Bergy, Flook, and Microorganisms as Patentable Products

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BERGY, FLOOK, AND MICROORGANISMS AS PATENTABLE PRODUCTS

Pursuant to its constitutional power to secure for inventors the exclusive right to their inventions for a limited time, Congress enacted the Patent Code in 1790. The purpose of the Code was to encourage the development of useful technology and to disseminate knowledge so that both the "useful arts" and free enterprise would flourish. Realizing it could not anticipate the scope of future technological advancement, Congress set forth a broad definition of patentable subject matter to include any useful art, manufacture, or machine or any new and useful improvement of them. Although this definition has remained virtually intact since the original statute's passage, the kinds of patentable inventions have changed significantly. In this century, chemical, mechanical, and electrical contrivances have comprised the bulk of patentable subject matter. Recently, however, as life forms have begun to demonstrate a commercial

1. The Constitution gives Congress the express power to grant patents and "To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." U.S. Const. art. I, § 8, cl. 8.


3. Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-82 (1974). Granting patents strengthens free enterprise in two ways. First, it encourages competition among inventors. The first inventor to conceive and patent an invention acquires the right to exclude others from making, using, or selling that invention for a limited term. 35 U.S.C. § 154 (1976). Second, when a patented invention is marketed, it spurs others in the field to develop a competing but noninfringing product, see Potts v. Coe, 145 F.2d 27, 31 (D.C. Cir. 1944), or to improve on the original patented invention by developing more beneficial or economical alternatives, see 35 U.S.C. §§ 100-101 (1976) (improvements on patented inventions are patentable). Moreover, the patent law stimulates competitive markets in new technologies by exacting public disclosure of inventions as a quid pro quo for the limited protection, thereby facilitating the flow of new information to potential inventor-competitors. For a discussion of economic objectives of the patent law, see Chief Justice Burger's opinions in Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480-82 (1974), and C.H. Boehringer Sohn v. Watson, 256 F.2d 713, 714 (D.C. Cir. 1958) (per curiam) (Burger, J., concurring).


5. The present Patent Code provides in pertinent part that "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). The primary "conditions and requirements" pertaining to patentability are codified in §§ 102, 103, and 112 of the Act. See notes 21-24 and accompanying text infra.
potential not previously contemplated, the biological sciences have become a source of useful inventions.6

Despite its goal of fostering technological advancements, the patent system has been hesitant to accept these biological inventions within the realm of patentable subject matter. This reluctance was manifested in the nineteenth century when the patent office promulgated a policy against patenting plants.7 More recently, this reluctance has hampered attempts to patent inventions based on microbiological advancements.8 Not until In re Bergy were the myriad of policy considerations restricting the patentability of microorganisms finally overcome. In Bergy the United States Court of Customs and Patent Appeals (CCPA) held that section 101 of the Patent Code does not exclude microorganisms from patent protection solely because they are “alive.”9

This note will explore the statutory matrix in which the controversy over patenting microorganisms has developed and evaluate the policy considerations offered by the Patent and Trademark Office (PTO) and examined by the courts in adjudicating the patentability of microorganisms.

I. PATENTABLE SUBJECT MATTER UNDER SECTION 101 OF THE PATENT CODE

The scope of patentable subject matter is governed by section 101 of the Patent Code.10 This section establishes three requirements for patentable inventions. First, an invention must fall within one or more of four broad statutory categories; namely, process, machine, manufacture, or composi-

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7. For example, patents could not be secured for plants prior to 1930, since their organic nature was assumed both to present unsoluble problems in satisfying the statutory requirement of description of the invention now codified in § 112, see notes 23-24 and accompanying text and note 42 infra, and perhaps exclude them from potential categorization as inventions. See Ex parte Latimer, 1889 Dec. Com. Pat. 123. Congress later remedied this situation by enacting the Plant Patent Act, 35 U.S.C. § 161 (1976). See notes 42-47 and accompanying text infra.

8. The Patent Office has offered several policy reasons in support of its reluctance to patent microbiological inventions. See notes 42-47 & 119-28 and accompanying text infra.


10. See note 5 supra.
tion of matter. These categories are divisible into two general classes: process and product inventions. A process invention generally consists of a new art or method of achieving a useful end. Product inventions encompass the three remaining statutory categories and comprise any new and useful apparatus, article, or substance.

The second prerequisite is that of "utility," requiring the invention to have the capacity to perform the function ("product" invention) or attain the result ("process" invention) claimed in the application's description.

11. The term "machine," as used in § 101, refers to any mechanical device, or combination of mechanical powers and devices, that performs some function and produces a certain effect or result. See Corning v. Burden, 56 U.S. (15 How.) 252, 267 (1853). A "manufacture" is any useful product made directly or indirectly by human labor and derived from either raw materials or from materials worked into a new form. BLACK'S LAW DICTIONARY 870 (5th ed. 1979). The term "composition of matter" refers to a substance composed of two or more different substances without regard to form. Id. at 259. Although the terms "manufacture" and "composition of matter" are stated separately in the Code, they have been treated in commentary as functionally indistinguishable. See Frederico, Section 101: Subject Matter for Products, in THE LAW OF CHEMICAL, METALLURGICAL AND PHARMACEUTICAL PATENTS 53, 58 (H. Forman ed. 1967).

12. The term "process" is defined by the Patent Code as a "process, art or method, and includes a new use of a known process, machine, manufacture or composition of matter, or material." 35 U.S.C. § 100(b) (1976). This definition was added in the Patent Act of 1952 to resolve possible semantic discrepancies between the terms "process," "method," "art," all of which are virtually synonymous for patent law purposes, and to clarify that a new use of an old product or process is patentable if both "novel" and "nonobvious" to one skilled in that particular field. See H.R. Rep. No. 1923, 82nd Cong., 2d Sess. 6 (1952).


14. See CBS v. Sylvania Elec. Prods., Inc., 415 F.2d 719 (1st Cir. 1969), cert. denied, 396 U.S. 1061 (1970); Ilsenstedt v. Watson, 157 F. Supp. 7 (D.D.C. 1957) (utility implies capacity to perform function or attain result claimed in applicant's disclosure). In addition, the utility standard requires that the invention not be injurious to public health and safety. Inventions "injurious to the morals, the health, or the good order of society" have been held to lack the utility necessary to constitute patentable subject matter. See Brenner v. Manson, 383 U.S. 519, 533 (1966). Thus, inventions which would defraud the public fail to meet the utility standard. See Scott & Williams, Inc. v. Aristo Hosiery Co., 7 F.2d 1003 (2d Cir. 1925) (process for making imitation seam for seamless stockings to make them resemble silk stockings held unpatentable); Rickard v. DuBon, 103 F. 868 (2d Cir. 1900) (process for marking tobacco leaves of inferior variety to resemble a superior variety held unpatentable). But see Denton v. Fulda, 225 F. 537 (2d Cir. 1915) (simulated precious stones held patentable); In re Corbin, 6 F. Cas. 538 (D.C. Cir. 1857) (No. 3,224) (imitation honey is useful and therefore patentable). A more difficult balancing situation arises when beneficial inventions are also potentially harmful. See In re Anthony, 414 F.2d 1383 (C.C.P.A. 1969) (beneficial drug with potential adverse side effects held patentable). Therefore, absolute safety in an invention is not required under section 101. See In re Hartop, 311 F.2d 249 (C.C.P.A. 1962). While the patent system has not been insensitive to the dangers inherent in many inventions, the courts have held that Congress delegated to agencies other than the PTO the responsibility to determine whether an invention is safe enough for human consumption. See In re Anthony, 414 F.2d 1383, 1395 (C.C.P.A. 1969) (determination of whether a particular drug is sufficiently safe rests with the Food and Drug Administration).
The invention need only present a feasible means for achieving the ends desired by its inventor; the fact that additional research might be necessary before an invention is perfected or made safe for public consumption has been held to be immaterial.

Third, an inventor may not claim any of the "natural phenomena" operative in the invention in the patent application. The term "natural phenomena" encompasses any organic or abstract constituent of an invention such as naturally occurring plants, gravity, electricity, or a mathematical theory or equation. Although all inventions depend in some measure on natural forces or phenomena for their efficacy, claims directed solely to such phenomena instead of to new and useful applications of them have been held unpatentable without exception. The rationale underlying this proscription is that patents would deprive the public of access to natural forces and dispossess researchers in the field of a basic tool.

Beyond the section 101 requirements, an invention must satisfy several additional statutory conditions before being patentable. First, section 102 requires all patentable inventions to be "novel." If a claimed 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 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.
tion had been either known, used, or described in a publication prior to the applicant's claim, the invention is deemed to lack novelty and is therefore unpatentable. Second, section 103 requires that an invention be "nonobvious." This section requires an investigation into the state of the art in the field from which the invention originates to determine whether 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 [the] subject matter pertains." Finally, section 112 of the Patent Code requires a written description of the invention sufficient to enable one skilled in the applicable field to practice it. This requirement is designed to give notice of the invention to others in the field in order to guard against infringement and to avail the public of the knowledge the patent contributes to the art.

Biological sciences, now a source of new and useful inventions, have severely taxed the statutory requirements for patentable subject matter. Biological inventions, seemingly within these statutory requirements on their face, have presented new problems for the patent system with regard to both the proscription against natural phenomena and the Supreme

22. 35 U.S.C. § 103 (1976), which provides:
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.


Some inventions are difficult to describe with sufficient specificity to enable other inventors to employ the invention. There are chemical inventions, for example, that encompass thousands of compounds. Applicants in such situations are thus presented with the problem of determining how many classes must be described individually in order to meet the description requirements. In addition, in many chemical inventions there is no guarantee that the combination of prescribed compounds will always result in the desired product or that the product will achieve the desired results. See In re Angstadt, 532 F.2d 498 (C.C.P.A. 1976). In such cases, rejection under § 112 will depend on the predictability of successful productions of the desired end. Id. For patentable inventions involving microorganisms, an alternative method of satisfying § 112 has been developed in which a subculture of the microorganism is deposited at one of the national culture depositories. Thus, anyone wanting to practice the invention after the patent has expired could simply obtain a sample from a depository. See In re Argoudelis, 434 F.2d 1390, 1392-93 (C.C.P.A. 1970).
Court's narrow interpretation of legislative intent concerning patent protection for inventions from new and complex fields.

II. THE ADVENT OF COMMERCIALLY USEFUL MICROORGANISMS

In the last forty years, great advances have been made in microbiology. Recent large investments in research aimed at the development of new strains capable of performing important commercial functions have prompted corporations to seek patent protection for inventions involving microorganisms. Accordingly, the controversy over the patentability of microorganisms began reaching the courts only a short time ago. The first case addressing the patentability of processes employing microorganisms did not reach the CCPA until 1974. Likewise, the patentability of "product" microbiological inventions themselves did not reach the Supreme Court until 1978.

The patentability of an industrial process employing microorganisms first arose in an infringement case, Guaranty Trust Co. v. Union Solvents Corp. In Guaranty Trust, the United States District Court for Delaware upheld a patent on a bacteriological process for the production of acetone and alcohol. The defendants had denied any infringement of the plaintiff's patent and alternatively attacked the patent's validity on several grounds, including a claim that the process did not constitute patentable subject matter since it was a "life process of a living organism." The district court rejected this contention, stating that the patent was not for...
bacteria *per se* but rather for a fermentation process employing bacteria. Addressing the patentability of microorganisms as "products," however, the court cautioned that "[w]ere the patent for bacteria *per se*, a different situation would be presented."  

The CCPA did not squarely address the patentability of processes involving microorganisms until *In re Mancy*.  In *Mancy*, the PTO had denied the applicant's claim to a process for producing the antibiotic daunorubicin on grounds that the "starting material" cultivated to produce the antibiotic was "obvious" under section 103. The CCPA reversed, stating that the starting material in such a process (a novel microorganism) need not itself be patentable in order for the process to be patentable. The court cautioned in dicta, however, that the applicants "not only have no allowed claim to the [microorganism] used in their process but would . . . be unable to obtain such a claim because the [microorganism], while new in the sense that it is not shown by any art of record, is, as we understand it, a 'product of nature.'" Thus, the court was careful to limit its holding based on the possibility that the strain might constitute a natural phenomenon.

The caution expressed in these cases has today ripened into a PTO policy of denying patents on microorganic product inventions until specific legislation provides for these claims. This position has two bases. First, the PTO contends that the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970 illustrate the necessity of an express congressional provision before granting patents on any living matter, including microorganisms. Second, the PTO interprets the case law on the patentability of computer programs to have pronounced a bar against granting patents in technological areas unforeseen by Congress when it enacted the patent statutes.

The purpose of the Plant Patent Act was to grant agricultural innovators the same opportunity to reap the benefits of the patent system as had been accorded industry. Under the Act, breeders were afforded patent protec-

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34. *Id.*
35. 499 F.2d 1289 (C.C.P.A. 1974).
36. *Id.* at 1294.
37. *See* notes 41-47 and accompanying text infra.
40. *See* notes 48-69 and accompanying text infra.
41. Both the 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, 71st Cong., 2d Sess. 2 (1930); S. REP. No. 315, 71st Cong., 2d Sess. 2 (1930).
tion for certain kinds of asexually reproducing plants.\(^4\) The PTO maintains that this specially enacted legislation demonstrates congressional intent that the patent law should not extend to living matter. If it did, then presumably plants, as living things, would already have been patentable under section 101, thus making a specific provision for plant patents unnecessary.\(^4\) This position is supported by a letter from then Secretary of Agriculture Hyde, appended to the contemporaneous House and Senate committee reports on the plant patent bill, wherein the Secretary interpreted the existing patent laws to cover “only inventions or discoveries in the field of inanimate nature.”\(^4\)

The PTO draws further support for its position from the Plant Variety Protection Act of 1970.\(^4\) This Act empowers the Secretary of Agriculture to issue certificates for new varieties of asexually reproduced plants.\(^4\) The PTO contends that the Act, like the Plant Patent Act of 1930, extends protection to material not previously covered under section 101. This contention is consistent with congressional intent that living matter requires special legislative action before qualifying for patent protection.\(^4\)

\(^4\) The Act provided patent protection for any new and distinct 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.” 35 U.S.C § 161 (1976). The reason why protection was not available under the existing patent statutes was not explicitly discussed. It appears, however, that protection was unavailable before 1930 simply because of a presumption that plants could not meet the statutory description requirement. See A. Allyn, The First Plant Patents 58 (1934).

Prior to the Act, plant developers did not apply for patents, but appealed directly to Congress for a special provision. See, e.g., H.R. 18851, 59th Cong., 1st Sess. (1906) (a bill to amend the laws of the United States relating to patents in the interest of the originators of horticultural products); H.R. 5435, 52d Cong., 1st Sess. (1892) (a bill for the advancement of agricultural sciences). Similarly proposed bills include H.R. 24010, 61st Cong., 2d Sess. (1910); H.R. 21951, 60th Cong., 1st Sess. (1908); S. 59, 60th Cong., 1st Sess. (1907).

That a plant patent applicant would have received a cold reception from the PTO before 1930 is supported by Ex parte Latimer where rejection of a claim directed to the fiber of a pine needle was affirmed by the Commissioner of Patents. 1889 Dec. Com. Pat. 123. The Commissioner stated that granting patents in such circumstances would lead to the patenting of “trees of the forest and plants of the earth, which of course would be unreasonable and impossible.” Id. at 126.


\(^46\) 7 U.S.C. § 2401 (1976). The protection provided by these “certificates” authorized under the Act embody the same legal rights and protections to the inventor. Unlike patents, however, these certificates are administered by a special office in the Department of Agriculture, not by the Patent and Trademark Office.

\(^47\) See Petitioner’s Brief for Certiorari, supra note 43, at 13, 14.
The second basis for the PTO's denial of product patent protection for microorganisms focuses on a series of cases rejecting patent applications for computer programs on "natural phenomenon" grounds. In *Gottschalk v. Benson*, one of the first Supreme Court cases on computer program patentability, an applicant sought patent protection for a new method of programming digital computers. The method consisted of a mathematical formula used by a digital computer to convert decimal numbers to pure binary numbers. The formula had no substantial practical application except in connection with the computer. In reversing the CCPA's finding that the claims were patentable, Justice Douglas, writing for the majority, observed that phenomena of nature, mental processes, and abstract intellectual concepts— all descriptions applicable to the formula claimed— "are the basic tools of scientific and technological work." Consequently, a patent on the programming method would monopolize the formula and effectively constitute a patent on the formula itself. The Court thus found the method to be unpatentable as a "process" within the meaning of section 101. The Court suggested, however, that computer programs were not *per se* unpatentable but stated that this area involved policy matters beyond the competence of the Court since "considerable problems [were] raised which only committees of Congress [could] manage."

If any uncertainty remained after *Benson* as to the Court's attitude toward patent applications for inventions involving natural phenomenon, it was dispelled in *Parker v. Flook*. *Flook* strengthened and expanded *Benson* by rejecting, for similar reasons, claims directed not to a computer program itself, but to a process employing a program. In *Flook*, the applicant claimed a method of controlling certain aspects of the catalytic conversion of hydrocarbons, a process indigenous to petroleum refining and

49. Id. at 65.
50. *See In re Benson*, 442 F.2d 687 (C.C.P.A. 1971). The C.C.P.A., in an opinion by Judge Rich, held that the number conversion process did not constitute a "mental process" and was therefore patentable under § 101. Id. at 687.
51. 409 U.S. at 67. The Court stated that "he who discovers a hitherto unknown phenomenon of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end." Id. at 71-72 (quoting Funk Bros. Seed Co. v. Kalo Co., 333 U.S. 127, 130 (1948)).
52. 409 U.S. at 71-72.
53. Id.
54. Id. at 72-73. It has been suggested that the Court may have been inconsistent here since earlier in the opinion the Court stated that its decision did not preclude a patent for any computer program. Id. at 71. *See Note, Parker v. Flook and Computer Program Patents*, 30 HAST. L.J. 1627, 1632-33 (1979).
petrochemical processing. During the process, variables such as heat, pressure, and reactant product flow rates are monitored. When the value for a variable exceeds a predetermined alarm limit, for example, if a pressure level becomes excessive, it must be corrected in order for hydrocarbon conversion to continue. Correction is done by a computer using a mathematical control equation. Flook's claim covered the use of his discovered formula for correcting the value of an alarm limit on any process variable involved in the catalytic conversion of hydrocarbons.

In holding Flook's invention to be patentable, the CCPA interpreted Benson narrowly, stating that Benson's proscription was limited to claims which monopolized a mathematical formula. The court then found that Flook's application did not monopolize the formula because it claimed only the method of correcting alarm limit values, i.e., an application of a mathematical formula, not the formula itself.

On appeal, the Supreme Court reversed, holding that Flook's process application was outside the statutory limit for two reasons. First, the Court declared that a process invention that implements a principle in a specific manner does not automatically comprise statutory subject matter under section 101. Justice Stevens, writing for the majority, reasoned that, if this were so, satisfaction of section 101 would "depend simply on the draftsman's art and would ill serve the principles underlying the prohibition against patents for 'ideas' or 'phenomena of nature.'" Second, the Court stated that the particular application of the formula to correct alarm limits was not "inventive" and could not be since the formula must be considered a familiar part of the prior art.

On the issue of patenting the implementation of mathematical principles, prior case law, including Benson, had established that an invention applying natural phenomena such as a mathematical formula in a new and useful process constituted patentable subject matter. Based on this precedent, the Court should merely have inquired whether Flook's invention embodied a new and useful application of the natural phenomena in-

56. Id. at 585-86.
57. Id.
59. Id. at 23.
60. Justice Stewart, joined by Chief Justice Burger and Justice Rehnquist, dissented, concluding that the invention was patentable because the formula involved comprised only one step in the process, and thus no claim to natural phenomena had been attempted. 437 U.S. at 598 (Stewart, J., dissenting).
61. Id. at 593.
61a. Id. at 591-92.
62. See notes 48-53 and accompanying text supra.
involved. An affirmative answer to that question would have resulted in the Court's holding the invention patentable. By declaring that such an application was no longer a satisfactory standard for patentability, however, the Flook Court narrowly construed section 101 and abandoned this prior case law. The Court gave no explanation for its deviation from prior interpretations of section 101 and proceeded as if only the patentability of the formula itself was at issue. Since the Court never returned its focus to the proper factual context, i.e., the patentability of a claim to a process employing a mathematical formula and not a claim to the formula itself, its reasoning is disconcerting. Thus, after Flook, any claim in which natural phenomena play too prominent a part could be viewed as a camouflaged attempt to obtain protection for the phenomena themselves, and on that basis be rejected.

The Court's second reason for rejecting Flook's claim, that the formula's application was not "inventive," is no more persuasive than the first. The House Report accompanying the latest reenactment of the Patent Code explicitly states that the old "invention" requirement of section 103 is replaced by the new standard of "nonobviousness." Thus, since Flook only involved the construction of section 101, the Court's discussion of

63. 437 U.S. at 593.
64. Id.
65. See, e.g., In re Diehr, 602 F.2d 982 (C.C.P.A. 1979) (applying Flook).
66. The "inventiveness" requirement stems from an 1851 decision wherein the Supreme Court stated a general condition of patentability:

[U]nless more ingenuity and skill . . . were required . . . than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute [sic] essential elements of every invention. In other words, the improvement is the work of the skilful [sic] mechanic, not that of the inventor. Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248, 267 (1851). The language in that case and in later decisions "gave birth to 'invention' as a word of legal art signifying patentable inventions." Graham v. John Deere Co., 383 U.S. 1, 11 (1966). In John Deere, the Court said it had often observed that the "invention" requirement could not be defined in a manner that provided "any substantial aid in determining whether a particular device involves an exercise of the inventive faculty or not." Id. (quoting McClain v. Ortmayer, 141 U.S. 419, 427 (1891)). This disparity between judicial interpretations of the invention requirement led Congress in 1952 to enact the § 103 nonobvious requirement in the hope that it would "have some stabilizing effect." Id. at 16. See note 22 supra for the text of 35 U.S.C. § 103 (1976). John Deere, then, delineated the factual inquiry to be undertaken pursuant to § 103 and concluded that "strict observance of the requirements laid down here will result in that uniformity and definiteness which Congress called for in the 1952 Act." Id. at 18. For an argument that nonobviousness is as incapable of precise definition as its predecessor invention requirement, see Schneider, Non-obviousness, the Supreme Court, and the Prospects for Stability, 60 J. PAT. OFF. SOC'Y 304 (1978).
“inventiveness” was unwarranted.⁶⁷

Finally, the Court noted “difficult questions of policy” with respect to the appropriateness of patent protection for computer programs, an issue Congress was better equipped to decide.⁶⁸ This expression of caution puts prospective inventors on notice of the doubtful availability of patent protection for inventions involving sophisticated new technologies that the patent system is not prepared to handle, at least until Congress has specifically so provided.⁶⁹ Thus, *Flook* portends difficulty for the applicant claiming patent protection for a product of “genetic engineering” since such an invention embodying sophisticated and problematic technology is likely to be rejected just as computer programs have been.

### III. *In re Bergy*: Microorganisms As Patentable “Products” Under Section 101

After *Flook*, the Supreme Court remanded a case to the CCPA for it to decide whether, in light of *Flook*, product patent claims to industrially useful microorganisms should be denied because directed to living things. In *In re Bergy*,⁷⁰ the CCPA refuted the arguments of the PTO against patenting living things, denied the applicability of *Flook*, and held that being “alive” did not affect the patentability of the microorganisms.

*Bergy* involved two cases, both arising from rejections of “product” patent claims of microorganisms. In *Bergy*, the applicant invented a process for the production of a familiar antibiotic, lincomycin, and, while doing so, discovered a previously unknown microorganism which he called Streptomyces vellosus (“Sv”). Bergy filed both “process” and “product” claims with the PTO. The process involved fermenting Sv in an aqueous nutrient solution in order to produce lincomycin in recoverable quantities.⁷¹ The PTO held this process to be patentable. Bergy also claimed Sv itself as a patentable product.

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⁶⁷. Indeed, discussion of “inventiveness” in any patent case is now considered irrelevant. See note 66 supra.

⁶⁸. The Court stated that it “must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress.” 437 U.S. at 596.


⁷¹. The advantage of using Sv over S. lincolnensis, the former reactant, lies in Sv’s ability to produce lincomycin without concomitantly producing less valuable lincomycin B. The result is more efficient recovery of lincomycin.
“manufacture or composition of matter” under section 101, describing it as a “biologically pure culture” of the microorganism Sv. The patent examiner rejected Bergy’s “product” claim as being directed to a product of nature. The PTO Board of Appeals upheld the rejection on the sole ground that the claim covered a “living organism.”

On appeal, the CCPA reversed on the grounds that a biologically pure culture of Sv was not a product of nature and that patentability was not affected by the microorganism’s being “alive.” The Supreme Court subsequently vacated the decision and remanded it for further consideration in light of Parker v. Flook, decided four days earlier. On remand, the CCPA reheard Bergy together with another case, In re Chakrabarty, involving the same issue of law.

In Chakrabarty, the PTO gave similar treatment to another inventor with both “product” and “process” claims to a microorganism-related invention. The invention entailed the use of “genetic engineering” techniques to create a microorganism capable of degrading oil spills. Chakrabarty manufactured a new strain of bacteria capable of degrading oil’s several hydrocarbon components into a cell mass that would be consumed by sealife. Existing strains were only able to degrade one component at a time and as a result were ineffective. His “process” claim was

72. 596 F.2d at 967. In its natural state Sv is a useless component of Arizona soil. Bergy reduced it, however, to a biologically pure culture, capable of producing lincomycin.
73. Id. at 972.
74. See Ex parte Bergy, 197 U.S. PAT. Q. 78 (Bd. App. 1976). The “products of nature” and “living organism” discussions in Ex parte Bergy were substantially adopted by the PTO Board of Appeals in deciding the Chakrabarty appeal. See 596 F.2d 952 (C.C.P.A. 1979). In Ex parte Bergy, the PTO took an unwavering stance against patenting microorganisms. See 197 U.S. PAT. Q. at 79-80.
75. The court found that a basically pure culture of Sv is not a product of nature because it does not exist naturally but rather is man-made and producible only under carefully controlled laboratory conditions. In re Bergy, 563 F.2d 1031, 1035 (C.C.P.A. 1977).
76. Id. The court stated that the microorganism complied with all the statutory prerequisites other than the enumerated statutory categories, and thus there was no reason to deprive its creator or owner of the protection and advantages of the patent system by excluding it from those categories. Id. at 1037-38.
79. Chakrabarty's product claims to the microorganism were rejected by both the PTO examiner and the PTO Board of Appeals. See In re Chakrabarty, No. 77-535 (Bd. App., May 20, 1976) (unreported decision), rev'd, 571 F.2d 40 (C.C.P.A.), cert. dismissed, 439 U.S. 801 (1978).
80. Using a mixture of existing strains on oil spills was ineffective because the metabolic properties of the strains were such that only part of the initial combination of strains would survive after intermixture. Thus, the bulk of an oil spill would remain unaffected, increasing the probability of its spreading or sinking. 596 F.2d at 969. Chakrabarty mechanically incorporated compatible DNA (deoxyribonucleic acid) molecules from four of the existing
directed to the manner of application of the new bacterial strain to oil spills, and the PTO held it patentable. His "product" claim to the new strain itself was rejected by the PTO Board of Appeals, however, on product-of-nature grounds, and because it was directed to live organisms.\footnote{The PTO Board of Appeals reviewed Chakrabarty's application before Bergy's.} The CCPA reversed after reiterating the point it had made earlier in Bergy that claims were not outside the statutory categories of section 101 merely because they utilized living organisms.\footnote{See In re Chakrabarty, 571 F.2d 40 (C.C.P.A. 1978). The CCPA did not address the "natural phenomena" issue, after noting that the PTO Board of Appeals had conceded without discussion that the organism was not a product of nature. Id. at 43. Judges Baldwin and Miller dissented. Judge Baldwin essentially accepted the PTO's argument that the invention's being alive precluded it from patent protection. Id. at 44 (Baldwin, J., dissenting). Judge Miller contended that the Plant Patent Act evidenced congressional intent that microorganisms were unpatentable. Id. at 45 (Miller, J., dissenting).}

On remand, the CCPA, in an opinion by Judge Rich, essentially affirmed its two previous decisions and held that Bergy and Chakrabarty claimed subject matter within the scope of section 101.\footnote{596 F.2d 952 (C.C.P.A. 1979).} Moreover, the court found Flook to be inapplicable because it construed "process" under section 101 while Bergy construed "manufacture or composition of matter," i.e., product claims.\footnote{Before discussing Flook, the majority set forth a method of construction of the statutory requirements for patentability by comparing patentability to unlocking the three successive doors of §§ 101, 102 and 103, respectively. Id. at 959-64. The analogy represented the court's view that these sections form three discrete stages of inquiry into patentability. This discussion laid the foundation for its treatment of Parker v. Flook, since the court perceived in Flook "an unfortunate and apparently unconscious" commingling of the "distinct statutory provisions which are conceptually unrelated." Id. at 959. The court noted that the Supreme Court's "confusion" in Flook pertained to "the categories of inventions in § 101 which may be patentable and to the conditions for patentability demanded by the statute for inventions within the statutory categories, particularly the nonobviousness condition of § 103." Id. (emphasis in original). See notes 66-67 and accompanying text supra.}

Judge Baldwin concurred after having dissented in the first round of the Bergy and Chakrabarty appeals.\footnote{See In re Chakrabarty, 571 F.2d at 44-45 (Baldwin, J., dissenting); In re Bergy, 563 F.2d at 1039-42 (Miller & Baldwin, JJ., dissenting).} He argued that Flook was controlling through its stated prohibition on patenting natural phenomena. Since both inventions involved nonnaturally occurring "products" not monopolizing any natural phenomena, he believed that Flook confirmed the patentability of their inventions. In a dissenting opinion, Judge Miller accepted the PTO's argument that the Plant Patent Act of 1930\footnote{35 U.S.C. §§ 161-164 (1976).} and the Plant Variety

strains into the bacterium Pseudomonas aeruginosa, thereby creating a strain with the capacity to degrade, by itself, all four main components of oil at once. See Gore, The Awesome Worlds Within a Cell, 150 Nat'l Geographic 355, 374-75 (1976).
Protection Act of 1970\textsuperscript{87} demonstrated Congress' intent that living things are not patentable absent specific legislation.\textsuperscript{88}

In \textit{Bergy}, the majority expanded upon its earlier reasoning for patenting the product inventions of Bergy and Chakrabarty.\textsuperscript{89} Though correctly rejecting the PTO's arguments that inventions employing "life" are unpatentable, the majority's dismissal of \textit{Flook} was mechanical since \textit{Flook} speaks to the issue of natural phenomena in \textit{Bergy} and to the question of congressional intent regarding the patentability of complex new technologies. Nevertheless, an analysis of \textit{Bergy} in light of \textit{Flook} will reveal that the court's affirmation of the patentability of microorganisms remains unchanged.

\textbf{A. Natural Phenomena}

In remanding \textit{Bergy} in light of \textit{Flook} it is likely that the Supreme Court believed \textit{Flook} to raise the issue of natural phenomena in \textit{Bergy}. Both Bergy's and Chakrabarty's inventions involved natural phenomena by employing naturally occurring microorganisms as starting material. Although microorganisms and the mathematical formulas at issue in \textit{Flook} are distinguishable, both involve substances or principles that are the "basic tools of scientific and technological work."\textsuperscript{90} On remand, the \textit{Bergy} majority refused to acknowledge the presence of natural phenomena, observing that the issue involved "only the construction of the terms 'manufacture or composition of matter.'"\textsuperscript{91} The court offered no support for its position but did agree that natural phenomena are unpatentable.\textsuperscript{92} The court, however, did not address the question of whether natural phenomena constituted a significant part of the inventions.

The majority also avoided \textit{Flook}'s effect on the natural phenomena is-

\textsuperscript{87} 7 U.S.C. §§ 2321-2583 (1976).
\textsuperscript{88} 596 F.2d at 999. See text accompanying notes 42-47 supra.
\textsuperscript{89} See notes 75-76 and accompanying text supra.
\textsuperscript{91} 596 F.2d at 965.
\textsuperscript{92} Id. The court stated that "principles, laws of nature, mental processes, intellectual concepts, ideas, natural phenomena, mathematical formulations, methods of calculation, fundamental truths, original causes, motives, the Pythagorean theorem, and computer-implementable method claims" were not within § 101's category of patentable subject matter, and summarily concluded that the "present appeals do not attempt to patent any of these things." \textit{Id}. 
By stating that even though *Flook* and *Bergy* both construed section 101, *Flook* was inapplicable because it involved a "process" claim and not a "manufacture or composition of matter," *i.e.*, the product claim at issue in *Bergy*. The court's interpretation here is questionable since under this view "process" and "product" invention cases could seldom be compared even though they both involved construction of section 101. Moreover, such an analysis contradicts the Supreme Court's pronouncements on section 101 construction. For example, in *Gottschalk v. Benson*, the Court relied on a "product" case to demonstrate that natural phenomena had to be applied to a new and useful end in order to constitute part of a patentable invention. The *Benson* Court stated: "[W]e dealt there with a 'product' claim, while the present case deals with a 'process' claim. But we think the same principle applies." Thus, contrary to the *Bergy* court's rationale for dismissing *Flook*, "product" and "process" claims involving construction of section 101 are to be compared.

In contrast to the majority's cursory disposition of the natural phenomena issue, Judge Baldwin offered a better-reasoned approach in his concurring opinion. He interpreted *Flook* to warrant an inquiry into whether *Bergy* and *Chakrabarty* claimed natural phenomena or only new and useful applications of them. After examining several decisions relied upon by the Supreme Court in *Flook*, he concluded that in all of the decisions the Court had employed a two-step analysis. First, the Court identified the particular natural phenomenon used in the invention and then considered the inventor's claims in order to ascertain whether he was attempting to monopolize it. Thus, in Judge Baldwin's view, a claimed invention

93. *Id.* At the outset, the court noted that the only common element shared by the *Flook* and *Bergy* appeals "is that they both involve section 101." *Id.* at 964.

94. 409 U.S. 63, 67 (1972). *See* notes 48-54 and accompanying text supra.


96. 409 U.S. at 67-68. *Flook* impliedly reaffirmed this point by bringing *Funk*, a "product" claim case, to bear upon *Flook*, a "process" claim case.


98. *Id.* at 988.

99. The phenomenon characterized was "that which made the invention valuable to the inventor." *Id.* at 996. The cited cases include Funk Bros. Seed Co. v. Kalo Co., 333 U.S. 127 (1948); Mackay Co. v. RCA, 306 U.S. 86 (1939); Eibel Process Co. v. Minnesota & Ont. Paper Co., 261 U.S. 45 (1923); Tilghman v. Proctor, 102 U.S. 707 (1880); O'Reilly v. Morse, 56 U.S. (15 How.) 61 (1853); Leroy v. Tatham, 55 U.S. (14 How.) 156 (1852).

100. The unpatentable natural phenomenon in *Flook* was a mathematical equation used to adjust the alarm limits on process variables in a catalytic conversion process. Since the
entailing a new and useful application of the phenomenon without monopolizing it would be held patentable.

The Bergy and Chakrabarty inventions survive the application of this two-step inquiry. Bergy's "product" claims were not directed to naturally occurring Sv incapable of producing lincomycin. By extracting a biologically pure culture which could produce lincomycin, Bergy sufficiently altered the naturally occurring Sv to serve a useful end for the first time. Thus, Bergy's "product" claims were directed to the useful form of Sv, not the natural form, and did not monopolize natural phenomena; i.e., the Sv in the soil. Hence Bergy's product claim would be patentable. Similarly, Chakrabarty altered five naturally occurring strains of the bacteria species Pseudomonas by transplanting the genetic properties of four of them into the fifth. This new strain could thereby digest four major components of oil, a result no previous strain could produce. Consequently, Chakrabarty's "product" claims likewise embodied no threat of monopoly over a natural phenomenon.

Under Judge Baldwin's analysis, then, it is clear that the inventions of Bergy and Chakrabarty do not claim natural phenomena but new and useful applications of them and are thus not outside the categories of statutory subject matter.\textsuperscript{101} The majority's refusal to conduct such an inquiry by distinguishing both Flook's "process" application status and the physical disparity in subject matter in order to avoid the natural phenomena issue may have been ill-advised. By holding that the microorganisms do not raise the natural phenomena issue, the court has weakened a barrier to patentability which the Supreme Court had maintained when products of nature were employed in an invention.\textsuperscript{102} As a result, it is doubtful that patents issued on inventions such as Bergy's and Chakrabarty's will with-
stand challenges to patent validity that will be raised as a defense in subsequent infringement suits. In contrast, Judge Baldwin's analysis is consistent with the Court's policy of observing the natural phenomena prescription and thus is more in line with the Supreme Court's intent in remanding Bergy for reconsideration in light of Flook.

B. A "Clear Signal from Congress"

Bergy raises three issues respecting the relationship between congressional action and the patentability of microorganisms. Perhaps the central issue involves whether the Supreme Court's pronouncements in Flook, Benson, and other new complex technology cases are to be taken as restricting or even barring the patentability of product microorganism inventions because Congress could not "foresee" patent applications in that area. A second issue is whether the Plant Patent Act demonstrates that no living matter is patentable unless specific enabling legislation is passed. The final question is whether the existing patent law can be interpreted as proscribing outright the patenting of living matter.

The congressional foreseeability issue, like the issue of natural phenomena, was hastily dismissed by the Bergy court. Flook cites Deepsouth Packing Co. v. Laitram Corp. for the proposition that a "clear signal from Congress" is a necessary prerequisite to granting patents in new fields unforeseen by Congress. In Deepsouth, however, the Court warned against expanding patent rights "by overruling or modifying [the Supreme Court's] prior cases." Viewing the quotation in its original context, the

103. When a party is sued for infringement of the patentee's, or his assignee's, exclusive right to make, use, and sell his invention, see 35 U.S.C. § 271 (1976), the party commonly will raise the defense of patent invalidity. Often the accused infringer will claim that the invention fails to satisfy one or more of the statutory requirements of patentability such as § 101's subject matter requirement. There are at least 28 defenses to infringement actions based upon patent invalidity. See 9 A. Deller, Deller's Walker on Patents § 818 (2d ed. 1976).

104. See 437 U.S. at 596 (quoting Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 531 (1972)).

105. 596 F.2d at 966 (quoting Deepsouth, 406 U.S. at 531). The quotation in Deepsouth states:

[We] 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 . . . that the beachhead of privilege is wider, and the area of public use narrower, than courts had previously thought.

406 U.S. at 551.

Deepsouth involved an infringement suit against a competitor by the assignee of patents on a particular machine. The competition was manufacturing all the necessary parts for the patented machine and then shipping them abroad where they could be assembled in under
CCPA observed that this directive was not applicable since Bergy involved no interpretation of a specific word or words in a patent statute requiring prior cases to be overruled. But Flook, like Bergy, did not involve a request by a party to overrule prior cases interpreting the language of a patent statute.

Prior to quoting from the Deepsouth passage, the Flook Court cited a "dearth of precedent" on the issue of computer program patentability and stated its duty to "proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress." The Flook Court did not quote Deepsouth for the proposition that prior cases should not be overruled or modified; otherwise it would not have alluded to the "dearth of precedent" in the computer area. Rather, it relied on Deepsouth, however misguided, to articulate its view that caution must accompany the consideration of patents in complex new technological fields — "areas wholly unforeseen by Congress." Thus, under this interpretation of the Deepsouth passage in Flook, the CCPA should have considered the technological problems inherent in patenting inventions in these new fields.

Instead, the court denied that the inventions even comprised new technologies. Citing an admission by the PTO Solicitor that the technologies involved were "not new," the court summarily agreed and concluded that the appeals were unaffected by Flook's warning. Thus, the CCPA shirked its duty to consider Flook's mandate to proceed cautiously in its analysis.

To comply with Flook, however, and to consider the potential ramifications of such a complex and unforeseen technology would not necessarily change the majority's result. It has been suggested that, if inventions involve technologies "wholly unforeseen by Congress," consideration should be given to special problems warranting Congress' consideration before an hour. The Supreme Court rejected the assignee's claim that the competitor had "made" his invention in violation of the infringement statute by literally interpreting the statute's requirement that the invention be manufactured so as to be operable within the United States. See 35 U.S.C. § 271 (1976).

106. 437 U.S. at 596.
107. Id.
108. Id.
109. The court additionally concluded that there were no problems in examining inventions from the involved fields since the PTO has been handling similar claims "for years." In fact, however, the PTO has never handled a § 101 appeal on a "product" claim directed to a microorganism, much less directed to a genetically altered one.
approval of the claims. Nevertheless, commentators have persuasively argued that these types of microorganisms do not present prohibitive problems in satisfying the statutory description requirement. Furthermore, the PTO's claim that it lacks the necessary manpower to examine anticipated applications for microbiological "product" patents after Bergy should not be a factor in adjudicating the patentability of these inventions. Finally, concern for health and safety, fueled by stories of the potential spread of an andromeda strain from the molecular geneticist's laboratory, should be expressed to the Department of Health and Human Services (formerly Department of Health, Education and Welfare), and not to courts charged with construction of the patent statutes.

The issues of public concern in patenting microorganisms are analogous to those that motivated Congress in 1946 to remove nuclear-related inventions from statutory coverage, which, if patented, might have adversely

110. See Kiley, supra note 90 at 468 (Flork requires implementation of a "cautionary approach to patenting of the cutting edge of new technology").
111. See 1978 Coursebook, supra note 25, at 272.
112. In its petition for certiorari, the PTO stated that the economic implications of the CCPA's holding in Bergy were "very significant," opening up a vast new area of patentability. Petitioner's Brief for Certiorari, supra note 43, at 8-9. The "economic implications" refer to the PTO's lack of resources with which to deal with the complex and numerous microbiological inventions for which patent protection will be sought. This problem is treated in the Domestic Policy Review submitted by the Department of Commerce to the President in 1979, in which an advisory subcommittee recommended that the PTO be significantly upgraded in order to better handle applications from this and other new areas. See U.S. Dep't of Commerce Draft Report of the Advisory Subcommittee on Industrial Innovation ii (December 20, 1978). The Domestic Policy Review is to provide the basis for legislation submitted by the President.

Staffing is the preferable vehicle by which to solve the PTO's problems with microorganisms. While their present difficulties do not warrant depriving inventors of patent protection, they do support expediting appropriate legislative action. Thus, instead of fighting to defeat microorganism applications and thereby possibly slowing progress in this field, the PTO should lobby for sufficient funds to hire personnel capable of handling the new technology.


114. A patentee can be effectively prevented from using his or her invention by the appropriate regulatory agency if it subsequently exhibits a threat to the public health. See Amicus Curiae Brief for Genentech, Inc. at 11-12, In re Chakrabarty, 571 F.2d 40 (C.C.P.A. 1978).
affected the national security. However, to allow generalized concerns over genetic engineering to bar the patenting of microbiological inventions would thwart the efforts of researchers working toward well-defined and clearly beneficial ends, such as producing human insulin or developing genetic therapy to combat deadly sickle cell anemia. While the CCPA did not articulate any of the aforementioned policy reasons in its decision, it is possible that the court thought it necessary to avoid the Flook warning in order to hold the inventions patentable.

The second issue in Bergy relating to congressional intent was raised by the PTO in its broad assertion that no living organism is patentable in light of the Plant Patent Act of 1930 and the Plant Variety Protection Act of 1970. The PTO argued that these Acts demonstrate that section 101 is not applicable to "living things."

The CCPA convincingly rejected this argument. The court stated that the PTO had failed to consider the explicit purpose of the Plant Patent Act, which was solely to elevate the art of plant breeding to a position of parity with industry by allowing it also to participate in the benefits of the patent system. The legislation was designed to permit this nonindustrial field to grow into a viable industry itself. The court stated that the same goal was intended in the 1970 Act. Additionally, the court believed that the PTO misused legislative history in support of its position. Its reliance on Secretary Hyde's letter to demonstrate that the patent laws covered only

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118. Research in this area has been carried on at the University of Wisconsin Genetics Department for the last few years. Interview with Dr. Oliver Smithies, Professor of Genetics, University of Wisconsin (Nov. 29, 1979).
119. In rededucing Bergy, the court limited its consideration to "what bearing Flook has on these appeals" and instructed the parties to limit their briefs and oral arguments accordingly. 596 F.2d at 964. Despite this advice, the solicitor said during oral argument that the PTO was depending mainly on its plant legislation argument. Id. at 978.
120. See id.; notes 41-47 supra.
121. The experimental nature of plant development at the time is reflected in the committee reports which stated that "[t]oday plant breeding and research is dependent, in large part, upon government funds to government experiment stations, or the limited endeavors of the amateur breeder." H.R. REP. No. 1129, 71st Cong., 2d Sess. 2 (1930); S. REP. No. 315, 71st Cong., 2d Sess. 2 (1930). See notes 41-47 and accompanying text supra.
122. A second, less compelling but plausible reason advanced by the CCPA was that the Act was designed to avoid the rejection of patents on natural phenomena grounds. 596 F.2d at 982.
123. See id. at 984.
inventions "in the field of inanimate nature" was unsupportable since no reason existed for attributing his views to Congress. Moreover, since his letter was merely a response to a request for his views on the proposed participation of his department in the administration of the new Act, it should not be given much weight.

The final issue in Bergy relating to congressional intent stems from the PTO's argument that the CCPA should not allow the patent laws to "encompass living organisms — life itself." The court rejected this plea, noting that the PTO had already granted patents on living "product" inventions.

The PTO's argument is not only contradictory but also reflects its desire not to deal with patent applications in this area. Furthermore, in at least the limited context of these industrially applied microorganisms, the "life" argument is indefensible on its face. To allow the isolated characteristics of a claimed substance to control its patentability would, in effect, unwarrantedly expand the utility requirement under section 101. Under the cases construing utility in section 101, a new drug, for example, is patentable based on its function and not on its composition. The majority and concurring opinions in Bergy, in evaluating the two inventions on the basis of whether they produced the desired result and not on whether they were "alive," followed the accepted interpretation of utility in section 101. The new interpretation of utility embodied in the PTO's "alive" proscription is in effect an attempt to override case law construing utility in section 101 and as such should not be voiced to the CCPA, but to Congress.

**IV. Conclusion**

"Product" inventions involving microorganisms are one of a group of new technologies "wholly unforeseen by Congress" when it enacted the

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124. *See* note 44 and accompanying text *supra.*
125. 596 F.2d at 984.
126. *Id.* at 985-86 (several such patents listed).
127. *See* note 112 *supra.*
128. *See* notes 13-16 and accompanying text *supra.*
129. This proscription is supported by the fact that a knowledge gap exists between "living" and "dead" things, which is a major reason why arguments against patenting living things are still plausible. Great advances in microbiology are diminishing this gap, fulfilling the prophecy of scientist Claude Bernard, who stated many years ago:

Today we differentiate three kinds of properties exhibited in phenomena of living beings: physical properties, chemical properties, and vital properties. But the term "vital properties" is only provisional; because we call properties vital which we have not yet been able to reduce to physico-chemical terms; but in that we shall doubtless succeed someday.

C. BERNARD, EXPERIMENTAL MEDICINE II 2 (1957).
Patent Code notwithstanding the CCPA's characterizations to the contrary. Thus, under *Parker v. Flook*, the patent system must "proceed cautiously" when presented with claims from complex new technologies in order to avoid expanding the patentee’s monopoly privilege beyond present statutory limits. With microbiological inventions, this caution logically is exercised through an inquiry into problems in meeting the health and safety aspect of the statutory utility requirement. In *In re Bergy*, no problems have been articulated by the PTO that would demand leaving the matter to Congress.

Nevertheless, by failing to comply with the Supreme Court’s *Flook* directive and by avoiding the natural phenomena issue, the *Bergy* court’s position becomes more vulnerable. Unless the inventors' assignees convince the Supreme Court that an actual application of *Flook* does not warrant a contrary result, the tentative status of microorganisms as patentable subject matter under section 101 may be short-lived.

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