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Chakrabarty in the Era of Genomics: Diamond v. Chakrabarty

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CASE COMMENT

CHAKRABARTY IN THE ERA OF GENOMICS
Diamond v. Chakrabarty, 447 U.S. 303

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The respondent filed a patent application for the invention of bacteria,[1] *Pseudomonas*,[2] stably transformed[3] with plasmids[4] that allowed the bacteria to degrade crude oil. The plasmids containing genes for hydrocarbon degradative pathways are not found naturally in *Pseudomonas* in the environment. This invention was engineered to provide bioremediation of oil spills. The respondent filed a patent claim for the bacteria themselves[5], which the patent examiner rejected because products of nature and living things are not patentable under 35 U.S.C. § 101.[6] The Patent Office Board of Appeals affirmed the decision of the Examiner on the grounds that living things are not patentable.[7] Then the Court of Customs and Patent Appeals reversed the decision since the living nature of microorganisms is irrelevant in regard to patent law.[8] The United States Supreme Court granted certiorari, affirmed, and HELD, that a genetically engineered microorganism is not a product of nature, but

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1. *See* U.S. Patent No. 4,259,444.

2. Dr. Chakarabarty filed claims for two recombinant *Pseudomonas* strains. *P. aeruginosa* strain 1c (ATCC 15692) was transformed with plasmids containing genes for octane, salicylate, and naphthalene degradative pathways to produce *P. aeruginosa* NRRL B-5472. *P. putida* NRRL B-5473 was created by transforming *P. putida* strain PpG1 (ATCC 17453) with plasmids containing genes for camphor, salicylate, and naphthalene degradative pathways in addition to RP-1 drug resistance.

3. Transformation is the transfer of cloned DNA (cDNA) to a competent recipient bacterial cell.

4. A plasmid is an extrachromosomal genetic element that can stably function and replicate. In the recombinant *Pseudomonas*, the function of the plasmids was to express the degradative genes.

5. The respondent's claim consisted of the method for producing this bacteria and an inoculum of a carrier material, to float on the water with the bacteria, in addition to the bacteria themselves. The patent examiner allowed the first two claims.

6. *Diamond v. Chakrabarty*, 447 U.S. 303, 306 (1980).

7. *Id.*

8. *Id.* The Court of Customs and Patent Appeals cited its previous decision in *In re Bergy* to support its reversal. 563 F.2d 1031, 1038 (1977).

rather a product of a person's work and is thus patentable under 35 U.S.C. § 101.[9]

To foster ingenuity, Article I, Section 8, Clause 8 of the United States Constitution allows Congress to provide exclusive rights to an invention for a limited time.[10] During the second session of the First Congress, the legislature quickly used its power to enact the Patent Act of 1790. The current requirements for patents are codified in Title 35 of the United States Code. A patent must meet the criteria of proper subject matter[11], novelty,[12] utility[13], nonobviousness[14], and disclosure.[15] Once a patent is granted, the inventor has exclusive rights to that invention for twenty years from the date of filing the patent request.[16]

The Court expressly stated a modern view of the public policy argument for granting patent holders a limited monopoly in the analysis of *Kewanee Oil Co. v. Bicron Corp.*[17] The exclusivity granted to patent holders encourages the risk of the initial costs of the time and money necessary for research and development.[18] New products, methods, and ideas theoretically have a positive effect on society as a whole and improve the quality of life, the economy, etc.[19] Additionally, new and innovative ideas stir the creativity of others.[20] Due to the full disclosure of the invention during the patent application, society benefits from the access to the innovations so those with the knowledge and skill can reproduce the invention after the period of exclusivity expires.[21] The gains to society outweigh the negative aspects of a limited monopoly.[22]

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9. *Id.* at 306-307. The Court granted the petition for certiorari by the Acting Commissioner of Patents and Trademarks in *Bergy*, vacated the judgment, and remanded the case to the Court of Customs and Patent Appeals consistent with the decision of *Parker v. Flook*. 437 U.S. 584 (1978). The Court of Customs and Patent Appeals vacated the judgment in *Chakrabarty* and consolidated it with *Bergy*. After another review of *Bergy* and *Chakrabarty* consistent with *Flook*, the Court of Customs and Patent Appeals affirmed its earlier decisions. The Court granted certiorari for both *Bergy* and *Chakrabarty*, but *Bergy* was subsequently dismissed as moot. 444 U.S. 1028 (1980). Thus, the Court held on *Chakrabarty* only.

10. U.S. CONST. art. I, §8, cl. 8. "[The Congress shall have Power] To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries"

11. 35 U.S.C. § 101 (2000).

12. 35 U.S.C. § 102 (2000).

13. 35 U.S.C. § 101 (2000).

14. 35 U.S.C. § 103 (2000).

15. 35 U.S.C. § 112 (2000).

16. 35 U.S.C. § 154(a)(2) (2000).

17. *Kewanee Oil Co. v. Bicron Corp*, 416 U.S. 470 (1974).

18. *Id.* at 480.

19. *Id.*

20. *Id.* at 481.

21. *Id.* at 480-481.

22. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948).

In *Funk Bros. Seed Co. v. Kalo Inoculant Co.*[23], the Supreme Court reviewed a bacterial patent application for the first time. During this period, farmers inoculated their leguminous crops with monocultures of *Rhizobium* species for nitrogen fixation. The two parties isolated strains that did not have inhibitory effects on other strains, and thus packaged these strains together so a single mixed culture could be applied to leguminous plants instead of six separate monocultures.[24] Kalo Inoculant Co. filed a patent infringement suit against Funk Brothers Seed Co., and Funk Brothers Seed Co. counterclaimed that the patent was invalid.[25]

The Court held that the patent was invalid since the bacterial characteristics were not created.[26] The bacterial characteristics existed naturally, but were just unknown to date.[27] Hence, the patent applicant did nothing more than discover an unknown, natural microorganism.[28] Patents should not be issued for natural phenomena and scientific laws of nature.[29] Thirty years later, the Court affirmed the decision of *Funk Brothers*. In *Parker v. Flook*[30], the Court reviewed a patent application for a "Method for Updating Alarm Limits."[31] The method consisted of 1) a value measurement of the process variable, 2) an algorithm calculation of a value for the updated alarm limit, and 3) an adjustment to the new alarm limit.[32] The application represented a novel formula that supplied a better method to update the alarm limit.[33] Since only the mathematical formula was novel, the method was not patentable since the formula represents a mathematical law of nature.[34]

The instant Court held that the respondent's genetically engineered *Pseudomonas* was patentable under 35 U.S.C. § 101.[35] The naturally occurring microorganism was the basis for the invention, but the plasmid encoded non-*Pseudomonas* genes that degraded crude oil made it

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23. *Id.* at 130.
24. *Id.*
25. *Id.* at 128, 132.
26. *Id.* at 131.
27. *Id.*
28. *Id.*
29. *Id.* at 130.
30. *Parker v. Flook*, 437 U.S. 584 (1978).
31. Within the decision, alarm limits were explained as a predetermined signal of a measurement of an operating condition (e.g. temperature, pressure) that indicates dangerous conditions or inefficiency. Since many catalytic conversion processes involve changing variables, the respondent submitted a patent for determining a method of periodic alarm limit updates. Essentially, an alarm limit is a number or value.
32. *Id.* at 585.
33. *Id.* at 586.
34. *Id.* at 594.
35. *Diamond, supra* note 5, at 310.

patentable subject matter.[36] The engineered *Pseudomonas* did not occur in nature. Therefore, the bacteria were not natural phenomena. The Court found the language of § 101 sufficiently broad to allow inventions of genetically engineered microorganisms to be patentable.[37] Additionally, the Committee Reports of the Patent Act of 1952 reported that Congress intended patentable subject matter "to include anything under the sun that is made by man."[38] The instant Court also stated that Congress could amend § 101 if the ruling was against the intent of the legislation.[39] Since the bacteria were man made, the engineered microorganism was patentable.

The instant Court's ruling allowed a broad reading of patentable subject matter in the instant case since § 101 did not explicitly bar man made living organisms.[40] Biotechnology was an emerging field at time of this decision. Congress could not have envisioned the scope of biotechnology when the patent laws were enacted.[41] The ambiguity within the law permits unforeseen developing technologies to be patented.[42]

Use of the committee reports also allowed the instant Court to interpret the legislative intent during the law's formation.[43] The instant Court's ruling is a continuance of public policy to support biotechnology developments. The limited exclusivity granted to the inventor provides an important incentive for further advancements.[44] Much of biotechnology is a high risk, high reward system. Many products fail or take a long time to develop due to the complexity of biological systems.[45] Additionally, the product could be copied once injected into the stream of commerce. Thus, the exclusivity granted to the inventors of genetically engineered

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36. *Id.*

37. *Id.* at 308.

38. *Id.* at 309.

39. *Id.* at 318.

40. *Id.*

41. Biotechnology is the use of biological pathways, systems, and/or components to make commercial, research, and/or therapeutic processes and products. Rochelle K. Seide & Janet M. MacLeod, *Drafting Claims for Biotechnology Inventions*, 543 PLI/PAT 377, 381 (1998).

42. *Diamond, supra* note 5, at 316. The Court did not want to limit the law to what Congress could envision. Inventions are inherently unforeseeable, and not to protect such inventions would be at conflict with the basis of patent law. The Congressional discussion of the 1952 Patent Act was the year before Watson and Crick's landmark article on the description of DNA. James D. Watson and Francis H.C. Crick, *Molecular Structure of Nucleic Acids*, 171 NATURE 737 (1953). Hence, biotechnology was totally unforeseeable to Congress in the creation of the Patent Act of 1952.

43. *Id.* at 309.

44. *See* Byron V. Olsen, *The Biotechnology Balancing Act: Patents for Gene Fragments, and Licensing the "Useful Arts,"* 7 ALB. L.J. SCI. & TECH. 295, 310 (1997).

45. *Id.*

microorganisms provides an economic incentive to develop new and improved technologies.

Due to advancements in molecular genetics,[46] a large quantity of research shifted to the genomic level. The entire genomes of many microorganisms[47] and mammals[48] have been sequenced. Genomic sequences, from bacteria to humans, are readily available on the internet.[49] With the knowledge of the DNA sequence and the tools to manipulate the sequences, living organisms are easier to modify, which has led to an explosion of genetically engineered organisms.

Genetically modified organisms are now used as tools to accomplish specific goals. Organisms are designed and manipulated to perform specific functions. Further, the modified organisms do not occur naturally in the environment. Microorganisms are used as vaccines,[50] gene therapy vectors,[51] research tools,[52] and a means to produce industrial-scale volumes of recombinant proteins.[53] Under the language in § 101, these microorganisms are tools just as patentable as man-made chemicals, machines, or any other manufactured article.

These advancements in biotechnology directly impact society's quality of life. The impact is most readily visible with new medical therapeutics and diagnostic tools.[54] Biotechnological advancements in agriculture also

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46. *Diamond, supra* note 5, at 318.

47. U.S. CONST. art. I, §8, cl. 8.

48. *See, e.g.*, U.S. Patent No. 4,736,866, a transgenic mouse; *See, also*, U.S. Patent No. 5,557,032, a knockout mouse.

49. Several technical developments of the last twenty years have revolutionalized molecular biology. For example, polymerase chain reaction (PCR) is a method to exponentially amplify specific DNA fragments in cycles of dsDNA denaturation, primer annealing, and replication. Now it is possible to start with miniscule amounts of DNA and amplify the DNA to workable quantities. More recently, microarray technology uses computer software to assess the mRNA hydbridization to a microchip and thus approximates the level of gene expression.

50. *See, e.g.*, Frederick R. Blattner, *The Complete Genome Sequence of Escherichia Coli K-12*, 277 SCIENCE 1453, (1997).

51. *See* International Human Genome Sequencing Consortium, *Initial Sequencing and Analysis of the Human Genome*, 409 NATURE 860 (2001); *See also* J. Craig Venter et al., *The Sequence of the Human Genome*, 291 SCI. 1304 (2001). There are several current projects to sequence mammalian genomes including the mouse (http://www.celera.com/MouseGenome).

52. *See* http://www.ncbi.nlm.nih.gov/Microb_blast/unfinishedgenome.html.

53. *See, e.g.*, U.S. Patent No. 5,888,799 issued to Roy Curtiss, III, who developed a system whereby a strain of *Salmonella enterica* serovar Typhimurium presents a desired antigenic determinant to the immune system. The *Salmonella* strain is rendered avirulent due to deletion mutations of the adenylate cyclase and cyclic AMP receptor protein genes. The antigenic determinant of choice (e.g. *Streptococcal* proteins) is encoded on a plasmid transferred to the *Salmonella*. The recombinant vaccine is delivered orally to provide mucosal immunity since *Salmonella* localizes to the gut-associated lymphoid tissue. Thus, secretory IgA antibodies are generated against the antigenic determinant presented by the *Salmonella*.

54. *See, e.g.*, U.S. Patent No. 5,139,941 issued to Kenneth Berns, Paul Hermanot, Nicholas

have great promise to increase crop production and to provide greater quantities of necessary nutrients within the same volume of food.[55] Society benefits from the biotechnology products that enhance health and social well-being.

The instant Court also implicitly allowed Congress to determine the patentability of a living organism.[56] The United States Constitution specifically grants Congress the duty to legislate the promotion of science and its discoveries.[57] Congress has implicitly endorsed the Court's opinion of the instant case since § 101 has not been amended to expressly exclude living organisms. Congress can clearly state its intent of the law. In fact, the United States Patent and Trademark Office (USPTO) subsequently allowed non-human mammals to be patented under § 101.[58] Since the instant case, Congress continues to allow living organisms to be patentable subject matter in order to spur biotechnology.

Due to the advancements in genetics and cell biology, scientists have successfully cloned and patented a variety of mammals.[59] Cloned animals have the potential to be useful in immunological research and in commercial livestock trade. An international consortium recently announced that they would attempt to clone a human for infertile

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Muzyczka, and Richard Samulski. This group developed a recombinant adeno-associated virus vector (rAAV) for use as a vector to transduce mammalian cells with exogenous DNA. rAAV infects humans via the respiratory system, but does not stimulate an immune response. Thus, this vector has great potential use in gene therapy, e.g cystic fibrosis. For instance, the rAAV could infect lung tissue and integrate into the host genome. Then the epithelial cells in cystic fibrosis patients could possibly express a functional cystic fibrosis transmembrane conductance regulator (CFTR), thereby correcting the defective chloride channel in this genetic disorder.

55. *See, e.g.*, Carmen Alvarez-Dominguez & Philip D. Stahl, *Increased Expression of Rab5a Correlates Directly with Accelerated Maturation of Listeria Monocytogenes Phagosomes*, 274 J. OF BIOLOGICAL CHEMISTRY 11459 (1999). The authors used a Δ*hly* mutant of *L. monocytogenes*, which remains in a specific intracellular compartment, to determine which isoform of Rab5 signals early phagosome/endosome maturation.

56. *See, e.g.*, David V. Goeddel et al., *Expression in Escherichia coli of Chemically Synthesized Genes for Human Insulin*, 76 PROC. OF THE NAT'L ACAD. OF SCI. USA 106 (1979). Plasmids containing genes for human insulin were transformed into *E. coli*. The insulin genes were expressed in *E. coli*, and the insulin was extracted and purified. This process decreased the harvesting of insulin from slaughtered pigs and is able to be performed on an industrial scale.

57. *See, e.g.*, Julian K.-C. Ma, *Characterization of Plant Monoclonal Secretory Antibodies and Preventive Immunotherapy in Humans*, 4 NAT. MED. 601, (1998). This six-month study demonstrated the preliminary efficacy of a topical application of antibodies to an adhesin of *Streptococcus mutans* to prevent tooth decay. The antibodies were produced in transgenic tobacco plants.

58. *See, e.g.*, Ingo Potyrkus, *Golden Rice and Beyond*, 125 PLANT PHYSIOLOGY 1157, (2001).

59. *See, e.g.*, Meredith Wadman, *Issue of Patents on 'Dolly' Technology Stirs Controversy*, 403 Nature 351 (2000); *See, also*, Elizabeth Pennisi, *Cloned Mice Provide Company for Dolly*, 281 SCI. 495 (1998).

couples.[60] The USPTO has unequivocally announced that it will not grant patents to living, human organisms.[61] Although a cloned, living human organism may be man-made and meet the test of pantentable subject matter similar to non-human organisms under § 101, a denial of a patent would almost certainly be upheld by the Court since Congressional committees have been outspoken in their disproval of human cloning.[62]

In the era of genomic research, manipulation and modification of genomes have produced many organisms that are not found naturally in the environment. These organisms are patentable subject matter according to the holding in the instant case. Genetically engineered, living organisms are not explicitly barred by § 101, thus the ambiguity in patent law allows new and developing technologies, such as biotechnology in this case, to be patented. The patents aid emerging technologies to develop. This fostering of ingenuity is a furtherance of an implicit Congressional public policy to aid society's advancement and quality of life. By its inaction, Congress has approved the instant holding and its public policy ramifications.

60. Sarah Delaney, *Scientists Prepare to Clone a Human*, WASH. POST, March 10, 2001, at A16.

61. Seide & MacLeod, *supra* note 41, at 384.

62. Rick Weiss, *Scientists Testify on Human Cloning Plans*, WASH. POST, March 29, 2001, at A10.