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The right to obtain patent protection on living material: the causes and consequences of the United States Supreme Court decision in the case of Diamond v. Chakrabarty

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The right to obtain patent protection on living material: The causes and consequences of the United States Supreme Court decision in the case of *Diamond v. Chakrabarty*

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ABSTRACT

In 1980, the United States Supreme Court ruled in the case of *Diamond v. Chakrabarty* that living material was in the category of patentable subject matter, provided that the living material was a product of human invention as opposed to a product of nature. The fact that the material was living or inanimate was held to be irrelevant to the issue of eligibility for a patent. This ruling was the centerpiece in a series of events that combined to secure the status of animate material as private property. These events fundamentally changed the nature of scientific research in the academic community and the relationship between the university and the private market. These events also had a chilling effect on the pubic debate over the safety, ethics, and morality of commercializing biological material. As a result, the citizens of the United States have never fully dealt with this complex ethical issue except from a purely economic perspective

CHAPTER 1. OVERVIEW

1.1 Introduction

This thesis examines events in the late 1970s and early 1980s that combined to transition living material from public property to private commercial property eligible for patent protection. The circumstances of these events suggest that the social and ethical debate over manipulation and ownership of living material was subordinated by the interest, or perhaps the urgency, of economic advancement in the global marketplace. The initial characterization and ultimate resolution of this issue in economic terms precluded any basic value statement or definitive rule of law against which to measure the explosion of progress that it unleashed. The door to commercializing living material was cracked open by a margin of one vote in the case of *Diamond v. Chakrabarty* in which a pragmatic, cautious and somewhat dysfunctional United States Supreme Court ruled that living material was in the category of patentable subject matter, provided that the living material was a product of human invention as opposed to a product of nature.[1] The fact that the material was living or inanimate was held to be irrelevant to the issue of eligibility for a patent. The Court's decision, albeit narrow, was adequate to unleash a stampede of development from which the United States has never looked back and with which it has never fully come to terms.

The United States patent law is a practical economic tool that is nearly as old as the nation it helped to build. The ability of the United States' inventors to secure patents was considered critical to compete economically with England. Accordingly, the authority of Congress to grant patents was established in the original draft of the United States Constitution. Congress wasted no time in exercising this authority. Modeled after the British

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

law, the first patent laws were enacted by Congress in 1790, followed by the original Patent Act in 1793.

The purpose of the patent law was to establish a mutually beneficial process of exchange between an inventor and the public. The inventor was offered a temporary right to exclude others from using the thing or the process that was the subject of the patent. With this power in hand, the inventor could use his invention exclusively or license its use to others. In exchange for this exclusive right, the inventor was required to disclose the workings of the invention with sufficient detail and clarity to permit others to use it after the patent expired. Ideally, once the invention entered the public domain, others would improve or expand upon the inventor's work until they too had something eligible for patent protection. Through this cycle, the body of common public knowledge continued to expand.

The values embodied by this exchange were grounded upon economic principles. The criteria for analyzing a patent application were not couched in terms of "good" or "bad." Patent applications were not judged according to moral or ethical principles except in the most extreme circumstances.[2] Patent laws were couched in practical terms that focused on operability, novelty, and utility. The patent law was designed to assure that an invention was something new and useful. It did not comment on the wisdom of the invention however. How the invention actually performed and its value was determined between the inventor and the marketplace.

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[2] A patent can be withheld for reasons of national security. *U.S. Code* 35 (2000) § 181. In addition, the United States Court of Customs and Patent Appeals has ruled that, although safety is not an explicit criteria for patentability, it is nevertheless a factor in the broader question of whether an invention is useful. For example, a patent would not be granted for a material that is lethal under all conditions of its intended use of treating human disease. *Application of Anthony*, 414 F.2d 1383 (C.C.P.A. 1969).

This framework does not mean that the patent doors were flung wide for every person who was first in line with something new and useful. The patent law contained basic limits to its scope, the primary one being that all inventions must fall within the category of patentable subject matter. As this standard suggests, there were certain things not eligible for patent protection, primarily things that existed in nature. Inventions necessarily owed their existence to human agency. Natural products could be discovered and applied to wonderful new uses, but they could not be invented. As such, they were already in the public domain and did not need to be "purchased" through the patent law.

Although products of nature could not be invented, they could certainly be improved upon through human ingenuity. Inventors routinely experimented with natural materials and their efforts often yielded new and useful products, particularly where they were able to isolate and purify them to the point where the end product was not naturally occurring. The patent laws were not originally drafted and have never been amended to specifically address isolation and purification of natural materials. Over time, however, these standards developed through judicial interpretations of the meaning and intentions behind the broad and general language of the patent laws. For example, vitamin B12 can be found in nature in impure trace amounts. In 1958, the Fourth Circuit Court of Appeals upheld a patent for pure, human-made B12 because it satisfied the patent criteria of being new and useful.[3] These standards were re-evaluated constantly by the courts as science advanced and new products were brought forward. Critically, the test was always one of economic benefit. Did the patent applicant present something new and useful that was not already in the public domain? The standards

[3] *Merck v. Olin Mathieson Chemical Corporation*, 253 F.2d 156 (4th Cir 1958). Discussed further in Section 2.3.2.2.

worked efficiently throughout much of the patent law's history. Interpretations of the law remained relatively consistent throughout the nineteenth and early twentieth centuries. Profound scientific changes in the second half of the twentieth century created significant shortcomings in the jurisprudence however.

In the late 1970s and early 1980s the simple, serviceable assumptions that girded the patent law ran up against two freight trains of discovery. On one track was the train of scientific research that had advanced to the point of manipulating living material at the genetic level. The ability to splice genes made laboratory creation of new biological material possible. This quantum leap in science presented a new and complex set of issues for the patent law and the courts. This new technology could be used to copy and create entirely new human and animal genes. The second train was one of economic potential. Recombinant DNA technology offered hope for curing diseases previously thought incurable. The potential profits were nearly incalculable.

In tandem, these two trains represented a scientific breakthrough on the same level as atomic fusion and one of the greatest potential economic booms to the United States since industrialization. Realization of this potential did not come cheap. Genetic research demanded staggering amounts of time, resources, and money. Those who invested this time and money needed some assurance that they would be able to protect their work and recoup their investment. As a result, these trains were bearing down at full speed on the United States Patent and Trademark Office (PTO), which was not well equipped to address this new technology with the existing law.

Genetic research raised serious questions about the impact on public health and safety from experimenting with bacterial and viral agents. It also raised ethical questions about

manipulating human and animal life and, moreover, doing so for profit. The ability to secure patents necessarily signaled a key factor in the economic success or failure of this new technology. Patent applications for living proteins and microorganisms clearly met the test for being new and useful but they also raised serious social questions about the meaning of American cultural values.

1.2 Key Factors in the Commercialization of Living Material

Genetic technology demanded a re-evaluation of the underlying values and goals behind the patent law. That re-evaluation resulted in the United States Supreme Court's decision in *Diamond v. Chakrabarty* (1980), which held that human invention was the key to patent protection regardless of whether the thing invented was animate or inanimate. The events leading up to and immediately following that decision combined to solidify genetic technology as a viable economic tool. This thesis examines four of these events. The first is the development of Recombinant DNA technology by university researchers at Stanford and the University of California San Francisco, which made plain the economic potential of human-made biological material. The second is the Supreme Court's decision in *Diamond v. Chakrabarty*, which resolved eight years of debate and uncertainty on whether living material was in the category of patentable subject matter in the law. The third is two key pieces of legislation enacted by Congress in 1980, shortly after the Supreme Court's decision in *Diamond v. Chakrabary*. These were the Stevenson-Wydler Technology Innovation Act, which enhanced and accelerated the flow of government owned technology to the private sector, and the Bayh-Dole Act, which made it easier for universities and small businesses to secure patent rights on government-funded research. The fourth is the economic policy of the

Reagan administration that firmly established usefulness and practicality of research as a criteria for government funding.

1.2.1 The Evolution of Recombinant DNA Technology

In 1973, researchers at Stanford University and the University of California San Francisco established a procedure to splice and clone DNA. Stanford was well versed in technology licensing and aggressively pursued patents in this revolutionary field. Its actions heralded a change in the relationship between the academic research community and the private sector. As the commercial potential of the new science was realized, university researchers specializing in genetic research were hired or contracted by private investors. This development had a profound impact on the traditional academic protocols of information sharing and peer review. It also opened a floodgate of debate over the safety and wisdom of manipulating genetic material. The National Institutes of Health as well as state and federal lawmakers began a public dialogue on how the fledgling science should be regulated. In 1977, concurrent with the public policy debate, an upstart company called Genentech demonstrated the feasibility of using recombinant DNA technology to create human proteins in bacteria that were virtually identical to their naturally occurring counterparts. This accomplishment focused attention on the commercial potential of mass-producing valuable human genes. The resulting lobbying effort helped to convince Congress that the potential benefits of the new science outweighed the risks. By 1978, all the existing proposed bills to regulate recombinant DNA research had died in congress, and the private, self-regulatory initiatives were greatly relaxed.[4] Some uncertainty remained however about

[4] Sally Smith Hughes, "Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology 1974-1980," *Isis*, vol. 92, no. 3 (September 2001): 566-68.

the commercial potential of recombinant DNA because ownership rights in proteins were not vested. The accomplishments of Genentech placed this issue in urgent need of resolution.

1.2.2 The Supreme Court Decision in Diamond v. Chakrabarty

In June 1980, the United States Supreme Court ruled in the case of *Diamond v. Chakrabarty* that living material was in the category of patentable subject matter, provided that the living material was a product of human invention as opposed to a product of nature. The fact that the material was living or inanimate was held to be irrelevant to the issue of eligibility for a patent. It was a five to four decision. This was the first and only time the Supreme Court had commented directly on the issue of living organisms and patentable subject matter.[5] The Court avoided any general or sweeping statement on the ownership of living material and instead issued a narrow and technical ruling. While cautious to the point of evasion and disputed by four of the nine justices, the decision in *Chakrabarty* nevertheless evinced a major change in the Supreme Court's attitude toward both products of nature and deference to Congress to address new scientific advancement not contemplated when the law was drafted. Following the *Chakrabarty* decision, the PTO released 114 pending patent applications involving biotechnology. It had been holding these applications pending the outcome of the Chakrabarty appeal. As a result, biotechnology was firmly established as private commercial property. Access to the patent system provided comfort and incentive for investors in recombinant DNA technology, turning it from a university-based scientific research pursuit to a multi-billion dollar industry. The availability of patent protection solidified the marriage of private money and academic expertise in a union where the direction of research was dictated by profit and secrecy trumped publication.

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[5] Annotation to *Diamond v. Chakrabarty*, 65 L. Ed. 1197 at 1202.

1.2.3 Legislative Action After Diamond v. Chakrabarty

In the wake of the *Chakrabarty* ruling, the Stevenson-Wydler Technology Innovation Act (1980) made technology transfer an integral part of the research and development responsibilities of federal laboratories and their employees.[6] Its goal was to enhance and expedite the transfer of government research to the business and academic sectors where it could be used, improved upon, and made commercially viable. Similarly, the Bayh-Dole Act (1980) gave small businesses and non-profit organizations, including university research departments, the right to hold and benefit from patents on inventions created in part through federally funded research.[7] The Bayh-Dole Act created a significant new incentive for universities and small businesses to undertake practical and commercially useful research. As a result, private funding of university research rose 93 percent from 1980 to 1984 while federal funding for university increased by 31 percent, largely in the area of military defense research.[8]

1.2.4 Reagan Economic Policy

In January of 1981, Ronald Reagan was sworn in as President of the United States. The Reagan administration was a staunch proponent of private money as a source of research funding based on market demand and profitability. Reagan's economic policy greatly accelerated private for-profit development of technology. In 1983, President Reagan significantly extended the reach of this new policy by directing the heads of executive

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[6] Pub. L. 96-480, 94 Stat. 2311, codified at U.S. Code 15 (2000) §§ 3701 - 3717.

[7] Pub. L. 96-517, 94 Stat. 3018, codified at U.S. Code 35 (2000) §§ 200 - 212.

[8] Rebecca S. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," *The Yale Law Journal,* vol. 97, no. 2 (December 1987): 178, n 2.

departments and agencies to extend the Bayh-Dole Act to all government contractors, including large businesses, so that they too could benefit from patents derived through government funded research.[9] Reagan's Executive Memorandum, later ratified by Congress, contributed to changing the fundamental role of the university from one of pure public knowledge to practical commercial research. The Reagan administration policy also signaled the resolution of five decades of tension arising from questions of patenting and commercializing living material.

[9] Rebecca S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research," *Virginia Law Review,* no. 8 (November 1996): 1665.

CHAPTER 2. THE UNITED STATES PATENT LAW

2.1 Introduction

This chapter examines the constitutional and statutory history of the United States patent law. It focuses on revisions made by the Plant Patent Act of 1930, the Plant Variety Protection Act of 1970 and the 1952 patent law revision, which represented the corpus of the law when *Chakrabarty* was decided. It also examines appeals court cases interpreting the patent laws. Illuminating this context is necessary in order to place the four key factors into their proper historical context.

A patent is a property right that allows its holder to exclude another party from using the thing that is patented.[1] As a property right, it may also be assigned or licensed to others. The specific right under a granted patent is the right to exclude others from making, using, selling, offering to sell, or importing into the United States the patented invention.[2] The current term of a patent is usually twenty years from the date the application was filed.[3] It falls to the owner of the patent to enforce its rights. If a violation is alleged, the owner must seek an injunction and damages in federal court. The patent enjoys a presumption of validity, but the accused infringer may rebut that presumption on multiple grounds.[4]

The United States patent law had its origin in English law. The 1624 Statute of Monopolies was intended primarily to restrict the crown's rights in granting exclusive rights,

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[1] David B. Resnik, *Owning the Genome: A moral Analysis of DNA Patenting* (Albany: State University of New York Press, 2004), 2.

[2] *U.S. Code* 35 (2000) § 281.

[3] *U.S. Code* 35 (2000) § 154.

[4] Roger E. Schechter and John R. Thomas, *Intellectual Property: The Law of Copyrights, Patents and Trademarks* (St. Paul: Thomson West, 2003), 283.

although it permitted letters of patent to true inventors of new manufacture.[5] The American colonies and, later, the new states followed suit. The Constitutional Convention took up the issue, presumably to bring some uniformity to the field.[6]

Following the Convention, patent rights were established by federal statute. Authority of Congress to enact the statute is derived from a grant of power in the United States Constitution. The foundation of the patent law is economic benefit.[7] This foundation provided no framework to evaluate the concerns premised on natural law and ethics that were generated by unsettling advancements in biotechnology however. Such moral arguments never found a home in the patent law because they were not the catalysts behind the constitutional clause from which the patent law flowed.

2.2 Constitutional Basis

Among the eighteen specific powers granted to Congress in the United States Constitution is the 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.[8]

It was intended by the drafters that the clause be read disjunctively. In the late eighteenth century, "science" generally referred to knowledge in any field. Thus, science was

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[5] Schechter and Thomas, *Intellectual Property: The Law of Copyrights, Patents and Trademarks*, 284.

[6] Ibid.

[7] Li Westerlund, *Biotech Patents: Equivalence and Exclusions under European and U.S. Patent Law* (New York: Kluwer Law International, 2002), 9.

[8] U.S. Constitution, art. 1, sec. 8, cl. 8.

promoted by securing to authors the rights to their writings while useful arts were promoted by securing to inventors the rights to their discoveries.[9]

The clause does not mandate any specific action on the part of Congress or, for that matter, any action at all. It simply grants Congress the power to legislate at its discretion so long as the resulting law is a tool to promote science and the useful arts.[10] The foundation of this clause is not benevolence or recognition of inventors' natural rights to their inventions. It is economic. The clause is premised on a belief that the best way to promote science and useful arts is by expanding the body of public knowledge. This is accomplished by offering temporary exclusivity as an incentive to create and share useful information. The United States Supreme Court summarized this philosophy succinctly in 1954:

> The economic philosophy behind the clause empowering Congress to grant patents and copyrights is the conviction that encouragement of individual effort by personal gain is the best way to advance public welfare through the talents of authors and inventors in 'Science and useful Arts.' Sacrificial days devoted to such creative activities deserve rewards commensurate with the services rendered.[11]

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[9] Michael S. Greenfield, "Recombinant DNA Technology: A Science Struggling with the Patent Law," *Stanford Law Review,* no. 5 (May 1992): 1056.

[10] Compare, for example, with U.S. Constitution, art. 3, sec. 1, which provides that the president of the United States must be a natural born citizen, at least thirty-five years of age and having been a resident of the United States for at least fourteen years. Congress would have no power to pass a law permitting a 30-year-old French citizen to serve as president. Such a law would be unconstitutional. Congress, however, could pass a law specifically providing, for example, that living material is or is not eligible for a patent because that discretionary power has been granted to it in the constitution.

[11] *Mazer v. Stein*, 347 U.S. 201, 219 (1954). See also, *Brenner v. Manson*, 383 U.S. 519, 536 (1966), in which the Supreme Court noted that a patent system must be related to the world of commerce rather than the realm of philosophy.

Thus, Congress may not enact a law pursuant to this constitutional clause premised on a moral or ethical desire that authors and inventors own the results of their hard labor. The law must be designed to strike a bargain for the benefit of the public. Protection of authors and inventors can be offered, but only as a means to promote the public welfare.[12]

2.3 Patent Rights Under the United States Code

Although the objective of the constitutional clause was clear, its guidelines left Congress with considerable discretion in crafting a patent law. The requirements and manner of review evolved during the first hundred years but the current structure of application, claim, and examination was essentially in place by 1870. Congress enacted the first patent law in 1790, followed closely by the Patent Act of 1793.[13] The 1790 Act called for examination of all submitted inventions by an appointed commission in order to verify their eligibility for patent protection. The 1793 Act replaced the examination commission with a registration system. Examination of applications was re-established in 1836, and this was supplemented in 1870 by the obligation of the applicant to submit a detailed claim.[14]

The original Patent Act was authored by Thomas Jefferson, who took a keen interest in the inventive process and the need to promote it in a fledgling country while, at the same time, protecting against monopolies.[15] The drafters of the country's founding documents embraced the concept of private property, but to the ultimate end of the public good as reflected in a stable social structure. Jefferson's patent law likely offered something

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[12] *Martinetti v. Maguire*, 16 Fed. Cases 920 (C.C. Cal 1867).

[13] 1 Stat. 109, ch. 7 (1790), cited in Michael S. Greenfield, "Recombinant DNA Technology: A Science Struggling with the Patent Law," *Stanford Law Review,* no. 5 (May 1992): 1057; Act of Feb 21, 1793, sec. 1, 1 Stat. 319, cited in *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

[14] Schechter and Thomas, *Intellectual Property: The Law of Copyrights, Patents and Trademarks*, 285.

[15] *Graham v. John Deere Co*. 383 US 1, 7 (1966).

acceptable to everyone. As a political relativist, Jefferson believed that property rights were a social creation reflected in the laws of society and not the laws of nature.[16] The creation of a property right tied directly to the public good exemplified Jefferson's philosophy, particularly in a new society with a fledgling economy, not to mention a fledgling psyche. The law also should have created little conflict with the Federalist view that innovation, creativity and ambition were inherently virtuous and consistent with the self-interested pursuit of wealth.[17]

2.3.1 The 1952 Revision of the Patent Law

The most recent major reorganization of the patent law occurred in 1952 and resulted in the statutory language and format on patentability of inventions that was in place when the Supreme Court issued its opinion in *Diamond v. Chakrabarty*.[18] Therefore, a threshold question is whether the 1952 revision reflects any intention by Congress to make a policy statement on the patentability of living material. The legislative history suggests that while the 1952 review of the patent statute was quite detailed, Congress had no intention of making any substantive changes in the law or establishing a new attitude toward what could or could not be patented.

The primary motivation behind the 1952 Act was to rescue the patent law from a growing anti-monopoly sentiment in the courts. By codifying common law standards and addressing misuse of patents, Congress hoped to stem the tide of court cases rejecting patent

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[16] Gregory S. Alexander, *Commodity and Property: Competing Visions of Property in American Legal Thought 1776-1970* (Chicago: The University of Chicago Press, 1997), 27.

[17] Ibid., 76.

[18] Pub. L. 593, 66 Stat. 792 (1952), cited in Greenfield, "Recombinant DNA Technology," 1057 n 32.

rights.[19] Beyond this, it appears that Congress was simply trying to clean up and reorganize a statute that had not received such attention for eighty-two years. For example, in a January 28, 1952 speech given prior to enactment of the revisions, Rep. Joseph R. Bryson, Chair of the House Judiciary Subcommittee with jurisdiction over the bill, emphasized that Congress had no intention of making substantive changes to the law but was merely trying to simplify and clarify its meaning. He went on to note that while the United States Department of Justice had expressed fears that the upcoming revision might ". . . open the door to a new era of patents and permit the creation of monopolies in some of the fundamental discoveries of science. I can assure you that was not our intention."[20]

The bill was introduced in the House of Representatives on May 19, 1952 and passed without comment.[21] The bill was referred to the Senate and was taken up by the full chamber on July 4, 1952. Senator Saltonstall specifically asked if the bill would change the patent law in any way or merely codify the present patent laws. He was assured that it would only do the latter. The bill was passed without further comment.[22]

Therefore, there is nothing in the 1952 revision to suggest that Congress intended to establish or change policy with regard to the patentability of living material. This is not surprising since technology would not bring the issue into the limelight until the 1970s. Nevertheless, the law as revised would be the one against which the new technology would eventually be measured. This was not ideal for the courts because biotechnology was not

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[19] Schechter and Thomas, *Intellectual Property: The Law of Copyrights, Patents and Trademarks*, 285.

[20] 82nd Cong., 2nd sess., *Congressional Record* 98, pt. 8 (28 January 1952): A415-A417.

[21] 82nd Cong., 2nd sess., *Congressional Record* 98, pt. 4 (28 January 1952): 5455-5463.

[22] 82nd Cong., 2nd sess., *Congressional Record* 98, pt. 7 (28 January 1952): 9323.

specifically addressed in the patent law. When faced with biotechnology-related patents, the courts were called upon to determine what Congress intended when it wrote and amended the patent law over the years.

Interpretation of laws and regulations is a routine function of the judicial branch of government. There is an extensive body of appellate opinions on the rules of statutory construction. Generally, the courts are obligated to effectuate the legislative intent behind the law. If the language of a statute is clear, the court must give it effect and not look elsewhere for aids to its interpretation.[23] If legislative intent cannot be ascertained from the clear language of the statute, the court may look to legislative history, administrative interpretations and the language in question in the context of the entire statute.[24] This section concludes with a review of the statutory language and the basic judicial interpretations that were available to the courts when they reviewed the Chakrabarty application.

2.3.2 Basic Requirements for Patent Protection

The 1952 revision to the patent law established three primary standards of review in the section on patentability of inventions. This thesis focuses primarily on the first standard in Section 101 of the statute. The intention of Congress, as reflected in the language of Section 101, was the primary issue created by the Chakrabarty application.

2.3.2.1 Section 101: Patentable Subject Matter

The first standard is Section 101, which establishes the categories of patentable subject matter. It states in pertinent part:

Whoever invents or discovers any new and useful process, machine,

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[23] *In re Marriage of Logston*, 469 N.E.2d 167 (Illinois 1984).

[24] *Woodmont Country Club v. Montgomery County*, 486 A.2d 218 (C.S.A. Md. 1985).

> manufacture, or composition of matter, or any new or useful improvement thereof, may obtain a patent therefore . . . [25]

This language, authored by Thomas Jefferson, dates back to the original Patent Act of 1793.[26] It establishes two basic requirements. First, the thing presented for patent protection must be one of four things: a process, machine, manufacture, or composition of matter. If it falls into one of these four categories, it must then be something that is new and useful. If an invention cannot meet this threshold test, it cannot be patented regardless of the amount of money, effort, logic, or ingenuity that went into its creation. As discussed above, the law does not seek to reward effort in and of itself. It seeks to create an incentive for effort but will reward it only if there is something to be gained by the public. As will be discussed, this section created myriad issues for living material. Could one "manufacture" DNA? If so, was it "new"?

2.3.2.2 Court Decisions Interpreting Section 101

As the courts have interpreted the language currently found in Section 101, some basic rules have evolved regarding eligibility for patent protection. For example, one cannot patent a scientific or mathematical principle. Such principles fail the Section 101 test. First, they are not a process, machine, manufacture, or composition of matter. Second, while quite useful, they are not "new" in the sense that they were created by human agency. The value judgment underlying this restriction is that certain things simply exist. They cannot be invented; they can only be discovered. Therefore, they already reside within the public domain. There is no bargain to be struck under the patent law because the public already

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[25] *U.S. Code* 35 (2000) § 101.

[26] See n. 13.

"owns" what the inventor is offering. The discovery that the circumference of a circle is *pi* times the radius squared was a groundbreaking achievement but it could not have been patented. Similarly, Isaac Newton could not have patented the scientific laws of gravity. Newton derived the laws of gravity, but he did not invent them. This may seem a harsh result when one contemplates the effort and brilliance needed to derive a basic law of science or mathematics, but it is consistent with the economic focus of the patent law.

This general rule does not, however, ban such principles from all aspects of the patent law. In the 1852 case of *LeRoy v. Tatham*, the United States Supreme Court stated that while a scientific principle is a fundamental truth that cannot be patented, that same truth can be employed in a patentable process.[27] The Court offered an excellent analogy: one could patent the invention of a steam engine but could not patent the principle of steam power. The invention of a machine to extract, modify, and concentrate the natural agency of steam power clearly constitutes a patentable invention. In other words, the inventor did not invent steam power. Rather, he discovered the properties of steam power (which had always existed) and used this knowledge to invent a machine that was new and useful. The steam engine was a process (patentable) to make productive use of the properties of steam power (not patentable). The Court went on to state that a patent should not be awarded for the result of a process since that would discourage other inventors from obtaining the same result by a different means, which is contrary to the policy behind the patent law.[28] Thus, if the goal of the patent law is to maximize public knowledge, why then should the inventor of the steam engine be allowed exclusive license for all uses of steam power or all manner of engines? To

[27] *LeRoy v. Tatham*, 14 How. 156 (1852).

[28] *LeRoy v. Tatham,* 175.

do so would discourage another inventor from trying to invent, for example, the internal combustion engine or the steam boiler to heat buildings.

This concept is illustrated in the 1932 case of *Guaranty Trust Co. of New York v. Union Solvents Corporation*, a pioneering patent case in the field of natural product patents and microbiology.[29] Charles Weizmann was a scientist who discovered a new species of bacteria that was previously unknown. He used the bacteria to create a new process for the fermentation of starch from potatoes for the production of acetone and butyl alcohol.[30] Producing the materials by fermentation was not remarkable; it had been done before. What Weizmann invented was a process to isolate a particular bacteria and then use that bacteria to produce commercial quantities of acetone and butyl alcohol.

In 1916, Weizmann applied for a patent for "improvements in the bacterial fermentation of carbohydrates and in bacterial cultures for the same."[31] The patent was approved in 1918 but withheld from publication for reasons of national security. The patent was awarded in 1919 and licensed by Weizmann to a commercial manufacturer. The lawsuit for patent infringement was instigated by Weizmann's licensee in 1930 when Union Solvents Corporation began commercial production of the same materials. Among the numerous defenses offered by Union Solvents was the claim that Weizmann had been awarded a patent

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[29] *Guaranty Trust Co. of New York v. Union Solvents Corporation*, 54 F.2d 400 (D. Del. 1931). Note that this was not a United Sates Supreme Court case. It was decided by a federal district court of appeals in Delaware, the first level of appeal after the trial court level, and affirmed without comment by the United States Court of Appeals for the Third Circuit. 61 F.2d 1041 (3rd Cir 1932). The next appeal would have been to the United States Supreme Court, which was not pursued in this case. These cases have precedential value but are not binding. There are twelve federal circuit courts of appeal and, prior to 1982, the Court of Customs and Patent Appeals. They can issue contrary opinions on the same subject.

[30] Acetone was a solvent used in the manufacture of film, gas containers and artificial silk. It was also a key component in cordite, an explosive used during World War I. Butyl Alcohol was a solvent used in the manufacture of lacquers used in finishing automobiles and furniture. *Guaranty Trust v Union Solvents,* 401.

[31] *Guaranty Trust v. Union Solvents.*

for something not patentable: the life process of a living organism. The Federal Appeals Court for the District of Delaware countered by stating that Weizmann's patent had not been awarded for the new bacteria per se, but rather for the process in which the new bacteria were employed, which the Court called "the exercise of inventive genius."[32] The Weizmann process allowed for production of commercial quantities of butyl alcohol, which was a good substitute for amyl alcohol. At that time, amyl alcohol was obtained as a byproduct in the production of spirits, which was threatened by prohibition. Thus, Weizmann discovered a bacteria and employed it in a process of his own invention. He was rewarded for the process that he invented but not for the bacteria that he discovered.

Compare the result in *Guaranty Trust* with the 1948 decision in the case of *Funk Brothers Seed Company v. Kalo Inoculant Company*.[33] Both companies in the case were involved in the packaging and selling of plant inoculants. The process used by sellers of plant inoculants was to select the strongest strains of bacteria that enhanced plant growth and health, produce them in a laboratory, and then package them in liquid or powder form for sale to the public. The inoculants were highly specialized because specific strains of bacteria were useful only for specific plants. Therefore, the inoculants had to be packaged and sold separately for each type of plant. It was common knowledge at the time that bacteria of the genus *Rhizobium* enabled plants to take nitrogen from the air, fix it in the plant and convert it to organic nitrogenous compounds. There were six species of *Rhizobium* and each species had distinct strains that varied in efficiency. A scientist named Bond discovered that certain strains of *Rhizobium* did not inhibit each other when mixed together. With this knowledge, he

[32] *Guaranty Trust v. Union Solvents*, 403.

[33] *Funk Brothers Seed Company v. Kalo Inoculant Company*, 333 U.S. 127 (1948).

was able to combine the strains and market a single product suitable for multiple plants. This would have greatly decreased the cost of packaging and marketing plant inoculants. Bond applied for and was granted a patent for the new mixed-plant inoculant. When his employer sought to enforce the patent against its competitors, the validity of the patent was challenged. The United States Supreme Court ruled that Bond's efforts were not eligible for patent protection. Bond had done nothing to the bacteria in question. He had simply discovered their respective properties and used this knowledge to mix them together in a way that enhanced their commercial value. The Court first noted that a patent could not have been awarded for the bacteria, stating that:

> . . . patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none. He who discovers a hitherto unknown phenomena of nature has no claim to a monopoly of it which the law recognizes. If there is to be invention from such a discovery, it must come from the application of the law of nature to a new and useful end.[34]

In support of its analysis, the Court cited the 1887 decision in the Alexander Graham Bell telephone patent case in which the Court noted that electricity was a force of nature employed by Bell in his invention.[35] If left to itself however, electricity would not do what Bell needed for it to do. Bell's invention was the process to control the force of nature to

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[34] *Funk Brothers v. Kalo*, 130.

[35] *Dolbear v. American Bell Telephone Company*, 126 US 1, 532-33 (1887).

make it accomplish the purpose needed. In other words, Bell employed a force of nature in a new and practical use. Comparing Bell's achievement to what Bond had done, the Court concluded that the mere aggregation of biological species fell short of invention. Bond had discovered no new bacteria, had not caused the known bacteria to do anything other than what they had always done, and had not improved their function. He had simply made a commercial advance in packaging. Unfortunately for Bond, the most impressive part of his work, his discovery of the principles of the bacteria, was not within a category of patentable subject matter. In the opinion of the Court, Bond had demonstrated skill and insight but not invention.

In addition to being eligible for patent protection within a patentable process, products of nature are also eligible for patent protection when they are isolated or purified. This is illustrated in the 1958 case of *Merck v. Olin Mathieson Chemical Corporation*.[36] In 1926, it had been discovered that people suffering from anemia benefited greatly from cattle liver, although the medical world was ignorant as to why. There were some liver extracts available by 1947 but they were expensive and some patients could not tolerate them. After many years of trial and error, scientists succeeded in isolating a useful material for treatment of anemia that was identified as a vitamin of the "B" class and given the numeral extension of "12" since that was the next number in line. Everyone else had been looking for an anemia treatment in liver, but those who ultimately discovered that the answer was vitamin B12 had found it in other substances. They applied for patents on the B12 compositions. They did not try to patent crystalline B12 in its natural state nor did they seek patents on B12 derived from other sources. A lower Federal Court of Appeals denied the patent, holding that what had

[36] *Merck v. Olin Mathieson Chemical Corporation*, 253 F.2d 156 (4th Cir 1958).

been produced was a product of nature and that the application lacked evidence of invention. The Fourth Circuit Court of Appeals reversed the decision. There was no question that vitamin B12 occurred in nature. It could be found in trace amounts in cattle and was also produced by certain microorganisms. It had no utility in its naturally occurring state for two reasons however. First, not enough B12 was produced in nature to be commercially useful. Second, the B12 produced in nature was not pure. The Court ruled that the patent applicants had used a new source to create pure vitamin B12 in commercial quantities. The Court ruled that this satisfied the Section 101 standard because it was a composition of matter, and it was new and useful. The Court further ruled that nothing in Section 101 precluded a patent simply because the composition was a product of nature. After all, the Court reasoned, nature provided the source material for everything that was patented.

To summarize, natural products can be used in patentable processes. In addition, a patent can be awarded when a naturally occurring product is produced in a way that does not occur in nature (*i.e.* in pure, commercial quantities).[37] The issue of patentability of living material was far from resolved by these precedent-setting cases, however. Neither the *Merck* nor the *Guaranty Trust* case was reviewed by the United States Supreme Court and neither case tread on the more sacred ground of living material.

2.3.2.3 Section 102: Novelty

If a patent applicant can produce something that falls within the category of patentable subject matter, the next gatekeeper is novelty. Section 102 builds on the "new and

[37] Another example would be the 1911 patent awarded for purified adrenalin extracted from the adrenal gland and thus free of problems found in previously used adrenal gland tissue. The purified adrenaline was found to be 'a new thing commercially and therapeutically.' *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (S.D.N.Y. 1911). Patentable novelty may also be found upon superior efficiency, purity and cheapness. *Union Carbide Co. v. American Carbide Co.*, 181 F. 104, 106--107 (2nd Cir. 1910).

useful" criteria of Section 101 by requiring that an invention must be new, original, and not used previously.[38] No patent is allowed if the invention was previously known or if the inventor fully and definitively communicates it to the public more than one year prior to the date of application.[39] Note again the rigid nature of the law. The patent right is not presumed. The onus is on the inventor to seek it out. The patent opportunity is lost if an inventor fails to file an application within one year of public disclosure.

2.3.2.4 Section 103: Non-Obviousness

The final basic standard is found in Section 103. Even if an invention is in a patentable category and is new, useful and novel, it must still represent an advancement that is not obvious to someone skilled in the prior art, which refers to the existing body of knowledge in a field. This standard prevents someone from taking a patented invention and working minor modifications to it and then claiming a new patent. The courts have enforced this standard through the development of the Doctrine of Equivalents, which states that a patent claim may be expanded beyond its specifications to include inventions that perform substantially the same function in substantially the same way with substantially the same result.[40] In fact, it is not even necessary that the invention already exists. The prior art can "anticipate" a patent if all claimed elements of the new patent application are present in the prior art. The general rule is that "An invention that would literally infringe if later in time anticipates if earlier than the date of the invention."[41]

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[38] *U.S. Code* 35 (2000) § 102.

[39] *U.S. Code* 35 (2000) § 102(b). See also, *Application of Brown*, 329 F.2d 1006, 1011 (C.C.P.A. 1964).

[40] *Interdent Corp. v. United States*, 531 F.2d 547, 550 (Ct. Cl. 1976).

[41] *Lewmar Marine, Inc. v. Barient, Inc*., 827 F.2d 744, 747-748 (Fed. Cir. 1987).

To use an example, suppose a person invents a plow with a yoke for a beast of burden and obtains a patent. Another person subsequently notes that plowing is more efficient if done by two animals instead of one. Therefore, he widens the harness frame and combines two yokes side-by-side and attempts to patent the double-yoke plow. This second person would not be likely to obtain a patent because what he did was obvious. He did not invent a plow, nor did he invent a yoke. He simply observed that two yokes could be fixed side-by-side to accommodate two animals instead of one. All of the elements of the double-yoke plow were in the prior art, and the new plow did exactly the same thing as the patented plow. Although clever and observant, the double yoke plow inventor has contributed nothing new to the body of public knowledge, which is the price for a patent.

The first United States Supreme Court review of patentability following the 1952 statutory rewrite did not occur until 1966, and it was a Section 103 case. *Graham v. John Deere* turned on the question of obviousness.[42] John Deere brought an infringement suit against the inventor of a plow blade spring clamp that allowed the plow blade to bump up and over obstructions in the dirt. Deere already had a patent on spring clamps for plows. The inventor had taken the Deere clamp and rearranged its position on the plow in order to distribute the stress over a larger section of the plow, thus reducing wear. The Supreme Court ruled that the mere shifting of the stress points was simply a refinement of the existing art and obvious to anyone with ordinary skill in the art. As such it was ruled to not be a new invention and not eligible for a patent. The Supreme Court reiterated the harsh reality of the

[42] *Graham v. John Deere*, 383 U.S. 1 (1966).

patent law, stating that a patent is not designed to secure any natural right to an invention based on hard work or ingenuity. It is an inducement to bring forth new knowledge.[43]

In sum, these three gatekeepers demand of the applicant something that is patentable, new, useful, and not obvious. An essential part of proving that an invention satisfies these three basic standards and making sure that the public gets the benefit of its bargain is Section 112 of the patent law. This section requires a written description of the invention and the manner of making the invention in full, clear, and concise terms such that any person skilled in the same art can make and use the same.[44] The description requirement captures the essence of the patent law. It documents the practical use of the invention and creates a public record that allows others to verify and ultimately replicate the invention once the patent has expired. It also reflects yet another limitation of the patent law in the area of biotechnology, which Congress attempted to address in the area of plant breeding in 1930.

2.4 Plant Patents

In order to fully understand the legal dispute over patentability of living material, it is necessary to step away from the patent law chapter on patentability of inventions and examine the separate chapter on plant patents. The need to harmonize the Section 101 criteria on patentability with the specific legislation on plants led to conflicting opinions within the judiciary as to the intent of Congress toward living material.

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[43] *Graham v. John Deere*, 9.

[44] U.S. Code 35 (2000) § 112.

2.4.1 The Plant Patent Act of 1930

Congress enacted the Plant Patent Act of 1930 for the specific purpose of authorizing patents on asexually produced plants.[45] Asexual production is achieved by budding, grafting, rooting clippings, or dividing bulbs.[46] In taking this action in 1930, Congress made a specific and limited statement on the question of patenting living material. The legislative history suggests that this was not the primary motivation behind the action however.

The Plant Patent Act of 1930 was the brainchild of Paul Stark, who was a principal in Stark Brothers Nursery, the largest seed breeder in the country in the early twentieth century. Stark was also a friend and business partner of Luther Burbank, a respected horticulturist. Burbank died in 1926 and bequeathed to Stark his research farm, which included hundreds of new plant varieties that had been developed by Burbank but never marketed. The varieties were worth a fortune if Stark could secure exclusive rights to them. In 1929, Stark formed and served as president of a lobbying group called the National Committee on Plant Patents. From this vantage point, Stark drafted and served as the prime catalyst behind the Plant Patent Act of 1930.[47] The bill was introduced by Sen. John Townsend, Jr. of Delaware who was also the owner of 13,000 acres of apple orchards.[48]

In 1930, the United States was struggling under the Great Depression. The country was mired in issues of hunger and government relief and these were compounded by the

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[45] 71st Congress, 2nd Sess. Congressional Record vol. 72, pt. 8 (13 May 1930): 8866, codified at US Code 35 (2000) §§ 161-164.

[46] Glenn E. Bugos and Daniel J. Kevles, "Plants as Intellectual Property: American Practice, Law, and Policy in World Context," Osiris, vol. 7, (1992): 83.

[47] Bugos and Kevles, "Plants as Intellectual Property," 81.

[48] Ibid.

drought of 1930-1931. The bill was generally viewed as a Hoover administration farmer relief act. It was thought that the bill would stimulate private investment in plant breeding and reduce the need for government assistance in that particular field.[49] The bill was an ideal vehicle for Hoover who, both as Secretary of Commerce and as President, was adamantly opposed to government relief and price controls. He also believed that farming was hopelessly inefficient, and farmers badly needed to conduct themselves as businessmen.[50]

The committee report on the plant patent act addressed the legal issue of patentability of a plant under the patent law scheme by stating that a new plant variety from cultivation, being created by human agency, was a "discovery" within the meaning of Art. I, Sec. 8 of the Constitution.[51] Numerous telegrams of support were read into the record when the bill was being debated in Congress.[52] This included a telegram from Thomas Edison, who urged Congress to "Give plant breeders the same status as mechanical and chemical inventors now have through the patent law."[53] Some members of congress expressed doubts about the wisdom of allowing a patent on something produced in nature, particularly a plant of a food producing variety. The bill was referred to as "remarkable" and a "departure from anything we have ever done."[54] Sen. LaGuardia of New York voiced strong objection to the bill. He

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[49] Ibid., 82.

[50] Roger Lambert, "Food from the Public Crib: Agricultural Surpluses and Food Relief Under Herbert Hoover," in *Herbert Hoover and the Republican Era*, ed. Carl Krog and William Tanner (University Press of America, 1984), 158-9.

[51] Bugos and Kevles, "Plants as Intellectual Property," 82.

[52] 71st Congress, 2nd Sess. Congressional Record vol. 72, pt. 7 (17 April 1930): 7200-01; pt. 8 (12 May 1930): 8750-51.

[53] 71st Congress, 2nd Sess. Congressional Record vol. 72, pt. 6 (9 April 1930): 6764-65.

[54] 71st Congress, 2nd Sess. Congressional Record vol. 72, pt. 7 (14 April 1930): 7017-18.

seemed to be convinced that the language of the bill permitted seed patents and could prevent a farmer from harvesting his own crops if planted with patented seeds.[55] Ultimately, however, the bill passed on a voice vote, framed primarily as economic stimulus legislation.[56]

Key to the debate that would ensue nearly fifty years later was new patent law Section 162 established by the Plant Patent Act, which provided that: "No plant patent shall be declared invalid for noncompliance with Section 112 of this title if the description is as complete as reasonably possible."[57] In other words, Congress was acknowledging the fact that a plant breeder could not possibly provide specifications for a plant in the same way that an engineer could provide schematics for a steam engine. In 1985, this variation in the description requirement, as opposed to a policy statement on the patentability of living material, was held to be the primary reason for enactment of the Plant Patent Act.[58] Until then, the existence of the Plant Patent Act served as the foundation of the dissenting opinions in *Chakrabarty* and related cases.

2.4.2 The Plant Variety Protection Act of 1970

The Plant Variety Protection Act of 1970 complemented the Plant Patent Act by granting limited nonpatent protection to sexually produced plants.[59] An international union for the protection of plant varieties was established in 1961. Its standards for intellectual property protection on plant varieties became effective in 1968 when they were ratified by

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[55] 71st Congress, 2nd Sess. Congressional Record vol. 72, pt. 8 (5 May 1930): 8391-92.

[56] Bugos and Kevles, "Plants as Intellectual Property," 82.

[57] US Code 35 (2000) § 162.

[58] *Ex Parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. 1985).

[59] 91st Congress, 2nd Sess. Congressional Record vol. 116, pt. 33 (28 December 1970): 43590.

the requisite minimum of three states (Germany, the Netherlands, and the U.K.).[60] American seedsmen responded by urging Congress to amend the Plant Patent Act of 1930 to include sexually produced plant varieties. Numerous objections were raised, including the fact that crop plants changed genetically from year to year. A plant patented one year would no longer fit its patent description after one or two generations.[61] The final version of the law was taken out of the Patent title of the United States Code and placed in the Agriculture title. It mimicked the international standard by setting up a system of seventeen-year protection certificates issued through the United States Department of Agriculture.[62]

As with the 1930 law, the motivation for the 1970 law appears to have been economic relief. During floor debate, Senator Pogue of Texas spoke of a "tremendous blight" affecting that year's corn crop. Plant breeding would alleviate the blight. The proposed bill would enable people to "get some research done in a hurry."[63] Senator Kleppe of North Dakota stated that the bill would permit public expenditures on applied plant breeding to be diverted to other important areas that private industry may not pursue.

Given the content of the congressional debate, it appears that both of these plant-related laws were motivated by a desire to address an immediate economic problem. In both 1930 and 1970 Congress was attempting to create financial incentives for private investment to replace government support in the plant breeding industry. Although there was certainly some comment in 1930 on the wisdom of granting patents to things that grew in the soil,

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[60] Bugos and Kevles, "Plants as Intellectual Property," 91.

[61] Ibid., 92

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[62] Ibid., 94.

[63] 91st Congress, 2nd Sess. Congressional Record vol. 116, pt. 30 (8 December 1970): 40295.

there does not appear to have been a conscious decision by Congress in either 1930 or 1970 to take up and resolve the question of patentability of living material. At best, this question was tangential and did not form the basis for floor debate.

Of note, however, is the fact that the 1970 law specifically excludes bacteria from its coverage.[64] The reason for this is not clear in the legislative history. It could have been motivated by court decisions interpreting the 1930 Act and holding that even though bacteria were technically categorized as plants, the term "plant" in the 1930 law was intended to be understood in lay person's terms.[65] Regardless of the reason, bacteria are excluded from both laws - by court decision interpreting the 1930 Act and by statutory language in the 1970 Act. This fact would not be lost on the dissenters in *Chakrabarty*.

[64] *U.S. Code* 7 (2000) § 2402(a).

[65] *In re Arzberger*, 112 F.2d 834 (C.C.P.A. 1940).

CHAPTER 3. THE EVOLUTION OF RECOMBINANT DNA TECHNOLOGY

3.1 Introduction

The discovery of Recombinant DNA technology created a new set of problems for interpreting the patent law as well. Recombinant DNA technology is the controlled joining of DNA from different organisms.[1] It was popularly known as "gene-splicing" in the 1970s. All living entities obey a program encoded in their DNA. Recombinant technology takes advantage of this by splicing DNA to obtain a specific section and then "recombining" that section of DNA with the DNA in a simple organism such as bacteria or yeast. This allows researchers to isolate the desired gene of one species for insertion into the cell of another species where it can replicate itself. The result is the ability to mass-produce proteins that are active ingredients in drugs.[2] For example, one portion of DNA contains the information for production of Factor VIII:C, which is a blood-clotting agent. Another contains the information for erythropoietin, a regulator of red blood cell production. With recombinant DNA technology, researchers could isolate those strands from the DNA and mass-produce them in a host organism. For the microbiology community, this represented a breakthrough on the same level as nuclear fission.[3]

3.2 The Boyer-Cohen Breakthrough

The recombinant DNA breakthrough came in March of 1973 when Dr. Stanley Cohen of Stanford University and Dr. Herbert Boyer of the University of California, San Francisco (UCSF), established a simple process to isolate and amplify any gene or DNA sequence and

[1] DNA is an acronym for deoxyribonucleic acid.

[2] Michael S. Greenfield, "Recombinant DNA Technology: A Science Struggling with the Patent Law," *Stanford Law Review*, vol. 44, no. 5 (May 1992): 1051.

[3] Ibid.

move it with controlled precision.[4] Boyer revealed his and Cohen's work at a conference in November 1973. His announcement immediately raised concerns over public safety and also started the clock ticking on a one-year deadline to obtain a patent.[5]

The National Academy of Science responded to the announcement by forming a committee on recombinant DNA safety. In 1974, the committee called for a voluntary moratorium on recombinant DNA research until the risks could be assessed and procedural guidelines established. A Stanford University biologist chaired the committee. Boyer and Cohen supported its conclusions. In fact, they were both signatories to a letter calling for the moratorium, although Boyer had already begun to share the recombinant DNA plasmid with other researchers if they agreed to follow his self-styled safety precautions.[6]

Following Boyer's publication of the results, Stanford University hustled to complete and file a patent application before the one-year publication deadline tolled in November 1974, after which time the information would become public property. Stanford had a well-established technology licensing program and its director was routinely copied on announcements relating to faculty research with commercial potential. His suggestion to file patents on the Boyer-Cohen research took the scientists, at least temporarily, by surprise. In addition to the safety concerns, such an action ran counter to academic traditions of information sharing and generous attribution of results. The patent application ultimately filed by Stanford University claimed both the recombinant DNA process and the resulting

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[4] Sally Smith Hughes, "Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology 1974-1980," *Isis*, vol. 92, no. 3 (September 2001): 542.

[5] Ibid., 556.

[6] Ibid., 554-555.

composition. In other words, Stanford wanted to own both the process and the thing it had produced, which was new and living biological material.

3.3 Impact on the Academic and Commercial Sectors

At that time, the Boyer-Cohen discovery was a purely academic achievement. There was no practical use for the thing they had created. The potential for what the process could conceivably create was mind-boggling however. Stanford's rush to secure a patent underscored its view that the academic achievement could quickly move into the practical commercial realm. This fact was not lost on the researchers. In 1976, Boyer joined with venture capitalist Robert Swanson to form a new company called Genentech, which quickly advanced recombinant DNA research to the threshold of economic viability.[7]

The entire process was fraught with turf battles, egos, and acrimonious debate over the propriety of Stanford's patent application and Boyer's business venture. The aggressive actions of Stanford and Boyer were treading on sacred ground. Traditionally, patent applications in academic biomedicine were suspect on ethical grounds. The scientific community was largely founded on the sharing of information for purposes of evaluation, validation, and extension of knowledge. Any accomplishment in the field was usually the result of extensive collaboration among scientists. New knowledge was critiqued, scrutinized, and ultimately owned collectively by the academic scientific community. The reward to the scientific researcher was peer recognition and esteem derived via publication. Attribution to all contributors was common in published results. The patent application and

[7] Nicholas Wade, "Gene Splicing Company Wows Wall Street." *Science,* vol. 210 no. 4469 (October 31, 1980): 506.

the creation by Boyer and his investors of a for-profit company soon created issues of fairness, propriety and professional evaluation.

Noteworthy among Genentech's research was its work on recombining the human gene containing genetic information for the synthesis of interferon, a natural antiviral protein. Touted as an effective tool for battling cancer, interferon's market value for a mass producer was estimated to reach three billion dollars by 1987.[8] Genentech successfully cloned the gene under a contract with pharmaceutical company Hoffmann-LaRoche.[9] There was a dispute however over where and how Roche Laboratories, a research lab funded by but considered independent from Hoffmann-LaRoche Pharmaceutical Company, obtained the gene that Genentech successfully cloned. The University of California claimed that Roche made unauthorized use of material developed by two UCSF researchers. The attorney for the university claimed that the academic relationship, defined by a free and easy exchange of materials, was being subverted for commercial profit by private industry. If that was not adequate ammunition for a fight, the disputed genes that UCSF claimed to own were extracted from the bone marrow of a cancer patient in 1977.

The sequence of events in this episode demonstrates the validity of the academic tradition. After the cancer patient voluntarily donated his genes, they were then nurtured and grown in a test tube at the UCSF medical school, a significant feat in itself. A sample of the cell line was sent to a scientist at the National Cancer Institute (NCI) who discovered that the cells were producing interferon. Although not a surprising revelation, this was news to the UCSF researcher, and he shared it with a colleague who was interested in interferon research.

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[8] Nicholas Wade, "University and Drug Firm Battle Over Billion-Dollar Gene," *Science*, 26 September 1980, 1492-1494.

[9] Ibid.

This colleague worked at the Roche Institute of Molecular Biology. The Roche researcher contacted the NCI and requested samples from the UCSF cells. The NCI passed the samples to the Roche lab after a conversation between the NCI researcher and the UCSF researcher that would later be the subject of conflicting interpretations. The Roche lab took the cell line and, with Genentech's help, converted it into a super producer of interferon.

Until this breakthrough, this type of sharing between researchers had been routine. The work done at Roche labs, however, yielded an extremely valuable commercial property. At about the same time in January 1980, a company called Biogen had also announced the successful cloning of the interferon gene. Although the Roche–Genentech method for cloning was far superior to that of Biogen, the announcement increased the value of Biogen and its contractor by hundreds of millions of dollars.[10]

The primary breach of protocol had occurred when the NCI gave the UCSF cells to a third party. There was an unwritten agreement in academia that forbade recipients of materials from passing them on to a third party. The NCI thought it had permission from UCSF to pass the UCSF cells on to Roche labs and also thought it was giving the cells to a non-profit entity. For its part, the Roche lab never specifically asked for permission to clone the cells and, having done so, then filed for patents on the clones even though multiple parties could claim responsibility for contributing the cells, nurturing them, and discovering their properties. The interferon cells played a major role in the value of Genentech's initial public offering, which would come on the heels of the United States Supreme Court's decision in *Chakrabarty*.[11]

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[10] Ibid.

[11] Ibid.

Despite this blow-up, Genentech continued to work closely with UCSF. The biotech start-up shared laboratory space and employees with the university. In one case, there was noticeable overlap between Genentech's development of a growth hormone and published results from university staff. In that case, Genentech paid the university three hundred and fifty thousand dollars in June 1980 to resolve the matter.[12]

The Genentech and related accomplishments also quickly dampened the ethical debate over recombinant DNA in favor of great excitement over its commercial possibilities. Progress on safety guidelines was rolled back. In 1978, NIH revised it guidelines and eased restrictions on experiments. All bills introduced to regulate recombinant DNA technology died in one of the largest lobbying campaigns on a technical issue in the history of Congress.[13] Genentech and its peers were poised to become giants in the emerging field of commercial biotechnology. A number of issues remained outstanding however; foremost among them was whether a patent applicant could secure rights not only to the recombinant DNA process, but also the materials it produced. Here the shortcomings of the patent law became increasingly apparent.

3.4 Problems with the Patent Law

As discussed in Chapter Two, a patent application must present an invention that is a new and useful process, machine, manufacture, or composition of matter. It must be novel

[12] "Investors Dream of Genes." *Time*, 20 October 1980, 72. There is no mention of exactly what the payment was intended to represent (damages, costs, royalties, etc). Given the potential market value of a growth hormone, it was likely a negotiated settlement to reimburse UCSF for its expenses, possibly reflecting the value of UCSFs work relative to the amount if investment yet to be made in order to bring the product to market.

[13] Sally Smith Hughes, "Making Dollars out of DNA," 566-68. This effort cannot be attributed exclusively to the private sector. The scientific community was an active participant. While it clearly stood to gain immensely from employment / business opportunities in this new commercial field, it was also, no doubt, becoming increasingly confident in its ability to use genetic material in a safe and responsible manner.

and cannot be obvious when compared with the prior art. It must be described in full, clear and concise terms such that any person skilled in the same art can make and use the same. Recombinant DNA technology was certainly novel and was not represented in any prior art. Cohen and Boyer's work was made possible by discovery of an enzyme called "restriction endonucleases", which can cut DNA in specific places, and another enzyme called "DNA ligases", which can join pieces of DNA together to make a single longer piece. These discoveries led to the invention of the process to create recombinant DNA, by which new biological material was created.[14] The patent standards clearly prohibited patent protection for discovery of the naturally occurring enzymes and just as clearly allowed patent protection in the new process. The PTO readily granted process patents for recombinant DNA when they were applied for. The thornier issue was the resulting proteins. Were they truly new and useful, and could their use be adequately described such that the public received its end of the patent bargain?

The problem was that biotechnology was being judged against standards drafted primarily to accommodate mechanical inventions. The patent law is most efficient in the area of mechanics, where function precedes structure. For example, an engineer observes a field of hay being cut with scythes and bundled by hand. He sees the need for a machine to cut, pick up, and bundle the hay for easy transport and storage. He designs a machine that will perform the needed functions of cutting, combining, and binding. When the machine is ready, he applies for the patent.

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[14] Li Westerlund, *Biotech Patents: Equivalence and Exclusions under European and U.S. Patent Law* (New York: Kluwer Law International, 2002), 8.

Biotechnology is counter to this model. The scientist derives a new compound from a known compound and then experiments with it in order to discover what practical use it might have. In other words, structure precedes function. The scientist has his new invention before he knows what it can do. These types of discoveries require much time and resources. Manipulation of genetic materials took years and millions of dollars before its potential uses were fully understood. This is one reason why most of the research took place at university research facilities.[15]

The patent law was not well suited to the scientific model. It was founded on economic reward for the inventor. If two inventors were working in the same area, the first one to file a valid application was granted the patent. Thus, the law encouraged a patent application at the earliest stage in the development of the invention. This was fine when the item at issue was a hay baler. For the biological researcher however, it meant having to secure a patent before the claim was fully understood. It also meant less ability to amend the patent application as new information was discovered. Another problem was the Section 112 claim. How did one describe a new protein in a way that could enable reproduction?

On top of these procedural problems was the fundamental question of whether the protein produced by the recombinant process was truly new. There was no question that the process of natural isolation of a desired strand of DNA was very inefficient and could not produce a therapeutic amount of the desired protein. The recombinant process solved this problem and was therefore eligible for patent protection. The proteins it produced, however, were identical to the same proteins that occurred in nature. That, after all, was the objective: to mass-produce a valuable protein identical to its naturally occurring counterpart. This

[15] Ibid., 10.

begged the question: Should patent protection be available for a protein that was not in any way "new"?

The purpose of recombinant DNA technology was to create a protein identical to a natural protein. The core value embraced by the patent law was to reward something completely new. For example, proteins derived from blood plasma and proteins created through recombinant technology were identical in composition and, more important, had identical blood-clotting characteristics. The recombinant protein did not do anything new, nor was it intended to. It was valuable precisely because it was identical. This presented the biotechnology industry with a conundrum. It had to argue similarity before the Food and Drug Administration, convincing it that recombinant products were identical to their naturally occurring counterparts in order to obtain approval for their sale to the public. In nearly the same breath, it had to argue dissimilarity before the PTO, convincing it that the recombinant protein was something new in order to qualify for a patent. Under the law as it was interpreted in the 1970s, the inventor could easily patent a process to produce the proteins but could not patent the proteins themselves because they were not new. The Board of Patent Appeals complicated matters further when it established a position that living material such as microorganisms and proteins were not patentable subject matter under Section 101 of the patent law.[16]

As long as Genentech had patent protection on the only process for creating recombinant proteins, its investment was safe and its profits were assured. Biogen, however, had achieved the same result through a different, albeit less efficient, process. As soon as someone else could create the same protein through a more efficient method - publication of

[16] *Application of Bergy*, 563 F.2d 1031, 1033-34 (C.C.P.A. 1977).

the Boyer-Cohen research had certainly laid the groundwork for doing so - Genentech was threatened with loss of its most valuable asset.[17] Given the time and money required to produce recombinant proteins and the fact that the market value lay as much in the proteins as the process, the situation was untenable for the marketplace.

Because of the uncertainty over ownership of the resulting product, Stanford University amended its patent application to drop the end product and seek rights only to the process.[18] Stanford, Genentech, and all of the others with expertise in the science needed a fresh reading of the Patent statute in light of this new science. This task fell to the 1980 term of the Burger Court. The road leading to its landmark decision would not involve recombinant DNA technology. It would begin with an oil spill and a General Electric researcher named Ananda Chakrabarty.

[17] Two other options were available to protect the invention: legal trade secrecy and actual secrecy. Actual secrecy is as simple as it sounds. Do not let anyone know how you do what you do. This is not ideal for machines since they can be reverse engineered. It is exceedingly difficult with microorganisms since they are easily stolen and propagate rapidly. Secrecy also frustrates scientific norms of publication. Trade secrecy is a state law concept and requires that the owner of the secret maintain and document certain standards of confidentiality in order to claim the right. Rebecca S. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," *Yale Law Journal*, vol. 97, no. 2 (December 1987): 190-195.

[18] Sally Smith Hughes, "Making Dollars out of DNA," 563.

CHAPTER 4. THE CASE OF *DIAMOND V. CHAKRABARTY*

4.1 Introduction

Neither Stanford University nor Genentech would be first to present the question of ownership of living material to the United States Supreme Court. That distinction belonged to an India-born biochemist employed by the environmental division of General Electric in its New York research lab. Ananda Chakrabarty was educated in Calcutta and developed the concepts for his work at the University of Illinois, Urbana. He joined General Electric in 1971 and began doing groundbreaking research in the science of cleaning up oil spills, resulting in a patent application that included a claim for a new form of bacteria that Chakrabarty had created in the laboratory.[1] The resulting case of *Diamond v. Chakrabarty* was argued before the United States Supreme Court on March 17, 1980.[2] The original application for the Chakrabarty patents had been filed in 1972 and had been wending its way through the appeals system for eight years. Although Chakrabarty's process claims were approved, the patent examiner denied the claim for a new microorganism on the grounds that it was living material and thus not within any class of patentable subject matter. The resulting appeals climbed from the Board of Patent Appeals to the Court of Customs and Patent Appeals, where Chakrabarty was the victor. Therefore, when the case ultimately came before the United States Supreme Court, it was on appeal by the PTO seeking to reverse the lower court ruling in favor of patentability of the new microorganism.

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[1] Sheppard, Nathaniel, Jr. "Developer of a New Life Form: Ananda Mohan Chakrabarty," *The New York Times*, 18 June 1980, 22 (A).

[2] *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). Note: Diamond appears in the case caption by virtue of being Director of the United States Patent and Trademark Office at the time.

Chakrabarty did not work with recombinant DNA technology. His methodology employed cross-breeding and fusing of bacterial strains. It was Stanford University and Genentech that were making the recombinant DNA headlines and fanning the fires of economic potential. The common denominator for all of these applications however, in addition to the process claims, was that they were yielding new and valuable living material. As Chakrabarty's case was moving up the appeal ladder, the United States PTO was accumulating a growing stack of patent applications in the field of biotechnology. The PTO took the position that product patents should not be issued for any of the mounting applications but elected to hold the applications in suspense rather than rejecting them. This would allow the filers to preserve their claims and have benefit of their filing dates should the Supreme Court hear the case and establish a new precedent in their favor.

4.2 The Case of Application of Bergy

The legal history of *Chakrabarty* actually begins with a companion case, *Application of Bergy*, which was decided by the Court of Customs and Patent Appeals prior to *Chakrabarty*. The cases were eventually combined into one case by the Court of Customs and Patent Appeals due to their similar facts and their timing but it was *Chakrabarty* that was appealed to and heard by the United States Supreme Court. Both cases must be reviewed to understand the evolution of the law in this area.

In 1977, *Application of Bergy* was decided by a five-judge Court of Customs and Patent Appeals.[3] It was a three to two decision, presaging the one-vote majority that also characterized *Chakrabarty*. Malcom Bergy and two colleagues developed a new process for preparing an antibiotic known as lincomycin by using a newly discovered microorganism

[3] *Application of Bergy*, 563 F.2d 1031 (C.C.P.A. 1977).

called *streptomyces vellosus*. This microorganism was found in nature but had been purified for use in the new process. Use of this new microorganism allowed Bergy to accomplish two new things. First, he was able to prepare lincomycin at temperatures ranging from 18 to 45 degrees Celsius; second, he was able to prepare licomycin without concomitant production of a byproduct, lincomycin B. This new process greatly increased the efficiency of lincomycin recovery.[4]

Bergy applied for five patents, four on the process for recovering lyncomycin and a fifth for the newly discovered microorganism *streptomyces vellosus*. The fifth application was supported by affidavits from three microbiologists at Upjohn Research Laboratory stating that *streptomyces vellosus* did not exist as a biologically pure culture in nature and asserting that it had been manufactured.[5] The patent examiner approved the four process applications but rejected the fifth application based solely on the fact that it was a claim on a product of nature and therefore not patentable subject matter under Section 101 of the patent law. In support of his decision, the patent examiner cited three appellate decisions: *Application of Mancy, Guaranty Trust Co. of New York v. Union Solvents Corporation* and *Funk Brothers v. Kalo, Co.*[6] All three cases contained support for the general rule that a

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[4] *Application of Bergy* , 1032.

[5] *Application of Bergy* , 1033. Bergy's affiliations are not made clear in the opinion, nor does the opinion explain why an arm of Upjohn, a large pharmaceutical company, was involved. It can be assumed, however, that Bergy and Upjohn had some type of legal relationship and mutual economic interest in the research.

[6] *Application of Mancy*, 499 F.2d 1289 (C.C.P.A. 1974); *Guaranty Trust Co. of New York v. Union Solvents Corporation*, 54 F.2d 400; *aff'd* 61 F.2d 1041 (D. Del. 1932); *Funk Brothers v. Kalo, Co*., 333 US 127 (1948).

naturally occurring bacteria or a property of that bacteria was not eligible for patent protection.[7]

Mancy was a 1974 case in which a patent application was filed for a process for producing the antibiotic daunorubicin through cultivation of a specific strain of the microorganism *streptomyces bifurcus*, which was found in and isolated from a soil sample taken in France. *Streptomyces bifurcus* was a known antibiotic, as was the process for producing it via aerobic cultivation of strains of *streptomyces*. The applicants had simply found a brand new strain of the antibiotic to which the same process could be applied. The process application was rejected on the basis of obviousness.[8] The applicants argued that they had found and isolated a novel strain of the microorganism and that it was not at all obvious that this strain could be used in the process because most strains did not produce such results. In other words, the strain they found and used in their process was not known in the prior art. The Court of Customs and Patent Appeals held that the applicant's process was not prima facie obvious.[9] One skilled in the art would not find it obvious to do what appellants did with the materials they discovered. The Court also noted that the applicant had made no claim on the new strain of *streptomyces bifurcus* but:

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[7] *Guaranty Trust* and *Funk Brothers* are both summarized in Section 2.3.2.2 relating to judicial interpretations of Section 101 of the patent law. In Guaranty Trust, a naturally occurring but previously unknown bacteria was used in a patentable process. In Funk Brothers, the discovery and commercial application of that fact that certain bacteria had non-inhibiting properties was ruled not adequate to warrant a patent.

[8] Obviousness is the third standard in Section 103 of the patent law, discussed in Section 2.3.2.4.

[9] The United States Court of Cusotms and Patent Appeals was originally established in 1909 as a five-judge federal court of appeals to help with customs cases. In 1929, its jurisdiction was extended to patent and trademark cases. It was abolished in 1982 when its jurisdiction was transferred to the newly created U.S. Court of Appeals for the Federal Circuit. United States Government Federal Judiciary History, www.fjc.gov/history/home.nsf/page/patent_bdy.

> ". . . would, we presume (without deciding), be unable to obtain such a claim because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a "product of nature."[10]

Citing the holdings in *Application of Mancy, Guaranty Trust,* and *Funk Brothers*, the patent examiner reviewing the Bergy application concluded that Bergy's newly discovered microorganism could be employed in a patentable process but could not be the subject of a patent because it was a product of nature. Bergy appealed the ruling, claiming that his process employed a biologically pure form of the microorganism *streptomyces vellosus*. Bergy conceded that the microorganism existed in nature but claimed that it had to be isolated and purified in order for it to be of use in the process for recovering lyncomycin. In other words, Bergy claimed that he had "manufactured" the purified form of *streptomyces vellosus* for purposes of Section 101 of the patent law.

Bergy's appeal was heard by the Patent and Trademark Office Board of Patent Appeals. This is a board within the United States Patent and Trademark Office. It is made up of the Director of the PTO, the Commissioner for Trademarks and the administrative patent judges within the office who are appointed by the Director.[11] Upon written appeal of an applicant, the Board reviews adverse decisions of patent examiners.[12] The Board of Patent Appeals affirmed the examiner's rejection of Bergy's fifth application for the new microorganism. The Board, however, completely ignored the examiner's stated basis for rejecting the application (that it was for a product of nature.) Instead, the Board ruled that

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[10] *Application of Mancy*, 1294.

[11] *U.S. Code* 35 (2000) § 6.

[12] Ibid.

claim five of the Bergy application was for a living organism. The Board also ruled that, given the absence of any precedent, a strict construction of Section 101 of the patent law precluded a patent on a living organism because it was not within the scope of any Section 101 category.[13] Note that the Board of Patent Appeals distinguished between products of nature and living things. Products of nature could include inanimate materials such as minerals and chemicals that were not living. The Board essentially carved a subset, consisting of living things, out of the larger set of products of nature. The Board concluded that the subset of living things was not eligible for patent protection under any circumstances. Thus, living material was not in any Section 101 category of patentable subject matter.

It is here that the Plant Patent Act of 1930 became central to the issue of patents on living material. In support of its decision, the Board of Patent Appeals cited *In re Arzberger*, a 1940 decision from the Court of Customs and Patent Appeals.[14] The Arzberger application for a patent on a species of bacteria had been filed under the Plant Patent Act. The applicant argued that standards of botany and bacteriology stated that bacteria were properly classified as plants. While the Court in *Arzberger* conceded that this was true, the application was nevertheless rejected on the grounds that the Plant Patent Act was not intended by Congress to apply to bacteria but only to plants in the layman's sense of the word. The Court cited the legislative history of the Plant Patent Act, which identified asexual reproduction as "grafting, budding, cuttings, layering, division, and the like, but not by seed.[15]

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[13] *Application of Bergy*, 1033-34.

[14] *In re Arzberger*, 112 F.2d 834 (C.C.P.A. 1940).

[15] Ibid, 837.

Based on the holding in *Arzberger*, the Board of Patent Appeals reasoned that the Plant Patent Act of 1930 represented the one and only instance where Congress had determined to extend patent-type protection to living things. In so doing, Congress had clearly limited the extension of this protection to asexually produced plants and nothing else and had further defined what it viewed as asexual reproduction. Therefore, the only type of patent available to a living thing was a plant patent. Bacteria explicitly did not qualify as a plant under the Plant Patent Act. Accordingly, the fifth component of the Bergy application was neither sanctioned by Section 101 of the patent law by virtue of being for a living thing nor by the Plant Patent Act by virtue of being for a bacteria. In support of its ruling, the Board of Patent Appeals noted that Bergy's argument for an expansive reading of the meaning of "manufacture" in Section 101 to include isolated and purified bacteria could arguably open up the patent laws to cross-bred animals, such as honeybees, which did not occur naturally but were "manufactured" by the breeder. The Court also noted that the interpretation urged by Bergy would take plants that were excluded under the Plant Patent Act and make them patentable under Section 101, a result that Congress did not intend.

The PTO and the Board of Patent Appeals had thus made a clear statement on the limits of the patent law as it applied to living things. The realm of patentable living things was identified, defined and limited by the Plant Patent Act of 1930. If one did not have an asexually produced plant, one did not have an option to patent a living thing. The decision of the Board of Patent Appeals in *Bergy* was appealed to the United States Court of Customs and Patent Appeals. It was during the appellate arguments that the groundwork was laid for the eventual declaration by the United States Supreme Court that living material was in the category of patentable subject matter.

The Solicitor General, arguing before the Court of Customs and Patent Appeals on behalf of the PTO, cited a 1975 case, *Application of Merat*, relating to a patent application for chicken breeding.[16] In *Merat*, the applicant had discovered a dwarfism gene in chickens and, through careful breeding, had produced dwarf hens that laid normal sized eggs but consumed less food. The applicant applied for patents on the breeding process and on the dwarf hens. The patent examiner rejected all claims under Section 101 on the grounds that animal breeding was not a process eligible for patent protection and that a thing occurring in nature (in this case, a chicken) was not a "manufacture" for purposes of Section 101. The Board of Patent Appeals agreed and noted that if animal breeding was recognized as patentable under Section 101 of the patent law, then plant breeding would certainly be allowed as well and there would have been no need for a specific plant patent statute. The Board of Patent Appeals also rejected the application for failure to comply with the Section 112 claim requirement. The applicant had failed to state with adequate specificity exactly what he was claiming as his invention. The Court of Customs and Patent Appeals affirmed the rejection based on Section 112 and did not address the Section 101 basis for rejection.

In considering these facts in connection with the *Bergy* appeal, the Court of Customs and Patent Appeals first noted that the microorganism *streptomyces vellosus* in the Bergy application was clearly not a product of nature because the material was in a biologically pure form as a result of human intervention. Therefore, the patent examiner's rejection based on the product of nature exemption was fatally flawed from the start. In fact, the Court of Customs and Patent Appeals speculated that the Board of Patent Appeals was well aware of

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[16] *Application of Merat*, 519 F.2d 1390 (C.C.P.A. 1975).

this fatal flaw in the patent examiner's logic and therefore went looking for a better reason to reject the claim, ultimately settling on the "living material" argument.[17]

The opinion of the three-judge majority stated that there was clear legal precedent for patenting a purified product of nature, which is precisely what Bergy had argued. The Court cited two cases for its position: *Merck v. Olin Mathieson Chemical Corporation* and *Parke-Davis v. Mulford.*[18] Having established a basis for allowing a patent on purified products of nature, the Court saw one remaining issue: Was a purified product of nature, otherwise patentable under Section 101 of the patent law, disqualified because it also happened to be alive? For three of the five judges, the answer was "No". The Court appears to have been mindful of the warning issued by the Board of Patent Appeals about the potential consequences of opening the patent door too wide to living things. The majority took pains to note that it was not deciding if living things *in general* qualified under Section 101 of the Patent law, but only whether microorganisms did. Other questions involving living things would have to be decided on a case-by case basis. Thus, the Court was clearly not trying to establish a broad new policy on living material and, in fact, was consciously avoiding it.

The majority opinion attempted to address the arguments running contrary to its holding. In doing so, it suggested a more expansive reading of previous holdings. The majority opinion first noted that it was well established that processes employing living organisms were nonetheless eligible for patents. In fact, the PTO examiner had approved Bergy's four process applications utilizing *streptomyces vellosus*. From this fact, the majority

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[17] *Application of Bergy*,1035.

[18] *Merck v. Olin Mathieson Chemical Corporation*, 253 F.2d 156 (4th Cir 1958). This case is discussed in Section 2.3.2.2. It involved the patent awarded for pure vitamin B-12; *Parke-Davis*, *v. Mulford Co.*, 189 F. 95 (SDNY 1911); aff'd 196 F. 496 (2nd. Cir. 1912) was a case permitting a patent on isolated and purified adrenaline.

opinion concluded that if living material was a permissible component of a process claim, it should therefore not be barred from a product claim. This position seemed to expanded long held precedent that a new and useful process could be the subject of a patent but that a product of nature within that process could not. The Court dismissed fears of patents on crossbred animals as "far-fetched" but did not carry the analysis any further than to state that the larger issue was not before the Court.[19] The Court suggested that microbiology was more akin to a chemical reaction than a complex animal. Clearly the Court was attempting to discount the fears about crossbred animals by drawing a distinction between bees and bacteria. In doing so, however, the Court also opened the door to the possibility of patent eligibility based on different levels of life forms. As to the intent of Congress, the Court stated that the Plant Patent Act of 1930 was silent on the question of patentability of microorganisms and that "the collective mind of Congress was not turned in that direction" when it passed the Plant Patent Act.[20] This was a paper-thin ruling in terms of the vote (3-2) and the substance of the holding.

The two dissenting judges focused on the intent of Congress as evidenced by the structure of the patent law. They reasoned that if Section 101 of the patent law was intended by Congress to be broadly construed to allow for patents on living things, then plants would be patentable under Section 101, and there never would have been need for Congress to enact the Plant Patent Act. By enacting the Plant Patent Act, Congress evidenced an intent to extended patent protection for living material only to plants. They cited the legislative history of the Plant Patent Act, saying that it was intended to remove discrimination between plant

[19] *Application of Bergy*, 1038.

[20] Ibid., 1039.

developers and industrial inventors. That discrimination was an inability to patent plants. The dissenting opinion also challenged the majority's attempt to equate living organisms with chemical compositions such as reactants, reagents and catalysts. The dissent claimed that living was fundamentally different from inanimate. In addition, the dissenting justices challenged the notion that using a microorganism in a patentable process logically compelled that the organism itself was patentable. Ultimately, the dissenting justices concluded that whether it was in the public interest to allow patents on microorganisms was a question for Congress and not the courts.[21] Whether dissenting justices were focused on the public interest in terms of economics or ethics or both is not clear. The dissent clearly suggests, however, that Congress had been willing to draw some policy lines on the issue during the past fifty years and there should be no reason why Congress could not revisit and clarify those lines in light of the new science.

4.2.1 Chakrabarty in the Lower Courts

The *Chakrabarty* case followed closely on the heels of *Bergy*. It presented the Court with nearly identical facts, including a claim for both a new process and a new bacterium. Chakrabarty's area of research was oil spills. Oil spills can be degraded with certain bacteria that act to break oil down into simpler components suitable as food for aquatic life. Numerous forms of bacteria are required to break down the various components of oil however. Unfortunately, the different bacteria strains tended to inhibit each other's growth when mixed together and compromised their efficiency. Ananda Chakrabarty determined that the information necessary for degradation of oil was carried in only a part of the bacterial cell

[21] *Application of Bergy*, 1041-1042. "We should fill the statutes with judge-made law only under the gravest and most impelling circumstances."

- by plasmids in DNA separate from the bacterial cell's main chromosome. He developed a method for removing the specific degradative information from four different bacteria and inserting them into a single bacterium. He then combined the new bacterium with a buoyant material so that it would float when applied to oil spills. He applied for three patents: one for the process to create a single bacterium with the properties of several existing bacteria; a second for the resulting new bacterium itself; and a third for the process to mix the bacterium with the buoyant carrying material.[22]

The Chakrabarty application ran the identical gauntlet as the Bergy application. The patent examiner accepted the two process claims but the claim on the new bacterium was denied, this time on the grounds that living material was not statutory subject matter under Section 101, the examiner having apparently discarded the "product of nature" rationale and adopted the reasoning of the Board of Patent Appeals in *Bergy*. Chakrabarty's appeal was heard by the same Board of Patent Appeals, which upheld the patent examiner's ruling. This decision was appealed to the Court of Customs and Patent Appeals, which followed its decision in *Bergy* by reversing the Board's opinion by the same three to two vote and holding that a new bacterium could be considered a "manufacture" under Section 101.[23]

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[22] Peter B. Maggs, "New Life for Patents: Chakrabarty and Rohm & Haas Co.," *Supreme Court Review*, vol. 1980 (1980): 58.

[23] Application of Chakrabarty, 571 F.2d 40 (C.C.P.A. 1978). Note that the Chakrabarty patent application was actually reviewed by the PTO before the Bergy application. However, Chakrabarty requested reconsideration by the patent office examiner, while Bergy elected to appeal the patent office decision to the next level, the Board of Patent Appeals. Thus, the patent examiner must have ruled on the Chakrabarty application first, presumably rejecting the claim for the new bacteria as a product of nature, and then ruled on the Bergy application on the same grounds. The Chakrabarty application stayed in the patent office for reconsideration while the Bergy application went to the Board of Patent Appeals. By the time the Chakrabarty application came up for reconsideration, the Board of Patent Appeals had ruled on the Bergy appeal and established the new criteria that living material was ineligible under Section 101. It is likely that the patent examiner was waiting for some guidance on the Bergy appeal before reconsidering Chakrabarty. At any rate, when the Chakrabarty application was reconsidered, it was rejected on the new grounds. Bergy was first before the Court of Customs and Patent Appeals in 1977, followed by Chakrabarty in 1978. The Court of Customs and Patent Appeals elected to

The same two judges dissented in the *Chakrabarty* case, this time offering a more refined analysis than in *Bergy*. The two dissenting judges argued that one could not view a thing as both a product of nature and a product of man. They conceded that there was a middle ground: a modified product of nature. Such modification did not establish patentability until the object's essential nature was substantially altered however.[24] In support of their position, they cited the Supreme Court's 1930 decision in *American Fruit Growers, Inc. v. Brogdex Co.*[25] In that case, the patent applicants had discovered that Borax was an ideal compound for fighting blue mold on citrus plants, although the reasons for this were not entirely understood. Borax was a well known substance and all one had to do was dilute it in water and use the water to wash the fruit. The Supreme Court ruled that this was not an invention because the fruit was still fruit before and after washing. It was simply better protected against disease. The applicant had not invented, isolated or purified the fruit or the borax.[26]

The dissenting justices in the *Chakrabarty* Case argued that, in similar fashion, Chakrabarty had taken an organism that was suitable for digesting oil and had grafted onto it

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combine the two cases into one when the United States Supreme Court remanded *Bergy* back to the Court of Customs and Patent Appeals while the same court still had *Chakrabarty* on its docket. It issued its new opinion on both cases in 1979. Interestingly, Chakrabarty's petition for reconsideration before the original patent examiner put forth a compelling argument that the intention of Congress in passing the Plant Patent Act of 1930 was to address the fact that plants could not be described in the patent specification required under Section 112 of the patent law. Chakrabarty argued that the Plant Patent Act represented no expression of any kind by Congress on the subject of patentability of living materials. This argument was not addressed or commented on in any way but would later form the basis of the holding in *Ex Parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. 1985) discussed below.

[24] Ibid., 45-47.

[25] American Fruit Growers, Inc. v. Brogdex Co., 283 US 1 (1930).

[26] See also, *Hartranft v. Wiegmann*, 121 US 609 (1887). This was not a patent case but it offered the same rationale. It held that the application of labor to an article, by hand or mechanism, did not make it a manufactured article. Thus, polished seashells were still seashells in the same sense that ginned cotton was still cotton. One did not 'manufacture' cotton by ginning it.

an extra plasmid, thus making it even better at digesting oil. He had not, however, changed the organism's essential nature. Therefore, the rule established by the Supreme Court in *American Fruit Growers* should apply. Moreover, the dissenting justices cautioned that the nature of Chakrabarty's work with oil spills and its potential for society should not be a factor in determining the intent of Congress. It was better left to Congress to determine if Chakrabarty's breakthrough warranted a change in the law.

As to the argument that the Plant Patent Act was enacted simply to get around the description problem in Section 112, the argument made sense only if plants were *already* patentable subject matter under Section 101 but difficult to patent because they were ill-suited to the description requirement. If the only problem was Section 112, then Congress need only have amended Section 112 in order to ease the description requirement where the patent application was for a plant. Instead Congress enacted an entirely new law with a new description section that conflicted with and indirectly repealed Section 112. If plants were already patentable, this legislation reflected poor and illogical drafting.

4.2.2 Bergy Remanded

While the Court of Customs and Patent Appeals was applying its *Bergy* logic to the *Chakrabarty* facts, the PTO appealed the decision in *Bergy* to the United States Supreme Court. The Supreme Court did not issue an opinion. Instead, it vacated the ruling of the Court of Customs and Patent Appeals and remanded the case for further consideration in light of the Supreme Court's recent holding in *Parker v. Flook*, which had been decided four days

before *Bergy*.[27] In light of this directive, the Court of Customs and Patent Appeals voluntarily vacated its similar ruling in *Chakrabarty* and engaged in a new review of both applications.

The case that prompted the United States Supreme Court to vacate the *Bergy* ruling was the patent case of *Parker v. Flook*, decided on June 22, 1978, by a vote of six to three.[28] The *Parker* case did not present the Supreme Court with a patent application on living material but rather a patent on a law of nature in the form of a mathematical formula. In *Parker*, a patent was sought for a unique mathematical formula used in setting alarm limits for catalytic converters. A previous Supreme Court case, *Gottschalk v. Benson* (1972), had established the general rule that a unique mathematical formula could only be discovered, not patented.[29] The difference between *Benson* and *Parker* was that Benson had applied for a patent on a mathematical formula *per se.* In *Parker*, the patent was sought only for a single useful application of a mathematical formula. In other words, Benson had sought licensing rights to all uses of a formula in all situations, whereas Parker was seeking rights to a formula only when used in a process to calculate alarm limits in catalytic converters. Nevertheless, the Supreme Court upheld the rule in *Benson* and affirmed the decision to deny Parker's patent application. The Court held that setting alarm limits for catalytic converters was not new or unique and it could be accomplished in other ways. The only thing novel about Parker's new process was the mathematical formula used to achieve the same result and mathematical formulas were not patentable subject matter under Section 101 of the patent law.

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[27] *In re Bergy*, 438 U.S. 902 (1978).

[28] *Parker v. Flook*, 437 U.S. 584 (1978).

[29] *Gottschalk v. Benson*, 409 U.S. 63 (1972).

Parker had argued that he was not seeking exclusive rights to the mathematical formula, but only for a single application of the formula. The Supreme Court found Parker's position to be an argument of form over substance. For example, one could not patent the Pythagorean theorem on the grounds that the patent was limited to instances where the theorem was used to solve surveying problems.[30] The Court conceded that a process was not rendered ineligible for a patent simply because it utilized a law of nature or an algorithm. In order to obtain a patent, however, the process *itself* had to be new and useful, not just the algorithm within the process. New math formulas were discoveries, but not the kind of discovery that public policy sought to protect. In a statement that would later be cited against it, the Supreme Court said that it must proceed cautiously when asked to extend patent protection to areas not foreseen by Congress when it enacted the law.[31]

The three dissenting justices in the *Parker* case opined that Parker had presented facts far different than Benson. The issue in *Parker* was whether a process patent application lost its eligibility because one step in the process was not patentable. The dissenters accused the majority of importing a standard of novelty and inventiveness into Section 101 of the patent law, which should be concerned only with patentable subject matter. The process claim might be defeated on numerous grounds, but Section 101 was not one of them.

With the *Parker* opinion freshly in hand, the Court of Customs and Patent Appeals combined the Bergy and Chakrabarty applications and undertook a fresh review. Upon

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[30] *Parker v. Flook*, 590. Interestingly, the Court also expressed concern over the impact of a contrary decision on the emerging computer software industry, which relied heavily on mathematics in writing new software. In dicta, the court noted that it made no comment on the patentability of computer programming. That was a job for Congress. Like the recombinant DNA industry, the computer industry was bursting with economic potential and the court was clearly mindful of the possibility of disrupting the new industry. *Parker v. Flook*, 595.

[31] *Parker v. Flook*, 596.

reconsideration, the Court reached the same conclusion - that a purified product of nature otherwise patentable under Section 101 of the patent law was not disqualified from eligibility because it was alive - this time on a 4-1 vote.[32] In its new opinion, the Court of Customs and Patent Appeals indicated that it would wipe the slate clean and start over with its analysis. The result was an excellent tutorial on the application of the United States patent law.

First, the Court noted that there were no standards for patentability in the United States Constitution, but simply authorization for Congress to act if it so desired. Second, the major revision of the Patent Act in 1952 organized the criteria for patentability into three sections: (a) Section 101–patentable subject matter: (b) Section 102–novelty (so as not to take from the public something it already owns); and (c) Section 103–non-obviousness (so as not to take from the public something it could potentially enjoy through application of knowledge it already had).

The Court characterized this structure as three doors through which an applicant had to pass in order to obtain a patent. To get through the first door, one had to have a process, machine, manufacture, composition of matter or some improvement thereon. To get through the second door, it had to be something new. To get through the third door, it had to be non-obvious when compared to the prior art.

The Court of Customs and Patent Appeals expressed some frustration at the United States Supreme Court for confusing the three sections in its analysis in *Parker.* Unlike Sections 102 and 103, Section 101 was not a standard. It was simply a list of eligible categories of things that a person could try to patent if he could comply with the conditions

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[32] *Application of Bergy: Application of Chakrabarty*, 596 F.2d 952 (C.C.P.A. 1979).

for patentability in Sections 102 and 103. The Court of Customs and Patent Appeals feared that the United States Supreme Court, as well as the parties filing appellate briefs, had used language and precedent relating to patentability when examining issues of eligibility. [33]

Referring to the Bergy application, the Court stated that the nature of the patent law was to stimulate the creation of new technologies. Therefore, one should not argue that living material was *per se* excluded under Section 101 simply because Congress did not contemplate it when the statutory language was drafted. The goal of the patent law was to encourage the creation of new things that no one previously contemplated. The fact that no one had contemplated them is what made them patentable in the first place. Therefore, if Bergy had invented something truly new and useful, he should not be denied a patent simply because the thing he invented happened to be alive.

The Court noted that the Section 101 phrase "any new" had been in the statute since its inception in 1793.[34] The Court then observed that the list of things that never would have been contemplated by Congress in 1793 was nearly endless. In *Bergy* and *Chakrabarty*, the thing being contemplated was molecular biology.[35] The Court offered no comment on whether living material could pass the tests set out in Section 102 or 103 of the patent law. Thus the case before the Court was decidedly not about patentability of living material, but

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[33] *Application of Bergy: Application of Chakrabarty*, 959. The Court of Customs and Patent Appeals, apparently felt some frustration at the higher court's pronouncements, stating: " . . . we find in *Flook* an unfortunate and apparently unconscious, though clear, commingling of distinct statutory provisions which are conceptually unrelated."

[34] *Applications of Bergy and Chakrabarty*, 973.

[35] *Applications of Bergy and Chakrabarty*, 974. The court tipped its hand somewhat by citing favorably from the amicus brief filed by Genentech, which observed that bacterial organisms are capable of producing human hormones, thus opening the door for drugs to treat diseases previously untreatable. This fact alone, while relevant to the Section 102 question of novelty, should have been irrelevant to the court's Section 101 analysis of patentable subject matter and yet it was mentioned, as if to justify the court's action.

about whether living material is in a category of things eligible for consideration. Clearly, with this reasoning, the Court was framing the conflict between the logical and practical goal of the patent law to stimulate new and useful things, and a long standing societal assumption that life processes were simply off limits in commercial enterprises.

As for the Plant Patent Act, the Court concluded that it should not stand as a congressional drawing of a strict boundary on the patentability of living things. The Court concluded that it was special interest legislation introduced at the behest of plant breeders. Moreover, one could not imply the intent of the 1874 Congress that enacted the original version of the modern Patent Act, from the actions of the 1930 Congress that enacted the Plant Patent Act. The Plant Patent Act dealt specifically with plants and was not intended as a position statement on living things. In addition, the motivation behind the Plant Patent Act was to spur growth in an agricultural industry that had been badly hurt by the Great Depression. It was also to help amateur plant breeders by extending patent protection into a non-industrial area. Finally it was enacted to avoid the previous judicial position that plants were things of nature and thus not subject to patent protection. The Court also noted that Louis Pasteur obtained a patent on yeast in 1873.[36]

Judge Baldwin, who had previously dissented, voted with the majority but wrote his own concurring opinion. He modified his former dissent based on the Supreme Court's holding in *Parker*. He stated that *Parker* established a rule that one could not patent a

[36] *Applications of Bergy and Chakrabarty*, 985. The court cited to a 1966 research paper that listed multiple instances where the PTO had awarded patents on things such as bacteria, yeast and virus vaccines between 1933 and 1963. The court concluded that it could hardly be viewed as expanding the patent law in light of the existence of those patents. The long and unchallenged existence of these patents could be no more complex than a patent examiner who did not appreciate (or perhaps did not agree with) the nuance of living vs. inanimate. This, combined with the fact that these patents were apparently never challenged in court, probably allowed them to lay dormant over the years. The Supreme Court gave these facts passing mention as well but they did not play a significant role in the opinion. *Applications of Bergy and Chakrabarty,* n. 116.

mathematical principle because a mathematical principle was a fundamental truth. The rule for *Bergy* and *Chakrabarty* should therefore be: What is the basic principle that makes their invention valuable and are they trying to preclude others from using that basic principle? He concluded that Bergy and Chakrabarty were not seeking to patent a basic principal in nature because the things they were using did not occur in nature. Thus, they relied on nature but did not try to patent it. The remaining vote, Judge Miller, continued to dissent. He stated that if there is a basis for doubt over the intent of Congress, the Court should await a clear signal from Congress.

In sum, the three opinions were disjointed, non-harmonious, and cried out for resolution. More importantly, the majority opinion essentially threw down a gauntlet before the Supreme Court. Without saying it bluntly, the majority appeared to be questioning whether the clear language of a statute should yield to a Judeo-Christian tenant that any life function is within the exclusive province of nature or a creator. The opinion of the Court of Customs and Patent Appeals challenged the Supreme Court to square the American values of economic reward for creativity and sacredness of life. The limits of science and technology had allowed these two values to exist in harmony but advancements were bringing them into conflict. The Supreme Court ultimately sidestepped the opportunity and elected instead to offer a very narrow ruling but one that cracked open the patent door, which was all the incentive needed by commercial industry to kick it down.

4.3 The Supreme Court Decision in *Diamond v. Chakrabarty*

Diamond v. Chakrabarty was decided on June 16, 1980. The United States Supreme Court settled the issue in the narrowest terms possible and by a five to four margin. The majority ruled that a live human-made organism is patentable subject matter under Section

101 of the Patent Act. The Court reasoned that the use of the word "any" in Section 101 of the patent law was to be given a broad reading - up to and including living material. In fact, the majority concluded that the issue presented was not properly captioned as one of living vs. inanimate material. Rather, *Chakrabarty* presented an issue of product of nature vs. human invention.[37] Accepting the guidance offered by the Court of Customs and Patent Appeals, the Supreme Court ruled that a bacterium was in the category of patentable subject matter if it was the product of human invention.

The majority opinion rejected the argument that the Plant Patent Act of 1930 represented a statement by Congress on the patentability of living material. The Court stated that prior to 1930 plants were viewed as products of nature based on Patent Office rulings that dated back to 1889 when a claim for fibers found in pine needles was rejected.[38] Also problematic was the fact that plants were not amenable to the description requirements in Section 112. The Plant Patent Act of 1930 was designed to address both of these issues. The majority dismissed reference to a 1930 letter from U.S. Secretary of Agriculture, Henry Hyde, who stated that the Plant Patent Act was needed because patent laws were at present understood to control only inanimate nature.[39] Instead, they emphasized the House and Senate Committee Reports that said a new plant resulting from breeding was unique, isolated and not producable or repeatable by nature.

The Court declined to examine in detail the treatment of bacteria in the Plant Patent Act and the Plant Variety Protection Act. The majority opinion touched on the argument only

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[37] *Diamond v. Chakrabarty*, 308, 313.

[38] Ibid., 311.

[39] Ibid., 312.

long enough to speculate that Congress was trying to keep bacteria out of the category of plants, consistent with the1940 holding in *Arzberger* that bacteria were not plants for purposes of the Plant Patent Act.[40] Moreover, the Court stated that the object of the patent system was to bring new technology into the public domain and thus have a positive impact on both society and the economy "by way of increased employment and better lives for our citizens."[41]

The Supreme Court declined to offer any guidance on the larger issue of patenting living material. The majority opinion specifically noted that its ruling addressed only the question of patentable subject matter in Section 101 of the patent law. As to the other gatekeepers in Section 102 and 103 of the patent law (novelty and non-obviousness) the Court made no comment. In essence, the Court was directing the PTO to let living material in the door to be considered for patentability, but leaving room for the PTO to decide if any further roadblocks should be thrown up on the issue. By rejecting the Bergy and Chakrabarty applications, the PTO had clearly established a policy that living material was not eligible for a patent. The Supreme Court rejected this policy but left the PTO with enough discretion to determine if living material could pass the tests set out in Sections 102 or 103.[42]

In similar fashion to the majority opinion, the dissenting Supreme Court justices followed the logic of the justices who had dissented in the Court of Customs and Patent Appeals. Congress had specifically addressed animate invention in the Plant Patent Act of

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[40] The court mentioned in passing that the Patent and Trademark Office had issued patents on claims that included microorganisms in 1873, 1967 and 1968 but provided no details or analysis. Ibid., 314, n.9.

[41] Ibid., 307.

[42] Ibid., n.5. For example, it would have been plausible to decline living material on the grounds that it was not novel under Section 102 of the patent law.

1930 and the Plant Variety Protection Act of 1970. They drew a very narrow line on the subject, having specifically excluded bacteria in 1970. The existence of these two acts clearly demonstrated that living organisms were not contemplated as patentable subject matter in Section 101 of the patent law. Otherwise, the Plant Patent Act and the Plant Variety Protection Act would not have been necessary. The dissenting justices concluded that the majority opinion extended Section 101 subject matter to living material while Congress had clearly excluded it.[43]

4.4 The Impact of Chakrabarty

Chakrabarty was argued in March 1980 and decided in June 1980. The original application had been filed in 1972. In the ensuing eight years, the patent office had been ignoring a growing stack of patent applications in the field of biotechnology, pending resolution of the issue by Congress or the Courts. In the wake of *Chakrabarty*, the PTO apparently decided not to pursue the issue any further and promptly released one hundred and fourteen pending patent applications including the recombinant DNA applications of Stanford University and Genentech.[44] Congress also declined to step in and moderate the Court's decision. In fact, as will be discussed later, it jumped squarely on the economic development bandwagon and passed laws to enhance the impact of *Chakrabarty*.

Genentech hailed the Supreme Court decision as assuring the country's technological future. Critics claimed that the Supreme Court had transformed Aldous Huxley's *Brave New*

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[43] Ibid., 322. The dissenting opinion should not be interpreted as opposition to patentability of living material any more than the majority opinion favored it. The dissenters simply asserted that the decision on such an emotional and fundamental issue was more properly made by Congress than the court. Similarly, the majority stressed the right of Congress to immediately pass legislation prohibiting patents on living material. Ibid., 318.

[44] Harold M. Schmeck, Jr., "U.S. to Process 100 Applications For Patents on Living Organisms," *The New York Times*, 18 June 1980, 22(A).

World from science fiction to reality.[45] Commentators were mixed on whether the true value of the research lay in the process patents or the product patents. A spokesperson for investment banker E. F. Hutton noted that the "sheer psychology" of the assurance of patent protection for all phases of genetic research, including the resulting bacteria, would be an important step in moving laboratory advances into the commercial arena.[46]

On the strength of *Chakrabarty*, these corporations enjoyed a new standing that clearly enhanced their value beyond the precautionary investments of industry giants. Genentech responded to *Chakrabarty* with a public offering on October 14, 1980. The founders of Genentech, Robert Swanson and Herbert Boyer, had each put up five hundred dollars in seed capital in January 1976. Between its founding and the initial public offering, Genentech's track record was seven hundred thousand dollars in losses and no marketable products. Twenty minutes after the markets opened on October 14, 1980, Boyer and Swanson had each earned eighty-two million dollars. Genentech stock opened at thirty-five dollars per share, hit eighty-nine dollars per share, and closed at seventy-one dollars and twenty five cents. At the closing bell, the market value of the company was five hundred twenty-nine million dollars.[47] Market analysts called the Genentech IPO the most striking price explosion in the past ten years. After a week of heavy trading, the stock stabilized at fifty-six dollars per share. At its peak, Genentech had a market value of six hundred fifty million dollars, the same as Chrysler and about one-third the size of Monsanto. Even when its stock had settled

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[45] Linda Greenhouse, "Science May Patent New Forms of Life, Justices Rule, 5 to 4," *The New York Times*, 17 June 1980, 1(A).

[46] Anthony J. Parisi, "Gene Engineering Industry Hails Court Ruling as Spur to Growth," *The New York Times*, 17 June 1980, 16 (D).

[47] Nicholas Wade, "Gene Splicing Company Wows Wall Street," *Science*, 31 October 31, 1980, 506-507.

down to fifty-six dollars per share, Genentech had a larger market value than American Airlines.[48]

Recombinant DNA emerged as one of the hottest investment fields of the 1980s. Venture capitalists scoured campuses for brainpower. The world's best molecular biologists were to be found at university research labs and, by 1980, most of them had ties to private companies by 1980.[49] Seven companies were working in the field of recombinant DNA at the time. The big pharmaceutical and chemical companies expanded their in-house research and partnered with or purchased interest in these companies.[50] For example, 60 percent of Cetus Corporation of Berkeley was owned by Standard Oil and the National Distillers and Chemical Corporation. Genentech was half owned by Monsanto, Emerson Electric and Lubrizol. Biogen was 16 percent owned by Schering-Plough and 24 percent owned by International Nickel.[51]

The upsurge in commercialization also dampened the attention to social, ethical, and environmental issues in connection with the new technology. University research in the area of biotechnology had a new value. It was transformed almost overnight from an academic pursuit to a multi-million dollar industry. These accomplishments, however, were partly the result of billions of dollars of public funding dating back to the Public Health Act of 1944.[52]

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[48] "Spliced Genes Make Splash on Market," *Science News*, 25 October 1980, 261.

[49] Harold M. Schmeck, "Justices; Ruling Recognizes Gains In the Manipulation of Life Forms," *The New York Times*, 17 June 1980, 16 (D).

[50] Gene Bylinsky, "DNA Can Build Companies, Too," *Fortune*, 16 June 1980, 144-154.

[51] Parisi, "Gene Engineering Industry Hails Court Ruling," 16 (D).

[52] Susan Walton, "Supreme Court Decision Gives New Life to Old Issues," *BioScience*, vol. 30, no. 9, (September 1980): 573-575.

Chakrabarty and his peers represented the final steps in a long series of developments which had been facilitated at tax payer expense. Now the public would be forced to buy the fruits of the research it had funded since mid-century. Critics also questioned the public safety of such science. For example, the *absence* of the Chakrabarty microorganism in nature contributed to the ability of oil to lubricate moving parts. Was it wise, then, to introduce into nature a bacterium that degraded oil's most useful function? [53]

These issues were drowned in the flurry of economic progress. Five years after *Chakrabarty*, the Court of Patent Appeals held in *Ex Parte Hibberd* that there was no conflict between the Plant Patent Act, the Plant Variety Protection Act and the patent statute.[54] Thus, a traditional patent could be awarded to a new plant variety. This ruling essentially converted the patent law and the plant laws into options with different application requirements and different protections. Researchers could choose which route they wanted to take rather than be directed a specific route based on the nature of the material. This dramatically expanded the commercial use of plants.

4.5 *Chakrabarty* and the Burger Court

United States Supreme Court justices are named by the President, subject to Senate approval. Since the justices receive a lifetime appointment, there is no guarantee that a President will have the opportunity to name a justice to the Supreme Court. If this opportunity presents itself, however, the President can select a jurist whose track record of votes and opinions matches the President's political philosophy. Research shows that ninety percent of Supreme Court justices share the political party of the appointing president and

[53] Ibid., 573-575.

[54] *Ex Parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. 1985).

that courts tend to follow the philosophy of the dominant political party.[55] Therefore, the political philosophy within the Executive Branch of government can be carried over to the Judicial Branch when it has the opportunity to make a Supreme Court appointment. This is one reason why Supreme Courts and individual justices are often characterized as conservative or liberal in their holdings. For example, Democrats dominated both the White House and Congress from 1932 to 1968. One hallmark of this era was the United States Supreme Court under Chief Justice Earl Warren and its landmark decisions on civil rights and personal liberties, particularly school segregation and criminal procedure.[56] The domination of Democrats in the White House began to wane in the late 1960s however. Richard Nixon was elected president in 1968.[57] Between the election of Richard Nixon and the 1980 decision in *Diamond v. Chakrabarty*, Republican presidents made five appointments to the Supreme Court. President Nixon alone made four appointments in four years. This was a key event in redefining the United States Supreme Court and its philosophy.[58] In the space of thirty months, the political profile of the Court transformed from one dominated by six liberal justices to one comprised of three liberal, two moderate and four conservative justices.[59]

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[55] John B. Gates, *The Supreme Court and Partisan Realignment*, (Westview Press, 1992): 12.

[56] *The Burger Court: Political and Judicial Profiles,* ed. Charles M Lamb and Stephen C. Halpern, (Urbana: University of Illinois Press, 1991), 2.

[57] Ibid., 3.

[58] Ibid., 6.

[59] Ibid., 18.

The make-up of the United States Supreme Court at the time of its 1980 decision in *Diamond v. Chakrabarty* was as follows:[60]

NAME	TERM	PARTY	APPOINTED BY
Burger, C.J.	69-86	R	Nixon
Stewart	58-81	R	Eisenhower
Blackmun	70-94	R	Nixon
Rehnquist	72-04	R	Nixon
Stevens	75-	R	Ford
Brennan	56-90	D	Eisenhower
White	62-93	D	Kennedy
Marshall	67-91	D	Johnson
Powell	72-87	D	Nixon

The transition of the Supreme Court from a fundamentally liberal to a fundamentally conservative body was set in motion when Chief Justice Earl Warren submitted his resignation to Lyndon Johnson prior to the 1968 presidential election. The assumption was that Johnson would nominate sitting justice Abe Fortas for Chief Justice and then nominate another liberal justice to fill Fortas' vacant seat. Fortas was a close friend and advisor to Lyndon Johnson.[61] This friendship, combined with the eleventh-hour nature of the nomination, subjected Johnson to a barrage of criticism and allegations of cronyism. Fortas ultimately withdrew his name from consideration. He was soon under new scrutiny when *Life* magazine reported that he had accepted a twenty thousand dollar annual lifetime retainer from a private foundation whose founder was subsequently indicted for SEC violations in 1966. Fortas resigned his Supreme Court seat under threat of prosecution.[62] Thus, instead of

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[60] Ibid.

[61] Bob Woodward and Scott Armstrong, *The Brethren: Inside the Supreme Court* (New York: Simon and Schuster, 1979), 16.

[62] Ibid., 18-20.

inheriting a liberally packed court, incoming President Richard Nixon, who had run against the Warren Court nearly as much as he had run against Hubert Humphrey, inherited a Supreme Court with two empty seats.[63] Nixon filled those seats with Warren Burger (replacing Earl Warren in 1969) and Harry Blackmun, a childhood friend of Burger's (replacing Abe Fortas in 1969). Nixon filled two more seats with Lewis Powell (replacing Hugo Black in 1972) and William Rehnquist (replacing John Marshall Harlan in 1972).[64] The trend continued with Gerald Ford, who appointed John Paul Stevens (replacing William O. Douglas in 1975).[65]

Warren Burger was a lifelong moderate Republican. President Eisenhower nominated him for the United States Court of Appeals in 1955.[66] His body of work made clear that he was an ardent critic of the Warren Court, especially in the area of criminal jurisprudence. While Burger proved to be extremely conservative in his opinions on the Court, one essayist described him as neither a philosopher nor a deep thinker. His Supreme Court opinions were workmanlike, short on constitutional theory and long on fine points required to dispose of cases.[67]

Legal commentators fully expected that the Burger Court would undo much of what the Warren Court had established. This complete overhaul never came to pass however. Burger turned out to be a micro-manager who annoyed and offended his colleagues on the

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[63] Ibid., 10.

[64] Ibid., 7-8.

[65] Ibid., 8.

[66] Ibid.

[67] Charles M. Lamb, "Chief Justice Warren E. Burger: A Conservative Chief for Conservative Times," in *The Burger Court*, ed. Lamb and Halpern, 158.

bench. The other justices never coalesced under his leadership as the Warren Court justices had under Felix Frankfurter and John Marshall Harlan.[68] Justices Blackmun and Stevens proved to be moderate and independent while Lewis Powell was somewhat unpredictable. As a result, there were not five dependable conservative votes on the bench in the Burger era.[69] Out of fifty major rulings in the 1980 term, thirty-four (including *Chakrabarty*) were decided by one vote, compared with nine one-vote majorities in the final term of the Warren Court (1968-69).[70] The Burger Court was a court of constantly shifting coalitions that offered little lasting guidance for courts, legislators or the public.[71]

Many scholars assigned the relative blandness of the Burger Court to the quality of its justices. There were four 'polar' justices on the Court: Burger and Rehnquist on the right and Brennan and Marshall on the left. The remainder of the Court was centrist and unpredictable.[72] One cannot say that the Court that produced *Roe v. Wade* was completely void of activism but essayists argue that it was a rootless activism. Even *Roe v. Wade* was an exercise in finding a compromise between a woman's right to avoid an unwanted pregnancy and the state's rights to protect life and health of the mother and the fetus.[73] This, ultimately, was the legacy of the Burger Court. It consistently avoided legitimizing or discrediting basic

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[68] Bennet H. Beach, "Nine Minds of its Own: At Term's End, the Burger Court Still Defies All Labels," *Time*, 21 July 1980, 75-76.

[69] *The Burger Court*, ed. Lamb and Halpern, 10.

[70] David F. Pike, "Blurred Signals from the Supreme Court," *U.S. News and World Report*, 21 July 1980, 60.

[71] Ibid.

[72] Bernard Schwartz, *The Ascent of Pragmatism: The Burger Court in Action* (Reading: Addison-Wesley Publishing Company, Inc., 1990), 400 – 401.

[73] Ibid., 410.

ideas.[74] It dealt with cases on an ad hoc basis, inspired less by moral vision than by pragmatism. Fundamental value choices were more often avoided than made. As result, the Burger Court tended to craft practical compromises rather than statements of moral force.[75]

This legacy stands in stark contrast to the legacy of the Warren Court, which re-made the constitutional law into an evolving entity to the applause of some and the horror of others. The Warren Court used its power to get to the "right" decision and was not inclined to defer to Congress simply because Congress' actions could be argued to be reasonable. Fundamental fairness trumped the rule of law in the Warren era.[76]

Chakrabarty stands as a clear example that the Burger Court did not have the personnel, leadership, or cohesiveness to develop and pursue any ideological agenda as to the proper place of living material within the patent law.[77] *Chakrabarty* is a careful, narrow and practical compromise. The Court takes no stand on the fundamental question of who should be allowed to own living material. It does not explore the idea of what it means to be "alive" and how this should be woven into the nation's diverse values and interests. The Court simply states that one section of the patent law cannot be a barrier to an application that happens to involve biological material. It is a pragmatic decision based on individual facts and not on any rigid philosophy.

It appears that recombinant DNA and similar technologies were both beneficiaries and victims of the Burger Court. The argument in favor of patentability presented in

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[74] Vincent Blasi, "The Rootless Activism of the burger Court," in *The Burger Court: The Counter-revolution That Wasn't*, ed. Vincent Blasi (New Haven: Yale University Press, 1983), 216.

[75] Ibid., 212.

[76] Schwartz, "The Ascent of Pragmatism," 407.

[77] Ibid., 413.

Chakrabarty was well suited not only to the Burger Court in general, but to the Burger Court as it existed in 1980. The fact that three of the four dissenting justices were alumni of the Warren Court suggests that the decision may well have gone against Chakrabarty if the Warren Court had heard the case. In addition, although the Burger Court was more than willing to test the legality of agency decisions, which were somewhat more hallowed prior to 1969, it decided few regulation cases that had any effect beyond the specific agency and the specific statute at issue.[78] There is a longstanding legal theory that agencies are expected to be given deference in their interpretation of the statutes under which they operate.[79] The underlying assumption is that the statutes are technical and the agency that enforces them is the most experienced and qualified in interpreting them. Prior to 1984, the Burger Court appeared to believe that court interpretation of statutes should prevail over agency interpretation. After 1984, the Court ruled that agency interpretations should stand if they were reasonable and if Congress had not spoken explicitly on the issue.[80] In this sense, Chakrabarty was a beneficiary of good timing in that his case came before the Court at a time when it was less deferential to agency decisions.

In addition, the Chakrabarty issues came before a court that valued economic practicality. The Warren Court had generally embraced an expansive view of anti-trust policy. It believed that the anti-trust laws existed to protect small businesses and to foster competition. The Burger Court, by comparison, was disdainful of competitive equality and

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[78] Alan B. Morrison, "Close Reins on the Bureaucracy: Overseeing Administrative Agencies," in The Burger Years: Rights and Wrongs in the Supreme Court 1969-1986, ed. Herman Schwartz (New York: Viking, 1987), 192.

[79] Ibid., 196.

[80] Ibid., 197.

wedded to the concept of economic efficiency.[81] Whereas the Warren Court was inclined to label a business practice per se illegal regardless of economic effect, the Burger Court embraced a rule-of-reason philosophy that allowed a practice to be defended based on its economic impact.[82] The Burger Court similarly gave narrow readings to consumer protection aspects of the federal securities laws.[83] While neither an anti-trust case nor a securities case, the Chakrabarty patent and others waiting in line clearly presented massive economic potential and Chakrabarty could only have benefited by having his case heard before a court that valued economic and business efficiency. This is reflected in the language of the decision.[84]

Balancing the benefits to the industry was the failure of the Burger Court to make a definitive statement regarding a profound issue: the proper place of living matter in American economic policy. While the Supreme Court's ruling in *Chakrabarty* was a watershed event for patent law, the ruling itself was very careful and limited.[85]

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[81] Jerry S. Cohen and Herbert E. Milstein, "The Burger Court and Business," Ibid., 208.

[82] Ibid., 209.

[83] Ibid., 215.

[84] Quoting from its opinion in *Kewanee Oil Co. v. Bicron Corp.* the court said: "[The object of the patent system is foster productive effort that] 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." *Diamond v. Chakrabarty*, 307.

[85] The fact that Burger assigned the *Chakrabarty* opinion to himself suggests that he thought it an important opinion. Nearly all of the general historiography on the Burger court that was reviewed for this thesis ignores *Chakrabarty*. In fact, no book was found that listed *Chakrabarty* among the court's landmark decisions with the exception of a volume of cases selected by Burger himself. Unfortunately, that volume simply re-prints the case with no commentary from Burger. See, *Significant Supreme Court Opinions of Chief Justice Warren E. Burger*, ed. Warren Burger (Manila: The Philippine Bar Association, 1984). Nevertheless, *Chakrabarty* can easily be viewed as illustrative of the overall pattern of the Burger court.

The press following the 1980 term of the Supreme Court illustrated the frustration and confusion with its seeming timidity. *Newsweek* complained that the Supreme Court contented itself with a piecemeal approach, trying to publish narrow judicial decisions, not philosophical tracts.[86] There was no guidance on controversial issues.[87] Other commentators suggested that the Court was simply trying to hide the fact that it was confused on matters of constitutional interpretation so it simply avoided them. It replaced broad examination of moral standards with narrow agreements based on highly detailed judgments about particular situations. When each case seemed to turn on what the justices thought was appropriate for that particular fact situation, little that was said by the Court in one decision binds it in the next. The Court tried so hard to avoid meddling in people's affairs that it left the people without benchmarks.[88]

This is evident in *Chakrabarty*. Rather than offer a sweeping treatise on the patentability of life, the Burger Court simply removed one of several potential impediments in the patent law, leaving the others firmly in place. As for those, the Court offered no guidance. Nevertheless, the entire patent apparatus was opened up to biological material and it readily succumbed to the momentum. *Chakrabarty* came before the right court at the right time and the result tipped the scale just enough for momentum to take over.

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[86] Diane Camper, "The High Court's Grand Finale," *Newsweek*, 14 July 1980, 22-25.

[87] Ibid.

[88] Rupert F. Nagel, "A Plague of Judges: The Burger Court's Secret plan for America," *The Washington Monthly,* vol. 12, no.9 (November 1980): 20-24.

CHAPTER 5. LEGISLATIVE AND EXECUTIVE ACTION

5.1 Introduction

Diamond v. Chakrabarty was decided in June of 1980. A few months later, Congress would take a significant step to expand the new commercial potential of recombinant DNA technology for the university campus, where much of the research was still taking place. In doing so, Congress would combine three powerful factors into one economic machine: private business, the university research laboratory and public money. The result would be a shift from pursuit of pure knowledge with free access to academics to practical research with an eye toward marketability.

5.2 Government Ownership of Patents

Following World War II, the United States engaged in vast federal funding of research. This created an issue of how the government should deal with the government-owned inventions that resulted from the research. In 1945, President Roosevelt's National Patent Planning Commission recommended that the government make its inventions available to anyone for commercial use with the proviso that government agencies have authority to grant exclusive licenses as warranted by individual circumstances. As for inventions by government funded contractors, the Commission generally recommended against full government ownership except where national security was at issue.[1] This idea ran contrary to the general patent philosophy because it offered the patented item to as many entrepreneurs as wanted to develop and market the invention. Depending on the invention,

[1] Rebecca S. Eisenberg, "Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research," *Virginia Law Review,* no. 8 (November 1996): 1672-73.

there could be few who wanted to make such an investment if anyone else could enter the market with the same product.

The Attorney General offered a counter position in 1947, recommending that the government hold full title to all inventions of government employees and contractors. If nonexclusive licensing did not provide enough incentive for the private market, the government should finance the development and marketing of government-owned patents rather than granting an exclusive license to a private third party.[2] This, of course, would have resulted in a sort of nationalization of emerging technologies and placed the government in the position of a public vendor of goods.

Presidents Kennedy, Nixon, and Carter all struggled with how to handle commercially viable property owned by the government. In 1963, President Kennedy issued a memorandum to government agency heads, authorizing them to grant exclusive licenses on government-owned patents if they deemed it necessary in order to call forth adequate private risk capital to bring an invention to the point of practical application.[3] This apparently did not result in the shelves being cleared of inventions. A 1968 report advised that utilization of government-funded patents was 23.8 percent when the government-funded contractor was allowed to hold title to its invention and 13.3 percent when it was not.[4] In 1971, President Nixon issued a second memorandum that clarified the authority of government agencies to grant exclusive licenses and also to revoke previously granted non-exclusive licenses in order

[2] Ibid., 1673.

[3] Ibid., 1678.

[4] Ibid., 1680.

to grant exclusive licenses.[5] The Nixon memorandum was promulgated into federal regulations in 1973. Both Ralph Nader and the Department of Justice challenged the regulations on the grounds that there was no legislative authority to support the action. The lawsuits were dismissed on procedural grounds, leaving the issue unresolved.[6] In 1978, President Carter recommended that commercial rights to government-funded research be transferred to the private sector through title or exclusive license, subject to retention of a non-exclusive license by the government.[7] This was close to the ultimate resolution embodied in the Bayh-Dole Act.

5.3 The Bayh-Dole Act

The Bayh-Dole Act of 1980 was passed on December 12, 1980.[8] It gave small businesses and nonprofit organizations the right to hold patents on inventions created with the help of federally funded research. This created a significant new incentive for universities and small businesses to engage in practical and commercially useful research. The Act allowed the government contractor, the funding agency and the inventor an opportunity to seek patent protection before a government-funded discovery could be given over to the public. There was an exception for the greater social good in the statute but only in rare cases. Under the law, a small business or nonprofit organization could notify the government of its election to retain title to an invention made possible in whole or part with federal

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[5] Ibid., 1684.

[6] Ibid., 1687-88.

[7] Ibid., 1689.

[8] Pub.L. 96-517, codified at *U.S. Code*, 35 (2000) §§ 200-212.

funds.[9] The federal funding agency was then given a nonexclusive, nontransferable, irrevocable, paid up license to practice the invention worldwide.[10] Special approvals and restrictions were in place to prevent the federal agency from requiring the licensing of the invention to third parties.[11] The private licensee was required to give strong preference to United States manufacturers in granting of licenses.[12] As a result, rather than the government holding the patent and granting licenses on request, the outside entity held the patent and granted one license to the government (which it presumably never used) and another to its licensee of choice.

The sponsors of the Bayh-Dole Act purported to be addressing a problem of government inactivity.[13] The problem, as expressed by the sponsors, was that the government owned the patent rights to twenty-eight thousand inventions that came from publicly funded research but did not have funds to develop and market the inventions and would not grant an exclusive license to private developers. Thus, only 4 percent of the twenty-eight thousand inventions had been successfully marketed. The Act was expressed as being in the best tradition of free enterprise.[14] Supporters of the law claimed that even after an invention was complete, the development and marketing costs posed the same issues and required the same incentives. In other words, they were suggesting that the patent process had two distinct phases before the public could benefit from the invention. First, the thing had to be invented.

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[9] *U.S. Code*, 35 (2000) § 202(a).

[10] *U.S. Code*, 35 (2000) § 202(c)(4).

[11] *U.S. Code*, 35 (2000) § 202(f)(1)&(2).

[12] *U.S. Code*, 35 (2000) § 204.

[13] 96th Congress, 2nd Session, *US Cong. & Adm. News*, vol. 5, 6460-61 (1980).

[14] 96th Congress, 2nd Sess. *Congressional Record* vol. 126, pt. 2 (5 February 1980): 1796.

Second, and just as critical, the inventor had to have some incentive to invest in post-invention commercial development. It was in this second phase that the government lacked the resources to be effective. As a result, government-owned patents were collecting dust.

Opponents to the bill argued that the remaining 96 percent of the twenty-eight thousand inventions were sitting on the shelf because they were junk, desired by no one in the private market place. They argued that if the government owned a patent, it should be given to anyone and everyone, and they should then compete. Public taxation for private gain was wrong. The Act created an outcry over the public's right to benefit from the fruits of publicly funded research. Why should the public pay twice for the same invention? And did the law run contrary to the basic patent philosophy of creating an incentive for inventors and investors to fund their own research?[15] There were forty co-sponsors and the bill ultimately passed on a 91-4 vote.[16]

5.4 The Stevenson-Wydler Technology Innovation Act

The Stevenson-Wydler Technology Innovation Act of 1980 made technology transfer an integral part of the research and development responsibilities of federal laboratories and their employees.[17] It obligated the head of each federal executive department to transfer to the newly formed National Technical Information Service unclassified scientific, technical, and engineering information from federally funded research for dissemination to the private

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[15] 96th Congress, 2nd Session, *US Cong. & Adm. News*, vol. 5, 6511-12. (1980).

[16] 96th Congress, 2nd Sess. *Congressional Record* vol. 126, pt. 7 (23 April 1980): 8746. The bill was amended in the House and passed on a voice vote. 96th Congress, 2nd Sess. *Congressional Record* vol. 126, pt. 22 (17 November 1980): 29901. The Senate made further amendments and the final form of the bill was accepted by the House. 96th Congress, 2nd Sess. *Congressional Record* vol. 126, pt. 23 (1 December 1980): 31394.

[17] 96th Congress, 2nd Sess. *Congressional Record* vol. 126, pt. 19 (8 September 1980): 24568, codified at *U.S. Code* 15 (2000) § 3701 et. seq.

sector, academia, state and local governments and other federal agencies.[18] If the technology resulted in a patent, the royalties were to be shared with the federal agency and the individual inventor within that agency. This helped to get government created research into the hands of academic and private researchers to hopefully improve and extend.

Working in tandem, these two laws acted to push government funding and government created technology out to the private sector and then enhance private sector control of the results. These laws did not create the right of private sector patents from government-funded research. It simplified and realigned the process. Instead of the government controlling the patent and the inventor standing in line for a license along with anyone else who had only to request one, the inventor now held the patent and granted one license to the government, which, although it held certain "march-in" rights under exceptional circumstances, would not likely be a competitor.[19]

5.5 Reagan Economic Policy

In November 1980, Ronald Reagan was elected President of the United States over one-term incumbent Jimmy Carter. Reagan destroyed the other Republicans in the primary and captured 97 percent of the convention delegate votes. He was never seriously threatened after the New Hampshire primary. Gerald Ford withdrew his name from consideration in March of 1980, and George H.W. Bush withdrew on May 26.[20] *Chakrabarty* was decided three weeks later.

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[18] *U.S. Code* 15 (2000) § 3704b-2.

[19] *U.S. Code* 35 (2000) § 203.

[20] William Crotty, "The Presidential Nominating Process in 1980," in *The Presidential Election and Transition 1980-1981*, ed. David H. Everson and Paul T. David (Carbondale: Southern Illinois University Press, 1983): 7-8.

Reagan had long coattails in the election as well, as evidence by the change in Congress:[21]

	Democrats	Republicans
SENATE Pre 1980 Election	59	41
SENATE Post 1980 Election	48	52
HOUSE Pre 1980 Election	275	160
HOUSE Post 1980 Election	242	193

Reagan campaigned on a platform of removing government control from the business sector and allowing prosperity to spread via the free market. One of Reagan's primary goals was to restructure the U.S. economy around the private marketplace.[22] Advancement in technology played a major role in Reagan economic policy. Budget requests for federal funding of basic research were well above the rate of inflation for the first three years of the Reagan presidency.[23] Reagan also freed the research community to select its own projects in cooperation with private industry and the demands of the market place.[24] Reagan's philosophy was to reduce federal support for science in favor of private money motivated by profitability. Under Reagan economic policy, federal money was to be channeled to areas that would help make private industry more competitive in the global marketplace. Reagan's science advisor, George Keyworth, made clear that science money was not an entitlement.[25]

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[21] *The Pursuit of the Presidency 1980* , ed. Richard Harwood (New York: G.P. Putnam's Sons, 1980), 356-357.

[22] *Looking Back on the Reagan Presidency* , ed. Larry Berman (Baltimore: The Johns Hopkins University Press, 1990), 124-125.

[23] David Dickson, *The New Politics of Science* (New York: Pantheon Books, 1984), 14.

[24] Ibid., 39.

[25] Ibid., 16.

It would be given where it could help foster United States leadership in the international marketplace. Private sector needs and profit would dictate the application of results.

The mandates of Reagan Economic policy and the incentives of the Bayh-Dole Act combined to shift the academic science community focus from pure knowledge to the bottom line. Reagan policy moved academics and industry closer together. Private funding of university research rose 93 percent from 1980 to 1984. Federal funding increased 31 percent but shifted largely toward defense.[26] By 1990, University held patents had increased by over ten times their 1980 number, from 150 to 1600.[27] Biotechnology professors were in such demand that nearly all of them held consulting contracts with private firms. In the fledgling industry with few marketable products, one quality of interest to investors was the expertise of its scientists and its ability to aggressively pursue patents.[28] This new philosophy had a chilling effect on the academic spirit of independence and sharing of information. Universities had to meet private corporate needs in order to obtain funding. This changed the fundamental role of the university from pure knowledge to practical research and created a conflict with notions of free exchange of information. This greatly increased secrecy and greatly reduced peer review. As a result of these ties, scientists doing basic research were hesitant to publish or even discuss their work with peers.[29] This ran counter to the traditional norms of publication and dedication of results to public use. While patent procedures ultimately resulted in detailed public disclosure, the timing was usually far behind normal

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[26] Rebecca S. Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," *The Yale Law Journal,* vol. 97, no. 2 (December 1987): 178, n 2.

[27] Sally Smith Hughes, "Making Dollars out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology 1974-1980," *Isis*, vol. 92, no. 3 (September 2001): 570.

[28] Ibid., 572.

[29] Schmeck, "Justices; Ruling Recognizes Gains In the Manipulation of Life Forms," 16 (D).

academic publication. The incentive for recognition was replaced by the mandate of secrecy until something patentable could be produced. Thus, the ability to build on prior research was delayed by years.[30]

In 1983, President Reagan significantly extended the reach of the Bayh-Dole Act by directing the heads of executive departments and agencies to extend the more generous title provisions given to small business and nonprofits to all government contractors, including large businesses, so that they too could own patents on inventions made possible through government-funded research.[31]

[30] Eisenberg, "Proprietary Rights and the Norms of Science in Biotechnology Research," 214-216.

[31] Rebecca S. Eisenberg, "Public Research and Private Development," 1665.

CHAPTER 6. SUMMARY AND DISCUSSION

Biotechnology evolved in an era when the United States was struggling to find its economic place in a technological world. The new science raised many questions but the timing was ideal for a resolution that focused on economic potential. The country was coming off of forty years of Democratic dominance in all levels of government. Lyndon Johnson had tried to build his great society while fighting a war in Viet Nam. The Warren Court had carved out a vast new understanding of the rights of individuals and the power of the Supreme Court to pursue an ideological agenda. The tide began to turn in the late 1960s when the American middle class began to send a message with its votes that perhaps the better focus of individual rights was empowerment of the businessperson and private industry. In the decade of the 1970s this ideal became an urgent need as the United States was threatened with losing its place in the world market for high technology.

This new science faced a major roadblock to commercial development in the form of the patent laws and the attitude of the United States Patent and Trademark Office toward patentability of living material. The patent laws, while not as friendly toward genetics as machines, nevertheless embodied a fundamentally economic philosophy: profit in exchange for ideas. This issue was placed before a pragmatic and conservative court that valued economic practicality and efficiency. Both the patent law and the philosophy of the court that interpreted it were geared toward an outcome focused on maximizing the commercial potential of biotechnology. At the same time, Congress was moving to maximize the economic potential of information owned or controlled by the government by giving inventors a much greater stake in their work. Its actions further enhanced the economic potential of biotechnology.

On the other hand, these actions wedded universities and industries together in a way that changed the basic protocols of academic research. Decisions on the subject and type of research became focused on what was practical and commercially viable. This was necessary in order to obtain funding. The research was done under a veil of secrecy so as to protect the commercial rights in the results. The potential benefits of theoretical research and free sharing of information were lost in the demand for practical bang from government bucks. Also lost were answers to the real but unprofitable needs of smaller and poorer segments of society that could not offer the marketplace profits demanded by the costly research.

In addition, the manner in which the Supreme Court and Congress set these changes in motion did not provide or leave room for any thoughtful reflection on the meaning and value of life in American society. The Burger Court did not take up the challenge (as the Warren Court may well have), and Congress also declined. This is not to suggest that the actions of Congress or the decision of the Supreme Court were either sound or unsound, or that the commercial explosion they fostered was good or bad. The point made is that neither the Court nor Congress seized the opportunity to prod the larger public into reflection and debate over its values. The Court offered no food for thought, no value statement, no substantive rationale, and no argument starters–nothing to stimulate a process of comment and reflection. *Chakrabarty* demanded a value statement. The public needed to wrestle with this issue and come to some conclusions. Commentators and philosophers needed to urge them along. The technical and sterile nature of the ruling preempted this exercise on any large scale. Science charged forward before the public knew what had hit it. As a result, issues that should have been anguished over were simply accepted as the new status quo.

Writing for the *New York Times* the week after the *Chakrabarty* decision, Harold Morowitz, professor of molecular biophysics and biochemistry at Yale, bemoaned the casual manner in which the Court had acted on an issue of such gravity. He believed that the nation as a whole would have been much better off considering the deep philosophical implications of what the Court had done. The Court, in his opinion, had brushed aside thousands of years of awe and respect for life that dated to pre-biblical times. He believed that the Court had not made a narrow decision on patent law. Rather, it had altered the view of humanity and done so in a way that cut off a grand philosophical debate by making it the law of the land that living material was for sale.[1] As a result, the ethical and philosophical debate was muted and did not evolve along with the technology. Twenty-seven years later, we do not know what we think about it or even how to think about it. We have simply stood by and allowed it to happen.

Clearly, this cannot all be dumped in the lap of the Burger Court or Congress, but equally clear is the fact that this Court and this Congress passed on a unique and timely opportunity to take the issue to the streets. The debate went on as an academic and theological exercise, but it held no candle to the comparative light speed of science.

Under no circumstances should this commentary be viewed as condemnation of biotechnology or what it has achieved to date. It could very well be that *Chakrabarty* was the best possible result. It could well be that this technology needed an overnight validation lest the nation let the opportunity pass while it struggled for years in gridlock. It could ultimately be that biotechnology will turn out to be a benevolent master, and the good we have gained

[1] Harold J. Morowitz, "Reducing Life to Physics," *The New York Times,* 23 June 1980, 23 (A).

and will continue to gain will make us better. If such turns out to be the case however, the positive result will have been purely fortuitous.

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