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Patent Law - Human-Made, Genetically Engineered, Living Microorganism Constituties a Manufacture or Composition of Matter under Title 35 U.S.C. 101 - Diamond v. Chakrabarty

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PATENT LAW—HUMAN-MADE, GENETICALLY ENGINEERED, LIVING MICROORGANISM CONSTITUTES A "MANUFACTURE" OR "COMPOSITION OF MATTER" UNDER TITLE 35 U.S.C. § 101

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

On June 7, 1972, Ananda M. Chakrabarty filed a patent application assigned to the General Electric Company seeking claims to a bacterium of the genus *Pseudomonas*, which he had created by the use of genetic engineering techniques. The bacterium possessed capabilities not present in any naturally occurring bacteria which allowed it to break down multiple components of crude oil.[1]

Among the thirty-six claims asserted in the application, the Patent Examiner allowed those for the process used in creating the bacteria[2] and for a floatable carrier inoculated with the organism, but rejected claims for the bacterium itself on the ground that it was a "product of nature".[3] Chakrabarty appealed to the Patent and Trademark Office Board of Appeals which, in an unreported decision, concluded that the bacterium was not a "product of nature" but rejected the claim on the basis that the bacterium was alive.[4] The Court of Customs and Patent Appeals (C.C.P.A.) reversed the Board's decision[5] on the authority of its holding in *In Re Bergy*[6] wherein it was stated that the fact that a microorganism is alive is not significant to the patent laws.[7]

The C.C.P.A. then vacated its judgment in the case[8] and consolidated it with *In Re Bergy*[9] in order to reconsider its decisions in light of the recent United States Supreme Court holding of *Parker v. Flook*.[10] The reversals were reaffirmed in both cases.[11]

The Commissioner of Patents and Trademarks sought and was granted certiorari to the United States Supreme Court[12] which, in a 5-4 decision, affirmed the C.C.P.A. ruling and held that the language of

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[1]Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[2]Process claims may be sustained independently of product patent claims as long as the product is not described "exclusively in terms of its use or function." Philip Sitton Septic Tank Co. v. Honer, 274 F.2d 811, 813 (10th Cir. 1959).

[3]Brief for Respondent at 8, n.3, Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[4]*Id.*

[5]*In re* Chakrabarty, 571 F.2d 40, 43 (C.C.P.A. 1978).

[6]563 F.2d 1031 (C.C.P.A. 1977).

[7]*Id.* at 1038.

[8]*In re* Chakrabarty, 571 F.2d 40 (C.C.P.A. 1978), *cert. dismissed sub nom.* Banner v. Chakrabarty, 439 U.S. 801 (1978).

[9]*In re* Bergy, 563 F.2d 1031 (C.C.P.A. 1977), *vacated sub nom.* Parker v. Bergy, 438 U.S. 902 (1978).

[10]437 U.S. 584 (1978).

[11]In re Bergy, 596 F.2d 952 (1979).

[12]Parker v. Chakrabarty, 444 U.S. 924 (1979).

35 U.S.C. § 101, which enumerates patentable subject matter, covered the bacterium and was, therefore, entitled to patent protection.[13]

THE INVENTION

In making the bacterium for which the patent application entitled "Microorganisms Having Multiple, Compatible Degradative Energy-Generating Plasmids and Preparations Thereof" was sought, Chakrabarty discovered the means whereby two or more cellular components called "plasmids"[14] capable of breaking down separate components of crude oil could be transferred into a single *Pseudomonas* cell.[15] The purpose of the invention was to devise a more efficient organism for use in cleaning up oil spills. When a mixture of several species of naturally occurring bacteria capable of degrading single components of oil was used to fight oil spills, the results were unsatisfactory. Numerous bacteria would die leaving the majority of the spill unattacked.[16]

In his research Chakrabarty discovered that the genes controlling the synthesis of enzymes responsible for the degradation of crude oil were located in plasmids of certain bacteria. Normally, each bacterium contains only one plasmid, which provides for the breakdown of only one part of oil (e.g., camphor or octane). These different plasmids were not compatible within the same organism. Chakrabarty invented a process whereby two or more of these plasmids could be made compatible in a single cell so that one bacterium could have the capability of breaking down several components of crude oil.[17]

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[13]447 U.S. 303.

[14]DNA (deoxyribonucleic acid) is the major structural component of genes and is found in structures called chromosomes located in the nuclei of cells. Plasmids are small circular DNA molecules that are physically separate from the chromosomes and may, by genetic engineering techniques, readily be transferred to other cells. Joint App. to Briefs at 40-41, Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[15]*Id.*

[16]*Id.* at 48.

[17]Briefly described, the process in the patent application entailed the following steps: The oil mixture to be degraded was first selected and the degradative pathways needed in a single cell were identified. Bacteria were placed in the mixture and chosen on the basis of selectivity, i.e., superior growth capability, and a particular strain of bacteria was isolated. The bacteria thus selected were studied to determine if, in fact, this capability was plasmid-borne. After this had been decided, the plasmid was transferred by conjugation (a process whereby a bacterium transfers genetic material to another bacterium by cellular contact) to other cells of the same strain. These conjugatants (recipients of the plasmids by conjugation) were then purified and checked to ensure they contained the oil degradative characteristics needed. At this point a second plasmid was transferred by the same process to the conjugatants and then treated with radiation to cause the plasmids to fuse. The process was repeated until all the degradative pathways needed for oil breakdown were available in one cell. Bacteria used to combat oil spills would serve as food for aquatic life after breaking down the spill. Joint App. to Briefs at 46-48, Diamond v. Chakrabarty, 447 U.S. 303 (1980). *See generally* "The New Biology," NATIONAL GEOGRAPHIC, Sept., 1976 at 374-75.

It should be noted that Chakrabarty did not utilize recombinant DNA techniques[18] in the correct sense of the term. All of the plasmid transfers in the bacteria took place in the cells themselves or "in vivo" rather than "in vitro" in which the splitting and recombination of genes are handled by man outside of the cells.[19]

ORIGINS AND APPLICATION OF TITLE 35 U.S.C. § 101

There is no common law of patents, but Congress has been granted legislative power to issue patents by virtue of the United States Constitution.[20] There is subsequent case law upholding that power.[21] Congress has exercised this power by enacting patent laws which are set out in Title 35 of the United States Code. Title 35 U.S.C. § 101 gives categories of patentable subject matter and reads as follows: "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." This section is derived from a series of patent legislation beginning in 1790 with the first patent act and culminating in the Patent Act of 1952 which codified the laws into Title 35 and which is in effect today.[22]

While 35 U.S.C. § 101 gives categories of statutory subject matter, 35 U.S.C. § 102 gives the conditions for patentability, including novel-

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[18]Recombinant DNA techniques involve taking pieces of the genetic material called deoxyribonucleic acid (DNA) from an organism and joining it by biochemical methods to pieces of DNA from another organism.

> [R]ecombinant DNA methods can be used to join two pieces of genes that code for different but complementary functional properties in which one is interested. This new combination of genes has advantageous properties found in neither set alone. Usually the advantage is a technical one, in that the new combination of genes allows us to isolate some of them [the properties sought] in quantities and purities previously unattainable. D. Jackson, *Principles and Applications of Recombinant DNA Methodology*, THE RECOMBINANT DNA DEBATE, 39, 42, (1979).

[19]Brief for Respondent at 25-26, Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[20]U.S. CONST. art. I, § 8, cl. 8, reads in its pertinent part: "The Congress shall have the power . . . to promote the progress of science and the useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

[21]*See, e.g.*, United States v. Dubilier Corp., 289 U.S. 178 (1933); Dr. Miles Medical Co., v. Park & Sons, Co., 220 U.S. 373 (1911); Railway Eng'r Co. v. Oregon Short Line R.R. Co., 79 F.2d 469 (10th Cir. 1935).

[22]The first patent act allowed patents for any "useful art, manufacture, engine, machine, or device, or any improvement therein." A second patent act in 1793 changes the requirements to "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter." The Consolidated Patent Act of 1870 shortened the provision to "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement thereof," and in the Patent Act of 1952 the word "art" was replaced by the word "process".

ty and loss of right to patent. Section 103 of that same title gives additional conditions of patentability, specifically, the requirement of nonobvious subject matter. Because of long-standing practices in the Patent Office, the words "new" and "useful" in § 101 are not usually considered under that section but rather under the "novelty" requirement of § 102.[23]

Since initiation of patent legislation, patents have been issued to such diverse inventions as adrenalin,[24] vitamins,[25] hamster cells in culture, viruses for vaccines, and processes or carriers involving the use of microorganisms.[26] However, until *Chakrabarty*, the Supreme Court had never addressed the question of whether a living microorganism, standing alone, was patentable subject matter.

The terms "manufacture" and "composition of matter" in § 101 entail classes or categories of inventions that may be patented. One of the earliest interpretations of "manufacture" was given in 1894 in *Johnson v. Johnston*,[27] which stated that the term covered a broad area of patentable products and included anything made by man in art or industry that was not a process, machine, composition of matter, or design.[28] The word has been interpreted to cover an extensive span of inventions but necessarily excludes other categories and classes of inventions covered elsewhere in Title 35.

A "manufacture" as applied to patent claims cannot be something that is simply new or never before made,[29] it must have been altered in some way so that it appears in a different and distinct form.[30] *American Fruit Growers v. Brogdex Co.*[31] is a much cited case in discussions of what constitutes a "manufacture" under the law. The Supreme Court expressed in that case that an orange whose skin had been impregnated with borax was not a "manufacture" because it did not produce a new or different article, that is, the borax merely protected the fruit from mold and there was no change in the "name, appearance or general character of the fruit."[32] On the other hand, a fur treated with a chemical to enable it to be dyed by a method which

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[23]A. DELLER, DELLER'S WALKER ON PATENTS § 13 (2d ed. 1964). *See also* historical discussion in *In re* Bergy, 563 F.2d 1031, 1039 (Miller, J. dissenting) (C.C.P.A. 1977).

[24]Parke-Davis and Co. v. H.K. Mulford Co., 189 F. 95 (C.C.S.D.N.J. 1911), *modified*, 196 F. 496 (2d Cir. 1912).

[25]Merck and Co. v. Olin Mathieson Chem. Corp., 253 F.2d 156 (4th Cir. 1958).

[26]Brief for Respondent at 20-21, Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[27]60 F. 619 (C.C.W.D. Pa. 1894).

[28]*Id.* at 620.

[29]Union Paper Collar Co. v. Van Dusen, 90 U.S. (23 Wall.) 530, 563 (1874).

[30]Anheuser-Busch Brewing Ass'n v. United States, 207 U.S. 556, 562 (1908); Hartranft v. Weigman, 121 U.S. 609, 615 (1887).

[31]203 U.S. 1 (1931).

[32]*Id.* at 11-12.

was before impossible was held to be a "manufacture" because it had acquired a new appearance, quality and use.[33]

Even though an article is made by a newly invented process it does not necessarily follow that the article is a new "manufacture".[34] It must still meet the requisite standards of the statute. However, it has been standard practice to issue patents on new processes for "old" articles as long as the processes are unobvious and novel.[35] A process patent may also be allowed for an article while the article itself may be unpatentable.

Patents for processes using live microorganisms have been allowed for many years without any hesitation on the part of the courts.[36] In fact, patents on living microorganisms themselves have often been allowed when in combination with a carrier material; for example, the living organism lactic acid baccillus mixed with cocoa or chocolate has been patented for use as a food product.[37]

The expression "composition of matter," as used in § 101, has been described as covering "all compositions of two or more substances," and as including "all composite products whether they are the result of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders, or solids."[38] An invention may be a "composition of matter" if it is the result of the combination of two or more substances which produce distinctive or additional properties which the substances individually do not possess.[39]

Patents will not be allowed on inventions if they are considered to be "products of nature." This restriction is a judicially created standard based on the idea that the laws of nature and scientific principles cannot be patented so that they may be available to all men to use and enjoy.[40] Illustrative of this standard of unpatentability of things that exist in nature is *Funk Bros. Seed Co. v. Kalo Co.*[41] In *Funk* it was held that a mixture of naturally occurring non-inhibitive strains of bacteria were not patentable because the mixture did not cause the

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[33]Steinfur Patents Corp. v. William Beyer, Inc., 62 F.2d 238, 240 (2d Cir. 1932).

[34]Cochrane v. Badische Anilin and Soda Fabrik, 111 U.S. 293, 311 (1882).

[35]1 A. DELLER, DELLER'S WALKER ON PATENTS § 15 (2d ed. 1964).

[36]*See, e.g.*, Cameron Septic Tank Co. v. Village of Saratoga Springs, 159 F. 453, 455-56 (2d Cir. 1908), *cert. denied*, 209 U.S. 548 (1908); Guaranty Trust Co. v. Union Solvent Corp., 54 F.2d 400 (D. Del. 1931), *aff'd* on lower court opinion at 61 F.2d 1041 (3rd Cir. 1932), *cert denied*, 288 U.S. 614 (1933).

[37]Brief for Respondent at 18, Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[38]1 A. DELLER, DELLER'S WALKER ON PATENTS § 15 (2d ed. 1964).

[39]P.E. Sharpless Co. v. Crawford Farms, Inc., 287 F. 655, 658 (2nd Cir. 1923); Commercial Acetylene Co. v. Avery Portable Lighting Co., 116 F. 907, 910 (C.C.E.D. Wis. 1909).

[40]1 A. DELLER, DELLER'S WALKER ON PATENTS § 23 (2d ed. 1964).

[41]333 U.S. 127 (1943).

bacteria to perform in any new or different way. They acted the same way as they did in nature without any improved use.[42]

In *Gottschalk v. Benson*[43] a patent was denied for a process to convert binary-coded decimal numerals into pure binary numerals. The Supreme Court recited that "it is conceded that one may not patent an idea. But in practical effect that would be the result if the formula . . . were patented in this case."[44]

Prior to 1930, patents were not issued to plants because of the theory that they were "products of nature." The first case so holding was *Ex parte Latimer*,[45] decided in 1889. In *Latimer* the Commissioner of Patents held that claims to extractions from pine needles were not patentable because all Latimer had done was discover the character of the particular pine needle. The claimant had taken no additional steps to convert the article. The Commissioner reasoned that to allow such a patent would be to give way to patents for "the trees of the forest and the plants of the earth."[46]

In 1930 Congress enacted the first plant patent act to enable developers of new breeds of plants to patent their discoveries. This first act was included in the 1952 codification in § 161 of the patent title. In 1970 the Plant Variety Protection Act[47] was enacted to extend the area of plants that could be patented.[48]

A recurring theme in arguments by critics of the patenting of living microorganisms is the presumption that Congress, by adopting the plant acts, specifically excluded living things.[49] Those who rely on such arguments may do so because of a misunderstanding of a case involving the plant acts, *In re Arzberger*.[50] In that case a patent for a bacterium sought under the plant patent act was denied. However, a closer reading of that case reveals the C.C.P.A. held only that the word "plant" was to be given its common, everyday usage, not its scientific meaning, under which some bacteria are classified as plants. It did not hold, however, that the living nature of the bacterium made it unpatentable. In the House and Senate reports behind the plant acts there is no mention of the subject of living or non-living inventions. In those reports the stated purpose of the laws was to give agriculture the same

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[42] *Id.* at 130. It should be noted that the patent sought in *Funk Bros.* was for a mixture of bacteria, not the bacteria alone.

[43] 409 U.S. 63 (1972).

[44] *Id.* at 71.

[45] 46 Off. Gaz. Pat. Office 1633 (1889).

[46] *Id.* at 1641.

[47] 7 U.S.C. § 2402 (1976).

[48] 3 A. DELLER, DELLER'S WALKER ON PATENTS §§ 190-92 (2d ed. 1964).

[49] 91 HARV. L. REV. 1357, 1362 (1975); Luckern, *Living Organisms are not Compositions or Manufactures Under 35 U.S.C. 101*, 7 AM. PAT. L. ANN. Q. 236, 263 (1979).

[50] 112 F.2d 834 (C.C.P.A. 1940).

benefits afforded other industries.[51] To argue that Congress intended to exclude living subject matter by enacting the plant acts is to draw inferences where there is no solid evidence on which to base them. It has been held that the intentions of earlier Congresses should not be guessed at by later ones.[52] From an overall standpoint of the law interpreting § 101 it appears that if an invention is unobvious, novel, or useful and has a distinct or new characteristic or utility, and is not a product of nature, it may be patentable statutory subject matter.

PATENT OFFICE PROCEDURE

In order to give the reader a clearer understanding of how the courts handle patent claims, an explanation of patent office procedure is included here. An individual seeking a patent claim files an application with the Patent Office which assigns the application to a Patent Examiner. The Examiner makes the initial decision of whether the invention should be patented. If the patent is rejected, the applicant may appeal to the Patent and Trademark Office Board of Appeals which can either affirm or reverse the Examiner's decision. If the Board of Appeals affirms the rejection, the applicant may take an appeal to either a federal district court, which has original jurisdiction over patent claims under 28 U.S.C. §1338, or to the United States Court of Customs and Patent Appeals, on the basis of 35 U.S.C. §14.[53]

THE PATENTABILITY OF MICROORGANISMS: THE C.C.P.A. DECISIONS

The C.C.P.A. first considered the question of patenting a living microorganism in *In Re Bergy*, the case with which *In re Chakrabarty* was consolidated to be reheard. *Bergy* involved a patent claim for a biologically pure culture of the microorganism *Streptomyces vellosus*, which did not occur in nature in that particular form. Like Chakrabarty's claim, the Patent Examiner rejected Bergy's patent to the bacterium because it was a "product of nature." The Board of Appeals sustained the rejection, not on the "product of nature" ground, but because the bacterium was alive. In a subsequent appeal the C.C.P.A. reversed the denial and granted Bergy a patent, holding that the fact that the organism was alive did not remove it from the categories of statutory subject matter in § 101.[54] The Supreme Court granted certiorari and ordered the C.C.P.A. decision vacated and remanded for fur-

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

[52]*See, e.g.*, United States v. Price, 361 U.S. 309, 309-14 (1960).

[53]9 A. DELLER, DELLER'S WALKER ON PATENTS § 807 (2d ed. 1964).

[54]*In re* Bergy, 563 F.2d 1031, 1035 (C.C.P.A. 1977).

ther consideration in light of *Parker v. Flook*, a case just decided which the court felt would be controlling.[55]

In *Flook*, the Supreme Court reversed a C.C.P.A. decision which allowed process patent claims for use of a mathematical formula involved in computer technology. The Court denied the patent because "a claim for an improved method of calculation, even when tied to a specific end use, is unpatentable subject matter under § 101."[56] The patent was rejected by the Court because the formula was merely a scientific principle or phenomena of nature. The Court also quoted from an earlier case in which it was stated that patent rights should not be extended by the Court unless it had received a "clear and certain signal from Congress."[57]

In its reconsideration of *Bergy* and *Chakrabarty* in light of *Flook*, the C.C.P.A. majority opinion could find no relevant connection between the issues in the cases. In *Flook* the claim was for a process using a mathematical formula while in *Bergy* and *Chakrabarty* the claims were to live bacteria. The only similarity between the cases was that they all involved the question of inclusion under § 101.[58] After exploring all the possible reasons for which the case was remanded, the majority of the C.C.P.A., speaking through Judge Rich, decided that *Flook* had no bearing at all on the cases.[59]

The claims presented by *Bergy* and *Chakrabarty* were considered by the C.C.P.A. to be "industrial product[s] used in an industrial process in a useful or technological art"[60] and accordingly no legal distinction was found between the living bacteria and the "dead" chemicals. It was also found to be insensible to allow patents on processes for microorganisms which use the life processes of the organisms to perform a particular use without allowing a claim on the living microorganism itself.[61] Therefore, both of the reversals of the Examiner's decisions in *Bergy* and *Chakrabarty* were reaffirmed.[62]

THE PATENTABILITY OF MICROORGANISMS: THE SUPREME COURT'S ANALYSIS

The Supreme Court described the issue in *Chakrabarty* as, "a narrow one of statutory interpretation"[63]—to determine if Chakrabarty's

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[55]437 U.S. 584 (1978).

[56]437 U.S. at 595, n.18.

[57]*Id.* at 596 (quoting from Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518, 531 (1972)).

[58]*In re* Bergy, 596 F.2d 452, 464 (1979).

[59]*Id.* at 967.

[60]*Id.* at 974.

[61]*Id.* at 977.

[62]*Id.* at 955. The Government was granted certiorari to both *Bergy* and *Chakrabarty* again, 444 U.S. 924 (1979), since then *Bergy* has been dismissed as moot, 444 U.S. 1028 (1980).

[63]447 U.S. 303, 307 (1980).

bacterium fell within the classification of a "manufacture" or "composition of matter" under § 101.[64] Earlier cases were cited where it was shown that both terms had previously been given their common or dictionary definitions. References were also made to the legislative history behind the enactment of § 101 to indicate that Congress intended for the section to cover a large range of inventions.[65] Because the bacterium was not naturally occurring and was a direct result of Chakrabarty's own inventiveness, the Court found that it fell within the construction it had previously given the statute and was appropriately patentable subject matter. In Chief Justice Burger's words, "The language of that section fairly embraces respondent's invention."[66]

The majority opinion considered two of the petitioner's arguments against the patent. In addressing the first argument in which the petitioners claimed that Congress, by enacting the 1930 Plant Patent Act and 1970 Plant Variety Act, indicated that it did not intend to include living things as "manufactures" or "compositions of matter", the Court asserted what it thought were the true reasons behind those acts. One of the reasons given was that plants were generally believed to be products of nature and therefore not patentable. Another important factor was that many plants were not easily distinguished by the required written description of the patent laws. The new laws were necessary to remedy such situations. The court rationalized that the plant acts were not enacted to differentiate between living and non-living subject matter but rather between products of nature and man-made inventions.[67]

The dissenting opinion shared the petitioner's view in this argument stating that the significance of the plant acts was to enable new varieties of plants, not naturally occurring, to be issued patents. However, the dissenters reasoned that if § 101 did cover non-natural living objects the plant acts would have been completely unnecessary and termed the majority's explanation as assuming that, "Congress was engaged in either idle exercises or mere correction of the public record when it enacted the 1930 and 1970 Acts."[68]

The second argument set out by the Commissioner of Patents was also rejected by the Court. This argument asserted that patents on living microorganisms should not be allowed without express statutory authority. The Commissioner supported its view on the basis that genetic engineering was unforeseen when the patent laws were drafted.

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[64]The novelty or unobviousness as required by 35 U.S.C. §§ 101, 103 of the invention was not in issue, 447 U.S. at 307, n.5.

[65]447 U.S. at 308.

[66]*Id.* at 318.

[67]*Id.* at 312.

[68]*Id.* at 320. (Brennan, J., dissenting).

In answer to this the court stated that although it is the function of Congress to enact laws, it is the Court's duty to interpret those laws. Accordingly, the majority found that when § 101 was written many new technologies were unforeseen which have since been patented. Furthermore, the drafters of the law necessarily used broad, expansive language to cover such unforeseeables.[69] As to their seemingly contradictory statement in *Parker v. Flook* that, "we must proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress",[70] the court explained that in *Flook* the patent claim was construed to be an "idea" and therefore unpatentable because of the established doctrine that ideas cannot be patented. The court rejected the contention that the statement in *Flook* made technologies unforeseen by Congress at the drafting of § 101 "unpatentable *per se*".[71] Again the dissenting judges agreed with the Commissioner and stated that the majority's decision did indeed extend patent protection into areas that Congress did not intend to cover.[72]

The Commissioner attemped to reinforce its arguments by including an *amicus* prepared by the People's Business Commission[73] which illustrated what the court called "a gruesome parade of horribles"[74] in an effort to demonstrate the risks associated with recombinant DNA research. The majority thought that it was not within its realm to consider the genetic research controversies set out in the *amicus*, stating that such considerations are a "matter of high policy for resolution within the legislative process."[75] It was also pointed out that even if Chakrabarty's claim were rejected, it was not likely to put an end to genetic research.

ANALYSIS

In deciding the issue in *Chakrabarty* the Supreme Court was faced with a question of first impression in which only two practical solutions were available. The Court could have either allowed the claim for the bacteria as falling under the statutory categories of § 101 or set a new judicial precedent for denying patents to articles that meet the requirements of statutory subject matter, but which are alive.

The Court chose to use the first solution in deciding the case, based on prior case law interpreting what constitutes a "manufacture" or "composition of matter". This decision is sure to raise a considerable amount of fervor in the genetic research controversy, an area already

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[69] *Id.* at 315.
[70] Parker v. Flook, 437 U.S. 584, 596 (1978).
[71] 447 U.S. at 316.
[72] *Id.* at 319.
[73] A consumer group based in Washington, D.C.
[74] 447 U.S. at 316.
[75] *Id.* at 316.

tense with fear. When genetic engineering is mentioned many questions of considerable magnitude arise. Issues of morality, social consideration, and legal consequences are but a few that surround the subject. Genetic technology is a rapidly expanding industry that is fast becoming a significant part of the commercial world. Companies that specialize solely in genetic technology have developed in the past few years[76] and major pharmaceutical and chemical companies are beginning to venture into the business. If such industry continues to prosper the impact on the nation as a whole and especially on its economy could be of great significance.

The beneficial applications of genetic technology are notable. Researchers have already discovered ways to artificially mass produce many medicinal substances by the use of genetic engineering on bacteria. Such substances include insulin, human growth hormone, and interferon, which, until now, have been extracted from animals or humans by involved mechanisms at high costs. By developing ways that these drugs can be manufactured at low costs and in great quantities, many diseases, before difficult or impossible to treat, can be brought under control. Foreseeable also are great advances in the treatment of incurable genetic diseases such as sickle cell anemia and Down's Syndrome.[77] The advantages of genetic technology extend likewise into the areas of agriculture and energy where new methods for improved crops and new fuels are under study.[78]

The argument most expressed against genetic engineering is the fear that a potentially lethal organism will escape from some laboratory and infect human beings. This fear is not totally ungrounded. Chakrabarty himself once felt it was necessary to destroy a bacteria he had manufactured in his lab.[79] Also, others opposed to genetic research have stated fear that the gene pool of the entire world could be seriously affected by tampering with DNA. They are afraid normal patterns of evolution will be changed to a dangerous extent.[80] But these considerations must be weighed against the potential benefits by all of society.

An example of one of the benefits that genetic research may bring is the production of interferon by artifical means. This substance has been shown useful in combating a large variety of virus infections, and has been extremely promising in fighting cancer. So promising in fact

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[76]Genetech, a San Fransisco firm engaged solely in genetic technology, has developed from a one million dollar business in 1976 to a sixty-five million dollar business today. U.S. NEWS AND WORLD REPORTS, June 30, 1980 at 34-35.

[77]*Id.*

[78]*Id.*

[79]Wade, *Dicing with Nature: Three Narrow Escapes*, 195 SCIENCE 378 (1977).

[80]Kiley, *Learning to Live with the Living Invention*, 7 AM PAT. L. ANN. Q. 220, 231, (1979).

that the United States government has spent millions of dollars for research on it. However, a major obstacle to widespread use of interferon exists in the amazingly high cost of its manufacture by conventional means. The cost of a single gram of interferon can go as high as a million dollars. The production of interferon by genetically made bacteria could reduce the cost to a practical level to allow all of society to benefit from it.[81]

Intriguing legal questions are raised when one considers a hypothetical situation in which a disease-producing microorganism did escape and infect humans: who would be potentially liable for tort claims arising from the injuries? In cases of large groups of the population becoming ill, how would damages be assessed and who would have to pay? Tort law as we know it today would have to be reassessed in light of such considerations.[82]

One may reasonably ask why Chakrabarty felt it necessary to take his patent claim to the highest court of the nation when the Patent Examiner had already allowed his claims to the process for making the bacteria and for the bacteria plus a carrier material. The answer is based on the nature of the invention. Because they are living organisms, the bacteria can and will multiply in the right growth medium. All one would have to do to obtain it would be to go to a site where it is being used on an oil spill and "scoop up a tablespoon and grow their own batch."[83] Additionally, products of microbiological process patents are required by law to be placed in national culture collections so that they may be available to the public.[84] Anyone could simply go to the nearest depository, "check out" a sample of a particular microorganism, let it grow and reproduce and engage its particular functions to their own use without ever infringing on a process patent.[85]

Since patents can now issue on live organisms some fear that higher life forms will in the future be patented. This idea is rather unlikely to come about because of the difficulty in higher life forms being sufficiently described, as required by the patent laws. For those who think one day that even humans could be genetically engineered, conceivably, the basic human rights set out in the Constitution would prevent such from ever being patented.[86]

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[81]B. Davis, *Evolution, Epidemiology and Recombinant DNA*, THE RECOMBINANT DNA DEBATE, 139 (1979).

[82]R. Dworkin, *Biocatastrophe and the Law: Legal Aspects of Recombinant DNA Research*, THE RECOMBINANT DNA DEBATE, 219 (1979).

[83]NEWSWEEK, June 30, 1980, at 74.

[84]*In re* Argoudelis, 434 F. 2d 1890 (C.C.P.A. 1970).

[85]Kiley, *Learning to Live with the Living Invention*, 7 AM. PAT. L. ANN. Q. 220, 224 (1979).

[86]Luckern, *Living Organisms are not Compositions or Manufactures under 35 U.S.C. §101*, 7 AM. PAT L. ANN. Q. 236, 262 (1979).

CONCLUSION

The Supreme Court, in holding that Chakrabarty's bacterium was patentable subject matter under § 101, made the only decision possible without subtracting from the applicable patent laws. The bacteria fit precisely into every category necessary for a patent. It was not naturally occurring; it was new and unobvious; and it had acquired a new name, character and use. The only obstacle in the Court's way was the fact that it was alive. The Court felt this was not a great enough barrier to warrant denying the patent. This decision will likely spur commercial interest in the field of genetic technology but will probably have minimal effect on the scientific community, which would have continued its research regardless of the outcome of the case. In any event, if Congress so chooses, it may still enact legislation curtailing aspects of genetic research or increase the strictness of the federal regulations that control it.

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