Abstract


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AGRICULTURAL BIOTECHNOLOGY: UNITED STATES CASE LAW

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I. Introduction

Intellectual property law in the United States has been an ever-emerging field when it comes to patent protection for living matter, such as plants, animals and micro-organisms. Historically, the federal government denied patent protection for living matter.1 Today, one seeking federal statutory patent protection for living matter may have up to three alternatives: The Plant Patent Act of 1930,2 Plant Variety Protection Act of 19703 or Patent Act of 1952.4

A select line of significant U.S. Supreme Court cases accurately presents how the United States arrived at its current policy regarding the patentability of living matter. This e-brief traces this historical development through Supreme Court decisions and interpretations of U.S. federal law.5

1 See Ex parte Latimer, 1889 Dec. Com. Pat. 123 (finding plants are products of nature and therefore not subject to patent protection).
5 This e-brief discusses the U.S. policy regarding the patentability of living matter. It does not discuss patent infringement.
II.  *Graham v. John Deere Company of Kansas City*

When tracing U.S. intellectual property law, a reasonable place to start is at its origin. In *Graham v. John Deere Company of Kansas City*, the Supreme Court summarized the purpose, source and foundation of intellectual property law in the United States.

In *Graham*, the Court referred to Thomas Jefferson as the “first administrator of our patent system.” Jefferson despised monopolies, but believed a limited monopoly, provided through patents, may prove beneficial to society by encouraging ingenuity. Thus, a patent monopoly was designed to reward and bring forth new knowledge. Jefferson believed, however, that limited monopolies were not to be freely given. The Court found that Jefferson did not believe in granting patents unless the invention furthered human knowledge, was new and useful, and was not just a small, frivolous or obvious improvement.

The primary source of power for granting patents rests in the Constitution, which grants Congress broad power to legislate to “promote the Progress of Science and the useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” In *Graham*, the Court stated that within the scope of the Constitution, “Congress may set out conditions and tests for patentability.” From this authority, Congress has established conditions for patentability. The first standards were outlined in the Patent Act of 1790, passed during the second session of the First Congress. Shortly thereafter,

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7 *Id.* at 7.
8 *Id.* at 8.
9 *Id.* at 8-9.
10 *Id.* at 9.
11 *Id.*
12 *Id.* at 5; U.S. CONST., Art. I, § 8, cl. 8.
14 *Id.* at 6-7.
Thomas Jefferson expanded upon the Act, and it was recodified as the 1793 Patent Act.\textsuperscript{15} This Act established the original requirements for patentability of “novelty,” which means newness in its conception, and “utility,” which simply means usefulness.\textsuperscript{16} Since then, Jefferson’s conditions have remained, despite the approximate 50 amendments, revisions or codifications.\textsuperscript{17} In 1952, Congress added a condition of “non-obviousness,” which requires the invention not be obvious at the time to a person skilled in the art.\textsuperscript{18}

\section*{III. Funk Brothers Seed Company v. Kalo Inoculant Company}

Early decisions of the Court regarding the patentability of living matter involved discussion of a foundational premise: Discoveries in nature are not patentable, only inventions. In \textit{Funk Brothers Seed Company v. Kalo Inoculant Company},\textsuperscript{19} the Court focused on the theory that the discovery of a previously unknown phenomenon in nature was not a proper subject matter for a patent. In \textit{Funk Brothers}, Kalo Inoculant Company (“Kalo”) held a patent on a product that contained a mixed variety of different species of Rhizobia bacteria, which was capable of inoculating seeds of leguminous plants that belonged to several different cross-inoculation groups.\textsuperscript{20} Kalo brought a patent infringement suit against Funk Brothers Seed

\textsuperscript{15} \textit{Id.} at 7.
\textsuperscript{17} \textit{Graham}, 383 U.S. at 10.
\textsuperscript{19} Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).
\textsuperscript{20} \textit{Id.} at 127-30. Rhizobium infects the roots of leguminous plants, causing them to form nodules so they are able to take nitrogen from the air and fix it in the plant for conversion to organic nitrogenous compounds. Rhizobium includes at least six different species, and not one species will infect the roots of all leguminous plants, but each species will infect a certain group of leguminous plants. The method of packaging Rhizobium bacteria so it may be used in the inoculation of leguminous plant seeds was well known. However, Kalo discovered that there are strains of each species of root-nodule bacteria which can be used in mixed cultures. Thus, he provided a product capable of inoculating seeds of several different plants. Prior to the invention, farmers would have to buy separate strains of Rhizobium for each crop.
Company ("Funk Brothers"), wherein Funk Brothers filed a counterclaim asking for a declaratory judgment that the patent was invalid.\(^\text{21}\)

The Court had to determine whether the mixed bacteria \textit{product} was patentable. The Court ruled the product a handiwork of nature and therefore not patentable.\(^\text{22}\) The court stated that Bond, who created the bacteria mixture, did not create the characteristics in the bacteria; instead, what he did was discover the strains and discover that they could be combined into one particularly useful product.\(^\text{23}\) The Court said the qualities of the bacteria strains were the work of nature, and combining the species produced no new bacteria or change in the bacteria. Each species had the same effect as before they were mixed. To be patentable, a product must satisfy the requirement of invention.\(^\text{24}\) "For 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."\(^\text{25}\)

\textbf{IV. \textit{Diamond v. Chakrabarty}}

Probably the most influential decision regarding patents and living matter came in 1980, when the Court decided \textit{Diamond v. Chakrabarty}.\(^\text{26}\) In this case, Chakrabarty applied for a general utility patent for his invention of a man-made, genetically engineered bacterium capable of breaking down crude oil, a property possessed by no naturally occurring bacteria. The Patent Office Board of Appeals affirmed a patent examiner’s rejection of the patent application on the

\begin{footnotes}
\item[21] \textit{Id. at} 127.
\item[22] \textit{Id. at} 130-31.
\item[23] \textit{Id. at} 130.
\item[24] \textit{Id. at} 131.
\item[25] \textit{Id. at} 130.
\end{footnotes}
ground that living things were not patentable subject matter under the Patent Act of 1952.\textsuperscript{27} The Court of Customs and Appeals reversed, and the U.S. Supreme Court granted certiorari.\textsuperscript{28}

The Court ruled that a live, human-made micro-organism is patentable subject matter under section 101 of the Patent Act.\textsuperscript{29} Section 101 of the Patent Act provides for the issuance of a patent to anyone who invents or discovers any new and useful\textit{manufacture} or\textit{composition of matter}.\textsuperscript{30} Thus, the issue for the Court was whether a micro-organism constituted a “manufacture” or “composition of matter” within the meaning of the statute. The Court first examined the text of the statute. The Court gave “manufacture” and “composition of matter” their common ordinary meanings,\textsuperscript{31} because they were not otherwise defined within the statute itself. Given these expansive terms, the Court found that Congress plainly contemplated that the patent laws would be given wide scope.\textsuperscript{32}

Additionally, the Court examined the legislative history behind the Act and found it too supported a broad construction of the Act.\textsuperscript{33} When the Patent Act was amended in 1952, Congress replaced the word “art” with “process.” “Process” gave a more expansive meaning.\textsuperscript{34} The Court found the Committee Reports accompanying the 1952 Act to reveal that Congress intended the statutory subject matter to “include anything under the sun that is made by man.”\textsuperscript{35}

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\textsuperscript{27} Prior to\textit{Chakrabarty}, Patent Board decisions represented a general policy that living matter was not within the subject matter of the Patent Act of 1952. See\textit{In re Mereat}, 519 F.2d 1390 (1975); \textit{In re Bergy}, 596 F.2d 952 (1979).
\textsuperscript{28} \textit{Chakrabarty}, 447 U.S. at 303-305.
\textsuperscript{29} \textit{Id.} at 307-18
\textsuperscript{31} The Court found “manufacture” to mean “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery. \textit{Chakrabarty}, 447 U.S. at 308. The Court found “composition of matter” to mean “all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.” \textit{Id.}
\textsuperscript{32} \textit{Id.} at 308.
\textsuperscript{33} \textit{Id.} at 308-310.
\textsuperscript{34} \textit{Id.}
\textsuperscript{35} \textit{Id.} at 309. S. REP. NO. 82-1979 (1952); H.R. REP. NO. 82-1923 (1952).
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Thus, the Court found living matter patentable subject matter under the general Patent Act, so long as the “claim is not to a hitherto unknown natural phenomenon, but to a non-naturally occurring manufacture or composition of matter— a product of human ingenuity having a distinctive name, character and use.”\textsuperscript{36} The Court distinguished the invention in \textit{Chakrabarty} from that in \textit{Funk Brothers}, finding the patentee in Funk Brothers merely discovered handiwork of nature, but the patentee’s discovery in \textit{Chakrabarty} was “not nature’s handiwork, but his own.”\textsuperscript{37} He produced a new bacterium possessing characteristics unfound in nature.

Diamond, the Commissioner of Patents and Trademarks, urged the Court to find that the Patent Act did not include living things. He argued that the enactment of the Plant Patent Act of 1930 (PPA), which afforded patent protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act (PVPA), which authorized protection for certain sexually reproduced plants but excluded bacteria from its protection, evidenced Congress’ intent that living matter was not within the general Patent Act. Diamond believed if Congress intended living matter to be patentable under the general Patent Act, then neither the PPA nor the PVPA would have been necessary.\textsuperscript{38} The Court disagreed. The Court stated that the PPA was enacted for two primary reasons. First, prior to 1930 there was a belief that plants, even those biologically created by man, were products of nature.\textsuperscript{39} Also, prior to 1930, “plants were thought not amenable to the ‘written description’ requirement of the patent law.”\textsuperscript{40} Congress addressed

\textsuperscript{36} \textit{Chakrabarty}, 447 U.S. at 309-310 (quoting from \textit{Hartranft v. Wiegmann}, 121 U.S. 609, 615 (1887)).
\textsuperscript{37} \textit{Chakrabarty}, 447 U.S. at 310.
\textsuperscript{38} \textit{Id}. at 310-311.
\textsuperscript{39} \textit{Id}. at 311-312. The Court cited \textit{Ex parte} Latimer, 1889 Dec.Com.Pat. 123, which set forth the general belief that plants were natural products not subject to patent protection.
these concerns when it enacted the PPA, allowing patents for certain asexually reproduced plants with a relaxed description requirement.41

Similarly, the Court found the enactment of the PVPA did not evidence Congress’ intent that living matter was excluded from protection by the general patent law. The PVPA was enacted in 1970 when it became evident to Congress that true-to-type sexual reproduction was possible. Thus in enacting the PVPA, Congress extended plant patent protection beyond the PPA’s requirement of asexual reproduction, to sexually reproduced plants. Nothing in the history of the PVPA suggested it was enacted because the general Patent Act did not include living things.42

Finally in Chakrabarty, the Court found that Congress’ failure expressly to authorize protection for living matter under the Patent Act was not dispositive. Congress defined patentable subject matter in section 101 of the Act, and the Court took the text of the Act, along with the legislative history to determine that Congress unambiguously drafted the subject matter provision to be broad.43 The wide scope fulfills “the constitutional and statutory goal of promoting ‘the Progress of Science and the useful Arts’… for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad terms.”44 The Court found Congress used such broad language because many inventions, such as the one in Chakrabarty, are often unforeseeable. Congress created the subject matter provision with this in mind.45 A narrow interpretation of “matter” and “composition of matter” within section 101 would frustrate the purpose of the Act,

42 Chakrabarty, 447 U.S. at 313.
43 Id. at 315.
44 Id.
45 Id. at 316.
because an invention clearly envisioned to be within the subject matter of the Act could not meet the standards of novelty and non-obviousness. “A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability.”

V. J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.

The decision in Chakrabarty led to the United States Patent and Trademark Office’s (PTO) issuance of patents for living things pursuant to section 101 of the Patent Act, including hundreds of patents for plants, plant parts and seeds. However, it was more than twenty years after the Chakrabarty decision that the U.S. Supreme Court issued a clear-cut decision that plants were in fact patentable subject matter under the Patent Act, despite their coverage under the plant-specific Acts, the PPA and PVPA.

In J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc., Pioneer Hi-Bred International, Inc. (“Pioneer”) held utility patents issued under the general patent law to protect its inbred and hybrid corn seed products. Pioneer filed a patent infringement suit against J.E.M. Ag Supply, Inc. (“J.E.M.”). J.E.M. filed a counterclaim alleging the patents were invalid because plants were not patentable subject matter within section 101 of the Patent Act. J.E.M. argued that the PPA and PVPA were the exclusive statutory means for protecting plant life. J.E.M. conceded that some living matter was patentable under the Patent Act pursuant to Chakrabarty, but sought to differentiate this case by urging that protection under the Patent Act extended only to living

46 Id.
47 See J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l., Inc., 534 U.S. 124, 127 (2001). See also In re Hibberd, 227 USPQ 443, 444 (1985) (Board of Patent Appeals and Interferences held that plants were within the understood meaning of “manufacture” or “composition of matter” and therefore were within the subject matter of section 101).
49 The plant life at issue in J.E.M. was not created through agricultural biotechnology (i.e. crossing genes in a lab), but through traditional cross-breeding.
matter not protected under another Act, such as micro-organisms. The PPA and PVPA were specifically enacted for plants. J.E.M. therefore maintained the patentable subject matter of each of these Acts (plant life) was carved out of the general Patent Act.

The U.S. Supreme Court held that plants fall within the subject matter of the Patent Act, and neither the PPA nor the PVPA limits this coverage. In J.E.M., the Court first recognized its decision in *Chakrabarty*, where it found the language of section 101 to be extremely broad. The Court noted that *Chakrabarty* held a man-made micro-organism patentable under section 101, because living matter fell within the broad terms of “matter” or “composition of matter.” The Court also noted that its decision rested on its finding that the relevant distinction for patentability was between products of nature and man-made inventions, not between living and non-living things.

In J.E.M., the Court also acknowledged early in its decision the requirements for a utility patent: novelty, utility and non-obviousness, as well as the written description requirement. Thus, for a plant breeder to meet the stringent requirements of the general Patent Act, the breeder

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50 In *Chakrabarty*, Diamond urged the Court to decide that living matter did not fall within the Patent Act because if it did, Diamond argued, Congress would not have enacted the Plant Patent Act or the Plant Variety Protection Act. The Court did not agree and found living matter patentable under the Act. In J.E.M., J.E.M. accepts that living matter falls within the Patent Act (pursuant to the decision in *Chakrabarty*), but argues that the *Chakrabarty* decision encompassed only living matter that did not fall under another act, such as the bacteria strain mixture at issue in *Chakrabarty*. There is no law specifically targeted to the patentability of micro-organisms, but because there are Acts specifically targeted to the patentability of plants and plant life (the PPA and PVPA), J.E.M. believed plant life should not fall within the subject matter of the Patent Act. The Court did not agree. *J.E.M.* at 132.
52 *Id.* at 145.
53 *Id.* at 130.
54 *Id.*, citing *Chakrabarty* at 313.
must show the plant is new, useful and non-obvious. In addition, the breeder must meet the written description requirements and deposit seed.\textsuperscript{56}

Finally, the Court found the two plant-specific statutes did not foreclose utility patent coverage for plants.\textsuperscript{57} The PPA of 1930 provides protection for asexually reproduced plants. However, nothing within the statute or its legislative history indicates it was intended as the exclusive protection for asexually reproduced plants.\textsuperscript{58} As addressed in \textit{Chakrabarty}, the PPA was enacted to provide patent protection for plants because prior to 1930, plants, even those made by man, were considered products of nature, and thus not patentable.\textsuperscript{59} Also, plants were thought not amenable to the written description requirement of the Patent Act. The Court found that this did not mean that prior to 1930 plants could not have fallen within the subject matter of section 101.\textsuperscript{60} “Plants have always had the \textit{potential} to fall within the general subject matter of section 101, which is a dynamic provision designed to encompass new and unforeseen inventions.”\textsuperscript{61} After \textit{Chakrabarty}, we know that living things may be patentable subject matter. Also, due to biological advances we now know that plants may satisfy the stringent description requirement of the Patent Act. “Denying patent protection under section 101 simply because such coverage was thought technologically infeasible in 1930…would be inconsistent with the forward-looking perspective of the utility patent statute.”\textsuperscript{62} Thus, the Court refused to deny

\textsuperscript{56} \textit{J.E.M.} at 131. See CFR §§ 1.801-1.809 (2001) (Section 1.802(a) provides: “Where an invention is, or relies on, a biological material, the disclosure may include reference to a deposit of such biological material”).
\textsuperscript{57} \textit{J.E.M.}, 542 U.S. at 132.
\textsuperscript{58} \textit{Id.} at 132-133.
\textsuperscript{59} \textit{See Ex parte} Latimer, 1889 Dec. Com. Pat. 123 (finding plants are \textit{products of nature} and therefore not subject to patent protection).
\textsuperscript{60} \textit{Id.} at 134.
\textsuperscript{61} \textit{Id.} at 135.
\textsuperscript{62} \textit{Id.}
general utility patent protection to plants because it was unforeseen in 1930 that plants could receive such protection.63

Similarly, the PVPA does not preclude plant coverage under the general Patent Act. The PVPA, passed in 1970, offers patent-like protection to sexually reproduced plants.64 However, the Court ruled that the PVPA is not the exclusive statutory means of protecting sexually reproduced plants.65 Neither the text of the PVPA, nor its legislative history, supports a finding that Congress intended the PVPA to provide exclusive statutory protection.66 Also, the Court found the differences between the PVPA and the Patent Act reconcilable “because the requirements for obtaining a utility patent under section 101 are more stringent than those for obtaining a PVP certificate, and the protections afforded by a utility patent are greater than those afforded by a PVP certificate.”67 Because the Court found the statutes reconcilable, it concluded that the PVPA, which was passed later than the Patent Act, could not alter the Patent Act subject

63 Id.
64 See 7 U.S.C. § 2402(a) (2000), “The breeder of any sexually reproduced or tuber propagated plant variety (other than fungi or bacteria) who has so reproduced the variety . . . .”
65 J.E.M. at 138.
66 Id. at 138 and 140-141.
67 Id. at 142. The Patent Act provides broader protection than the PVPA. First, the PVPA has three exemptions to patent infringement: the Research Exemption, Public Interest Exemption, and Farmer’s Exemption, see 7 U.S.C. §§ 2544, 2404 and 2543 (2000), respectively. Also, utility patent protection exceeds a PVP certificate because a breeder can use a plant that is protected by a PVP certificate to “develop” a new inbred line while he cannot use a plant patented under § 101 for such purpose, see 7 U.S.C. § 2541(a)(4) (2000), infringement includes “use of the variety in producing (as distinguished from developing) a hybrid or different variety therefrom.” Also, it is more difficult to obtain a utility patent because the Patent Act’s requirements are more stringent than the PVPA. Under the Patent Act, the plant must be new, useful and nonobvious, see 35 U.S.C. §§ 101-103 (2000). Under the PVP, the plant variety must be new, distinct, uniform and stable, see 7 U.S.C. § 2402(a) (2000). Thus, there is no requirement for usefulness or nonobviousness for a PVP patent certificate. Also, to obtain a utility patent a breeder must describe the plant with sufficient specificity to enable others to make and use the invention after the patent term expires, see 35 U.S.C. § 112 (2000). The PVPA does not require as strict of a description as the Patent Act. The PVPA requires a “description of the variety setting forth its distinctiveness, uniformity and stability and a description of the genealogy and breeding procedure, when known,” see 7 U.S.C. § 2422(2) (2000).
matter by implication. The Court found the two statutes able to mutually coexist, despite their partial overlap.

VI. Conclusion

The selected U.S. Supreme Court cases discussed above illustrate two primary principles surrounding the current status of patenting living matter in the United States. First, living matter, including plant life, is patentable under the Patent Act. Living matter falls within “matter” or “composition of matter” in section 101 of the Act. Second, one wishing to patent living matter may have up to three alternatives: The Plant Patent Act of 1930, Plant Variety Protection Act of 1970 and Patent Act of 1952. A particular invention may fall within one, none or all of the three Acts. However, because an invention is within the subject matter of a plant-specific Act, it is not precluded from protection under the general Patent Act should it meet the more stringent requirements. Thus, one may select the law that provides greater protection. Each of the three Acts has different requirements for patentability and different scopes of protection. Therefore, the Acts are capable of mutual coexistence.

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68 J.E.M. at 141-142. See also (court cites) Morton v. Mancari, 417 U.S. 535, 550 (1974) (“... [T]he only permissible justification for a repeal by implication is when the earlier and later statutes are irreconcilable”). 69 J.E.M. at 143-144.