

# PATENT LAW

## *Patentability of Micro-organisms*

*Diamond v. Chakrabarty*, 100 S. Ct. 2204 (1980)

THE DECISION rendered by the Supreme Court in *Diamond v. Chakrabarty*<sup>1</sup> allows the new science of biotechnology to come out of the closet and to take its place in the public domain with other scientific achievements that have, for better or for worse, shaped the industrial life of the United States. It is probable that the products which will result from this emerging science will affect each of us in some way during our lifetimes.

Ananda Chakrabarty is a microbiologist employed by General Electric Corporation. During the course of Dr. Chakrabarty's research, he and an associate discovered plasmids<sup>2</sup> that were capable of degrading camphor and octane, the two components of crude oil. Chakrabarty discovered a process by which four different plasmids, capable of degrading four different oil components, could be transferred and maintained stably in a single bacteria.<sup>3</sup> Dr. Chakrabarty sought a patent on this process, making the following claims in his application: "first, process claims for the method of producing the bacteria; second, claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves."<sup>4</sup> All of the above claims dealt in some way with so-called "genetic engineering."<sup>5</sup>

The patent examiner allowed the claims in the first two categories but rejected the claims to the bacteria. This rejection was based on two reasons: 1) the micro-organisms were "products of nature;" and, 2) since the organisms were living, they were not patentable under 35 U.S.C. § 101.<sup>6</sup>

Chakrabarty appealed and the Patent Office Board of Appeals determined that the micro-organisms were not "products of nature" since

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<sup>1</sup> 100 S. Ct. 2204 (1980).

<sup>2</sup> "Plasmids are hereditary units physically separate from chromosomes of a cell. . . . [They] control the oil degradation abilities of certain bacteria." 100 S. Ct. at 2205 n.1. They are not living matter.

<sup>3</sup> *Id.*

<sup>4</sup> *Id.* at 2206.

<sup>5</sup> The process of genetic engineering involves altering basic genetic makeup to instill desired characteristics. Such altered genetic elements may be artificially inserted by scientists into a micro-organism with the result that the recipient micro-organism takes on new characteristics that it would not naturally have possessed. These characteristics then become reproduced as part of the normal reproductive process of the micro-organism. Brief on Behalf of the American Society for Microbiology, *Amicus Curiae*, at 4.

<sup>6</sup> 100 S. Ct. at 2206.

none having their unique qualities occurred without man's intervention. However the Board did affirm the examiner's second objection, stating that no living things other than plants, as provided for in the Plant Patent Act of 1930, were patentable under the United States Patent Code.

The Court of Customs and Patent Appeal (C.C.P.A.) reversed this decision, basing its opinion on an earlier case in that court, *In re Bergy*.<sup>7</sup> In that decision, the court had held that the fact that the micro-organism was alive was without legal significance for the purposes of patent law.

By this time, the United States Supreme Court had granted certiorari in the case of *Bergy*. The Court then remanded it to the Court of Customs and Patent Appeal for further consideration in light of the Court's decision in *Parker v. Flook*.<sup>8</sup>

The C.C.P.A. vacated its judgment in *Chakrabarty*, and consolidated this case with *Bergy* for the purpose of reconsidering them. It proceeded to reaffirm its earlier decisions.<sup>9</sup> The Government sought certiorari, which was granted. However, *Bergy* was dismissed as moot.<sup>10</sup>

By a vote of five to four, in this case of first impression, the Court affirmed the decision of the C.C.P.A., thereby allowing Chakrabarty to receive the patent sought on his micro-organism. "His [Chakrabarty's] discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101."<sup>11</sup>

This decision received much media attention because of the specter of patenting living things. If one eliminates the emotion-packed buzz words, and considers this holding in light of the totality of patent law, one can understand that this decision is but a step in the logical progression of the encouragement of American technical arts.<sup>12</sup>

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<sup>7</sup> 563 F.2d 1031 (C.C.P.A. 1977).

<sup>8</sup> 437 U.S. 584 (1978). This decision dealt with the patentability of a method of calculation which was determined by the Court to be non-patentable subject matter under section 101 because it consisted of an application of a mathematical algorithm. The formula was within prior art.

<sup>9</sup> 596 F.2d 952 (C.C.P.A. 1979). The decision here was four to one whereas in the first case, the decision had been reached by a vote of three to two. Judge Baldwin changed his view in the second case in light of the opinion in *Parker v. Flook*.

<sup>10</sup> 100 S. Ct. 696 (1980). *Bergy* canceled its claim to the bacterium so the Supreme Court granted *Bergy's* motion to dismiss. However the *Bergy* application was not abandoned. Claims to the method of use of the *Bergy* bacterium remain allowed and the application presumably will be granted. Brief for Respondent at 10, n.5, *Diamond v. Chakrabarty*, 100 S. Ct. 2204.

<sup>11</sup> 100 S. Ct. at 2208.

<sup>12</sup> Innovation in this country is badly in need of stimulation, according to President Carter. In announcing measures to spur innovation, President Carter listed nine critical areas, two of which were enhancing the transfer of information and strengthening the patent system. President's Message to Congress Transmitting Proposal Initiatives, 15 WEEKLY COM. OF PRES. DOC. 2069 (Oct. 31, 1979) as referred to in Brief on Behalf of the American Patent Law Association, Inc., *Amicus Curiae*, at 6, n.5.

It is possible that if Dr. Chakrabarty could have written his patent claim without using the words "genetic engineering," the patent examiner would not have rejected it.<sup>13</sup> These words, coupled with the stories of recombinant DNA technology,<sup>14</sup> were bound to have caused any bureaucrat to hesitate before passing on such an item. All persons in government during the early 1970's were suffering some type of fear-of-the-media induced by the Watergate revelations. It is hardly surprising that the examiner preferred to reject this potential controversy and leave it to the patentee to appeal if he wished. Other patent applications for living organisms had been approved earlier by the Patent Office without undue attention,<sup>15</sup> beginning with Pasteur's patent for yeast, granted in 1873.<sup>16</sup> In this particular instance, the *process* involving the use of Chakrabarty's living organisms was deemed patentable. As was stated by the C.C.P.A.:

It seems illogical to us to insist that the existence of life in a manufacture or composition of matter in the form of a biologically pure culture of a microorganism removes it from the category of subject matter which can be patented while the functioning of a living organism and utilization of its life functions in processes does does not affect their status under § 101.<sup>17</sup>

Nevertheless, this was the case. Even if Dr. Chakrabarty and General Electric, the assignee of the patents, had lost this case, this useful microorganism would have been available to degrade oil spills as part of their patentable process which the examiner had allowed.

Justice Brennan expressed his concern, in a dissenting opinion, over whether Chakrabarty should be "able to secure a monopoly on the living

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<sup>13</sup> The subject of *Funk Bros. Seed Co. v. Kale Inoculant Co.*, 333 U.S. 127 (1948) was also bacteria. This claim was not rejected because the bacteria involved were living, but because combining them was not an invention. The bacteria were naturally occurring and the only invention involved was the packaging of the six bacteria into a single product.

<sup>14</sup> "Recombinant DNA technology consists of alteration of a plasmid prior to its insertion into a micro-organism. Utilizing recombinant DNA technology, genes from any source may be introduced into a micro-organism in order to create a strain exhibiting new characteristics." Brief of Behalf of American Society for Microbiology, *Amicus Curiae*, at 5.

<sup>15</sup> Brief of Respondent at 50, and at App. 16a-18a (listing the living organisms that had received patents).

<sup>16</sup> 100 S. Ct. at 2210, n.9.

<sup>17</sup> Application of Bergy, 596 F.2d 952, 977 (C.C.P.A. 1979). The claimed matter for a patent in Bergy was a biologically pure culture which could not occur naturally.

<sup>18</sup> White, Marshall and Powell, J.J. joined Brennan, J. in his opinion. It was their contention that Congress, by passing both the Plant Patent Act of 1930 and the Plant Variety Protection Act in 1970, carefully limited the protection that it was extending. In the 1970 Act, bacteria were specifically excluded. The majority held that this was merely to show agreement with the holding in *In re Arzberger*, 112 F.2d 834 (1940), since there is nothing in the legislative history to indicate otherwise. 100 S. Ct. at 2210. However the dissent stated, "Congress, assuming that animate objects as to which it had not specifically legislated could not be patented, excluded bacteria from the set of patentable organisms." 100 S. Ct. at 2214. (Brennan, J., dissenting).

organism itself."<sup>19</sup> He stated that he believed that the majority was extending the coverage of the patent system, even though, in his view:

Congress plainly has legislated in the belief that § 101 does not encompass living organisms. It is the role of Congress, not this Court, to broaden or narrow the reach of patent law. This is especially true where, as here, the composition sought to be patented uniquely implicates matter of public concern.<sup>20</sup>

The large stumbling block here seems to involve the fact that by receiving a patent, a person or a company has the right to restrict the use of the patented thing. It is apparently more traumatic when this thing happens to be living although property rights in things which are living have existed for centuries.

The scientific ignorance of the American public may also contribute to the difficulty with this concept. We tend to equate "living things" with a person or a furry friendly animal. However, as was stated in the Brief of Dr. George Pieczenik:

The distinction between living and non-living matter has no real meaning in relation to this technology (biotechnology). That which is living is typically described in terms of a set of attributes which, when all present, are considered indicia of life. There is no single fundamental property, law of nature, or operating principle, which distinguishes that matter which we call living from that which we do not.<sup>21</sup>

When the Constitutional Convention gave Congress the right to issue patents<sup>22</sup> in article I, section 8,<sup>23</sup> it was balancing the antipathy of Americans to any type of monopoly with an understanding that to promote "useful arts," the inventor had to receive some reward. Thomas Jefferson, himself a renowned inventor, understood this point clearly. It was Jefferson who shaped the American patent system and who attempted to legislate the delicate, necessary balance into the requirements for patents which were incorporated into the Patent Act of 1793 and which, with very few changed words, are still the law.<sup>24</sup>

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<sup>19</sup> *Id.* at 2212.

<sup>20</sup> *Id.* at 2214 (Brennan, J., dissenting).

<sup>21</sup> Brief of Dr. George Pieczenik, *Amicus Curiae*, at 3.

<sup>22</sup> A patent is "a grant made by the government to an inventor, conveying and securing to him the exclusive right to make, use and sell his invention for a term of years." BLACK'S LAW DICTIONARY 1013 (5th ed. 1979). In effect, when a patent has been issued, someone else may use the item, but is required to pay the patent holder for the privilege.

<sup>23</sup> "The Congress shall have Power . . . (8) To promote the Progress of Science and Useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective writing and Discoveries." U.S. Const. Art. 1, § 8.

<sup>24</sup> 35 U.S.C. §§ 101-103 (1976) For an overview of the development of this doctrine, see *Graham v. John Deere Company of Kansas*, 383 U.S. 1, 5-10 (1966).

Because of a reluctance to allow any erosion of what may be considered "public property," *i.e.*, natural phenomena or things naturally occurring, the courts have strictly construed the patent law and have hesitated to extend it as they have other congressional acts. The Supreme Court stated this clearly in *Deepsouth Packing Co. v. Laitram Corp.*<sup>25</sup>

[W]e should not expand patent rights by overruling or modifying our prior cases construing the patent statutes unless the argument for expansion of privilege is based on more than mere inference from ambiguous statutory language. We would require a clear and certain signal from Congress before approving the position of a litigant who, as respondent here, argues that the beachhead of privilege is wider, and the area of public narrower, than the courts had previously thought.<sup>26</sup>

However, as Chief Justice Burger points out in *Chakrabarty*, "We have also cautioned that courts 'should not read into the patent laws limitations and conditions which the Legislature has not expressed.'"<sup>27</sup>

This dynamic tension between two desirable but conflicting policies is clearly seen in these writings of Jefferson:

Inventions then cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody.<sup>28</sup>

Apparently it has been the will of society not to give such an exclusive right to products of nature which the public had previously enjoyed or which were newly discovered. For an invention to be patentable, it must comply with 35 U.S.C. § 101 which states: "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."<sup>29</sup>

In other words, man has to be involved in the making or improving of the thing for which the patent is sought. Section 101 is very broad, including "anything under the sun that is made by man,"<sup>30</sup> but laws of nature, physical phenomena and abstract ideas have been held not patentable.<sup>31</sup>

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<sup>25</sup> 406 U.S. 518 (1972).

<sup>26</sup> *Id.* at 531.

<sup>27</sup> 100 S. Ct. at 2207, quoting *United States v. Cubilier Condenser Corp.*, 289 U.S. 178, 199 (1933).

<sup>28</sup> VI WRITINGS OF THOMAS JEFFERSON 180-81, quoted by the Court in *Deere*, 383 U.S. at 9, n.2.

<sup>29</sup> 35 U.S.C. § 101 (1976).

<sup>30</sup> 100 S. Ct. at 2207.

<sup>31</sup> *Id.* at 2208.

The other key element of the American patent system is the requirement of section 112 that disclosure of the invention be made in such a manner that someone skilled in the art could reproduce the invention.<sup>82</sup>

It is these two requirements that were the primary deterrents to the patenting of plants prior to the passage of the Plant Patent Act of 1930. The House and Senate both agreed that:

The purpose of the bill is to afford agriculture, so far as practicable, some opportunity to participate in the benefit of the patent system as has been given industry, and thus assist in placing agriculture on a basis of economic equality with industry. The bill will remove the existing discrimination between plant developers and industrial inventors.<sup>83</sup>

To solve the problem of the written description, section 4888 of the Revised Statutes was amended to read "No plant patent shall be declared invalid on the ground of non-compliance with this section if the description is made as complete as is reasonably possible."<sup>84</sup>

To counteract the description problem for bacteria and micro-organisms, the Department of Agriculture's Northern Regional Research Laboratory at Peoria, Illinois was established as a depository for these materials. A permanent culture collection is maintained there from which persons may obtain a sample of the micro-organism so that they may, if possessing the requisite skill, produce the antibiotic or the duplicate organism. This method of description was upheld by the Court of Customs and Patent Appeals in *Application of Argoudelis*.<sup>85</sup>

It is through the method of disclosure that the patent process adds to the knowledge in the public domain. As one judge stated:

The incentive to give this added measure of knowledge to the public, which clearly promotes the progress of the "Useful Arts" is the primary justification for the existence of the patent system. [But] [t]here is no sense in making an applicant publicly disclose any part of his invention, much less its very essence, (as giving a sample from the

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<sup>82</sup> 35 U.S.C. § 112 (1976) states:

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

<sup>83</sup> S. REP. No. 315, 71st Cong., 2d Sess. 1 (1930) and H. REP. No. 1129, 71st Cong., 2d Sess. 1 (1930) as quoted in *Bergy*, 596 F.2d at 982.

<sup>84</sup> Currently codified at § 162.

<sup>85</sup> 434 F.2d 1390 (C.C.P.A. 1970).

culture) before he has been assured that he will obtain the protection he is seeking in return for the disclosure.<sup>36</sup>

This is the basic trade-off that the public, through the government, engages in with the inventor, that is, knowledge for protection. Without this sharing of new discoveries, permitting scientists and investors to build on the successes and failures of others, vast amounts of time would be consumed virtually reinventing the wheel day after day.

The issue which the petitioner (Diamond) presented to the Court was very broadly stated, *i.e.*, whether a living organism is patentable subject matter under section 101.<sup>37</sup> Earlier the Court of Customs and Patent Appeal had said "That statement—typical of the PTO position from the outset—is overly broad which it calculated to magnify its importance. We are not dealing with all living things, including man, fruits, vegetables, and flowers. . . ." <sup>38</sup> But by stating the issue in this manner, media coverage and resultant public attention was certain to be achieved.

In truth the issue that the petitioner presented was whether genetically engineered micro-organisms could be patented; whereas Chakrabarty's issue appeared to be whether a new oil spill cleaning machine is patentable even though comprised of micro-organisms classified as living matter because of their ability to reproduce<sup>39</sup> The basic differences in the viewpoints of the parties are more clearly understood when the issues are restated in this way.

The Court, in its decision, limited itself as much as possible to a determination of "whether respondent's micro-organism constitutes a 'manufacture' or a 'composition of matter' within the meaning of the statute."<sup>40</sup> A key factor for the Court in seeking to determine the congressional intent behind section 101 was the fact that Congress retained the use of the word "any" in modifying both manufacturer and composition of matter in the 1952 re-enactment; that if Congress had wished to place restrictions on the meaning of these words, it would not have said "any." Another factor that the Court felt was compelling was the statement made during the hearings on the bill that these words referred to "anything under the sun developed by man."<sup>41</sup>

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<sup>36</sup> *Id.* at 1394-95 (1970) (Baldwin, J., concurring). For a casenote developing the thesis that the C.C.P.A. had extended their construction of these words far beyond that which is warranted, see 47 GEO. WASH. L. REV. 242.

<sup>37</sup> Brief for Petitioner at 3.

<sup>38</sup> *Bergy*, 596 F.2d at 976.

<sup>39</sup> As stated in the brief, the issue was whether patent claims to a concededly novel and unobvious bacterium, made by man for treatment of oil spills, should be denied solely because the bacterium is alive. Brief for Respondent at 1.

<sup>40</sup> 100 S. Ct. at 2207.

<sup>41</sup> *Id.*

The fact that Congress did not envision the possibilities of genetic engineering in 1952, and could not have imagined a patentable life form, should not be controlling. As was stated by the Court in 1859:

The true policy and ends of the patent laws enacted under this Government are disclosed in that article of the Constitution, the source of all these laws, viz: "to promote the progress of science and the useful arts," contemplating and necessarily implying their extension, and increasing adaptation to the uses of society.<sup>42</sup>

But the Court did say that there are some limits on section 101 and offered a test to the Patent Office to be applied in the absence of new legislation, stating that "[T]he relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions."<sup>43</sup>

Nevertheless, there are serious questions which must be answered before micro-organisms, even though patentable, are loosed on the environment. The Court recognized the existence of these problems, but stated:

The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides.<sup>44</sup>

Possible environmental effects are questions of policy which should be treated by the Congress and not by a court adjudicating a patent claim. If the protection of patent law had not been granted these micro-organisms, companies would have continued their work, but behind closed doors, with little or no public knowledge until after the fact of development and use. Now disclosure will be assured because it is an essential part of the patent process.

If, after public hearings and debate, Congress determines that the public interest in limiting further development of genetically engineered micro-organisms outweighs the public interest in providing possible incentives for new research, Congress has the ability to exclude this specific subject matter from the patent process as it did in the case of atomic material capable of producing weapons.<sup>45</sup>

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<sup>42</sup> *Kendall v. Winsor*, 62 U.S. 322, 328 (1859) quoted in *Bergy*, 596 F.2d at 973.

<sup>43</sup> 100 S. Ct. at 2210.

<sup>44</sup> *Id.* at 2211-12.

<sup>45</sup> 42 U.S.C. § 2181 (1976) states:

No patent shall hereafter be granted for any invention or discovery which is useful solely in the utilization of special nuclear material or atomic energy in an atomic



In a free society, serious problems of policy should be discussed openly. As a result of this decision, pressure will be exerted on Congress to address itself to the issue of genetic engineering.<sup>46</sup> Since to the non-scientist, the concept of engineering life is both frightening and mystifying, it will be necessary for Congress to carefully examine such work in light of the possible benefits and potential hazards to mankind. Every technological advance has created problems. Consistently the United States, as a matter of national policy, has opted not to stop the new technology, but to attempt to anticipate and to solve the attendant difficulties.

Clearly the public is intrigued with the subject of biotechnology. This is illustrated by the frenetic buying of the shares of Genetech, one of the four companies in the world doing recombinant-DNA research.<sup>47</sup> This company, the first to come to the stock market for capital, opened the fall of 1980 with exceptional trading activity. Even though the company's own prospectus states that the products it has developed, which include human insulin, a human growth hormone and two types of interferon,<sup>48</sup> may never be produced in commercially viable quantities, the shares were selling for 8900 times earnings at one point after the initial selling began. Compare this with IBM, an earlier, futuristic glamor issue, which was selling for a mere twelve times earnings.<sup>49</sup>

Obviously those who invest believe that genetic engineering-biotechnology is the new wave. Since capital is now involved, perhaps people will be more open to discussions of where this new industry may lead *before* we are faced with massive problems. Nonetheless, it is a subject which can not be avoided, and in that respect, *Diamond v. Chakrabarty* opens the way for full public discussion as well as opening the patent process to biotechnicians.

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weapon. Any patent granted for any such invention or discovery is revoked, and just compensation shall be made therefore.

<sup>46</sup> An example of this is an article in the Cleveland Plain Dealer, July 19, 1980, § C, at 6, col. 1, entitled "Creation of Life in Lab Raises Alarm." The article reports on a number of religious leaders who have urged that the spectrum of issues involved in genetic engineering be examined to determine what oversight and controls are necessary.

<sup>47</sup> TIME, Oct. 20, 1980, at 72.

<sup>48</sup> NEWSWEEK, Oct. 20, 1980, at 72.

<sup>49</sup> NEWSWEEK, Oct. 27, 1980, at 90.