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PRODUCTS LIABILITY

ers" to be obeyed only grudgingly, 130 or to be treated as no higher than case law. 131 By resting on policy preference and assumptions that sweep a bit too broadly, the court, in Austin v. Ford, chose improper means of accomplishing its valid ends. Austin has the effect of improperly preempting a liability theory provided by statute which could result in actual denial of recovery where it would otherwise obtain. The court should modify the Austin rule to make it clear that the restriction on products liability theories is only proper to avoid unnecessary duplication. The court should recognize that, because warranty and strict liability are not coextensive and that the necessity of concurrent theory pleading often would not be known until the factfinder completes its task, interference with maintaining concurrent theories should be minimized. The court should be guided in this problem area by the policies of judicial restraint and separation of powers.

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PATENTS — Patentable Subject Matter — Living Man-made Organisms Held to Be Patentable Subject Matter Under 35 U.S.C. § 101. Diamond v. Chakrabarty, 100 S. Ct. 2204 (1980). Article I, section 8 of the United States Constitution empowers Congress “[t]o promote the Progress of Science and useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries.” Pursuant to this grant of power, unknown at common law, Congress has authorized patent protection for the invention or discovery of “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof.” 1 In the much pub-

131. Landis, Statutes and the Sources of Law, in HARVARD LEGAL ESSAYS 213 (1934).

licized case of *Diamond v. Chakrabarty*, the United States Supreme Court held that under 35 U.S.C. § 101 a live, human-made micro-organism is a patentable subject matter. This article will analyze the Supreme Court's decision in *Chakrabarty* and evaluate its impact on three areas: patent law, industry, and the continuing debate over the potential costs and benefits of genetic engineering.

I. INTRODUCTION

A. Concepts of Patentability and Living Organisms as Patentable Subject Matter

A discovery or invention is not patentable unless it falls within the categories of patentable subject matter specified in 35 U.S.C. § 101. Assuming an invention to be patentable subject matter under section 101, other conditions and requirements of Title 35 must also be satisfied before a patent will issue. Conditions of patentability include utility, novelty, and nonobviousness. Additionally, the discovery or invention must lend itself to a precise, written description. If an invention constitutes patentable subject matter and fulfills all conditions and requirements of patentability, a patent is granted, giving the holder the right for seventeen years from the date of issuance to prevent all others from making, using or selling the invention.

Section 101 enumerates four categories of patentable sub-

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and useful art, machine, manufacture, or composition of matter, or any new and useful improvement [thereon].” ch. 11, 1 Stat. 319 (1793). Subsequent patent statutes in 1836, 1870 and 1874 carried over the same classes of statutory subject matter. In the Patent Act of 1952, the only change in the categories of patentable subject matter was that the term “art” was replaced by “process.” 35 U.S.C. § 101 (1970).

2. 100 S. Ct. 2204 (1980).

3. Patent protection is, in essence, a government sanctioned monopoly on the invention. The conditions and requirements of Title 35 serve to protect the public’s interests against the potentially adverse effects of such monopolistic grants.


5. Id. § 102.

6. Id. § 103.


The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains . . . to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Id. § 154.
ject matter: processes, machines, manufactures, and composition of matter. For almost 200 years, section 101 and its predecessor statutes have encompassed a wide spectrum of inventions ranging from neutronic reactors to purified vitamin B-12. This is not to say that all discoveries are patentable. Notably, several categories of discoveries have been denied patent protection under the "law of nature" and "product of nature" rules.

The "law of nature" rule, a poorly defined judicial creation, states in effect that abstract principles, physical phenomena, and ideas are not patentable discoveries. The purpose of the "law of nature" rule appears to be the prevention of undesirable restrictions on scientific and industrial progress that might result from granting a monopoly on basic principles and natural phenomena. However, the recent Supreme Court case of *Parker v. Flook* took the approach that laws of nature are not patentable because they are not statutory subject matter under section 101.

Closely related to the "law of nature" rule is the equally ill-defined doctrine that "products of nature" are not patentable. As generally defined in decisions, a product of nature is one occurring on the earth in a state that has not been changed by any act of a human being. While some decisions

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10. See O'Reilly v. Morse, 56 U.S. (15 How.) 62 (1853) where Samuel Morse unsuccessfully attempted to claim "electro-magnetism, however developed, for making or printing intelligible characters, letters, or signs, at any distances" as a patentable invention. See, e.g., LeRoy v. Tatham, 55 U.S. (14 How.) 156 (1852); Mackay Radio & Tel. Co. v. Radio Corp. of Am., 306 U.S. 86 (1939); Parker v. Flook, 427 U.S. 584 (1978).


13. In *Flook*, the Supreme Court held that an improved method of calculation for updating alarm limits in a catalytic conversion process was not patentable subject matter under section 101. The Court's decision has been criticized for confusing the question of whether a discovery constitutes patentable subject matter under section 101 with the question of whether the discovery satisfies the conditions of patentability, specifically, the nonobviousness condition of section 103. See *In re Bergy*, 596 F.2d 952, 959-64 (C.C.P.A. 1979).

imply a product of nature is not patentable subject matter, the bulk of the cases propounding the "product of nature" rule appear to rest on more orthodox grounds such as lack of novelty, or obviousness.\(^1\)

Living organisms and processes using them have received patents. Courts have long held such processes to be patentable subject matter.\(^2\) Despite a lack of judicial determination that the organisms themselves are patentable subject matter, the Patent Office has issued numerous patents for such organisms. The first of these was issued in 1873 when Louis Pasteur obtained United States patent 131,072 on "yeast, free from organic germs and disease, as an article of manufacture."\(^3\)

The only Supreme Court decision touching on the issue of the patentability of living organisms is *Funk Brothers Seed Co. v. Kalo Inoculant Co.*\(^4\) *Funk* involved a patent claim for a mixture of noninhibitive strains of nitrogen-fixing bacteria used as an inoculant in agriculture.\(^5\) Concluding that the patentee had only discovered the "handiwork of nature," the Court held the claims to the mixed inoculant invalid as not constituting an invention within the meaning of the patent statute.\(^6\) Although given an opportunity to address the issue of the patentability of living organisms, the Court premised its decision in *Funk* on lack of invention and not on the fact that the bacteria were alive. Nowhere in the opinion is there any indication that the characteristic of life alone would prohibit patentability. Indeed, the Court seemed to proceed on the assumption that living organisms were within the categories of patentable subject matter.

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19. The patentee had discovered that there exists in nature certain species of root-nodule bacteria which do not exert a mutually inhibitive effect on each other. He used that discovery to produce a mixed culture which proved to be more effective than prior bacterial strains in inoculating leguminous plants.

20. 333 U.S. at 131.
B. Chakrabarty's Invention

In 1971, geneticist Ananda Chakrabarty began work in the General Electric laboratory in Schenectady, New York. His task was to engineer a special bacteria for use in controlling oil spills. Prior to Chakrabarty's undertaking, several naturally occurring bacterial strains were known to possess the ability to decompose individual components of crude oil, any given strain degrading only a particular component. Biological control of oil spills had involved the use of a mixture of the strains on the theory that the cumulative degradative actions would consume the oil and convert it into simpler substances which, in turn, would serve as food for aquatic life. For various reasons, however, the bacteria literally could not tolerate each other's presence, and only a portion of the mixed culture survived to attack the oil spill. To overcome this problem, Chakrabarty employed a complex process in which he broke apart the various bacteria and grafted parts of their controlling genetic material into \textit{Pseudomonas Aeruginosa}, a bacterial strain which itself exhibited no capacity for degrading oil. The result was the creation of new strains of \textit{Pseudomonas} having the capability within themselves of degrading several different oil components with greater speed and efficiency.

C. Procedural Background

In 1972, Chakrabarty filed a patent application, assigned to General Electric Company, asserting thirty-six claims\footnote{An "invention" in the popular sense may have many aspects in the patent law sense and, technically speaking, may really be an aggregation of closely related inventions all pertaining to the same contribution the inventor is making to the technological arts. When this is so, as in the case of Chakrabarty's invention, an applicant may define his invention(s) in "claims" (technical legal definitions of the spheres of protection sought, not descriptions of the invention) which may fall into different section 101 categories. For example, an inventor may have produced a new product which is made by a new process and put to a new use. The invention is capable, therefore, of being defined or "claimed" as a manufacture or composition of matter, as a process for making the product, and as a process utilizing the product in some way. \textit{In re Bergy}, 596 F.2d 952, 964 (C.C.P.A. 1979).} relating to his newly invented \textit{Pseudomonas} bacteria. Chakrabarty's claims were of three types: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprised of the bacteria and a carrier material, such as straw, floating on water; and, third, claims to the bac-
Although allowing the claims falling into the first two categories, the patent examiner rejected claims for the bacteria. His decision rested on two grounds: (1) that the claimed bacteria were “products of nature” and (2) that as living things they were not patentable under 35 U.S.C. § 101.

Chakrabarty appealed the rejection of these claims to the Patent Office Board of Appeals, and in 1976 the Board affirmed the examiner on the second ground. In concluding that section 101 was not intended to cover living things such as Chakrabarty’s bacteria, the Board relied primarily on the legislative history of the 1930 Plant Patent Act, in which Congress intended patent protection to certain asexually reproduced plants.

In March, 1978, the Court of Customs and Patent Appeals reversed the Board’s decision in a tersely worded opinion. The Court of Customs and Patent Appeals based the reversal on its prior decision in In re Ber
gy in which it had held that “the fact that micro-organisms are alive is without legal significance” for the purposes of patent law.

In June, 1978, the Supreme Court granted the Government’s petition for certiorari in Ber
gy but then vacated the judgment and remanded the case “for further consideration in light of Parker v. Flook, . . . .” The Court of Customs and Patent Appeals then vacated its judgment in Chakrabarty and consolidated the case with Ber
gy for reconsideration. In 1979, the Court of Customs and Patent Appeals reaffirmed its earlier decisions and, in considering what light Flook shed on

22. Process patents, while available to biogenetic companies, are notoriously difficult to police against infringers. See Iron & Sears, Patents in Relation to Microbiology, 29 Ann. Rev. of Microbiology 319, 320 (1975).

23. The Board concluded that as a Pseudomonas bacteria with multiple energy-generating plasmids are not found in nature, the new bacteria were not products of nature.


25. 563 F.2d 1031 (C.C.P.A. 1977). Ber
gy involved a patent application for a pure culture of Streptomyces vellosus, a naturally occurring micro-organism found to be useful in the production of the antibiotic lincomycin. The Patent Office rejected the claims in Ber
gy on grounds identical to those in Chakrabarty.

26. In re Ber
gy, 563 F.2d 1031, 1038 (C.C.P.A. 1977).

27. Parker v. Ber
gy, 438 U.S. 902 (1978). See note 13 supra, for the holding in Flook. The salient feature of Flook was the Supreme Court’s statement that the courts “must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress.” 437 U.S. at 596.
these cases, concluded dryly, "very simply we find none."\textsuperscript{28} The Government again sought certiorari, and the Supreme Court granted the writ as to both \textit{Bergy} and \textit{Chakrabarty}.\textsuperscript{29}

II. THE \textit{Chakrabarty} OPINION

Writing for the Court's majority,\textsuperscript{30} Chief Justice Burger characterized the question presented as a narrow one of statutory interpretation, the question being whether Chakrabarty's micro-organism constituted a "manufacture"\textsuperscript{31} or "composition of matter"\textsuperscript{32} within the meaning of 35 U.S.C. § 101. In the majority's view, the choice of such expansive terms as "manufacture" and "composition of matter," modified by the pronoun "any," plainly indicated congressional intent to give broad scope to the patent laws. It found support for a liberal construction in the legislative history of the patent law, in particular, the committee reports which accompanied the 1952 recodification of the patent laws and which indicate Congress intended the statutory subject matter of section 101 to "include anything under the sun that is made by man."\textsuperscript{33} After distinguishing Chakrabarty's micro-organism from claims rejected in prior cases under the "law of nature" and "product of nature" rules,\textsuperscript{34} the Court concluded it was not nature's handiwork but a product of human ingenuity, and as such, patentable subject matter under section 101.\textsuperscript{35}

\textsuperscript{28} \textit{In re Bergy}, 596 F.2d 952, 967 (C.C.P.A. 1979).
\textsuperscript{29} Subsequently, \textit{Bergy} was dismissed as moot, leaving only \textit{Chakrabarty} for decision. 100 S. Ct. 696 (1980).
\textsuperscript{30} The Chief Justice was joined in his opinion by Justices Blackmun, Stevens, Stewart and Rehnquist.
\textsuperscript{31} The Chief Justice defined "manufacture" as "the production of articles for use from raw materials prepared by giving to these materials new forms, qualities, properties, or combinations whether by hand labor or by machinery." 100 S. Ct. at 2207 (citing \textit{American Fruit Growers, Inc. v. Brogdex Co.}, 283 U.S. 1, 11 (1931)).
\textsuperscript{32} "Composition of matter" was defined as "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids." \textit{Id.} (citing \textit{Shell Dev. Co. v. Watson}, 149 F. Supp. 279, 280 (D.C. Cir. 1957)).
\textsuperscript{33} S. REP. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess. 5 (1952).
\textsuperscript{34} In particular, the Court distinguished Chakrabarty's invention from that in \textit{Funk Bros. Seed Co. v. Kalo Inoculant Co. See} note 18 \textit{supra}, and accompanying text.
\textsuperscript{35} 100 S. Ct. at 2208. The Chief Justice did not specify whether Chakrabarty's micro-organism constituted a "manufacture" or "composition of matter" or both.
The Court rejected the Government’s two arguments. The Government first contended that the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act evidenced congressional understanding that the subject matter of section 101 did not include living organisms; if section 101 included living organisms, both Acts would have been superfluous. Rejecting this argument, the Court found nothing in the language or legislative histories of the 1930 and 1970 Acts to substantiate the view ascribed to Congress by the Government. It concluded that the Plant Patent Act was enacted to overcome two specific obstacles which, prior to 1930, were thought to deny patent protection for plants. First, plants, even those artificially bred, were thought to be unpatentable under the “product of nature” rule. The second obstacle was the stringent “written description” requirement of the patent law. Compliance with this requirement was viewed as being difficult, if not impossible, as new plants often differed from old only in color or fragrance. Accordingly, the 1930 Act relaxed the description requirement for plants within its protection. As for the 1970 Plant Variety Protection Act, the Court found its sole purpose to be that of extending patent protection to a


38. The sole indication in the 1930 Act’s legislative history that Congress was concerned with the patentability of all living organisms is found in statements made by Secretary of Agriculture Hyde. In a letter to the Chairman of the House and Senate Committees considering the 1930 Act, Secretary Hyde expressed the view that “the patent laws . . . at the present time are understood to cover only inventions or discoveries in the field of inanimate nature.” S. Rep. No. 315, 71st Cong., 2d Sess. 10-11 (1930). In the Chief Justice’s view, “Secretary Hyde’s opinion . . . is not entitled to controlling weight. His views were solicited on the administration of the new law and not in the scope of patentable subject matter — an area beyond his competence.” 100 S. Ct. at 2209.

39. 100 S. Ct. at 2209. According to the Chief Justice, this view arose from the Patent Office decision in Ex parte Latimer, 1889 Dec. Com. Pat. 123 in which a patent claim for fiber in the needle of pinus australis was rejected.


41. Section 4888 of the Revised Statutes, then in force, was amended by adding to the end, “no plant patent shall be declared invalid on the ground of noncompliance with this section if the description is made as complete as is reasonably possible.” 46 Stat. ch. 312, 376 (1930). The substance of this sentence is, today, the first sentence of 35 U.S.C. § 162.
group of plants specifically excluded under the 1930 Act. 42

The Government's second argument relied primarily on the Supreme Court's decision in *Parker v. Flook* 43 and the statement that the judiciary "must proceed cautiously when . . . asked to extend patent rights into areas wholly unforeseen by Congress." 44 The Government contended that since genetic engineering was unforeseen when section 101 was enacted, questions regarding the patentability of man-made organisms should be left to Congress. The majority rejected this argument, stating, "*Flook* did not announce a new principle that inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable per se. To read that concept into *Flook* would frustrate the purpose of the patent law." 45 The Court reasoned that Congress had employed broad general language in drafting section 101 because many inventions are by their nature unforeseeable.

Also rejected were arguments raised by the People's Business Commission, a public interest group which presented a "gruesome parade of horribles" and urged the Court to weigh the potential risks posed by genetic engineering in reaching its decision. 46 In declining to do so, the Court noted that "[t]he grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks." 47 Moreover, the Court considered that such policy matters should be deferred to the political branches of government for resolution. "Whatever their validity, the contentions now

42. 100 S. Ct. at 2210. Sexually reproduced plants were not included under the 1930 Act because new varieties could not be reproduced true-to-type through seedings. By 1970, however, horticultural advances had made true-to-type reproduction possible. As for the 1970 Act's exclusion of bacteria, the Chief Justice found two possible explanations. He reasoned it either reflected the fact that prior to 1970 the Patent Office had issued patents for bacteria under section 101 or indicated congressional recognition of the decision in *In re Arzberger*, 112 F.2d 834 (C.C.P.A. 1940). There it was held that the 1930 Plant Patent Act, read "in the common language of the people" did not encompass bacteria despite the fact that bacteria are scientifically classified as plants. *Id.* at 838.

43. 437 U.S. 584 (1978).

44. *Id.* at 596.

45. 100 S. Ct. at 2211.

46. The People's Business Commission contended that genetic research and its commercial application might spread disease and pollution, bring about a loss in genetic diversity and depreciate the value of human life. *Id.*

47. *Id.* at 2211-12.
pressed on us should be addressed to . . . the Congress and the Executive, and not to the courts.\(^4\)

Justice Brennan’s dissent faulted the Court for misinterpreting the significance of the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act.\(^4\) In Justice Brennan’s view, the Acts showed that Congress had addressed the general problem of patenting animate inventions and had plainly legislated in the belief that section 101 did not encompass living organisms. Justice Brennan added that he would still dissent even if the 1930 and 1970 Acts were not dispositive. “At the very least,” he contended, “these acts are signs of legislative attention to the problems of patenting living organisms, but they give no affirmative indication of congressional intent that bacteria be patentable.”\(^5\) Recalling the admonition of *Flook*, Justice Brennan concluded, “I should think the necessity for caution is that much greater when we are asked to extend patent rights into areas which Congress has foreseen and considered but has not resolved.”\(^6\)

### III. Analysis

Judging itself incompetent to properly deal with such matters, the Supreme Court correctly deferred to Congress the resolution of larger policy issues surrounding genetic research and its commercial application. Left with a narrow question of statutory interpretation, the Court’s determination rested on an examination of the facts of the case, the language employed in section 101, the relevant legislative history, and the constitutional and statutory purpose of the patent law.

Clearly, Chakrabarty’s micro-organism is a product of human ingenuity — a laboratory creation specifically engineered for use in controlling oil spills. While a living organism may not be considered to be a “manufacture” or “composition of matter” as these terms are commonly used, the dictionary definitions and judicial constructions applied to such terms fairly embrace Chakrabarty’s micro-organism.

The legislative history of section 101 is largely silent as to

\(^{4}\) Id. at 2212.
\(^{49}\) Justices White, Marshall and Powell joined Justice Brennan’s dissenting opinion.
\(^{50}\) 100 S. Ct. at 2213 n.2 (Brennan, J., dissenting).
\(^{51}\) Id.
the meaning and scope of the classes of patentable subject matter. However, what little light is shed by such history supports the Court's decision. As the majority noted, the committee reports accompanying the 1952 recodification of the patent law indicate that Congress intended statutory subject matter to "include anything under the sun that is made by man." In explaining the scope of section 101, P.J. Federico, a principal draftsman of the 1952 Act, employed identical language in his testimony regarding that legislation.

The Court's decision also accords with the general purpose of the patent laws. The stated constitutional objective of the patent law is to encourage the "Progress of Science and the useful Arts." It provides exclusive rights to inventors for their creations in exchange for publicly disclosing their ideas. These rights are of limited duration. Congress has enacted patent laws in order that "[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens." A contrary decision by the Court might well have denied the public important, useful information; without patent protection, inventors such as Chakrabarty may have found it more profitable not to disclose their discoveries, protecting them instead as trade secrets. By granting patent protection for Chakrabarty's micro-organism, the Court's decision encourages public disclosure and gives impetus to a field of endeavor offering innumerable benefits to mankind.

52. S. REP. No. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. No. 1923, 82d Cong., 2d Sess. 6 (1952).
53. "[U]nder section 101 a person may have invented a machine or manufacture, which may include anything under the sun that is made by man . . . ." Hearings on H.R. 3760 Before Subcommittee No. 3 of the House Committee on the Judiciary, 82d Cong., 1st Sess. 37 (1951). Federico has also described the language of section 101 as delineating a "general industrial boundary" in Federico, Section 101: Subject Matter for Patents, in The Law of Chemical, Metallurgical and Pharmaceutical Patents 53, 58 (H. Forman, ed. 1976). Viewing industry's domain as the production of any and all things made by man, Chakrabarty's micro-organism is within the general industrial boundary drawn by section 101.
56. Genetic researchers have already re-engineered bacteria to produce human insulin, growth hormone and interferon, an antiviral protein which shows great promise
As for the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act, whatever Congress meant in enacting such legislation, the legislative intent is sufficiently ambiguous to support either the patentability or nonpatentability of living organisms other than plants. Both the Senate and House reports state that the 1930 Act had been drafted to "remove the existing discrimination between plant developers and industrial inventors," so that agriculture could be "[a]fford[ed] . . . the benefits of patent protection." 57 However, the committee reports fail to clarify the source or nature of the perceived discrimination. The actual changes implemented by the 1930 Act in the patent law only relaxed the written description requirement for plant patents. Moreover, the discussion of economic and administrative considerations dominates the text of the Act and the record of legislative deliberations. Reference to the patentability of living organisms in general is all but absent. 58 The same is true with regard to the text and legislative history of the 1970 Act. To assert that the 1930 and 1970 Acts represent exceptions to a general prohibition against patenting living organisms is, therefore, to read a particular significance into Congress' silence on this topic.

In the absence of a compelling congressional mandate, the question arises as to the degree of discretion properly exercised in interpreting a law which is without basis in the common law. The Chakrabarty decision clearly illustrates the division within the Supreme Court regarding this question. On the one hand, there is a group of narrow constructionists, the

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for the treatment of cancer. In the future, new micro-organisms may be programmed to meet any number of medical needs. Outside the field of medicine, researchers predict the creation of micro-organisms for use in making fuels and plastics. Some may be created to produce amino acids, the building blocks of protein, and used to relieve world food shortages. Still others may be used to leech ores in mining operations or to assist in the clean up of such toxic waste sites as Love Canal. Says molecular biologist Herman Lewis, the National Science Foundation's adviser on recombinant DNA: "Theoretically, any process occurring in nature can be harnessed for man's use." Time, June 30, 1980, at 52.

As something of a postscript, General Electric has abandoned plans to develop Chakrabarty's micro-organism as a weapon against oil spills. Judging the market too small for direct involvement, General Electric plans instead to offer licensing rights to other firms. Id. at 53.


58. See note 38 supra.
dissenting members of the Court in Chakrabarty.\textsuperscript{59} Their approach is summarized in the following quote:

The patent laws attempt to reconcile this Nation’s deep seated antipathy to monopolies with the need to encourage progress. Given the complexity and legislative nature of this delicate task, we must be careful to extend patent protection no further than Congress has provided. In particular, were there an absence of legislative direction, the Courts should leave the Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available.\textsuperscript{60}

In the view of the strict constructionists, a liberal interpretation of the statutory classes of patentable subject matter invades a domain expressly left to Congress. If certain inventions, such as genetically engineered organisms, are arguably outside the statutory classes, then it is the duty of Congress to expressly bring these new technologies within the scope of the patent statutes.

On the other hand, there is a group of liberal constructionists, the Chakrabarty majority.\textsuperscript{61} The following quote characterizes their approach: “We have cautioned that courts should not read into the patent laws limitations and conditions which the legislature has not expressed.”\textsuperscript{62} The liberal constructionists contend that when Congress enacted statutory classes of patentable subject matter, it did not intend to have the speci-

\textsuperscript{59} Justices Brennan, White, Marshall and Powell. These same four justices plus Justices Blackmun and Stevens constituted the majority in Flook. The salient feature of Flook seems to support a narrow interpretation of the patent law.

\textsuperscript{60} 100 S. Ct. at 2213 (Brennan, J., dissenting) (citations omitted) (relying on Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972)). For Justice Brennan, Chakrabarty “present[ed] even more cogent reasons than Deepsouth Packing Co. not to extend the patent monopoly in the face of uncertainty.” Id. n.2. Justice Brennan’s reliance on Deepsouth Packing Co. would seem to be misplaced. The thrust of Deepsouth Packing Co., a patent infringement case, was that the courts “should not expand patent rights by overruling or modifying . . . prior cases construing the patent statutes, unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language.” 406 U.S. at 531. As Chakrabarty presented a question of first impression, the Supreme Court was not called upon to overrule or modify any prior cases construing the scope of patentable subject matter.

\textsuperscript{61} Chief Justice Burger and Justices Stewart, Rehnquist, Blackmun and Stevens. Although a member of the Chakrabarty majority, Justice Stevens wrote the majority opinion in Flook; he was joined in that opinion by Justice Blackmun.

\textsuperscript{62} 100 S. Ct. at 2207 (citing United States v. Dublier Condenser Corp., 289 U.S. 178, 199 (1933)).
fied classes narrowly interpreted so as to exclude the products of radical advances in science and industry. The statutory classes were merely broad guidelines, since Congress realized newer forms of technology might well outstrip conventional notions of patentable subject matter.

It would seem that the approach of the liberal constructionists is the preferable one. The very nature of technological advance militates against an inflexible interpretation of the statutory classes of patentable subject matter. Requiring Congress to specifically consider each substantive technical advance before patents are granted in that field would undermine the constitutional and statutory purpose of encouraging public disclosure and stimulating the creation of new technologies. Under the liberal constructionist approach, Congress remains free to focus on specific areas of technology and to deny or limit patent protection when policy considerations so dictate.63

IV. Chakrabarty's IMPACT

A. Patent Law

The Chakrabarty decision eliminates the possibility that patent claims for any living organism can be rejected solely on the ground that the organism is alive. Questions remain, however, regarding the types of living organisms eligible for patent protection in Chakrabarty's wake. While Chakrabarty's micro-organism was created by a relatively simple plasmid transfer process, micro-organisms produced through more complex recombinant DNA techniques should also qualify as patentable subject matter under the Court's decision.64 As a practical matter, higher life forms, such as animals created by selective breeding, will likely remain unpatentable despite the Court's holding in Chakrabarty. At the present time, the written description requirement of section 112 appears to be an

63. E.g., 42 U.S.C. § 2181 (1970) exempts from patent protection inventions "useful solely in the utilization of special nuclear material or atomic energy in an atomic weapon."

64. DNA (deoxyribonucleic acid) is the basic genetic material of all living organisms. Recombinant DNA or "gene splicing" techniques employ various enzymes to break apart DNA and isolate certain desirable genes; these genes may then be transferred into another organism. The recipient organism, in effect, becomes a new life form with all the characteristics and capabilities carried by the spliced genes.
insurmountable obstacle for patent claims involving more complex organisms. In contrast, simple micro-organisms such as Chakrabarty's are so readily described that little difficulty arises in achieving compliance with section 112. In the future it is possible that a sufficiently precise description of newly created varieties of higher life may be achieved. Congress may also choose to act, extending patent protection to animal breeders through an enactment analogous to the 1930 and 1970 plant patent legislation.

B. Industry

Whatever disagreement may exist regarding Chakrabarty's practical impact on the biogenetic industry, the Supreme Court's decision gives long awaited recognition to the commercial significance of genetic engineering and heralds the beginning of what is likely to become a new industrial revolution. In the eight years since Chakrabarty first applied for a patent on his oil-eating micro-organism, genetic technology has exploded. Almost monthly there are announcements of new advances. The potential markets seem limitless, and enthusiasm among investors for biotechnology is growing dramatically.

The genetic engineering industry now consists of at least a dozen firms, large and small, that are either working on developments in bioengineering or supporting the work of others. The attempt to apply laboratory advances in the commercial arena appears to center on five small privately held concerns, although larger firms have also established research and development programs. The lack of patent protection for living organisms has not hindered genetic research or the ability of biogenetic companies to acquire capital. Nelson M.

65. See In re Merat, 519 F.2d 1390 (C.C.P.A. 1975). The applicant in Merat sought a patent for a dwarf hen that resulted from a selective breeding process. The court upheld the rejection of this claim on the ground that it was indefinite under section 112. However, it is important to note that even if the written description requirement precluded obtaining a patent for the organism itself, a patent for the process could still be obtained.

66. Cetus Corp. of Berkeley, Calif.; Genetech Corp. of San Francisco, Calif.; Bethesda Research Laboratory, Inc. of Bethesda, Md.; Genex Corp. of Bethesda, Md.; and Biogen S.A. of Geneva, Switzerland. Parisi, Gene Engineering Industry Hails Court Ruling as Spur to Growth, N.Y. Times, June 17, 1980, § D. at 16, col. 3.

67. These include DuPont, Monsanto, Upjohn and General Electric Company.
Schneider, a vice-president at E.F. Hutton and Co., estimates that private capital for genetic research will approach $200 million in 1980; he expects that amount to climb to $1.9 billion by 1985.\(^{68}\) Thus it seems apparent that the bioengineering industry would have continued to expand whatever the decision reached in Chakrabarty.

Exponents of bioengineering have greeted Chakrabarty with mixed reviews. Niels Reimers, Stanford University’s manager of technological licensing, viewed Chakrabarty as a landmark decision that will “encourage prompt and full disclosure of inventions, accelerate their commercial development and thus bring beneficial results of microbiological research to the public earlier.”\(^{69}\) Others fear the decision will actually slow research. Jonathan King, a molecular biologist at Massachusetts Institute of Technology, said, “Previously there was a free exchange of organisms among scientists. But now if you can patent a strain and make a bundle, the organisms won’t be publicly available until a patent is granted.”\(^{70}\)

Most companies engaged in genetic engineering view Chakrabarty as having only a moderate impact on their operations. In practical terms, Chakrabarty will immediately affect only a portion of the biogenetic industry. At present, micro-organisms are used primarily as manufacturing agents in various production processes;\(^ {71}\) patent protection for processes involving micro-organisms was available prior to Chakrabarty.\(^ {72}\) Some experts also question the value of patents in a field where new developments are coming so rapidly; a micro-organism or process that might be worth patenting today may be obsolete in only a few years. Industry spokesmen generally agree, however, that Chakrabarty places United States firms on a better footing against foreign competitors.\(^ {73}\)

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70. *Newsweek*, June 30, 1980, at 75.


72. Chakrabarty should provide a greater measure of protection for processes utilizing new micro-organisms than if only the processes were patentable. *See* note 22 *supra*.

73. Christian Science Monitor, June 18, 1980, at 24, col. 1. Under European patent conventions, an inventor can obtain protection in a foreign country if he obtains a patent in his own country. *Id.*
and provides a welcome psychological boost. With the assurance of patent protection, more companies and investors will be willing to plunge into the expensive biogenetic field.

As of June, 1980, over a hundred patent applications for new organisms or processes for making organisms were stacked up on the Patent Office awaiting the outcome of Chakrabarty. Even the most optimistic observers do not expect a flood of patents to be issued in the near future as there are certain to be overlapping claims to litigate. The most important application pending is one covering basic gene-splitting techniques filed by Stanford University and the University of California. If this patent is granted, most companies engaged in biogenetic technology may have to obtain licenses from Stanford and pay royalties to both schools. Stanford officials say they will give nonexclusive licenses at a low royalty but may demand licensees to comply with certain safety requirements.74

C. The Debate Surrounding Genetic Engineering

Represented by the People’s Business Commission, critics of biogenetic technology urged the Court to weigh the potential hazards of genetic engineering in reaching its decision in Chakrabarty. Realizing that a decision denying patent protection would not halt the expansion of biogenetic technology, the People’s Business Commission sought, in effect, a stopgap measure to at least delay expansion until a laggard Congress could act. By rejecting the arguments of the People’s Business Commission and extending patent protection to man-made micro-organisms, Chakrabarty placed squarely in the lap of Congress the ever more pressing task of resolving the larger policy issues surrounding genetic engineering. The people of the United States, through their elected representatives must now decide the extent to which they believe man should seek to manipulate life at its most fundamental level and under what restraints this should be done. The courts cannot make that decision for them.

While genetic engineering has the potential for providing society with brilliant scientific advances and substantial

material gains, it also has the potential for generating serious health, environmental and other social costs. Prominent scientists have warned that recombinant DNA technology may result in man-made organisms capable of causing everything from global epidemics to environmental and evolutionary havoc. A larger number have stressed less drastic possibilities, suggesting that human exposure to recombinant genes in man-made organisms might disrupt the body's auto-immune system or that laboratory altered organisms might possibly take on characteristics of certain disease causing strains that exist in nature. Still other critics emphasize the frightening possibility of directing genetic engineering to the modification and control of human behavior.

While most genetic researchers view such fears as vastly exaggerated, it must be remembered that genetic engineering techniques represent a quantum leap in man's power to manipulate living things. Historically, when comparable advances in our power to alter the environment have occurred, it has been impossible to anticipate and adequately manage all of the consequences. Moreover, as the complex field of genetic engineering is still in its infancy, the expertise of genetic researchers is of limited value in predicting the possible impact of the new technology. With no body of experience to draw on to test opposing opinions, fundamental questions regarding potential costs and benefits must necessarily remain unanswered.

The present response to the potential dangers of genetic engineering is a limited attempt to find suitable technical solutions to the immediate hazards of laboratory research. In 1976, after prodding by scientists who made the early breakthroughs in recombinant DNA techniques, the National Institute of Health issued guidelines for government funded ge-

76. Id.
77. According to Jeremy Rifkind of the People's Business Commission, Chakrabarty "marks the beginning of the genetic age and gives corporations the green light to begin engineering the gene pool." NEWSWEEK, June 30, 1980, at 74. In Rifkind's view, "the Brave New World that Aldous Huxley warned of is now here." Christian Science Monitor, June 18, 1980, at 9, col. 3.
78. Our experience with nuclear energy and synthetic chemicals demonstrates man's inability to foresee and effectively cope with the adverse side effects of technology.
The N.I.H. guidelines established mandatory safety precautions for such research. Industrial research and development, however, is entirely unregulated. While most, if not all, biotechnical companies have voluntarily complied with N.I.H. guidelines, many observers feel that mandatory federal regulation is necessary to control the expanding industry. Too rapid commercial application of the new techniques could easily lead to tragic and irreversible mistakes.

Although committee hearings have been held since 1975, Congress has yet to enact a single piece of legislation for the control of genetic engineering. Recognition of the need of some form of regulation is widespread, and because of the accelerating pace of industrial development, presumably further spurred by Chakrabarty, there is an urgent need to keep regulations of genetic engineering on the political agenda. Moreover, given the far reaching implications of genetic technology, it is essential that the public be informed and involved in every step of the decision making process.

V. Conclusion

The Supreme Court's decision in Chakrabarty is a relatively well-reasoned holding and a sound interpretation of 35 U.S.C. § 101. The Court's decision is supported by the terms of the statute and the relevant legislative history. Moreover, the Court's liberal construction of section 101 accords with

80. In 1978, N.I.H. guidelines were revised and relaxed. 43 Fed. Reg. 60,080, 60,108, 60,134 (1978). The relaxation of N.I.H. guidelines was chiefly inspired by new research indicating that Escherichia coli K12, the standard bacterium used to propagate recombinant DNA molecules, is a safer host than originally believed. Science, Jan. 6, 1978, at 78. However, a considerable amount of debate still remains regarding the adequacy of N.I.H. safeguards. See generally Wright, Setting Science Policy, Environment, May, 1978.

81. Numerous proposed bills have been defeated largely because of the efforts of an active lobby of genetic researchers. Fearful of bureaucratic interference in their work, genetic researchers have begun to behave like a pressure group whose vital interests are at stake. This occurrence may make it even more difficult for the public to make informed decisions regarding genetic engineering. The evidence is so technically complex that we must rely on the judgments of experts as they filter down to us through the media. If the experts cannot maintain a position of neutrality in the debate, then the public is likely to remain ignorant of the potential risks involved. See generally, Milton, The Hazards of Altering Nature, The Nation, Oct. 15, 1977.
the general purposes underlying the enactment of the patent laws.

Although presenting only a narrow question of statutory interpretation, *Chakrabarty* deservedly received broad coverage in the popular press. While *Chakrabarty*'s impact on patent law appears to be relatively minor, the decision's implications in other areas may be far-reaching. Hailed as a classic example of law lagging behind technology, *Chakrabarty* gave recognition to the emerging genetic engineering industry. Further spurred by *Chakrabarty*'s grant of patent protection, the proliferation of this new technology promises to have a revolutionary impact on society. The Supreme Court wisely having bowed out, the many social, biological, environmental and ethical questions surrounding genetic engineering must now be resolved in the political arena, where the balancing of competing values and interests promises to be no easy task.

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