

2105 Patentable Subject Matter — Living Subject Matter [R-07.2015]

I. INTRODUCTION

The decision of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980), held that microorganisms produced by genetic engineering are not excluded from patent protection by [35 U.S.C. 101 \(mpep-9015-appx-I.html#d0e302376\)](#). It is clear from *Chakrabarty* and subsequent judicial decisions that the question of whether or not an invention embraces living matter is irrelevant to the issue of patentability. Note, however, that Congress has excluded claims directed to or encompassing a human organism from patentability. See The Leahy-Smith America Invents Act (AIA), Pub. L. 112-29, sec. 33(a), 125 Stat. 284 (September 16, 2011).

II. LIVING SUBJECT MATTER MAY BE PATENTABLE

•

A. Living Subject Matter May Be Directed To A Statutory Category

In *Chakrabarty*, the Supreme Court held that a claim to a genetically engineered bacterium was directed to at least one of the four statutory categories, because the bacterium was a “manufacture” and/or a “composition of matter.”

The Supreme Court made the following points in the *Chakrabarty* opinion:

1. “Guided by these canons of construction, this Court has read the term ‘manufacture’ in [§ 101 \(mpep-9015-appx-I.html#d0e302376\)](#) in accordance with its dictionary definition 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.’”
2. “In choosing such expansive terms as ‘manufacture’ and ‘composition of matter,’ modified by the comprehensive ‘any,’ Congress plainly contemplated that the patent laws would be given wide scope.”
3. “The Act embodied Jefferson’s philosophy that ‘ingenuity should receive a liberal encouragement.’ 5 Writings of Thomas Jefferson, 75-76 Washington ed. 1871). See *Graham v. John Deere Co.*, 383 U.S. 1, 7-10, 148 USPQ459, 462-464 (1966). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word ‘art’ with ‘process,’ but otherwise left Jefferson’s language intact. The Committee Reports accompanying the 1952 act inform us that Congress intended statutory subject matter to ‘include any thing under the sun that is made by man.’ S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H. R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)”
4. “Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent’s microorganism is the result of human ingenuity and research.”

A review of these statements as well as the whole *Chakrabarty* opinion reveals that the Court did not limit its decision to genetically engineered living organisms, and that the Court enunciated a very broad interpretation of “manufacture” and “composition of matter” in [35 U.S.C. 101 \(mpep-9015-appx-I.html#d0e302376\)](#).

Following the reasoning in *Chakrabarty*, the Board of Patent Appeals and Interferences determined that animals are patentable subject matter under [35 U.S.C. 101 \(mpep-9015-appx-I.html#d0e302376\)](#). In *Ex parte Allen*, 2 USPQ2d 1425 (Bd. Pat. App. & Inter. 1987), the Board decided that a polyploid Pacific coast oyster could have been the proper subject of a patent under [35 U.S.C. 101 \(mpep-9015-appx-I.html#d0e302376\)](#) if all the criteria for patentability were satisfied. Shortly after the *Allen* decision, the Commissioner of Patents and Trademarks issued a notice (Animals - Patentability, 1077 O.G. 24, April 21, 1987) that the Patent and Trademark Office would now consider nonnaturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter within the scope of [35 U.S.C. 101 \(mpep-9015-appx-I.html#d0e302376\)](#).

With respect to plant subject matter, the Supreme Court held that patentable subject matter under [35 U.S.C. 101 \(mpep-9015-appx-I.html#d0e302376\)](#) includes newly developed plant breeds, even though plant protection is also available under the Plant Patent Act ([35 U.S.C. 161 \(mpep-9015-appx-I.html#d0e304416\)](#) - [164 \(mpep-9015-appx-I.html#d0e304454\)](#)) and the Plant Variety Protection Act (7 U.S.C. 2321 *et. seq.*). *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int’l, Inc.*, 534 U.S. 124, 143-46, 122 S.Ct. 593, 605-06, 60 USPQ2d 1865, 1874 (2001) (The scope of coverage of [35 U.S.C. 101 \(mpep-9015-appx-I.html#d0e302376\)](#) is not limited by the Plant Patent Act or the Plant Variety Protection Act; each statute can be regarded as effective because of its different requirements and protections). In analyzing the history of the Plant Patent Act of 1930 in *Chakrabarty*, the Court stated: “In enacting the Plant Patent Act, Congress addressed both of these concerns [the concern that plants, even those artificially bred, were products of nature for purposes of the patent law and the concern that plants were thought not amenable to the written description requirements of the patent law]. It explained at length its belief that the work of the plant breeder ‘in aid of nature’ was

patentable invention. S. Rep. No. 315, 71st Cong., 2d Sess., 6-8 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., 7-9 (1930).” See also *Ex parte Hibberd*, 227 USPQ 443 (Bd. Pat. App. & Inter. 1985), wherein the Board held that plant subject matter may be the proper subject of a patent under [35 U.S.C. 101 \(mpep-9015-appx-I.html#d0e302376\)](#) even though such subject matter may be protected under the Plant Patent Act or the Plant Variety Protection Act.

See [MPEP § 2106 \(s2106.html#d0e197244\)](#), subsection I, for a discussion of the categories of statutory subject matter.

B. Living Subject Matter May Be Eligible for Patent Protection

The Supreme Court in *Chakrabarty* held a claim to a genetically engineered bacterium eligible, because the claimed bacterium was not a “product of nature” exception. In so holding, the Court made the following points:

1. “This is not to suggest that [§ 101 \(mpep-9015-appx-I.html#d0e302376\)](#) has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable.”
2. “Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.”
3. “His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter - a product of human ingenuity ‘having a distinctive name, character [and] use.’”
4. After reference to *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948), “Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature’s handiwork, but his own; accordingly it is patentable subject matter under [§ 101 \(mpep-9015-appx-I.html#d0e302376\)](#).”

A review of these statements as well as the whole *Chakrabarty* opinion reveals that “laws of nature, physical phenomena and abstract ideas” are not patentable subject matter. See [MPEP § 2106 \(s2106.html#d0e197244\)](#), subsection II, for a discussion of the judicial exceptions.

A more recent judicial decision from the Federal Circuit indicated that “discoveries that possess ‘markedly different characteristics from any found in nature,’ ... are eligible for patent protection.” *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1336, 110 USPQ2d 1668, 1671 (Fed. Cir. 2014), quoting *Chakrabarty*, 447 U.S. at 310. In *Roslin*, the claimed invention was a live-born clone of a pre-existing, non-embryonic, donor mammal selected from cattle, sheep, pigs, and goats. An embodiment of the claimed invention was the famous Dolly the Sheep, which the court stated was “the first mammal ever cloned from an adult somatic cell.” Despite acknowledging that the method used to create the claimed clones “constituted a breakthrough in scientific discovery”, the court held the claims ineligible because “Dolly herself is an exact genetic replica of another sheep and does not possess ‘markedly different characteristics from any [farm animals] found in nature.’” *Roslin*, 750 F.3d at 1337, 110 USPQ2d at 1671.

Office personnel are to consult the 2014 *Interim Guidance on Patent Subject Matter Eligibility*, 79 Fed. Reg. 74618 (December 16, 2014) and related materials available at www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0 (<http://www.uspto.gov/patent/laws-and-regulations/examination-policy/2014-interim-guidance-subject-matter-eligibility-0>) to determine whether a nature-based product such as living subject matter is eligible for patent protection. See also [MPEP § 2106 \(s2106.html#d0e197244\)](#), subsection II.

III. HUMAN ORGANISMS ARE NONSTATUTORY SUBJECT MATTER

Congress has excluded claims directed to or encompassing a human organism from patentability. The Leahy-Smith America Invents Act (AIA), Public Law 112-29, [sec. 33\(a\) \(mpep-9015-appx-I.html#aiasec33limitonissuance\)](#), 125 Stat. 284, states:

Notwithstanding any other provision of law, no patent may issue on a claim directed to or encompassing a human organism.

The legislative history of the AIA includes the following statement, which sheds light on the meaning of this provision:

[T]he U.S. Patent Office has already issued patents on genes, stems cells, animals with human genes, and a host of non-biologic products used by humans, but it has not issued patents on claims directed to human organisms, including human embryos and fetuses. My amendment would not affect the former, but would simply affirm the latter.

157 Cong. Rec. E1177-04 (testimony of Representative Dave Weldon previously presented in connection with the Consolidated Appropriations Act, 2004, Public Law 108-199, 634, 118 Stat. 3, 101, and later resubmitted with regard to the AIA; see 149 Cong. Rec. E2417-01). Thus, [section 33\(a\) of the AIA \(mpep-9015-appx-I.html#aiasec33limitonissuance\)](#) codifies existing Office policy that human organisms are not patent-eligible subject matter.

If the broadest reasonable interpretation of the claimed invention as a whole encompasses a human organism, then a rejection under [35 U.S.C. 101 \(mpep-9015-appx-I.html#d0e302376\)](#) and [AIA sec. 33\(a\) \(mpep-9015-appx-I.html#aiasec33limitonissuance\)](#) must be made indicating that the claimed invention is directed to a human organism and is therefore nonstatutory subject matter. Form paragraph [7.04.03 \(#fp7.04.03\)](#) should be used; see [MPEP § 706.03\(a\) \(s706.html#d0e66135\)](#). Furthermore, the claimed invention must be examined with regard to all issues pertinent to patentability, and any applicable rejections under [35 U.S.C. 102 \(mpep-9015-appx-I.html#d0e302383\)](#), [103 \(mpep-9015-appx-I.html#d0e302450\)](#), or [112 \(mpep-9015-appx-I.html#d0e302824\)](#) must also be made.

[\[top\] \(#top\)](#)

This page is owned by Patents.

Last Modified: 11/04/2015 11:01:45