does all the work. It reproduces itself and its new capabilities, time and time again. Within days, literally billions of copies of the organism are at work creating the intended substance and still recreating themselves. That process can go on indefinitely, certainly throughout the seventeen year term of a patent that has meanwhile been granted on the process by which the first organism in the line of descent was created. The bacteria can be freeze-dried into a powder having no semblance of "livingness", and stored indefinitely. At any time desired in the future, the powder can be added to a nutrient media and the process of production and procreation resumed.

Id.

102. *In re* Feldman v. Aunstrup, 517 F.2d 1351 (C.C.P.A. 1975); *In re* Argoudelis, 434 F.2d 1390 (C.C.P.A. 1970).

103. *See* note 52 *supra*.

104. 434 F.2d at 1393.

105. *See* note 52 *supra*. Bacteria can display totally different appearances when grown under differing conditions. Depending on the particular medium upon which the bacteria is cultured, the identical bacteria can appear rod-shaped or spherical. Therefore, cultures of a deposited strain eliminate doubt as to whether the new description is actually only a different description of a previously identified organism. Luckern & Hesseltine, *Living Organisms are Not Compositions or Manufactures Under 35 U.S.C. 101*, 7 AM. PAT. LAW. A.Q.J. 236, 275 (1979). The function of the culture collection depositories is the preservation of micro-orga-

After acquiring the micro-organism from the depository, others can derive the benefit of the organism without infringing upon the patented process itself.[106] This is especially true in the situation in which an additional beneficial use for the micro-organism might later be discovered, a use which does not involve the original patented process.[107]

As a result of the drawbacks of patenting only the process involving a novel micro-organism, companies in the past have utilized trade secret laws to protect their research.[108] No doubt this practice would have continued if patent protection had not been extended to micro-organisms by the Supreme Court. The protection furnished by trade secret laws, however, is much weaker than that provided by patent law.[109] In addition, trade secret laws frequently deny the public access to meritorious inventions.[110]

Trade secrets are protected only to the extent of disclosure which is gained by "improper means," or through unauthorized use by someone to whom the trade secret has been revealed "in confidence."[111] No protection is afforded against discovery of the trade secret by legitimate methods, for example, by independent discovery, unintentional disclosure or "reverse engineering."[112] On the other hand, when a patent is granted, although the information is available to the general public in order to stimulate further ideas, the inventor is entitled to the exclusive use of the invention for seventeen years.[113]

A trade secret, by its very nature, is not available to the public.[114] Although inventions protected by trade secret laws do not always frustrate the patent laws' foremost purpose of encouraging dissemination of inventions and ideas to the public,[115] trade secrets protecting research involving genetically engineered organisms may very well deny the public a free flow of information and ideas as well as decrease competition.[116] Although "reverse

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nisms in a viable state. Almost all cultures are lyophilized (freeze-dried). Daus, *Conditionally Available Cultures: An Appraisal of In re Argoudelis Et. Al.*, 54 J. PAT. OFF. SOC'Y 187, 188-90 (1972). Cultures which are not lyophilized can rarely be viably maintained for more than a year, whereas lyophilized cultures can be maintained indefinitely with only minimal loss. *See* note 101 and accompanying text *supra*. *See generally* Brief of Dr. George Piecznik as Amicus Curiae at 13, Diamond v. Chakrabarty, 100 S. Ct. 2204 (1980).

106. *See* Kiley, *supra* note 101, at 228-29.

107. *See* Behringer, *supra* note 7, at 885.

108. Cooper, *Patent Protection for New Forms of Life*, 38 FED. B.J. 34, 47 (1979).

109. Kewanee Oil Co. v. Bicron Corp., 416 U.S. at 489-90.

110. *Id.* at 480.

111. *Id.* at 475-76.

112. *Id.* at 476. Reverse engineering consists of analysing the product available to the public to discover the secret process. It is necessary to work backward from the completed product to unravel the process through which the invention was developed.

113. *Id.* at 481.

114. *Id.* at 484.

115. *Id.* at 485-86.

116. *See generally* Cooper, *supra* note 108, at 47 (process for producing citric acid was

engineering" can be utilized to discover some inventions, and as such, stimulate competition, "reverse engineering" of genetically engineered micro-organisms often requires time-consuming and tedious research.[117]

Now, after patenting the micro-organism itself, an inventor can exact royalties for the seventeen-year period of exclusive use on the use of the micro-organism without being required to prove that the process used by the other party infringes on his own process.[118] Additionally, companies no longer must resort to the use of trade secret laws to protect results of lengthy and tedious research. The opportunity to patent micro-organisms is likely to encourage the research and development of new, beneficial micro-organisms both in terms of increased competition and potential profitability.

Viewing the possible protection of the patent system as an incentive, private industry has already initiated research to develop new products through the use of micro-organisms.[119] Three recent achievements are the development of a micro-organism capable of producing human insulin,[120] development of an organism with the ability to synthesize human interferon and production of a growth stimulating hormone beneficial to humans.[121]

The anticipation of potential patent protection for micro-organisms has led to the rapid expansion of the genetic engineering industry.[122] Since 1976, several large pharmaceutical companies have initiated recombinant DNA[123] research and recently more large corporations have become involved in genetic research expected to be commercially profitable.[124] The Court's decision in *Chakrabarty* is likely to provide further incentive for companies to initiate or accelerate research on the synthesis of products with human health, agricultural, industrial or environmental potential.[125]

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used exclusively by one company for more than seventeen years).

117. *See* Guttag, *supra* note 7, at 277 n.152.

118. *See* Irons & Sears, *supra* note 98, at 320.

119. *See* Kiley, *supra* note 101, at 223-24.

120. *See* Begley & Abramson, *The DNA Industry*, NEWSWEEK, Aug. 20, 1979, at 53.

121. DeMott, *Test-Tube Life: Reg. U.S. Pat. Off.*, TIME, June 30, 1980 at 52. Interferon is a substance humans produce in small quantities. It effectively attacks some viruses and viral diseases and has shown some promise as a treatment for cancer.

122. *See* Luckern & Hesseltine, *supra* note 105, at 273 n.128.

123. DNA (deoxyribonucleic acid) is the basic genetic material of all cells. Through the use of particular enzymes, DNA molecules can be cut and recombined with other DNA molecules to form a hybrid molecule. The term "recombinant" is derived from this process. VAN NOSTRAND'S SCIENTIFIC ENCYCLOPEDIA 1894-96 (5th ed. 1976).

124. Luckern & Hesseltine, *supra* note 105, at 273. Genentech, a fairly new genetic engineering firm, "went public" in October 1980. Within twenty minutes of its offering, the stock was selling at 8,900 times its earnings. The stock fell later but still remained well above its original fixed price. Pauly, Abramson & Frons, *Scrambling for GENE*, NEWSWEEK, October 27, 1980, at 90. *See generally The Big IF in Cancer*, TIME, March 31, 1980, at 60-61.

125. *See* note 121 *supra*. *See generally* Marx, *Nitrogen Fixation: Prospects for Genetic Manipulation*, 196 SCIENCE 638 (1977). Research has occurred using bacteria to remove nitrogen from the atmosphere to enrich the soil. This method of enriching the soil increases crop yields at lower costs. Using this method, it would no longer be necessary to remove a field from

Public concern regarding the potential biohazard risks surrounding genetic research has repeatedly been expressed.[126] In response to this controversy, the National Institutes of Health promulgated guidelines for recombinant DNA research in 1976.[127] The guidelines established a procedure for genetic engineering and banned some extremely hazardous experiments totally.[128] These guidelines, however, apply only to federally funded projects and do not encompass any research being performed on a private basis.[129] In 1978, after anxiety over recombinant DNA research had abated, these guidelines were relaxed.[130] One publication has reported that a further relaxation of the original guidelines has been recommended.[131]

Congressional action limiting the extent to which living organisms could be patented would be appropriate if Congress determines that the hazards of certain inventions involving living organisms outweigh the benefits. Such prohibitions of patent protection for certain inventions has occurred in the past.[132] Congress has already considered whether control over recombinant DNA research should be exerted[133] and has failed to act.[134] Senators Kennedy and Javits stated in a letter to Secretary Califano dated June 1, 1978 that, in view of the accumulated evidence, it was impossible to conclude that statutory control of recombinant DNA research was necessary to protect the health and safety of the public.[135] Fears are apparently receding with regard to genetic engineering, and it appears unlikely that a statute designed to exclude organisms developed through recombinant DNA techniques will be enacted.

In the absence of Congressional action, patentability of living organisms might be limited to micro-organisms, since it is doubtful that multi-cellular organisms could be successfully patented under section 101. It is unlikely that multi-cellular organisms would be amenable to the enabling disclosure requirement of section 112 which teaches a person skilled in the pertinent field how to make and use the invention.[136] Unicellular micro-organisms are

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production in order to restore nitrogen to the soil.

126. *See* note 85 *supra*.

127. *Recombinant DNA Research Guidelines*, 41 Fed. Reg. 27,902-43 (1976). *See generally* Berger, *Government Regulation of the Pursuit of Knowledge: The Recombinant DNA Controversy*, 3 VT. L. REV. 83 (1978).

128. *Recombinant DNA Research Guidelines*, 41 Fed. Reg. 27,902-43 (1976).

129. *Id.*

130. *Recombinant DNA Research: Revised Guidelines*, 43 Fed. Reg. 60,080, 60,108, 60,134 (1978).

131. Wade, *Major Relaxations in DNA Rules*, 205 SCIENCE 1238 (1979).

132. 42 U.S.C. section 2181(a) (1976) states: "No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear materials or atomic energy in an atomic weapon. . . ." *Id.*

133. *See* Brief for the Respondent at 29, Diamond v. Chakrabarty, 100 S. Ct. 2204 (1980).

134. *Id.*

135. *Recombinant DNA Research Guidelines*, 43 Fed. Reg. 60,103-04 (1978).

136. *See* note 28 *supra*.

more easily described than multi-cellular organisms,[137] and the facilities necessary to store the simpler life forms have been in existence for years.[138]

Presumably, it would be necessary to establish depositories capable of maintaining more complex life forms in order to satisfy the written description requirements of section 112.[139] However, the physical and genetic instability of multi-cellular living organisms may make them difficult to maintain over an indeterminant length of time.[140] Physical changes in the organism would defeat the purpose of the depository and patent system.[141] Therefore, until improved storage techniques are available for multi-cellular organisms, and until genetic stability can be assured, patent protection for living inventions will likely be limited to micro-organisms.

The Court's decision in *Chakrabarty* will have far-reaching effects. Patent protection for the organism itself will stimulate research since companies can protect their investment in the development of novel micro-organisms. As a result of this protection, competition may be spurred and the public should benefit from the discoveries. Placing such research in the view of the public should also serve to allay fears regarding genetic engineering, and will allow the public and Congress to identify those areas where prohibitions may be advisable. It is doubtful that multi-cellular life forms are amenable to the patent laws, but for reasons unrelated to their nature as living organisms. If such discoveries can satisfy all the patent law requirements they can be controlled, if necessary, in the same manner as the simpler forms.

To continue to deny patent protection for living organisms would have forced industry to continue to rely upon trade secret laws to the detriment of the public. Research would not have been discontinued; it would simply have occurred behind locked doors.

Carol F. Fowler

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137. *In re* Bergy, 596 F.2d at 997 n.7 (Baldwin, J., concurring).
138. *Id.*
139. *See* note 28 *supra.*
140. Brief of Dr. George Piecznik as Amicus Curiae at 13, Diamond v. Chakrabarty, 100 S. Ct. 2204 (1980). The odds of bacteria mutating spontaneously are about one in a million per generation. Higher organisms reproduced by sexual mating have a probability of variation of nearly one.
141. *In re* Argoudelis, 434 F.2d at 1394.

CIVIL SERVICE COMMISSION—CIVIL SERVICE COMMISSIONS ARE GENERALLY ACCORDED WIDE DISCRETION BY THE COURTS IN THE PREPARATION AND ADMINISTRATION OF EXAMINATIONS TO MEET THE PUBLIC DEMAND FOR THE EMPLOYMENT OF INDIVIDUALS IN THE PUBLIC SERVICE.—*Patch v. Civil Service Commission* (Iowa 1980).

Plaintiffs, Dale Patch, Marvin Robinson, Wayne Lunders, and others, are members of the Des Moines police force who failed[1] to score above the 49.5 percentile[2] on a multiple choice examination[3] administered by the Des Moines Civil Service Commission for the purpose of selecting persons for promotion to police sergeant.[4] The plaintiffs alleged that the inclusion of biographical questions[5] in the examination caused it to fail to conform to

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1. This suit was initiated as a class action on behalf of the forty persons who took and "failed" the examination. Patch v. Civil Serv. Comm'n, 295 N.W.2d 460, 462 (Iowa 1980).

2. Persons failing to score above this percentile were eliminated from further consideration in the selection process. *Id.* at 462.

3. The examination consisted of biographical, psychological and situational judgment questions. *Id.* at 463.

4. IOWA CODE § 400.11 (1979) provides that the

> commission shall . . . certify to the city council a list of the . . . ten persons who qualify . . . as a result of the examination for the position they seek to fill. . . .
>
> In cities of fifty thousand or more population, the commission shall hold in reserve a second list of the ten persons next highest in standing.

Accord, DES MOINES CIVIL SERVICE COMMISSION RULES AND REGULATIONS ch. V, § 1 (1978).

5. The plaintiffs took particular exception to the following questions, which were asked in substance, although not in this exact form:

1. Did you have sex before you were 16?
2. Did you have a tatoo before you were 16?
3. Did your parents fight while you were in high school?
4. How many brothers and sisters do you have?
5. How many brothers and sisters did you have?
6. What is your age?
7. What is your sex?
8. What is your race?
9. What sports did you participate in while in high school?
10. What was your grade average in high school?
11. What level of higher education did you obtain?
12. What is your height and weight?
13. How many hours sleep do you need?
14. Were you president of the student body?
15. What was the size of your graduating class in high school?
16. What did you want to be as a child?
17. How many jobs have you had?
18. Did you work while in school?
19. Were you on the student council in high school?

295 N.W.2d at 463-64. Plaintiffs also complained that several of the situational judgment questions failed to provide the Des Moines procedure as an alternative. *Id.* at 464.