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OWNERSHIP OF LIVING INVENTIONS— *IN RE BERGY**

Statutory protection of new and useful inventions was first provided almost two centuries ago by Congress¹ pursuant to its constitutional 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.”² Throughout the years patent laws have provided a major impetus to scientific and technological advancement by rewarding the patentee with the right to exclude all others from making, using, or selling the patented invention for a limited period of time.³

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1. The first federal patent statute was enacted shortly after the United States Constitution became effective. Act of April 10, 1790, ch. 7, 1 Stat. 109 (current version at 35 U.S.C. §§ 1-376 (1976)).

2. U.S. CONST. art. I, § 8, cl. 8. This provision is generally regarded as granting Congress the power to establish a copyright system and to establish a patent system. See generally Fredrico, *Commentary on the New Patent Act*, 35 U.S.C.A. 1, 1 (1954); Lutz, *Patents and Science: A Clarification of the Patent Clause of the U.S. Constitution*, 18 GEO. WASH. L. REV. 50 (1949); Rich, *Principles of Patentability*, 28 GEO. WASH. L. REV. 393 (1960).

The constitutionally stated purpose for enacting the patent system is the promotion of progress in the “useful Arts” rather than in “Science.” This was the conclusion of both houses of Congress in enacting the 1952 Patent Act, Act of July 19, 1952, ch. 950, 66 Stat. 792 (current version at 35 U.S.C. §§ 1-376 (1976)).

The background, the balanced construction and the usage current then and later, indicate that the constitutional provision is really two provisions merged into one. The purpose of the first provision is to promote the progress of science by securing for limited times to authors the exclusive right to their writings, the word ‘science’ in this connection having the meaning of knowledge in general, which is one of its meanings today. The other provision is that Congress has the power to promote the progress of useful arts by securing for limited times to inventors the exclusive right to their discoveries. The first patent law and all patent laws up to a much later period were entitled ‘acts to promote the progress of useful arts.’

H.R. REP. NO. 1923, 82d Cong., 2d Sess. 4 (1952); S. REP. NO. 1979, 92d Cong., 2d Sess. 3 (1952). The term “useful arts” now refers to “technological arts.” See *In re Bergy*, 596 F.2d 952, 959, 201 U.S.P.Q. 352, 359 (C.C.P.A. 1979); *In re Waldbaum*, 457 F.2d 997, 1003-04, 173 U.S.P.Q. 430, 435 (C.C.P.A. 1972) (Rich, J., concurring); *In re Musgrave*, 431 F.2d 882, 893, 167 U.S.P.Q. 280, 289-90 (C.C.P.A. 1970).

3. The patent laws encourage scientific and technological advancement by providing to the holder of a patent the right to prevent all others from making, using, or selling the invention for seventeen years from the date of issuance. 35 U.S.C. § 154 (1976). The primary purpose of the patent laws, however, is scientific and technological advancement and is not the reward to the individual. *Sinclair & Carroll Co. v. Interchemical Corp.*, 325 U.S. 327, 330-31, 65 U.S.P.Q. 297, 299 (1945).

The subject matter for which a patent may be obtained is set forth in 35 U.S.C. § 101.⁴ Because patents deal with inventions, which by their very nature are entities that are not yet known, the classes of statutory subject matter in section 101 were constructed by Congress in very general and prospective terms. Thus, section 101 authorizes the grant of patents for the invention or discovery of "any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof."⁵ These statutory generalities, however, are occasionally the source of controversy, especially when the Patent and Trademark Office (PTO)⁶ must determine whether inventions exhibiting certain "unique features"⁷ constitute statutory subject matter under section 101.

One technological area that has raised such questions involves inventions of industrially useful microorganisms.⁸ The "unique feature" presented by these microorganism inventions is that they are alive. While section 101 has been held to provide patent protection for processes that utilize living organisms,⁹ no court until now has ever held that a living organism is patentable under section 101. In the recent decision of *In re Bergy*,¹⁰ the United States Court of Customs and Patent Appeals (CCPA) held that a living microorganism is patentable subject matter under section 101 when claimed as

4. Section 101 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 thereof, subject to the conditions and requirements of this title." 35 U.S.C. § 101 (1976).

5. *Id.*

6. The Patent and Trademark Office (PTO), an office in the Department of Commerce, keeps and preserves all records, books, drawings, specifications, and anything else pertaining to patents and trademarks registrations. The statutory provisions pertaining to the establishment and organization of the PTO are codified in 35 U.S.C. §§ 1-14 (1976).

7. The term "unique features" refers to those characteristics of the invention which have not been firmly established as patentable subject matter under § 101 by case precedent.

8. Microorganism inventions provide efficient means of producing various pharmaceuticals, useful chemicals, food additives, and rare enzymes and have proved to be useful in the disposal of industrial and municipal wastes. The true extent of their potential usefulness is far from realized. Despite the ever-expanding importance of microbiological advances, the patent protection granted these advances is considerably less than the protection granted for similar advances in chemistry, physics, engineering disciplines, and agriculture. See Irons and Sears, *Patents in Relation to Microbiology*, 29 ANN. REV. OF MICROBIOLOGY 319 (1975).

9. See *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 21 U.S.P.Q. 69 (7th Cir. 1934), *cert. denied*, 293 U.S. 576 (1934) (bacteriological purification of sewage); *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453 (2d Cir. 1908) (the original septic tank case); *Dick v. Lederle Antitoxin Laboratories*, 43 F.2d 628, 6 U.S.P.Q. 40 (S.D.N.Y. 1930) (process for producing scarlet fever antitoxin by injecting an animal with sterile toxin and obtaining the antitoxin therefrom).

10. 596 F.2d 952, 201 U.S.P.Q. 352 (C.C.P.A. 1979), *cert. granted*, 100 S. Ct. 261 (1979). In *Bergy*, the court pointed out that "[w]hatever we have to say in these cases is said here, though much of it was said before, and our prior opinions are to be deemed withdrawn." *Id.* at 957, 201 U.S.P.Q. at 358.

either a manufacture or composition of matter.¹¹ *Bergy* is the consolidation of two previous decisions by the CCPA, *In re Bergy*¹² and *In re Chakrabarty*,¹³ which both upheld patent claims directed to microorganism inventions. In *Bergy*, the CCPA also considered another technological area that has raised questions of statutory subject matter under section 101—computer programs (software). The difficulty in determining statutory subject matter with regard to computer programs is exemplified by the 1978 Supreme Court decision of *Parker v. Flook*.¹⁴ Shortly after *Flook*, the Supreme Court summarily vacated the CCPA's decision in *Bergy* and remanded it to the CCPA to be considered in light of *Flook*.¹⁵

The purpose of this Note is to analyze the basis of the *Bergy* decision and to discuss the effect, if any, of the *Flook* opinion on *Bergy*. This Note also analyzes the impact of *Bergy* on emerging technologies such as recombinant DNA research, some problems that may emerge in the patenting of microorganisms, and the possibility of patenting higher life forms. Finally, this Note discusses why *Bergy* should be affirmed upon review by the Supreme Court.

BACKGROUND

*The Patent Statute*¹⁶

The determination of whether a particular invention is entitled to patent protection involves a step-by-step analysis of the patent statute. The proper and logical method, therefore, is first to apply the requirements of section

11. See text accompanying note 21 *infra*. An invention may be claimed in as many different statutory classes as it will warrant. Two reasons have been proposed for this:

First, claims to one class are necessarily of different scope than those of another class and hence the coverage is greater when the claims are cast in a plurality of statutory classes than when they are all restricted to a single class. Second, some court may hold that claims in one statutory class are invalid because the invention belongs in another class.

1 A. DELLER, PATENT CLAIMS § 108, at 217 (2d ed. 1971). Thus, where there is doubt as to which class an invention properly belongs, it is permissible to direct the claims to two statutory classes. *Id.* § 111, at 219-20.

12. 563 F.2d 1031, 195 U.S.P.Q. 344 (C.C.P.A. 1977), *vacated sub nom.* *Parker v. Bergy*, 438 U.S. 902, 198 U.S.P.Q. 257 (1978). See Gutttag, *The Patentability of Microorganisms: Statutory Subject Matter and Other Living Things*, 13 U. RICH. L. REV. 247 (1979) [hereinafter referred to as Gutttag]; Note, *The Patentability of Living Organisms Under 35 U.S.C. § 101: In re Bergy*, 58 NEB. L. REV. 303 (1979); Case Comment, *The Patentability of Living Organisms Under 35 U.S.C. § 101: In re Bergy*, 91 HARV. L. REV. 1357 (1978).

13. 571 F.2d 40, 197 U.S.P.Q. 72 (C.C.P.A. 1978). See Note, *Living Matter Found to be Patentable*. In re Chakrabarty, 11 CONN. L. REV. 311 (1979).

14. 437 U.S. 584, 198 U.S.P.Q. 193 (1978). In *Flook*, a process for updating alarm limits in the catalytic conversion of hydrocarbons, in which the only novel feature was a mathematical formula, was held to be unpatentable subject matter under § 101. See note 61 *infra*.

15. *Parker v. Bergy*, 438 U.S. 902, 198 U.S.P.Q. 257 (1978).

16. The present patent laws are codified in 35 U.S.C. §§ 1-376 (1976). Title 35 was the result of the 1952 Patent Act, Act of July 19, 1952, ch. 950, 66 Stat. 792, which revised and

101 and then to proceed to the relevant inquiries under section 102 and 103.¹⁷ Section 101 states three requirements for patentability: novelty, utility, and statutory subject matter.¹⁸ Of these three requirements, however, only utility and statutory subject matter are applied under section 101.¹⁹ The utility of an invention is basically a subjective determination, for there is no comprehensive definition of the term "useful" in the law of patents.²⁰ Statutory subject matter requires that an invention fall into at least one of the four classes enumerated in section 101—process, machine, manufacture, or composition of matter.²¹

After the court determines that an invention is useful and that statutory subject matter exists under section 101, the court considers the requirements of sections 102 and 103. The essential thrust of section 102²² is that

codified what previously had been a hodgepodge of separate enactments. There are three main parts to title 35: part one pertains to the establishment and organization of the PTO; part two, the one involved in *Bergy*, covers the patentability and the grant of patents; part three relates to issued patents and the protection of the rights conferred by them. The statutory provisions which are relevant to *Bergy* are the first four sections of chapter 10, the first chapter of part two. These are: 1) § 100 Definitions; 2) § 101 Inventions patentable; 3) § 102 Conditions for patentability—novelty and loss of right to patent; 4) § 103 Conditions for patentability—non-obvious subject matter. 35 U.S.C. §§ 100-103 (1976).

17. The court in *Bergy* analogized the determination of patentability to using "keys to open in succession the three doors of sections 101, 102, and 103 . . ." 596 F.2d at 960, 201 U.S.P.Q. at 360.

18. See note 4 *supra* for the text of § 101.

19. That the novelty of an invention should be considered under § 102 and not under § 101 is the apparent intent of Congress. A reviser's note accompanying § 101, when it was enacted in the 1952 Patent Act, stated: "The corresponding section of the existing statute is split into two sections, section 101 relating to the subject matter for which patents may be obtained, and section 102 defining statutory novelty and stating other conditions for patentability." H.R. REP. NO. 1923, 82d Cong., 2d Sess. 6 (1952); S. REP. NO. 1979, 82d Cong., 2d Sess. 5 (1952).

In *Bergy*, the court noted that "[t]he PTO, in administering the patent laws, has, for the most part, consistently applied § 102 in making rejections for lack of novelty. To provide the option of making such a rejection under § 101 or § 102 is confusing and therefore bad law." 596 F.2d at 961, 201 U.S.P.Q. at 361. The court in *Bergy* also noted that there have been only two instances where the PTO has made rejections for lack of novelty under § 101. *Id.*, citing *In re Bergstrom*, 427 F.2d 1394, 166 U.S.P.Q. 256 (C.C.P.A. 1970); *In re Seaborg*, 328 F.2d 996, 140 U.S.P.Q. 662 (C.C.P.A. 1964).

20. See generally 1 A. DELLER, DELLER'S WALKER ON PATENTS §§ 83-101 (2d ed. 1964) [hereinafter referred to as DELLER].

21. 35 U.S.C. § 101 (1976).

22. See *id.* § 102:

A person shall be entitled to a patent unless—

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States, or
- (c) he has abandoned the invention, or
- (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant or his legal representatives or assigns in a

the invention be novel. The inventor must be the first to invent what he or she did in substantially the same manner that he or she invented it. The determination of novelty, therefore, involves a comparison with the prior art.²³ Next, a patentable invention must meet the nonobviousness requirement of section 103.²⁴ Under that section, a patent will be allowed only "if the difference between the subject matter sought to be patented and the prior art [is] such that the subject matter as a whole would [not] have been obvious at the time the invention was made to a person ordinarily skilled in the art"²⁵

Neither section 102 nor section 103 was involved in either appeal in *Bergy*. The only question presented was whether or not a living organism was statutory subject matter under section 101 when claimed as either a manufacture²⁶ or composition of matter.²⁷ The microorganisms in *Bergy*

foreign country prior to the date of the application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States, or

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent, or

(f) he did not himself invent the subject matter sought to be patented, or

(g) before the applicant's invention thereof the invention was made in this country by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

23. A practical definition of prior art is "[a]nything in tangible form that may properly be relied on by the Patent Office under the Patent Statutes and the Patent Office Rules of Practice in Patent Cases in support of rejection on matter of substance, not form, of claim in pending application for patent." 5 DELLER, *supra* note 20, § 453, at 361 (emphasis in original).

24. Section 103 states:

A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

35 U.S.C. § 103 (1976). The requirements of § 103 did not exist in a separate section until the 1952 Patent Act. "Section 103 is a restatement of the rule invalidating patents for lack of invention or lack of patentable novelty which has long been recognized by the courts and other authorities but has not before been spelled out in the statute." Zinn, *Commentary on New Title 35, U.S. Code "Patents"*, U.S. CODE CONG. & AD. NEWS 2507, 2513 (1952). For an excellent discussion of the application of § 103, see *Graham v. John Deere Co.*, 383 U.S. 1, 148 U.S.P.Q. 459 (1966).

25. 35 U.S.C. § 103 (1976).

26. In *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11, 8 U.S.P.Q. 131, 133 (1931), the Supreme Court adopted the following definition of manufacture: "[T]he production of articles for use from raw or prepared materials by giving to these materials new forms,

were claimed as such because a living organism cannot be claimed as a process²⁸ or a machine²⁹ within the meaning of the patent statute.

In addition to the classes of patentable subject matter under section 101,³⁰ another category of patentable subject matter was created by the Plant Patent Act of 1930.³¹ Under that law certain asexually reproduced plants are patentable. While it may be debatable, in the scientific sense, whether or not bacteria are "plants," the CCPA, in *In re Arzberger*,³² held

qualities, properties, or combinations, whether by hand-labor or by machinery." *Id.*, quoting CENTURY DICTIONARY (1911).

In *American Fruit*, the inventor claimed that an orange in which the rind had been impregnated with borax to resist mold was a "manufacture". In applying the aforesaid definition of manufacture to the impregnated fruit, the Supreme Court held:

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.

Id. at 11-12, 8 U.S.P.Q. at 133. This holding has been criticized as applying too strict a definition to the term manufacture. See Gutttag, *supra* note 12, at 257. Comment, *Patent Law—Patentability as Affected by the Law of Nature Rules—The Kalo Doctrine*, 47 MICH. L. REV. 391, 396 (1949).

27. Composition of matter has been defined as "the mixing of two or more ingredients resulting in a product with several different or additional properties not possessed individually by the several ingredients." *P.E. Sharpless Co. v. Crawford Farms, Inc.*, 287 F. 655, 658 (2d Cir. 1923).

28. "The term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." 35 U.S.C. § 100(b) (1976). The Supreme Court had defined process as "a mode of treatment of certain materials to produce a given result. It is an act, or series of acts, performed upon the subject matter to be transformed and reduced to a different state or thing." *Cochrane v. Deener*, 94 U.S. 780, 788 (1876). The generic definition of a process is "an operation performed by rule to produce a result." 1 DELLER, *supra* note 20, § 15, at 106.

29. "The term 'machine' includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain affect or result." *Corning v. Burden*, 56 U.S. (15 How.) 252, 267 (1853).

30. The four classes of statutory subject matter enumerated in § 101 relate to patents for invention or "utility" patents. In addition to utility patents there are also "design" patents which are provided for in 35 U.S.C. §§ 171-173 (1976). Section 171 provides patent protection for "[w]hoever invents any new, original and ornamental design for an article of manufacture"

31. Act of May 23, 1930, Pub. L. No. 245, 246 Stat. 376 (*amending* R.S. § 4886). The statutory provision for plant patents is 35 U.S.C. § 161 (1976), which provides:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated spores, 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.

32. 112 F.2d 834, 46 U.S.P.Q. 32 (C.C.P.A. 1940). Although the court in *Arzberger* recognized that bacteria were scientifically regarded as plants, it concluded that "Congress, in the use

that there was no evidence that Congress intended the term "plant" to cover bacteria. Thus, the microorganisms in *Bergy* could only be found to be patentable subject matter under one of the classes enumerated in section 101.

Facts and Procedure

Bergy is the consolidation of two previous decisions by the CCPA, *In re Bergy*³³ and *In re Chakrabarty*.³⁴ The judicial history of these two cases is unique and the source of potential confusion.

Chakrabarty

With an intent to develop a possible solution to the problem of dispersing oil spills, Dr. Ananda Chakrabarty³⁵ invented a new strain of the genus of bacterium *Pseudomonas*, which possessed the unique capability of breaking down several of the component hydrocarbon compounds of crude oil.³⁶ Chakrabarty's new microorganism was developed by the transfer of certain energy-generating plasmids,³⁷ each containing different pathways of hydrocarbon degradation,³⁸ to the existing strain of *Pseudomonas aeruginosa*, which itself exhibited no capacity for degrading any component of oil. The resulting new strain had the capacity to produce the enzymes required to degrade several of the main hydrocarbon components of oil.

Chakrabarty's patent application³⁹ contained thirty-six claims.⁴⁰ The patent examiner allowed those claims directed to a process or an improvement

of the word 'plant', was speaking 'in the common language of the people', and did not use the word in its strict, scientific sense." *Id.* at 838, 46 U.S.P.Q. at 35.

33. 563 F.2d 1031, 195 U.S.P.Q. 344 (C.C.P.A. 1977), *vacated sub nom.* *Parker v. Bergy*, 438 U.S. 902, 198 U.S.P.Q. 257 (1978).

34. 571 F.2d 40, 197 U.S.P.Q. 72 (C.C.P.A. 1978).

35. Dr. Chakrabarty is an employee of the General Electric Company, the real party in interest as the assignee of the patent application. 596 F.2d at 956, 201 U.S.P.Q. at 357.

36. *Id.* at 968-69, 201 U.S.P.Q. at 367-68.

37. A plasmid is believed to consist of double stranded DNA (deoxyribonucleic acid) molecules. Plasmid is "a term coined to include both intrinsic plasmogenes and extrinsic factors such as viruses, the effect of which may be mistaken for that of a true plasmogene." P. GRAY, THE DICTIONARY OF THE BIOLOGICAL SCIENCES 409 (1967).

38. A degradative pathway is "'a sequence of enzymatic reactions (e.g., 5 to 10 enzymes are produced by the microbe) converting the primary substrate (i.e., oil) to some simple metabolite, a normal food substance for microorganism.'" 596 F.2d at 969, 201 U.S.P.Q. at 368, *quoting* Chakrabarty's patent application.

39. 35 U.S.C. § 111 (1976) provides in part that each patent application shall include: "(1) a specification as prescribed by section 112 of this title; (2) a drawing as prescribed by section 113 of this title; and (3) an oath by the applicant as prescribed by section 115 of this title."

Section 112 requires in part that:

[T]he 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

in a process of transferring plasmids from a donor to a recipient bacterium⁴¹ as well as those claims directed to an inoculated medium.⁴² The claims directed to a bacterium⁴³ or to an inoculum⁴⁴ were rejected, however, on the ground that the microorganism was a "product of nature" and as such was unpatentable.⁴⁵

On appeal, the PTO Board of Appeals⁴⁶ erroneously interpreted the examiner's answer as stating *two* grounds for the rejection of the claimed

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.

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.

40. 596 F.2d at 970, 201 U.S.P.Q. at 369.

41. *Id.* The claims directed to the process were 27, 28, and 29. *Id.*

42. *Id.* at 970-71, 201 U.S.P.Q. at 369. The claims directed to the inoculated medium were 30, 31, 32, 35, and 36. The only independent claim was 30, which reads:

An inoculated medium for the degradation of liquid hydrocarbon substrate material floating on water, said inoculated medium comprising a carrier material able to float on water and bacteria from the genus *Pseudomonas* carried thereby, at least some of said bacteria each containing at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway and said carrier material being able to absorb said hydrocarbon material.

Id.

43. The claims directed to the bacterium were 7, 8, 9, 13, 17, and 21. *Id.* at 970-71, 201 U.S.P.Q. at 369. Representative of these claims is claim 7, which reads: "A bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway." *Id.* The court in *Bergy* also noted that the assignee of Chakrabarty's invention, General Electric Company, has been granted British Patent 1,436,573, containing claim 7 and other claims to the bacterium. *Id.* at 970 n.9, 201 U.S.P.Q. at 369 n.9.

44. The claims directed to the inoculum were 21, 24, 25, and 26. *Id.* at 970, 201 U.S.P.Q. at 369. The only independent claim, number 21 reads as follows:

An inoculum for the degradation of a preselected substrate comprising a complex or mixture of hydrocarbons, said inoculum consisting essentially of bacteria of the genus *Pseudomonas* at least some of which contain at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway.

Id. In *Bergy*, the court noted that "claims 7 and 21 are but alternative ways of claiming substantially the same thing since the inoculum consists essentially of the bacterium." *Id.*

45. *Id.* at 971, 201 U.S.P.Q. at 369. A claimed invention that is a "product of nature" is not eligible for patent protection because it is not "new" within the meaning of the patent statute. In contrast, a natural product claimed in a pure state or with some other characteristics which differentiate it from its natural state is patentable. *See Merck v. Olin Mathieson Chemical*, 253 F.2d 156, 116 U.S.P.Q. 484 (4th Cir. 1958) (vitamin B-12); *Merck v. Chase Chemical*, 273 F. Supp. 68, 155 U.S.P.Q. 139 (D.N.J. 1967) (same); *Parke-Davis v. Mulford*, 196 F. 446 (2d Cir. 1912) (adrenalin); *In re Bergstrom*, 427 F.2d 1394, 166 U.S.P.Q. 256 (C.C.P.A. 1970) (prostaglandin compounds).

46. The statutory provision setting forth the composition and duties of the Board of Appeals (Board) is 35 U.S.C. § 7 (1976). Section 7 directs that the Board be made up of the Commissioner, the deputy commissioner, the assistant commissioners, and the examiners-in-chief. *Id.* Each appeal must be heard by at least three members of the Board which shall be designated

invention: (1) that they were unpatentable as products of nature, and (2) that as live organisms they do not fit into any of the categories of patentable subject matter as defined by section 101. The Board reversed the "product of nature" ground and sustained the rejections on the ground that living organisms are not patentable subject matter under section 101.⁴⁷ The Board reasoned that Congress could not have intended section 101 to include any living thing because, if it had, Congress would not have found it necessary to pass the Plant Patent Act of 1930.⁴⁸ The Board felt that if Congress did not intend plants, which are alive, to be statutory subject matter under section 101, then nothing that is alive falls within section 101.⁴⁹

Bergy

Subsequent to the PTO's rejection of Chakrabarty's claims, Malcolm E. Bergy⁵⁰ filed patent applications for a microorganism and a microbiological process for preparing the antibiotic lincomycin by cultivating the newly discovered microorganism *Streptomyces vellosus* in an aqueous nutrient medium under aerobic conditions. The antibiotic had previously been obtainable, though less efficiently,⁵¹ from a different microorganism called *Streptomyces lincolnensis*.⁵²

Bergy's patent application contained four claims directed to the processes involved,⁵³ all of which were allowed. The patent examiner, however, rejected claim five,⁵⁴ which was directed to a biologically-pure culture of the

by the Commissioner. *Id.* Appeal to the Board is provided for in 35 U.S.C. § 134 (1976), which states that "[a]n applicant for a patent, any of whose claims has been twice rejected, may appeal from the decision of the primary examiner to the Board of Appeals, having once paid the fee for such appeal." *Id.*

47. 596 F.2d at 971, 201 U.S.P.Q. at 370.

48. *Id.*

49. *Id.*

50. Bergy's co-inventors were John H. Coats and Vedpal S. Malik. *Id.* at 967, 201 U.S.P.Q. at 366. The real party in interest was The Upjohn Company, as assignee of the patent application. *Id.* at 956, 201 U.S.P.Q. at 357.

51. The reason that *Streptomyces vellosus* is more efficient is that lincomycin is produced without the concomitant production of lincomycin B (4'-depropyl-4'-ethyl-lincomycin). The absence of lincomycin B production results in increased lincomycin recovery efficiency. *Id.* at 967, 201 U.S.P.Q. at 366.

52. The former process involving *Streptomyces lincolnensis* was the subject of U.S. Patent No. 3,086,912. *Id.*

53. *Id.* Of claims 1-4 the only independent process claim was claim 1 which reads as follows:

A novel process for preparing the antibiotic lincomycin which comprises cultivating *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, and lincomycin-producing mutants thereof, in an aqueous nutrient medium under aerobic conditions until substantial antibiotic activity is imparted to said medium by the production of lincomycin.

Id.

54. Claim 5 was: "A biologically pure culture of the microorganism *Streptomyces vellosus*, having the identifying characteristics of NRRL 8037, said culture being capable of producing the antibiotic lincomycin in a recoverable quantity upon fermentation in an aqueous nutrient medium containing assimilable sources of carbon, nitrogen and inorganic substances." *Id.*

microorganism *Streptomyces vellosus*, on the ground that it was a product of nature.⁵⁵ On appeal, the Board sustained the rejection, but, in so doing, it ignored the ground set forth by the examiner.⁵⁶ Instead, the Board relied on the reasoning of the *Chakrabarty* Board that claim five was properly rejected because it was drawn to a living organism and, therefore, was unpatentable subject matter under section 101.⁵⁷

Due to a delay caused by a request for reconsideration by the PTO in *Chakrabarty*, the *Bergy* appeal was the first to reach the United States Court of Customs and Patent Appeals. The CCPA reversed the Board's rejection of Bergy's claim five.⁵⁸ When *Chakrabarty* then was appealed to the CCPA, it too was reversed on the basis of the *Bergy* decision.⁵⁹ On appeal to the Supreme Court, *Bergy* was summarily vacated⁶⁰ and remanded to the CCPA for further consideration in light of *Flook*.⁶¹ The

55. *Id.* at 972, 201 U.S.P.Q. at 370. Bergy responded to the rejection with a request to reconsider that was supported by affidavits of three Upjohn microbiologists. *Id.* The affidavits pointed out that the claimed microorganism (*Streptomyces vellosus*) did not exist in nature as a "biologically pure culture." *Id.* They also asserted that such a culture is a "manufacture" under 35 U.S.C. § 101 (1976). *Id.* The point Bergy made is that a "biologically pure culture" is "a product of a microbiologist." *Id.* After considering the affidavits, the examiner adhered to his former position. *Id.*, 201 U.S.P.Q. at 371.

56. *Id.* These actions by the Board raised a technical procedural question which the court in *Bergy* quickly disposed of:

Since *In re Wagenhorst*, 64 F.2d 780, 20 CCPA 991, 17 USPQ 330 (1933), it has been the rule that when the board affirms an examiner's rejection generally without reversing a ground the examiner relied on, that ground is assumed to be affirmed. See 37 CFR 1.196 (a). We have an anomalous situation here in that the board affirmed on a *new* ground without so stating, not reaching the *sole* ground relied on by the examiner. Therefore, in case there is doubt as to whether the examiner's product-of-nature rejection is still an issue in this case, in the interest of judicial economy we rule on it now. It involves only a question of law and there is sufficient evidence in the record. . . . We hold that Bergy's claim 5 clearly does not define a product of nature.

Id. at 972-73, 201 U.S.P.Q. at 371 (emphasis in original).

57. *Id.* at 972, 201 U.S.P.Q. at 371.

58. *In re Bergy*, 563 F.2d 1031, 1039, 195 U.S.P.Q. 344, 351 (C.C.P.A. 1977), *vacated sub nom.* *Parker v. Bergy*, 438 U.S. 902, 198 U.S.P.Q. 257 (1978).

59. *In re Chakrabarty*, 571 F.2d 40, 43, 197 U.S.P.Q. 72, 75 (C.C.P.A. 1978).

60. *Parker v. Bergy*, 438 U.S. 902, 198 U.S.P.Q. 257 (1978).

61. See notes 14, 15, and accompanying text *supra*. Flook's patent application concerned a process claim for a mathematical algorithm ("[a] procedure for solving a given type of mathematical problem"). *Parker v. Flook*, 437 U.S. 584, 585 n.1, 198 U.S.P.Q. 193, 195 n.1 (1978), quoting *Gottschalk v. Benson*, 409 U.S. 63, 65, 175 U.S.P.Q. 673, 674 (1972)), which provided a more efficient method of updating alarm limits during the catalytic conversion of hydrocarbons. Flook's claim had previously been allowed by the CCPA in *In re Flook*, 559 F.2d 21, 195 U.S.P.Q. 9 (C.C.P.A. 1977), since the algorithm was tied to a specific end use and a patent on the method would not preempt the algorithm. The Supreme Court reversed, however, holding that because the only novel feature of the claimed method was the algorithm which must be considered to be part of the prior art, the process was not patentable subject matter under § 101 because there was no other inventive concept in its application. *Parker v. Flook*, 437 U.S. at 596, 198 U.S.P.Q. at 200 (1978).

CCPA subsequently vacated its decision in *Chakrabarty* so that it could be reconsidered together with *Bergy*.

ANALYSIS

When the Supreme Court summarily vacated⁶² the judgment in *Bergy* and remanded it to the CCPA for reconsideration in light of *Flook*, it issued no directives to indicate what bearing *Flook* had on *Bergy*. It was necessary, therefore, for the CCPA to analyze *Flook* diligently and to consider every possible application.

In *Bergy*, the court found that the only factor the *Bergy* and *Chakrabarty* appeals had in common with *Flook* was that both involved section 101.⁶³ The basic issues addressed in *Bergy* and *Flook*, however, were distinctly different. The *Bergy* court viewed the issue in *Flook* as the definition of a "process" under section 101 in the context of computer program protection;⁶⁴ the issue in *Bergy* was whether a living organism is patentable subject matter under section 101 as either a manufacture or a composition of matter.⁶⁵ Thus, even though both cases involved section 101, the claims at issue were directed to different classes of statutory subject matter.⁶⁶ Additionally, *Flook* involved a claim for an improved method of calculation; neither of the appeals in *Bergy* was concerned with methods of calculation. Thus, the court in *Bergy* held that the *Flook* holding had no bearing on either *Bergy* or *Chakrabarty*.⁶⁷

Judge Baldwin, in his concurring opinion, however, did not agree with that view.⁶⁸ He noted that in the determination of whether an invention falls into one of the four classes of subject matter in section 101, a literal interpretation of that section is precluded by Supreme Court precedent identifying certain categories of nonpatentable subject matter.⁶⁹ This precedent established the principle that the discovery of a so-called law of nature or scientific principle *per se* cannot form the basis of a patent because the abstract law or principle does not come within the statutory classes of patentable inventions.⁷⁰ If a patent were allowed on a natural law or scientific principle *per se*, the effect would be to preempt all others from using that law or principle, which is and should remain available for all to use.⁷¹ Thus, the Supreme Court has not allowed claims that attempt to define the limits of the invention in terms of the natural law or phenomenon involved be-

62. *Parker v. Bergy*, 438 U.S. 902, 198 U.S.P.Q. 257 (1978).

63. 596 F.2d at 964, 201 U.S.P.Q. at 364.

64. *Id.* at 964-65, 201 U.S.P.Q. at 364.

65. *Id.* at 956, 201 U.S.P.Q. at 357.

66. *Id.* at 964-65, 201 U.S.P.Q. at 364.

67. *Id.* at 965, 201 U.S.P.Q. at 365.

68. *Id.* at 988, 201 U.S.P.Q. at 383 (Baldwin, J., concurring).

69. See notes 72-73 *infra*.

70. See generally 1 DELLER, *supra* note 20, § 23.

71. *Id.*

cause all others would be preempted from using that phenomenon.⁷² Conversely, the Supreme Court has allowed claims where the natural laws or phenomena involved are applied to a practical purpose to produce a new and useful result and are expressly limited to the claimed invention.⁷³

Because the Court in *Flook* reviewed those Supreme Court cases that have examined the patentability of natural phenomena, Judge Baldwin considered them to be "particularly germane" to the appeals in *Bergy*, as both *Bergy's* and *Chakrabarty's* claimed inventions involved natural phenomena.⁷⁴ He felt that prior to the determination of statutory subject matter under section 101, the court first should ascertain whether or not the claim attempts to preempt the use of the natural phenomena involved.⁷⁵

72. In *O'Reilly v. Morse*, 56 U.S. (15 How.) 61 (1853), the inventor attempted to define the limits of his invention of the telegraph in terms of electromagnetism. Morse's claim 8 stated:

I do not propose to limit myself to the specific machinery, or parts of machinery, described in the foregoing specifications and claims; the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for making or printing intelligible characters, letters, or signs, at any distances, being a new application of that power, of which I claim to be the first inventor or discoverer.

Id. at 86. Because Morse's claim would have preempted all others from using electromagnetism in any telegraphic device the Court rejected it, stating:

If this claim can be maintained, it matters not by what process or machinery the result is accomplished. For aught that we now know some future inventor, in the onward march of science, may discover a mode of writing or printing at a distance by means of the electric or galvanic current, without using any part of the process or combination set forth in the plaintiff's specification. His invention may be less complicated—less liable to get out of order—less expensive in construction, and in its operation. But yet if it is covered by this patent the inventor could not use it, nor the public have the benefit of it without the permission of this patentee.

Id. at 113.

In *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 U.S.P.Q. 280 (1948), the inventor attempted to patent an inoculant containing an unspecified, mutually non-inhibitive mixture of bacteria of the genus *Rhizobium*, which infect the roots of leguminous plants (i.e. beans, peas) and form nodules and thus enable the plants to transform atmospheric nitrogen into organic nitrogenous compounds necessary for growth. Because the claim would preempt the use of the non-inhibitive phenomena of the bacteria, the Court disallowed the claimed invention, stating:

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.

Id. at 131, 76 U.S.P.Q. at 281. Justice Frankfurter noted, however, that if the claim had been drawn to a specific mixture of the bacteria, a patent would have been issued. *Id.* at 133, 76 U.S.P.Q. at 282 (Frankfurter, J., concurring).

73. In *Leroy v. Tatham*, 55 U.S. (14 How.) 156 (1852), the inventor implemented a newly discovered natural phenomenon of lead in the formation of lead pipes. The claim at issue was allowed because it was expressly limited to the claimed apparatus and did not directly or indirectly preempt the antenna system which utilized principles of electromagnetic wave propagation and the phenomena of standing waves to achieve new and useful results.

74. 596 F.2d at 988, 201 U.S.P.Q. at 384 (Baldwin, J., concurring).

75. *Id.* at 996, 201 U.S.P.Q. at 390.

In Bergy's invention, the natural phenomena are the metabolic processes by which *Streptomyces vellosus* synthesizes the antibiotic lincomycin. Bergy's inventive application of these phenomena was the cultivation of *Streptomyces vellosus* free from impurities under fermentation conditions that maximize lincomycin production.⁷⁶ There was no preemption of the phenomena involved, because Bergy's claim was directed to a particular strain of *Streptomyces* and there are other strains of *Streptomyces* that are also capable of synthesizing lincomycin.⁷⁷ In Chakrabarty's invention, the natural phenomenon was the metabolic degradation of hydrocarbon compounds. Chakrabarty's inventive application of this phenomenon is the creation of a new strain of *Pseudomonas*, achieved by the transfer of plasmids, which possess hydrocarbon degradative pathways.⁷⁸ Chakrabarty's claim was limited to those strains of *Pseudomonas* containing two or more of these plasmids.⁷⁹ There was no preemption of the phenomena because other strains of *Pseudomonas* exist that possess only one such plasmid.⁸⁰ Thus, Judge Baldwin agreed with the majority that the claimed microorganisms in *Bergy* define statutory inventions.⁸¹

The *Bergy* court also considered a passage from *Deepsouth Packing Co. v. Laitram Corp.*,⁸² adopted by the Court in *Flook*,⁸³ indicating that patent rights should not be expanded by overruling or modifying prior judicial interpretation of the patent statute without a clear and certain signal from Congress.⁸⁴ The *Bergy* court found no relevance in this passage,⁸⁵ because

76. 596 F.2d at 967, 201 U.S.P.Q. at 366.

77. As Bergy noted in his patent application, *Streptomyces lincolnensis* also possesses the capability to produce *lincomycin*. *Id.*

78. *Id.* at 968-69, 201 U.S.P.Q. at 367-68.

79. See note 43 *supra*.

80. 596 F.2d at 997, 201 U.S.P.Q. at 391 (Baldwin, J., concurring).

81. *Id.*

82. 406 U.S. 518, 173 U.S.P.Q. 769 (1972).

83. *Parker v. Flook*, 437 U.S. 584, 596, 198 U.S.P.Q. 193, 200 (1978). In *Flook* the Court relied on the passage as an indication that caution must be used when asked to extend the patent laws into areas wholly unforeseen by Congress.

84. The entire *Deepsouth* passage which the *Flook* opinion quoted reads:

[W]e should not expand patent rights by overruling or modifying our prior cases construing the patent statutes, unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language. We would require a clear and certain signal from Congress before approving the position of a litigant who, as respondent here, argues that the beachhead of privilege is wider, and the area of public use narrower, than the courts had previously thought. No such signal legitimizes respondent's position in this litigation.

Id. at 596, 198 U.S.P.Q. at 200, quoting *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. at 531, 173 U.S.P.Q. at 774. The issue in *Deepsouth* was whether the selling of unassembled parts of patented machines to foreign buyers who assembled and used them abroad constituted patent infringement. The relevant statutory provision, 35 U.S.C. § 271 (1976), explicitly limits infringement to actions performed within the United States. The precedent that the Court felt it would be overruling was *Dowagiac Mfg. Co. v. Minnesota Moline Plow Co.*, 235 U.S. 641, 650 (1915), and *Brown v. Duchesne*, 60 U.S. (19 How.) 183, 195 (1857). Thus, the Court in *Deep-*

the issue presented in *Bergy* was one of first impression in the courts, and no established precedent was overruled.⁸⁶ Thus, the court's holding in

south felt that upholding a claim for patent infringement, when the acts complained of were not performed in the United States, would be in derogation to established precedent and an extension of the patent laws which should only be done upon a signal from Congress. *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. at 531, 173 U.S.P.Q. at 774 (1972).

85. 596 F.2d at 966-67, 201 U.S.P.Q. at 365-66.

86. The PTO, in support of its position that living organisms are unpatentable subject matter under § 101, was able to cite to only two cases—*In re Mancy*, 499 F.2d 1289, 182 U.S.P.Q. 303 (C.C.P.A. 1974) and *Guaranty Trust Co. of N.Y. v. Union Solvents Corp.*, 54 F.2d 400, 12 U.S.P.Q. 47 (D. Del. 1931), *aff'd per curiam*, 61 F.2d 1041, 15 U.S.P.Q. 237 (3d Cir. 1932), for dicta which suggested that living organisms are unpatentable subject matter under § 101. *Mancy* involved claims to a process of producing a particular known antibiotic by cultivating the bacteria *Streptomyces bifurcus*. The claims had not been allowed on the ground that they were nonobvious under 35 U.S.C. § 103, because various other strains of *Streptomyces* were also used for the same purpose. The C.C.P.A. reversed, holding that *In re Kuehl*, 475 F.2d 658, 177 U.S.P.Q. 250 (C.C.P.A. 1973), was controlling and that the new strain (*S. bifurcus*) that *Mancy* discovered could not be viewed as prior art in determining the obviousness of his claim under § 103. The dicta that the PTO relied upon was the CCPA's comparison of *Mancy* to *Kuehl*:

We recognize the difference between this case and the situation in *Kuehl*, where the novel zeolite used as a catalyst in the claimed hydrocarbon cracking processes was itself the subject of allowed claims in the application. Here appellants not only have no allowed claims to the novel strain of *Streptomyces* used in their process but would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a "product of nature". However, it is not required for unobviousness of the method-of-use claims that the new starting material be patentable.

In re Mancy, 499 F.2d at 1294, 182 U.S.P.Q. at 306. In *Bergy*, the court made it clear that in *Mancy* it was not expressing any view on the patentability of living organisms as such:

[T]he thought underlying our presumption that *Mancy* could not have obtained a claim to the strain of microorganism he had described was simply that it *lacked novelty*. We were thinking of something preexisting and merely plucked from the earth and claimed as such, a far cry from a biologically pure culture produced by great labor in a laboratory and so claimed. . . . [I]n light of what we have learned in this case about the separation and identification of new strains of *Streptomyces* . . . our dictum was ill-considered. Had we known what we now know, we would likely have abjured the stated presumption.

596 F.2d at 976, 201 U.S.P.Q. at 374 (emphasis in original).

In *Guaranty Trust*, the court upheld a patent for a process for the production of acetone and butyl alcohol by bacteriological fermentation. In so doing, the court observed:

Lastly, the defendant contends that the invention of the Weizmann patent is unpatentable since it is for the life process of a living organism. Were the patent for bacteria per se, a different situation would be presented. As before stated, the patent is not for bacteria per se. It is for a fermentation process employing bacteria discovered by Weizmann under conditions set forth in the specifications and claims.

Undoubtedly there is patentable subject matter in the invention.

Guaranty Trust Co. of N.Y. v. Union Solvents Corp., 54 F.2d at 410, 12 U.S.P.Q. at 57. In *Bergy*, the court deemed this dicta "a trite observation of minimal magnitude as precedent, dealing with a non-issue on which no opinion was expressed." 596 F.2d at 977, 201 U.S.P.Q. at 374.

Bergy is simply an interpretation of section 101 that the court is free to make without a signal from Congress.⁸⁷

Judge Miller, in his dissent, however, did not agree⁸⁸ with the majority and felt that the passage quoted from *Deepsouth* was the essential thrust of the Court's opinion in *Flook*. He interpreted the passage as an indication that "where there is a basis for substantial doubt over the intent of Congress regarding the breadth of the language in the statute, the court will await a 'clear and certain signal from Congress' on the subject."⁸⁹ The basis for substantial doubt, in his opinion, was whether Congress intended inventions embodying organisms to be embraced by the words "manufacture" or "composition of matter." Judge Miller's doubt stems from his belief that Congress, by passing the Plant Patent Act of 1930, clearly did not intend that any organisms, other than plants, be within the scope of section 101. If Congress had intended otherwise it would not have enacted the legislation, because Congress is presumed not to legislate unnecessarily.⁹⁰

The Plant Patent Act of 1930, however, is inconclusive as evidence that section 101 was not meant to encompass living organisms when claimed as either manufactures or compositions of matter. The intent of a previous Congress cannot be inferred by looking to the legislative history of the Plant Patent Act. To do so is to attribute an intent to a preceding Congress which the members of that Congress did not themselves state. The Supreme Court has consistently frowned on this practice,⁹¹ and, as the court in *Bergy* noted, it "is not even rational speculation."⁹²

Also, the explicit purpose of the Plant Patent Act should be viewed from an historical perspective.⁹³ American agriculture at the turn of the century was experiencing difficulties, causing the farm lobby to petition Congress for relief.⁹⁴ Plant breeding at that time was, essentially, in an embryonic state

87. "Faced with the necessity of rendering a decision one way or the other on whether these inventions are encompassed by § 101, there being no prior decisions to guide us, we merely carry out our normal judicial function in deciding to say yes rather than no." *Id.* at 987, 201 U.S.P.Q. at 383.

88. 596 F.2d at 999-1002, 201 U.S.P.Q. at 392-95 (Miller, J., dissenting).

89. *Id.* at 999, 201 U.S.P.Q. at 392 (Miller, J., dissenting) (emphasis in original).

90. *Id.* As support for this premise, Judge Miller cited *Platt v. Union Pacific R.R.*, 99 U.S. 48, 58 (1878); *Skovgaard v. M/V Tungus*, 252 F.2d 14, 17 (3d Cir. 1957), *aff'd*, 358 U.S. 588 (1959); *United States v. Korpan*, 237 F.2d 676, 680 (7th Cir. 1956), *rev'd on other grounds*, 354 U.S. 271 (1957); *In re Finch*, 535 F.2d 70, 71, 190 U.S.P.Q. 64, 65 (C.C.P.A. 1976); *United States v. C.J. Tower & Sons*, 44 C.C.P.A. 1, 5 C.A.D. 626 (1956).

91. The Supreme Court has consistently and unequivocally concluded that "the views of a subsequent Congress form a hazardous basis for inferring the intent of an earlier one." *United States v. Price*, 361 U.S. 304, 313 (1960). *Accord*, *United States v. Southwestern Cable Co.*, 392 U.S. 157, 170 (1968); *United States v. Philadelphia Nat'l Bank*, 374 U.S. 321, 348-49 (1963); *Rainwater v. United States*, 356 U.S. 590, 593 (1958); *United States v. United Mine Workers*, 330 U.S. 258, 281-82 (1947).

92. 596 F.2d at 980, 201 U.S.P.Q. at 377.

93. "[S]tatutes are construed by the courts with reference to the circumstances existing at the time of passage." *United States v. Wise*, 370 U.S. 405, 411 (1962).

94. 596 F.2d at 981, 201 U.S.P.Q. at 378.

and had not yet developed into an industry.⁹⁵ By passing the Plant Patent Act, Congress felt that agricultural development would be placed on an equal economic basis with industry.⁹⁶ Thus, the intent of Congress in passing the legislation was to extend the patent system to what was then a non-industrial area.⁹⁷ The fact that plants were alive was completely ignored.

The Plant Patent Act also helped spur agricultural development by avoiding any deterrence resulting from faulty judicial interpretation.⁹⁸ Until plant breeding began its growth, the Patent Office had rejected patents for plants as products of nature.⁹⁹ The Plant Patent Act simply avoided any possible judicial disagreement over whether or not plants produced by breeding were products of nature.¹⁰⁰ Another problem that was avoided by passing the Act was compliance with the written description requirements of the existing statutes. The amended statute insured that no plant patent would be declared invalid for noncompliance with the description require-

95. *Id.* at 982, 201 U.S.P.Q. at 378-79.

96. *Id.*

97. *Id.* This premise was set forth in both the House and the Senate reports:

I. Purposes of the Bill

The purpose of the bill is to afford agriculture, as far as practicable, the same opportunity to participate in the benefits of the patent system as has been given industry, and thus assist in placing agriculture on a basis of economic equality with industry.

The bill will remove the existing discrimination between plant developers and industrial inventors.

S. REP. NO. 315, 71st Cong., 2d Sess. 1 (1930); H.R. REP. NO. 1129, 71st Cong., 2d Sess. 1 (1930).

98. 596 F.2d at 982, 201 U.S.P.Q. at 379.

99. The controlling law in the Patent Office at that time with respect to plants was *Ex Parte Latimer*, 1889 Dec. Com. Pat. 123, 46 Off. Gaz. Pat. Office 1638 (1889). In *Latimer*, a claim directed to the fiber of the needle of the tree *Pinus australis* was rejected on the ground that it was a product of nature:

It cannot be said that the applicant in this case has made any discovery, or is entitled to patent the idea, or fact, rather, that fiber can be found in the needle of the *Pinus australis*, or that it is a longer fiber than can be found in other leaves, or that it possesses more or less strength or fineness, because the mere ascertaining of the character or quality of trees that grow in the forest and the construction of the woody fiber and tissue of which they are composed is not a patentable invention, recognized by the statute, any more than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found The result would be that . . . patents might be obtained upon the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible

[T]he fiber . . . is a natural product and can no more be the subject of a patent in its natural state when freed from its surroundings than wheat which has been cut by a reaper or by some new method of reaping can be patented as wheat cut by such a process.

Id. at 125-27.

100. In concluding that the product of nature argument would be inapplicable to asexually produced plants both the Senate and House reports stated:

A plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man It is obvious that nature originally creates plants but it cannot be denied that man often controls and directs the natural processes and produces a desired result Furthermore, there is no apparent difference, for instance, between the part played by the plant

ments.¹⁰¹ In *Bergy* the court noted¹⁰² that no such modification of existing patent law was necessary to accommodate the patenting of industrially useful microorganisms.

The court in *Bergy* also strongly resisted the notion that it was extending the patent laws.¹⁰³ In support of this contention, the court noted that even though the issue involved in *Bergy* was one of first impression in the courts, it was not new to the PTO. For example, in 1873, Louis Pasteur obtained a United States patent for "[y]east, free from organic germs of disease, as an article of manufacture."¹⁰⁴ The court also noted several other patents obtained on living matter claimed as compositions of matter.¹⁰⁵ Because the PTO already had issued several patents pertaining to living organisms, the ruling in *Bergy* did not expand the patent laws. Indeed, the PTO's position was inconsistent with its own ruling on Chakrabarty's claims. One of the claims allowed by the PTO had been directed to Chakrabarty's bacterium carried on the straw,¹⁰⁶ the preferred method of application. (The bacteria carried on the straw is still alive.) The only difference between that claim and the rejected claim was that the latter represents a patent on "life itself" while the former does not. Apparently, this distinction bothered the PTO. The fact remains, however, that the allowed claim contained living organisms and was considered by the PTO to be patentable subject matter under section 101 as either a manufacture or a composition of matter.¹⁰⁷

The court in *Bergy* also noted several cases where claims to processes involving living organisms or their life processes were considered to be patentable subject matter under section 101.¹⁰⁸ The process claims of both

originator in the development of new plants and the part played by the chemist in the development of new compositions of matter.

S. REP. NO. 315, *supra* note 97, at 6-7; H.R. REP. NO. 1129, *supra* note 97, at 6-7.

101. 35 U.S.C. § 162 (1976) provides in part that "[n]o plant patent shall be declared invalid for noncompliance with section 102 of this title if the description is as complete as is reasonably possible."

102. 596 F.2d at 984, 201 U.S.P.Q. at 380. The court in *Bergy* noted that the microorganism inventions of both *Bergy* and *Chakrabarty* were described and claimed so as to comply with the written description and claiming provisions of 35 U.S.C. § 112 (1976).

103. 596 F.2d at 984-87, 201 U.S.P.Q. at 381-83.

104. *Id.* at 985, 201 U.S.P.Q. at 381. This claim is the subject of the United States Patent 141,072, claim 2. *Id.*

105. The *Bergy* court cited DAUS, BOND & ROSE, *Microbiological Plant Patents*, 10 IDEA 87 (1966). This article presented a critical examination of the CCPA's decision in *In re Arzberger*, 112 F.2d 834, 46 U.S.P.Q. 32 (C.C.P.A. 1940), where the court held that bacteria were not covered under the Plant Patent Act of 1930. The authors (all Assistant Examiners in the United States Patent Office) listed several existing patents drawn to living organisms and cultures used in foods, insecticides, and vaccines. 10 IDEA at 94-95 n.36, 596 F.2d at 85-86, 201 U.S.P.Q. at 381-82.

106. This was Chakrabarty's claim 30. *See* note 42 *supra*.

107. 596 F.2d at 986, 201 U.S.P.Q. at 382.

108. *Id.* at 977. *See* *City of Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 21 U.S.P.Q. 69 (7th Cir. 1934), *cert. denied*, 293 U.S. 576 (1934) (bacteriological purification of sewage); *Cameron Septic Tank Co. v. Village of Saratoga Springs*, 159 F. 453 (2d Cir. 1908) (the original septic tank case; bacterial action process claims were held valid and infringed); *Dick v. Lederle Antitoxin Laboratories*, 43 F.2d 628, 6 U.S.P.Q. 40 (S.D.N.Y. 1930) (process for producing

Bergy and *Chakrabarty* were allowed and they too encompassed living organisms.¹⁰⁹ In *Bergy*, the court felt that it was illogical to insist that the existence of life in a manufacture or a composition of matter removed it from patentable subject matter under section 101 while the utilization of living organisms in processes did not affect their status under section 101.¹¹⁰

THE IMPACT OF BERGY

The *Bergy* decision has opened the door to patent protection for the products of recombinant DNA research,¹¹¹ a relatively new¹¹² and highly controversial technology that exhibits tremendous potential for social benefit. The granting of such patent protection should prove to be a major impetus to the advancement of this technology in accordance with the constitutionally stated purpose of the patent laws.¹¹³ While not involved in *Bergy's* invention,¹¹⁴ recombinant DNA research is the technology that *Chakrabarty* utilized to develop his oil-eating microorganism.¹¹⁵ Other biologists have utilized recombinant DNA techniques to fashion microorganisms that can manufacture human insulin and antiviral compounds, synthesize vaccines and break down industrial waste.¹¹⁶ At this time, there appears to be no upper limit to the potential of recombinant DNA research.

The controversy surrounding recombinant DNA stems from fears expressed by many that it creates biohazards as well as benefits.¹¹⁷ Because these organisms are fashioned in a laboratory and are not the natural products of evolutionary processes, other living things may lack adequate natural defenses to any pathogenic¹¹⁸ tendencies of those organisms. Thus, the inadvertent or even purposeful release of the organisms into the environment

scarlet fever antitoxin by injecting an animal with sterile toxin and obtaining the antitoxin therefrom). See also *In re Mancy*, 499 F.2d 1289, 182 U.S.P.Q. 303 (C.C.P.A. 1974) (process for producing antibiotic using previously unknown microorganisms); *Ex parte Prescott*, 19 U.S.P.Q. 178 (Pat. Off. Bd. App. 1932) (bacteriological production of butyl and isopropyl alcohol).

109. See notes 41, 42, 53 and accompanying text *supra*.

110. 596 F.2d at 977, 201 U.S.P.Q. at 375.

111. DNA (deoxyribonucleic acid) is the basic genetic material of all living organisms. Recombinant DNA is the process of taking genes from one organism and splicing them into the genes of another. See VAN NOSTRAND'S SCIENTIFIC ENCYCLOPEDIA 1894-96 (5th ed. 1976).

112. See NEWSWEEK, August 20, 1979, at 53. Recombinant DNA technology was perfected only six years ago.

113. See note 2 *supra*.

114. The technology utilized by *Bergy* to develop his invention involves the culturing of microorganisms. This technology, not "new" in any sense, has been existent since the time of Louis Pasteur (1870's). 596 F.2d at 985, 201 U.S.P.Q. at 381.

115. *Id.* at 968-71, 201 U.S.P.Q. at 367-69.

116. See NEWSWEEK, August 20, 1979, at 53.

117. See generally J. GOODFIELD, PLAYING GOD (1977); J. RICHARDS, RECOMBINANT DNA: SCIENCE, ETHICS AND POLITICS (1978); M. ROGERS, BIOHAZARD (1977); Curtiss, *Genetic Manipulation of Microorganisms: Potential Benefits and Biohazards*, 30 ANN. REV. OF MICROBIOLOGY 507 (1976).

118. A pathogen is "a specific causative agent (as a bacterium or virus) of disease." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1655 (1961).

may have devastating effects of unknown proportions.¹¹⁹ As a result of these fears, recombinant DNA research has been the subject of several community hearings and has been studied by the Congress.¹²⁰ In addition, the National Institute of Health (NIH) has issued guidelines¹²¹ which, if followed, greatly lessen the risks by requiring escape-proof labs and weakened strains of bacteria that cannot survive outside the laboratory.

Despite these attempts to provide adequate safeguards for recombinant DNA research, the controversy has continued¹²² and may well have been a factor in the PTO's position against providing patent protection to microorganism inventions. The court in *Bergy*, however, correctly realized that the proper forum for such debate is the legislature and not the courts.¹²³ Microorganism inventions are now patentable subject matter under section 101. If Congress decides that certain microorganism inventions (*i.e.*, the products of recombinant DNA research) are not deserving of patent protection because the potential hazards outweigh the benefits, Congress can exclude such inventions from patent protection.¹²⁴ Even if such legislation is enacted, however, *Bergy* still will provide patent protection for a wide range of industrially useful microorganisms.

119. See Wade, *Dicing with Nature: Three Narrow Escapes*, 195 SCI. 378 (1977). The author reports on three incidents illustrating the potential hazards of recombinant DNA. Interestingly, one of the incidents involved Dr. Chakrabarty. Chakrabarty had put a gene for cellulase (an enzyme that breaks down the plant structural protein cellulose which is indigestible by humans and therefore gives bulk to the feces) into the bacterium *Escherichia coli* (a common inhabitant of the human gut). Chakrabarty had planned to insert methane-forming genes into the bacterium so that it could turn wastes such as sewage sludge directly into usable methane gas. Theorists warned, however, that should such an *E. coli* spread throughout the population, a large number of people might contract chronic or even fatal diarrhea. Because of this possibility, Chakrabarty destroyed the bug. *Id.*

120. See *Recombinant DNA Research of 1977: Hearings Before the Subcomm. on Health and the Environment of the House Comm. on Interstate and Foreign Commerce*, 95th Cong., 1st Sess. (1977).

121. See *Guidelines for Research Involving Recombinant DNA Molecules*, 41 Fed. Reg. 27902 (1976); *Recombinant DNA Research: Revised Guidelines*, 43 Fed. Reg. 60080 (1978). These guidelines, however, apply only to federally funded research. In order to induce private industry to voluntarily comply with the guidelines, the Assistant Secretary of Commerce for Science and Technology requested that the PTO accord special status to patent applications involving recombinant DNA. See *Recombinant DNA: Accelerated Processing of Patent Applications for Inventions*, 42 Fed. Reg. 2712 (1977), suspended in part by *Recombinant DNA: Suspension of Accelerated Processing of Patent Applications for Recombinant DNA Research Inventions*, 42 Fed. Reg. 13147 (1977).

122. See generally Berger, *Government Regulation of the Pursuit of Knowledge: The Recombinant DNA Controversy*, 3 VT. L. REV. 83 (1978).

123. 596 F.2d at 986-87, 201 U.S.P.Q. at 382-83.

124. Congressional legislation prohibiting patent protection for certain inventions would not be a new thing. For example, under the 1954 Atomic Energy Act, Act of Aug. 30, 1954, ch. 13 68 Stat. 943, the patenting of certain inventions relating to nuclear energy is prohibited. The provision currently is codified in 42 U.S.C. § 2181 (1976) and states in part: "No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon."

The effect of recombinant DNA research is the development of useful organisms through the recombination of various desired genetic properties of different organisms. An alternative means of combining the genetic properties of species without the expense and the dangers inherent in recombinant DNA involves mixed-culture systems of microorganisms.¹²⁵ These systems, however, are likely to create certain problems not evident in monoculture systems like Bergy's and Chakrabarty's.

The problems with mixed-culture systems are likely to surface with regard to the specification requirements of section 112.¹²⁶ That section provides that an inventor's specification sufficiently describe the claimed invention to enable one skilled in the art to reproduce it. In the case of microorganism inventions, these requirements are best satisfied by depositing a sample of the microorganism in a suitable depository where the microorganism can be maintained in a culture. In such a patent deposition, it is often desirable and usually necessary to be able clearly to identify and name the microorganism in a culture. While this may be fairly simple for a monoculture, it becomes much more complicated for mixed cultures. The ideal solution is to describe and deposit separately the component species of the mixture, a solution that may not be feasible for mixed cultures, where some of the component species are obligate symbionts.¹²⁷ In such a situation, it may be acceptable to deposit the culture as a mixture but it must still be readily stored and maintained under culture collection conditions. Again, there may be numerous difficulties in the case of complex mixed cultures because certain storage conditions may selectively kill one or more of the component species of the mixture.

In *Bergy*, the court did not foresee any problems with microorganism inventions meeting the requirements of section 112.¹²⁸ Thus, although the court correctly decided the issue of monoculture systems of Bergy and Chakrabarty, the court erred in its failure to address the problems attendant upon more complex mixed-culture systems.

Another consideration concerning the deposition problems is that the vast majority of the microorganisms currently on deposit are commonly occurring, easily isolatable, and relatively easy to maintain in a culture.¹²⁹ As further exploitation of these microorganisms becomes increasingly difficult, microbiological advances are likely to result in the appearance of more exotic and fastidious¹³⁰ kinds of microorganisms.¹³¹ In many instances, curators of

125. See generally Harrison, *Mixed Cultures in Industrial Fermentation Processes*, 24 ADV. IN APP. MICROBIOLOGY 129 (1978).

126. 35 U.S.C. § 112 (1976).

127. Symbiosis is "the condition of two or more different organisms living together in close association." An obligate symbiont, therefore, is "one which cannot exist apart from its partner." P. GRAY, *THE DICTIONARY OF THE BIOLOGICAL SCIENCES* 53 (1967).

128. 596 F.2d at 984, 201 U.S.P.Q. at 380.

129. See generally Pridham & Hesseltine, *Culture Collections and Patent Depositions*, 19 ADV. IN APP. MICROBIOLOGY 1 (1975) [hereinafter cited as Pridham & Hesseltine].

130. A fastidious microorganism is one "having complex nutritional requirements." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 827 (1961).

the depositories may not be able to work with these microorganisms because the handling of such materials may exceed their expertise or limitations. Thus, because the curators have a responsibility to both the patentee and to the public, depositories may be forced to limit the types of microorganism inventions that they can accept. It may be desirable, therefore, for the PTO to establish special depositories designed and equipped to cope with these problems.

Thus far the discussion has concerned only the present impact of *Bergy* given the current state of biotechnology. It is interesting to speculate, however, on what sort of living inventions will be eligible for patent protection now and in the future, and whether *Bergy* will be extended beyond microorganisms to higher life forms. The most likely candidates for patent protection will be animals that may have a marketable value either through the direct use of the animal or its byproducts. The majority of living inventions most likely will be aimed at solving the problems caused by the rapidly increasing size of the human population. Solutions will be required in the development of useful drugs for the treatment of disease, in handling municipal and industrial wastes, and most importantly, in the development of adequate food resources. The majority of the industrial applications will involve microorganism inventions, as is presently the case, because they are easier to manipulate and much more versatile than higher life forms. With regard to food, however, as conventional resources prove to be inadequate due to limitations of space and energy, science will develop more exotic and unconventional foods involving a wide range of plants and animals from microorganisms to livestock.¹³²

At present, it is doubtful that life forms other than microorganisms will be eligible for patent protection due to their inability to satisfy one of the requirements of section 112, namely, the enabling disclosure that teaches one skilled in the art how to make and how to use the claimed invention.¹³³ In

131. See Pridham & Hesselstine, *supra* note 129, at 9. The authors expect that "human, animal, and plant pathogens; extreme thermophiles or psychrophiles; diatoms; protozoa; nematodes; viruses; and cell lines of all kinds will appear among patent deposition strains in the years to come." *Id.*

132. See generally Kharatyan, *Microbes as Food for Humans*, 32 ANN. REV. OF MICROBIOLOGY 301 (1978) (microbes may someday be a major source of protein either by direct human consumption or indirectly as a more efficient feed for livestock); Rhyther and Goldman, *Microbes as Food in Mariculture*, 29 ANN. REV. OF MICROBIOLOGY 429 (1975) (in mariculture or sea-farming, certain aquatic organisms like clams, oysters and scallops are cultured in large tanks using microorganisms as a principal food source).

In addition to these unconventional sources of food, developments also will be seen in conventional sources. Genetic advances may someday allow the development of animals of superior nutritional value not now possible through traditional methods of hybridization. In agriculture, increasing genetic uniformity in crop plants has increased their vulnerability to pathogens thereby requiring increased use of pesticides. As the disastrous side-effects of these pesticides has become known, science has looked to the possibility of biological pest control, *i.e.*, developing insects that are natural predators of a particular pest.

133. 35 U.S.C. § 112 (1976). See note 39 *supra* for the pertinent part of section 112.

particular, problems will arise with regard to reproducing the invention. Because a written description of a living organism is generally insufficient to enable one skilled in the art to reproduce it, a sample of the organism must be made available. While depositories exist for the maintenance of microorganisms, it would be a practical impossibility to maintain higher life forms in a genetically unaltered state for indefinite periods. Given certain technological advancements, however, these problems may disappear. The technology of cloning is already feasible in some higher life forms¹³⁴ and may someday be applicable to a wide range of animals. Advances in cloning combined with improved storage techniques that would allow a viable tissue sample to be stored indefinitely without genetic damage would make the deposit of animal inventions a practical reality. Until that time, however, if it ever comes at all, patent protection for living inventions will be limited to microorganism inventions.

THE PREDICTED OUTCOME OF *BERGY* IN THE SUPREME COURT

The Supreme Court's forthcoming decision in *Parker v. Bergy* is dependent on the Court's reasons for granting certiorari. Because the Court issued no directives when it remanded *Bergy* to the CCPA,¹³⁵ these reasons are not readily apparent.

The most likely explanation concerns the economic implications of *Bergy*. The genetic industry is presently in an infant stage and is likely to become a billion-dollar industry. Thus, it is desirable for the Supreme Court to rule on *Bergy* to resolve whatever confusion may exist in the wake of the CCPA's decision.

One possible source of confusion concerns the fact that lawsuits testing the validity of a patent are brought in federal district courts.¹³⁶ On occasion, these district courts may invalidate claims previously held valid by the CCPA. Thus, a Supreme Court ruling will require consistency between the CCPA and the district courts regarding patent protection for living organisms.

Another source of confusion arises from the apparent disagreement between the Supreme Court and the CCPA concerning the Court's analysis of the patent statute in *Flook*. In *Flook*, the Court found Flook's algorithm to be one of the basic tools of scientific research that must be considered to be part of the prior art.¹³⁷ Because the only inventive aspect of Flook's invention was the algorithm, and because there was no other inventive concept in its application, the claim was rejected.¹³⁸ This analysis was strongly

134. See generally R. MCKINNEL, CLONING—NUCLEAR TRANSPLANTATION IN AMPHIBIA (1978).

135. *Parker v. Bergy*, 438 U.S. 902, 198 U.S.P.Q. 257 (1978).

136. 28 U.S.C. § 1338 (1976).

137. *Parker v. Flook*, 437 U.S. 584, 591-92, 198 U.S.P.Q. 193, 198 (1978).

138. *Id.* at 594, 198 U.S.P.Q. at 199.

criticized by Justice Stewart, in his dissenting opinion, for "importing into its inquiry under 35 U.S.C. § 101 the criteria of novelty and inventiveness."¹³⁹ The court in *Bergy* agreed with Justice Stewart and felt that, in *Flook*, the Court had given to the term "prior art" an "entirely new dimension with consequences of unforeseeable magnitude."¹⁴⁰

In *Flook*, the Court rejected the notion that it had improperly imported into section 101 the section 102 and section 103 criteria of novelty and inventiveness. Rather, the Court emphasized that natural phenomena and principles cannot be patented because "they are not the kinds of 'discoveries' that the statute was enacted to protect."¹⁴¹ In their petition for certiorari, the PTO has said that "[l]iving things—whether naturally occurring, isolated, or genetically engineered—are no more 'discoveries' of the kind the statute was enacted to protect than are the mathematical principles involved in *Flook*."¹⁴² Because this fundamental difference of opinion between the PTO and the CCPA in their interpretation of *Flook* is likely to cause considerable confusion in the administration of the patent laws,¹⁴³ Supreme Court review of *Bergy* is warranted.

While the criticisms of the Court's analysis in *Flook* are valid, the Supreme Court can minimize the confusion by expressly stating that *Flook* should apply only to abstract principles like *Flook*'s algorithm and not to tangible phenomenon like the microorganisms of *Bergy*. To hold otherwise would overrule established precedent concerning the patenting of purified products of nature.¹⁴⁴ Thus, upon review of *Bergy*, the Supreme Court

139. *Id.* at 600, 198 U.S.P.Q. at 201 (Stewart, J., dissenting). Justice Stewart was joined in his dissent by Chief Justice Burger and Justice Rehnquist.

140. 596 F.2d at 965, 201 U.S.P.Q. at 365.

[T]he . . . novel *Flook* doctrine may have an unintended impact in putting an untimely and unjustifiable end to the longstanding proposition of law that patentability may be predicated on discovering the cause of a problem even though, once that cause is known, the solution is brought about by obvious means. Such causes may often be classed as laws of nature or their effects. . . . The potential for great harm to the incentives of the patent system is apparent.

It is one thing to say that a principle, natural cause, or formula, *per se*, is not within the categories of 101, but quite another to say it is "prior art" in determining the nonobviousness of an invention predicated on it even though the inventor discovered it.

Id. at 966, 201 U.S.P.Q. at 365.

141. 437 U.S. at 593, 198 U.S.P.Q. at 198.

142. 439 BNA'S PATENT, TRADEMARK & COPYRIGHT JOURNAL D-4 (1979).

143. As evidence that the Supreme Court's analysis in *Flook* is resulting in confusion, see *In re Diehr*, 446 BNA'S PATENT, TRADEMARK & COPYRIGHT JOURNAL A-1 (1979). In *Diehr*, the CCPA held that a claim may not be rejected as non-statutory subject matter "merely because it involves a computer program or is computer-related." *Id.* (emphasis in original). In so doing the court was also forced to clarify that "[c]onsiderations of novelty and obviousness have no bearing on compliance with § 101." *Id.* at A-2; a notion which apparently arose from *Flook*.

144. See Kiley, *Common Sense and the Uncommon Bacterium—Is "Life" Patentable?* 60 J. PAT. OFF. SOC'Y 468, 472-73 (1978):

[E]xtension of *Flook* to pre-existing organisms requires the same extension to pre-existing things. Then to the extent anything predates its discovery, it is unpatentable in isolated form, whether aspirin, or adrenalin, or vitamin B-12. This would

should affirm the CCPA's conclusion that living organisms are patentable subject matter under section 101 when claimed as either manufactures or compositions of matter.

CONCLUSION

In *Bergy*, a court has held for the first time that living organisms are patentable subject matter under section 101 as either manufactures or compositions of matter, notwithstanding its reconsideration in light of *Flook*. The court in *Bergy* was entirely correct in holding that the *Flook* opinion had absolutely no bearing whatsoever on the "issue" in *Bergy*. Because the arguments offered to show why living organisms are not patentable subject matter under section 101 are unpersuasive, the Supreme Court should affirm the CCPA's decision in *Bergy*. The Supreme Court's affirmance is also required by the economic importance of recombinant DNA research and the impact *Bergy* will have on its advancement. In *Bergy*, the court underestimated the difficulties that will be encountered in meeting certain of the specification requirements of section 112, especially in connection with complex mixed cultures and exotic microorganisms. For the same reasons, *Bergy*, in the near future, should be limited to granting patent protection to microorganism inventions and should be extended to higher life forms only when the technology needed to maintain them in depositories is developed. The idea clearly has been established, however, that one now can own a living invention.

Joseph Drazek

reduce to denial of patents on 'products of nature' though they had never before existed in isolated form, overturning a long line of authority to the contrary, and then without regard to the positive good resulting from their isolation. *Id.* (emphasis in original). See note 45 *supra* for some of the precedent that would be overturned.