

PATENTABILITY OF CLONED EXTINCT ANIMALS

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INTRODUCTION

The rapid development of biotechnology has created significant challenges in many areas of law. In particular, patent law has been directly affected by advances in biotechnology. The Supreme Court's 1980 landmark decision in *Diamond v. Chakrabarty*,¹ holding that a patent could be obtained for a genetically engineered microorganism,² helped spark the biotechnology revolution. While the decision set forth the framework for determining whether an organism is patentable subject matter, it did not resolve all the issues associated with patenting organisms. Rather, it created the opportunity for further legal challenge to continue to arise with advances in biotechnology permitting scientists to manipulate organisms and their genetic code in novel ways.

One such advance is reproductive cloning, the ability to reproduce an organism from somatic (non-reproductive) cells without sexual reproduction. In 1996, Dolly, the sheep, made headlines as the first mammal successfully generated by cloning.³ Since then, numerous other animals have been cloned including mice, goats, mules, horses, and cats as well as endangered species such as the gaur.⁴

The process of cloning is conceptually straightforward.⁵ Briefly, unfertilized eggs are harvested from the species to be cloned or a related species and are enucleated by removal of their natural nuclei by microsurgery.⁶ The enucleated eggs are then placed next to embryonic or somatic cells taken

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¹ 447 U.S. 303 (1980).

² *Id.* at 318.

³ Ian Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 NATURE, Feb. 27, 1997, at 810.

⁴ See, e.g., Robert P. Lanza et al., *Cloning Noah's Ark*, SCI. AM., Nov. 2000, at 84; Joseph P. Martino, *Cloning of Animals and Human Beings* (2004) (unpublished manuscript), <http://www.prolife-technology.org/proceedings/2004/paper/2004-martino.pdf>.

⁵ For a detailed description of cloning, see DESMOND S.T. NICHOLL, AN INTRODUCTION TO GENETIC ENGINEERING 247-58 (2d ed. 2002); Tim Beardsley, *A Clone in Sheep's Clothing*, SCI. AM., Mar. 1997, available at <http://www.sciam.com/article.cfm?articleID=0009B07D-BD40-1C59-B882809EC588ED9F>.

⁶ Beardsley, *supra* note 5.

from the organism to be cloned, or donor.⁷ When treated with electrical pulses, the enucleated eggs and the donor cells fuse together.⁸ After this fusion, the recipient eggs contain the complete genome of the donor organism without the nuclear genome of the recipient animal (which was removed) “just as they would if they had been fertilized by sperm” in normal sexual reproduction.⁹ This process is called nuclear transfer. After nuclear transfer, the eggs are implanted in the womb of a surrogate mother and develop into a fetus genetically identical to the donor.¹⁰ In traditional cloning, the surrogate mother and the enucleated eggs are of the same species as the donor.¹¹ However, cloning of animals of several species has been reported using an interspecies surrogate mother and interspecies enucleated eggs from a species related to the one being cloned.¹²

The use of a surrogate mother and enucleated eggs from a species other than the donor raises a possibility hitherto reserved for science fiction—the cloning of an extinct animal from cells found in remains or otherwise preserved. Although scientists have yet to clone an extinct animal, they have attempted to clone animals such as the woolly mammoth, and efforts to clone several extinct animals, including the Pyrenean ibex, or bucardo, a Spanish mountain goat; the huia, a bird that once lived in New Zealand; the Indian cheetah; and the Tasmanian tiger, are currently under way.¹³ However, these attempts have met technological hurdles, and, as of now, no extinct animal has successfully been regenerated by cloning. Indeed, several recent attempts to clone the Tasmanian tiger and the bucardo have failed.¹⁴

To clone an animal using current technology, the nuclear DNA encoding the animal’s genome must be in nearly perfect condition, meaning that it is nearly free of degradation.¹⁵ Thus, to clone an extinct animal, the nuclear genomic DNA isolated from remains or otherwise preserved samples must be intact and undegraded. DNA is fragile and unstable, especially

⁷ *Id.*; Wilmut et al., *supra* note 3, at 813.

⁸ *See* Wilmut et al., *supra* note 3, at 813.

⁹ Beardsley, *supra* note 5. Reproductive cells, eggs and sperm, contain one-half of the genetic material that is contained in somatic cells (all other cells in an organism). Upon fertilization, the resulting zygote contains the somatic amount of genetic material. *See* BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 1128-30 (4th ed. 2002).

¹⁰ *See* Beardsley, *supra* note 5.

¹¹ *See, e.g.*, Wilmut et al., *supra* note 3, at 812-13.

¹² Lanza et al., *supra* note 4, at 86 (discussing cloning of a gaur (an endangered ox-like animal), African wildcat, Indian desert cat, red deer, mouflon sheep, and bongo antelope using an interspecies surrogate mother and interspecies enucleated eggs); *see also* Patrick Dixon, *Cow to Give Birth to a Bison*, <http://www.globalchange.com/cowbison.htm> (last visited Oct. 11, 2007).

¹³ Recently Extinct Animals, Cloning Extinct Animals, <http://extinctanimals.petermaas.nl> (follow “Reviving Animals” hyperlink; then follow “Cloning” hyperlink).

¹⁴ *Id.*

¹⁵ *See id.*

after an organism dies as the natural machinery to preserve it ceases to function.¹⁶ No meaningful genetic information can be preserved in most geological environments much longer than 10,000 years and almost certainly no longer than 100,000 years.¹⁷ Thus, cloning of dinosaurs, which have been extinct for millions of years, is technically impossible.¹⁸ Even the preservation of DNA for 10,000 to 100,000 years is only possible in favorable conditions.¹⁹ Most recent specimens of animal remains contain DNA in very small amounts that is severely damaged and often contaminated by microbial or fungal DNA.²⁰ Such DNA is unsuitable for cloning. The best preserved samples of DNA from archaeological samples have been recovered while frozen in permafrost.²¹ However, while well-preserved carcasses of woolly mammoths, which became extinct around 3,700 years ago, have been uncovered in permafrost, the DNA recovered from such remains is extremely fragmented and present in very small quantities and is unsuitable for cloning.²²

The prospects for cloning more-recently extinct species are much more promising as remains are better-preserved and some are artificially preserved by man.²³ However, isolating intact DNA specimens from recently-extinct animals has proven difficult. The failure to obtain undegraded DNA samples led to the suspension of a recent attempt to clone the Tasmanian tiger, which became extinct in 1936, although researchers are currently investigating promising newly found samples.²⁴ Likewise, all known DNA samples from remains of the dodo, which became extinct near the end of the seventeenth century, are highly degraded.²⁵

¹⁶ See Theresa Mecklenborg, Cloning Extinct Species, http://tiger_spot.mapache.org/Biology/extinct.html (last visited Oct. 11, 2007).

¹⁷ See Jeffrey Yule, *Cloning the Extinct: Restoration as Ecological Prostheses*, 1.2 COMMON GROUND 6, 6 (2002). The oldest confirmed samples of DNA were isolated from the remains of Neanderthals and are believed to be 30,000 to 50,000 years old. John Noble Wilford, *In Startling Advance, Study Identifies Dinosaur Protein*, N.Y. TIMES, Apr. 13, 2007, at A11.

¹⁸ Recently, scientists have isolated dinosaur proteins from remains that are approximately sixty-eight million years old. Wilford, *supra* note 17. This development has no impact on the feasibility of dinosaur cloning because, DNA, rather than protein, is required for cloning. DNA is far more degradable than protein, *see id.*, and as discussed in the text, scientists have not successfully isolated dinosaur DNA and believe isolation of undegraded dinosaur DNA suitable for cloning to be impossible.

¹⁹ Mecklenborg, *supra* note 16.

²⁰ *Id.*

²¹ *Id.*

²² See Yule, *supra* note 17, at 6; Katharine Mieszkowski, *A Mammoth Undertaking*, SALON, Jan. 3, 2002, <http://dir.salon.com/story/tech/feature/2002/01/03/mammoth/index.html>; Jonathan Sarfati, *Mammoth—Riddle of the Ice Age*, CREATION, Mar. 2000, at 10; Woolly Mammoths—Mammuthus Primigenius, <http://www.crystalinks.com/woollymammoth.html> (last visited Oct. 11, 2007).

²³ See Yule, *supra* note 17, at 6.

²⁴ See Recently Extinct Animals, Cloning Extinct Animals, *supra* note 13.

²⁵ See Recently Extinct Animals, Raphus Cucullatus, <http://extinctanimals.petermaas.nl> (follow "Most Recent Extinctions" hyperlink; then follow "Dodo" hyperlink) (last visited Oct. 11, 2007).

Despite these difficulties, real progress has been made towards the cloning of extinct animals. Undegraded DNA samples of extinct animals that can be used in cloning have been isolated. Before the bucardo became extinct in 2000, scientists took samples of its cells and artificially preserved them in a living state.²⁶ These samples are of sufficient quality for cloning, and scientists were able to reconstruct bucardo embryos and implant them into mountain goat and mountain goat-domesticated goat hybrid surrogate mothers.²⁷ However, none of the cloned bucardo embryos have completed gestation and developed into a cloned animal.²⁸ Despite the failure of attempts to clone the bucardo, efforts to clone the bucardo are currently ongoing and researchers are optimistic that they will be able to successfully clone this extinct animal.²⁹

The difficulty in obtaining intact DNA suitable for cloning of extinct animals coupled with the failure of scientists to clone the bucardo even when intact DNA was available suggest that biotechnology's current potential for restoring extinct species by cloning is modest at best. Nonetheless, the capacity to do so might be expanded in the future as innovation in cloning technology might permit cloning of animals from fragmented or degraded DNA or a microenvironment that is well suited to preserving fossilized DNA might be discovered.³⁰ As animals come close to extinction, scientists may artificially preserve living cells to use for cloning if the animal later becomes extinct.³¹ Thus, even without significant advances in cloning

²⁶ See, e.g., Edward R. Winstead, *In South Africa, the Quagga Project Breeds Success*, GENOME NEWS NETWORK, Oct. 20, 2000, http://www.genomenewsnetwork.org/articles/10_00/Quagga_project.shtml.

²⁷ See Recently Extinct Animals, Cloning Extinct Animals, *supra* note 13; Recently Extinct Animals, Capra Pyrenaica Pyrenaica, <http://extinctanimals.petermaas.nl> (follow "Most Recent Extinctions" hyperlink; then follow "Pyrenean Ibex" hyperlink) (last visited Oct. 11, 2007).

²⁸ See Recently Extinct Animals, Cloning Extinct Animals, *supra* note 13; Recently Extinct Animals, Capra Pyrenaica Pyrenaica, *supra* note 27.

²⁹ See Recently Extinct Animals, Cloning Extinct Animals, *supra* note 13; Recently Extinct Animals, Capra Pyrenaica Pyrenaica, *supra* note 27.

³⁰ *Id.* These possible advances are not completely far-fetched. Scientists have revived bacterial spores containing intact DNA that were twenty-five to forty million years old from amber. See Raúl J. Cano & Monica K. Borucki, *Revival and Identification of Bacterial Spores in 25- to 40-Million-Year-Old Dominican Amber*, 268 *SCI.*, May 19, 1995, at 1060. Furthermore, it is not inconceivable that cloning technology may advance to the point where fragmented genomes might be reassembled, although reassembling the millions of tiny fragments correctly is impossible by today's technology.

³¹ Scientists have isolated DNA from the baiji, a near-extinct type of dolphin found only in the Yangtze River in China, with the hope that they may be used to regenerate the animal were it to actually become extinct. Recently Extinct Animals, Lipotes Vexillifer, <http://extinctanimals.petermaas.nl> (follow "Most Recent Extinctions" hyperlink; then follow "Yangtze River Dolphin" hyperlink) (last visited Oct. 3, 2007). Another difficulty in cloning long-extinct animals is that there are no living cells preserved. Thus even if intact DNA is isolated, genomes would have to be introduced into enucleated eggs in a different manner than the nuclear fusion currently used, such as artificial amplification by polymerase chain reaction and microinjection. However, living cells were preserved and frozen in the case of the

technology, it is possible that an attempt to clone the bucardo might succeed or intact DNA samples of another type of animal may be uncovered. When an extinct animal is finally cloned, the federal courts will have to address the question of whether the person who cloned the animal is entitled to a patent for it.

While *Chakrabarty* provides for the patentability of nonnatural living things created by man, it reaffirms a long-standing principle in patent law that the products of nature, such as an animal discovered in the wild, are not patentable subject matter.³² *Chakrabarty* is not dispositive in the cloned extinct animal context because a cloned extinct animal shares attributes of both nonnatural manmade living things and naturally-occurring animals. A cloned extinct animal is created by man inasmuch as it would not exist save for the intervention of man. On the other hand, unlike the genetically engineered microorganisms in *Chakrabarty* where the inventor inserted additional genes into a bacterium, a cloned extinct animal has the same genome as an animal that formerly existed in nature and in this way might be considered a product of nature. Even if a court were to consider a cloned extinct animal patentable subject matter, the animal's prior existence in nature raises the issue of whether a cloned extinct animal meets the patent law's requirements of novelty and nonobviousness.³³

This Article explores the patentability of cloned extinct animals. Specifically, it confronts the patentability of product claims for the cloned or regenerated extinct animal itself. While other types of claims related to cloned extinct animals, such as a process patent for a process of cloning an extinct animal, may be sought, the patentability of such claims does not raise the complex issues that the patentability of the cloned extinct animal itself does. Claiming the animal itself implicates the issue of whether a cloned extinct animal that previously existed in nature is patentable subject matter or an unpatentable product of nature and whether such an animal is novel or nonobvious.³⁴ A novel and nonobvious process for cloning an extinct animal would certainly be patentable, regardless of whether the animal itself were patentable subject matter or not.³⁵ Part I traces the evolution of

bucardo. See *supra* note 26 and accompanying text. These cells could be used in traditional cloning methods.

³² *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); see also *infra* Part I.

³³ See 35 U.S.C. §§ 102-03 (2000) (providing the conditions for patentability).

³⁴ See Darren M. Jiron, *Patentability of Extinct Organisms Regenerated through Cloning*, 6 VA. J.L. & TECH. 9, ¶¶ 19-20 (2001), <http://www.vjolt.net/vol6/issue2/v6i2-a09-Jiron.html>. Likewise, an inventor might seek a product-by-process claim for an extinct animal produced by cloning. For a product-by-process claim, if the product is not novel or is obvious given the prior art, the claim is not patentable. See *In re Thorpe*, 777 F.2d 695, 697 (Fed. Cir. 1995). Thus, the viability of this claim turns on the analyses of the novelty and nonobviousness of a cloned extinct animal. See *infra* Part II.B-C.

³⁵ Indeed, the PTO has issued a patent claiming a method for cloning nonhuman mammals which would cover cloning an extinct animal. See U.S. Pat. No. 5,945,577 (filed Jan. 10, 1997) (issued Aug. 31, 1999). However, as discussed above, the cloning of an extinct animal poses technological challenges

the treatment of the patentability of living things by the courts and the Patent and Trademark Office (“PTO”). Part II examines the patentability of cloned extinct animals in light of the relevant statutes and case law. This article concludes that the statutory requirements of patentability of statutory subject matter, novelty, nonobviousness, and utility may be met in the cloned extinct animal context and also, patenting these animals is consistent with the goals of the patent system. Thus, these requirements do not foreclose patents for cloned extinct animals. In contrast, these requirements, in particular that of patentable subject matter, erect barriers to patentability of clones of near-extinct animals that are present in nature, even if the animal would have become extinct but for human action to clone it.

I. PATENTING ANIMALS AND OTHER LIVING THINGS

35 U.S.C. § 101 defines the scope of patentable subject matter.³⁶ To be patented, an invention must fall within one of the statutory categories of process, machine, manufacture, or composition of matter. Congress deliberately crafted these categories to be broad, and they seldom pose an obstacle to an inventor’s endeavors to patent his invention.³⁷ However, the Supreme Court has determined that certain categories of invention or discovery exceed the statutory boundaries of patentable subject matters including laws of nature, products of nature, physical or natural phenomena, abstract ideas, and unapplied mathematical algorithms.³⁸ In 1873, the PTO issued the first American patent for a living thing to Louis Pasteur for purified yeast as an article of manufacture under § 101.³⁹ However, prior to *Chakrabarty* in 1980, patents for living organisms independent of their use, such as the one issued to Pasteur, were very much an anomaly.⁴⁰ The PTO and the courts

not present in ordinary cloning that have hitherto impeded successful completion of the endeavor, such as DNA degradation and that an interspecies surrogate mother necessarily must be used because females of the extinct species cease to exist. As current cloning processes are unable to successfully overcome these hurdles and bring about the cloning of an extinct animal, a new process that does so is certainly novel and nonobvious for the purposes of the patent laws.

³⁶ 35 U.S.C. § 101 (2000) (“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore . . .”).

³⁷ See ALAN L. DURHAM, PATENT LAW ESSENTIALS 23 (1999); see also S. REP. NO. 82-1979, at 5 (1952) (stating that patents are available for “anything under the sun that is made by man”); H.R. REP. NO. 82-1923, at 6 (1952) (same).

³⁸ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980) (collecting cases); JANICE M. MUELLER, AN INTRODUCTION TO PATENT LAW 192 (2003).

³⁹ U.S. Patent No. 141,072 (issued July 22, 1873).

⁴⁰ David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exception for Agriculture*, 27 CASE W. RES. J. INT’L L. 83, 95 (1995). By 1937, a leading commentator opined that Pasteur’s patent would probably be refused because it arguably did not cover patentable subject matter. P.J. Federico, *Louis Pasteur’s*

almost invariably rejected patents that pertained to living organisms regardless of whether the organism is found in nature in the form claimed or not.⁴¹ These rejections were based on one of two grounds: (1) considering living things “products of nature” and thus excluded from the realm of patentable subject matter under the product of nature doctrine; and (2) rejecting the idea that living things were patentable subject matter under § 101 because Congress provided for plant patents separately in the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act, thereby indicating that plants and other living things were not covered by § 101 and that Congress intended for plants covered by these statutes to be the only living things afforded intellectual property protection.⁴²

This Part surveys the evolution of the treatment of the patentability of living things by courts and the PTO. First, this Part discusses the product of nature doctrine and its use to hold patents for living things invalid. Second, this Part describes the Supreme Court’s landmark decision in *Chakrabarty* holding that a living microorganism that does not occur in nature is patentable subject matter. Finally, this Part traces the extension of the holding in *Chakrabarty* to animals and plants.

A. *The Product of Nature Doctrine and Its Application to Living Things*

Simply stated, the product of nature doctrine restricts patentable inventions to those devised by humans and forecloses patentability of products of nature. The classic statement of the doctrine was made by the Commissioner of Patents in 1889 in rejecting a patent application for a plant fiber in *Ex parte Latimer*.⁴³ The Supreme Court has embraced the doctrine on nu-

Patents, 86 SCI., Oct. 8, 1937, at 327. The only other examples of patents for living things independent of their use issued by the PTO prior to 1980 identified in the case law and literature are two patents claiming living microorganisms issued in 1967 and 1969. *Chakrabarty*, 447 U.S. at 314 n.9. In 1977, the Court of Customs and Patent Appeals reversed the PTO’s rejection of a patent application for a biologically pure bacterial strain holding it to be a “manufacture” or “composition of matter” within § 101. *In re Bergy*, 563 F.2d 1031, 1036, 1038 (C.C.P.A. 1977), *vacated sub nom. Parker v. Bergy*, 438 U.S. 902 (1978) (mem.), *aff’d on remand sub nom. In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), *aff’d sub nom. Chakrabarty*, 447 U.S. 303 (1980). However, while the PTO and lower courts refused to permit patents for living organisms themselves, they repeatedly permitted patents for compositions containing living things and processes utilizing them. *E.g.*, *Milwaukee v. Activated Sludge, Inc.*, 69 F.2d 577, 587 (7th Cir. 1934) (recognizing a patent for a septic tank utilizing bacteria); *Union Solvents Corp. v. Guar. Trust Co.*, 61 F.2d 1041, 1041 (3d Cir. 1932) (upholding a patent for a bacterial process used in the synthesis of alcohol); *Cameron Septic Tank Co. v. Saratoga Springs*, 159 F. 453, 462 (2d Cir. 1908) (holding a patent claiming a septic tank using anaerobic bacteria valid).

⁴¹ Scalise & Nugent, *supra* note 40, at 95.

⁴² *Id.*

⁴³ 1889 Dec. Comm’r Pat. 123, 125-27.

merous occasions.⁴⁴ A patent rewards an inventor for the fruits of an inventive step, not for the discovery of something that already existed in nature.⁴⁵ Thus, an invention based on a product of nature is not patentable subject matter absent some degree of refinement or improvement by the patentee “resulting in characteristics different from those given by nature.”⁴⁶ The application of labor to a natural article is not sufficient to render it patentable.⁴⁷ For an invention derived from nature to be patentable, the inventor’s work must result in a transformation giving rise to a “new and different article . . . having a distinctive name, character, or use.”⁴⁸ Thus, cleaning and ginning cotton does not make it patentable.⁴⁹ Therefore, “even if [the patentee] was the first to uncover [a natural thing] and bring it into view, he cannot have a patent for it because a patent cannot be awarded for a discovery or for a product of nature”⁵⁰ Thus, under the product of nature doctrine, “a new mineral discovered in the earth or a new plant [or animal] found in the wild is not patentable subject matter.”⁵¹

The product of nature doctrine has become a mainstay of American patent law as neither the Supreme Court nor the Federal Circuit has thus far questioned its validity or propriety. Despite the doctrine’s entrenched nature, the Supreme Court and lower federal courts have provided little insight as to the rationale and policy considerations underlying the doctrine. Most courts applying the doctrine, including the Supreme Court, simply restate and apply it in a conclusory manner without elaboration.⁵² However, the Supreme Court provided some explanation for its application of the product of nature doctrine in *Funk Bros. Seed Co. v. Kalo Inoculant Co.*⁵³ where it advanced a somewhat epistemological justification for the doc-

⁴⁴ See, e.g., *Chakrabarty*, 447 U.S. at 309 (“[A] new mineral . . . or new plant found in the wild is not patentable subject matter.”); *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948) (“[T]he discovery of some of the handiwork of nature . . . is not patentable.”); *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931) (reasoning that a natural product is not a manufacture and thus is not patentable); see also *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 642 (3d Cir. 1928) (“[A] patent cannot be awarded for a discovery or for a product of nature”).

⁴⁵ See, e.g., James P. Daniel, Note, *Of Mice and ‘Manimal’: The Patent & Trademark Office’s Latest Stance Against Patent Protection for Human-Based Inventions*, 7 J. INTELL. PROP. L. 99, 105 (1999); Scalise & Nugent, *supra* note 40, at 90.

⁴⁶ *De Forest*, 28 F.2d at 642; see, e.g., Daniel, *supra* note 45, at 106.

⁴⁷ See *Am. Fruit*, 283 U.S. at 12-13.

⁴⁸ *Id.* at 13 (internal quotation omitted).

⁴⁹ *Id.* at 12.

⁵⁰ *De Forest*, 28 F.2d at 642.

⁵¹ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980). Under the product of nature doctrine, a rare plant or animal with medicinal properties discovered in nature would not be patentable. See *id.*

⁵² E.g., *id.*; *De Forest*, 28 F.2d at 642.

⁵³ 333 U.S. 127 (1948).

trine.⁵⁴ The Court reasoned that products of nature, such as naturally-occurring living things, are “manifestations of laws of nature” and as such are “free to all men and reserved exclusively to none.”⁵⁵ The Court reaffirmed this reasoning in *Chakrabarty*.⁵⁶ Underlying this argument is a moral or religious imperative whereby products of nature should be unpatentable as “there is something unidentifiably special about nature that it should merit special protection.”⁵⁷ John Locke identifies this special character of products of nature as stemming from the fact that they are “produced by the spontaneous hand of nature” as opposed to constructed by humans.⁵⁸ Thus, Locke concluded that products of nature, such as plants and animals, “belonged to mankind in common” as “nobody has originally a private dominion exclusive of the rest of mankind in . . . them.”⁵⁹ This reasoning is readily adapted to the patent context and is consistent with the policies underlying the patent system. Also, this argument is equally applicable to discoveries of new articles in nature and attempts at artificial synthesis of articles already known to exist in nature, as a patent in either situation would do violence to the special status of naturally-occurring items that renders them free for all mankind. Although a product of nature, such as a plant or animal, might be discovered by man, neither the discoverer nor any other human can be responsible for engendering it. One of the main goals of the patent system, the encouragement of creation of new innovation by humans, is not advanced by extending the patent monopoly to products of nature.⁶⁰ Thus, the policy underlying the doctrine seems to resonate with the fact that a product of nature does not satisfy the novelty requirement of the Patent Act because of the inherent truth that something cannot be new if it existed in nature before being discovered by the patentee.⁶¹

Furthermore, although the courts have never explicitly endorsed them, several commentators have advanced constitutional justifications for the product of nature doctrine.⁶² In conferring the power to institute a patent system on Congress, the Intellectual Property Clause of the Constitution gives Congress the power to “secur[e] to [i]nventors the exclusive right to

⁵⁴ *Id.* at 130; see also Jared Earl Grusd, *Internet Business Methods: What Role Does and Should Patent Law Play*, 4 VA. J.L. & TECH. 9, ¶ 12 n.24 (1999), <http://www.vjolt.net/vol4/issue/v4i2a9-grusd.html> (providing justifications for the product of nature doctrine).

⁵⁵ *Funk Bros.*, 333 U.S. at 130.

⁵⁶ *Chakrabarty*, 447 U.S. at 309.

⁵⁷ Grusd, *supra* note 54.

⁵⁸ JOHN LOCKE, TWO TREATISES OF GOVERNMENT 286-87 (Peter Laslett ed., Cambridge Univ. Press 1988) (1690).

⁵⁹ *Id.*

⁶⁰ See MUELLER, *supra* note 38, at 22.

⁶¹ See, e.g., Daniel, *supra* note 45; Scalise & Nugent, *supra* note 40, at 90.

⁶² E.g., ROBERT PATRICK MERGES & JOHN FITZGERALD DUFFY, PATENT LAW AND POLICY: CASES AND MATERIALS 124 (3d ed. 2002); Grusd, *supra* note 54, ¶ 12 n.24.

their . . . [d]iscoveries.”⁶³ Thus, because the Constitution requires that the recipient of the right be an inventor, it only gave Congress the authority to institute patent rights for discoveries that constitute invention—those discoveries resulting from an inventor’s innovative act.⁶⁴ The Supreme Court has made statements supporting this position several times, although the Court has never squarely faced this issue.⁶⁵ For instance, the Court has held “that the Constitution requires that there be some ‘invention’” for the result of an individual’s labors to be patentable.⁶⁶ The Court defines invention as entailing at least some ingenuity or creativity.⁶⁷ Thus, these elements are a prerequisite for patentability. This creativity requirement is consistent with the Court’s interpretation of the portion of the Intellectual Property clause referring to copyright where the Court has explicitly distinguished between creativity and discovery in holding that a “minimal degree of creativity” is a constitutional requirement for copyright protection.⁶⁸ In the copyright context, the Court noted that the “first person to find and report a particular fact has not created the fact; he or she has merely discovered its existence.”⁶⁹ In addition, the Constitution gives “[a]uthors . . . [an] exclusive right to their . . . [w]ritings.”⁷⁰ Thus, the Court does not consider a writing copyrightable if it does “not owe [its] origin to an act of authorship.”⁷¹ As the Constitution only confers patent rights on inventors, this interpretation gives support to the conclusion discussed above that a discovery is not patentable if it does not constitute invention as there appears to be no reason not to translate this reasoning into the patent portion of the Intellectual Property Clause. The discoverer of a product of nature does not create it—she merely discovers its existence. Thus, although the discovery of a product of nature involves a considerable amount of labor, it does not entail the element of creation that is a seminal part of invention as interpreted by the Court. Therefore, the Constitution may be said to require the product of nature doctrine because it only permits Congress to confer patent protection when invention occurs, and the discovery of a product of nature does not involve invention.

However, a valid counterargument can be made supporting the proposition that the Constitution embraces the patentability of both discovery and invention and that, thus, Congress could extend patent rights to newly discovered products of nature, such as plants and animals.⁷² At the time of the adoption of the Constitution, the term “inventor” was used to describe a

⁶³ U.S. CONST. art. I, § 8, cl. 8.

⁶⁴ MERGES & DUFFY, *supra* note 62, at 124.

⁶⁵ *See id.*

⁶⁶ *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 279 (1976).

⁶⁷ *See id.*

⁶⁸ *Feist Publ’ns, Inc. v. Rural Tel. Serv. Co.*, 499 U.S. 340, 345, 347-48 (1991).

⁶⁹ *Id.* at 347.

⁷⁰ U.S. CONST. art. I, § 8, cl. 8.

⁷¹ *Feist*, 499 U.S. at 347.

⁷² *See MERGES & DUFFY, supra* note 62, at 124.

discoverer who finds or learns of something in existence as well as an individual who creates something new that had not previously existed.⁷³ Furthermore, the Constitution itself gives Congress the power to authorize patents for discoveries, which appear to include finding a new product of nature. While these arguments have some merit, they are less than compelling. The language of the Intellectual Property Clause does not permit Congress to authorize the patentability of all discoveries. Rather, it restricts this power to discoveries by inventors. For an individual who makes a discovery to be an inventor, the discovery must entail invention, and thus must involve the element of creation inherent in invention that is lacking in the discovery of an object that exists in nature. Also, even if the argument that the term “inventor” was understood as encompassing the discoverer of an article existing in nature when the Constitution was adopted is correct, the Supreme Court has consistently rejected this interpretation of the term and requires the activities of an inventor to entail at least some creative activity.

Commentators have also advanced a second constitutional argument for the product of nature doctrine. The Constitution authorizes Congress to grant patents only to subject matter that is deemed a science or useful art.⁷⁴ Thus, some commentators have argued that discovery of a product of nature is not a science or useful art and thus that products of nature should not be entitled to patent protection.⁷⁵

Furthermore, some commentators have argued that the product of nature doctrine is based in § 101 as an article that is found in nature cannot constitute a manufacture.⁷⁶ The Supreme Court has indicated that a manufacture is an article made from raw or prepared materials by hand labor or machinery.⁷⁷ This definition plainly requires the contributions of man in the construction of an invention for it to constitute a manufacture. A product of nature, which is discovered in nature in its complete form by man, does not meet this definition.

However, other language in § 101 appears to cut against the product of nature doctrine. Section 101 permits patents for both discoverers and inventors. A cardinal principle of statutory construction is that a statute ought to be construed such that “no clause, sentence, or word shall be superfluous, void, or insignificant” if possible.⁷⁸ Thus, discovery and invention must have different meanings for the purposes of § 101. If invention necessarily entails a creative component, discovery does not and thus must encompass

⁷³ See *id.* (citing S. REP. NO. 71-315, at 8 (1930); H.R. REP. 71-1129, at 8-10 (1930)).

⁷⁴ See Grusd, *supra* note 54.

⁷⁵ See *id.*

⁷⁶ See ROBERT L. HARMON, PATENTS AND THE FEDERAL CIRCUIT 53 (7th ed. 2005).

⁷⁷ See *infra* note 133 and accompanying text.

⁷⁸ TRW, Inc. v. Andrews, 534 U.S. 19, 31 (2001) (quoting *Duncan v. Walker*, 533 U.S. 167, 174 (2001)); see also *Leocal v. Ashcroft*, 543 U.S. 1, 12 (2004) (“We must give effect to every word of a statute wherever possible . . .”).

the discovery of a product of nature. As § 101 gives patent rights to “whoever invents or discovers any new or useful . . . manufacture,”⁷⁹ this language suggests that a manufacture may be “discovered.” Thus, one might argue that a product of nature might constitute a manufacture and thus be patentable.⁸⁰ However, given the above discussion indicating that the Constitution does not authorize the patentability of discoveries that do not entail invention, a court would likely restrict the term “discovery” in this manner for the purposes of § 101 in light of the long-standing rule that courts should interpret statutes in such a way that will allow them to avoid deciding significant constitutional questions.⁸¹ For instance, a court might interpret “discovery” in § 101 to encompass discoveries that entailed some creation by the patentee, such as the successful synthesis of a novel compound, but would not ordinarily be dubbed an invention in common parlance, such as the telephone or light bulb.

Despite the product of nature doctrine’s constitutional underpinnings and universal acceptance by American courts, commentators have levied valid criticism against it as they argue that the patentability of products of nature would further the goals of the patent system. One goal is to encourage inventive activities and the unveiling of new articles for use by the public by granting inventors the right to exclude others from making, selling or using the invention for a limited period of time.⁸² At the same time, the patent system strives to maximize the benefits to society and minimize potential harms by not permitting inventors to remove articles from the public domain.⁸³ For instance, the discoverer of a new plant or animal in nature poses no harm to the situation of others and does not remove an article from the public domain.⁸⁴ Indeed, “if [the discoverer] did not stumble upon the [the naturally-occurring article] no one else would have, and the [public] would remain without it.”⁸⁵ Thus, patentability of products of nature would encourage people to expend effort in discovering naturally-occurring articles that might have a use, such as plants and animals but would not deprive

⁷⁹ 35 U.S.C. § 101 (2000).

⁸⁰ It can also be argued that a product of nature is patentable under § 101 as a composition of matter. The Supreme Court defines a “composition of matter” as “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.” *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980) (quoting *Shell Dev. Co. v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957)). While one might argue that the term “composition” entails composing or constructive activity by man, this definition appears to encompass composite articles that are naturally-occurring.

⁸¹ See, e.g., *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 575 (1988); *United States v. Jin Fuey Moy*, 241 U.S. 394, 401 (1916); *Ma v. Reno*, 208 F.3d 815, 822 (9th Cir. 2000).

⁸² See *Eli Lilly & Co. v. Premo Pharm. Labs., Inc.*, 630 F.2d 120, 137 (3d Cir. 1980).

⁸³ See *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 497 (1850).

⁸⁴ See ROBERT NOZICK, *ANARCHY, STATE AND UTOPIA* 181 (1974).

⁸⁵ *Id.*

the public of something already in its use. Indeed, in many cases discovery of a rare naturally-occurring creature will entail a great deal of effort, often as much or more than that required to create a new manmade creature by genetic engineering.⁸⁶ Thus, patentability of products of nature is consistent with the goals of the patent system.

However, while this argument is meritorious, it does not foreclose the possibility that the product of nature doctrine might be more effective in promoting the goals of the patent system. For instance, it is possible that there are more people in the position to search for and discover naturally-occurring objects, including plants and animals, than are capable of creating inventions. A new use or application of a naturally-occurring object, such as the use of a plant or animal or a product derived from it, can give rise to a patent, albeit one for that use only.⁸⁷ In contrast, a product patent gives the patentee broad rights to prevent all uses of the object. The product of nature doctrine proscribes product patents for naturally-occurring articles, not use patents for individual uses of them. In the absence of the broad protection afforded by a product patent, an inventor who devises an invention with one use might withhold the invention from the public while she studies the invention to find more uses that she may patent. If few people are in the position to invent, an inventor will withhold the invention for such study knowing that it is unlikely that another party is behind her. If more people are in the position to engage in discovery, the discoverer is less likely to be ahead of all other potential competitors, and thus will have an incentive to disclose the discovery to benefit from first-mover advantages, such as increased prestige and early profits, and avoid being scooped. Thus, broad product patent rights might be necessary to promote prompt disclosure of an invention and its first use by inventors while research on future uses continues as an inventor must disclose her invention to obtain a patent monopoly.

On the other hand, product patent rights might not be necessary to bring about quick disclosure by discoverers. Thus, the product of nature doctrine foreclosing patentability of discoveries of natural items but permitting patentability of inventions might further the goals of the patent system as it promotes invention and disclosure to the public of inventions in a timely manner, which might not have been disclosed to the public as quickly in the absence of the doctrine. In contrast, the patentability of natural products may not serve the goals of the patent system as well because, in

⁸⁶ A possible example would be a scientist spending years in a rainforest looking for novel plants and animals with medicinal properties.

⁸⁷ See MUELLER, *supra* note 38, at 192. For instance, an individual who discovers a novel plant or animal with therapeutic medicinal properties or who discovers that a known living thing has such properties may obtain a use patent for the use of the living thing for that medicinal purpose. Such a patent holder may not exclude others from using the natural item for other purposes. However, the product of nature doctrine forecloses a product patent for the plant or animal itself.

the absence of product patent protections, discoverers have incentives to disclose their discoveries to the public in the absence of the restrictions on public use inherent in a patent. Thus, the public obtains a smaller benefit from the grant of patent protection than in the invention context. Some lower courts have seized on the difference between creation and discovery in applying the product of nature doctrine. Without explanation, these courts conclude that only the creator of an invention may patent it.⁸⁸ These courts reason that one who discovers a naturally-occurring article in nature is not entitled to a patent because she did not create it and that it likely existed in nature for centuries.⁸⁹ The fact that humans had failed to find it in nature prior to the discoverer's actions "does not negative its origin or [prior] existence."⁹⁰

Despite the legitimate questions associated with the underpinnings of the product of nature doctrine, the doctrine is entrenched in American law. At first blush, the product of nature doctrine itself and its application to living things appear straightforward. A plant, animal, or microorganism found in the wild is not patentable.⁹¹ Applying this principle, the Supreme Court first delved into the patentability of living organisms when it decided *Funk Bros.* in 1948. In *Funk Bros.*, the patentee claimed a patent for a mixture of naturally-occurring bacterial strains, which farmers used to infect plant roots in order to aid the plant in the fixing of nitrogen.⁹² Different species of bacteria infect different types of crops.⁹³ The strains of each species of bacteria used in the claimed mixture could be mixed without inhibiting each other's growth while strains previously used were unable to grow together.⁹⁴ Thus, the claimed invention allowed farmers to use a mixed inoculum for all of their crops in lieu of different inocula for different types of crops.⁹⁵ Despite the utility of the patentee's mixture, the Court held that it was not patentable because discovery that certain naturally-occurring strains could be mixed without inhibiting each other's growth was a discovery of a natural property of the strains and that the aggregation of select strains into one product was simply an application of this natural principle.⁹⁶ The Court reasoned that no species acquired a different use because the species in the mixture still infected the same types of crops.⁹⁷ Furthermore, the combination of species produced no new bacteria, no change in

⁸⁸ See, e.g., *Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641, 642 (3d Cir. 1928).

⁸⁹ See *id.* at 642-43.

⁹⁰ *Id.*

⁹¹ See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

⁹² *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 129-30 (1948).

⁹³ *Id.* at 129.

⁹⁴ *Id.* at 129-30.

⁹⁵ *Id.* at 130.

⁹⁶ *Id.* at 131.

⁹⁷ *Id.*

the naturally-occurring bacteria used, and no enlargement in their utility.⁹⁸ Thus, the Court concluded that the patentee's effort, resulting in the use of the bacteria in combination, did not improve their natural functioning in any way as they function in the ways nature originally provided independently of the patentee's actions.⁹⁹ The effect of the mixture was merely the combination of the effect that the naturally-occurring strains in it would have had on their own. Thus, the simple aggregation of products of nature without conferring any new function or changing their character was insufficient to warrant patentability.

However, prior to *Chakrabarty*, the courts manipulated the product of nature doctrine to reject the patentability of living things.¹⁰⁰ The courts' historic pattern of manipulation is readily apparent in cases where the courts held that living things were not patentable where it appeared that the inventor "contribut[ed] something to the [living thing] that alters its natural qualities and renders something new" and thus were patentable under the product of nature doctrine.¹⁰¹ Such manipulation was possible because the courts had precariously defined the degree of intervention by the patentee, that is, the magnitude of the inventive step required to transform the subject matter from a product of nature into a patentable organism created by man.¹⁰²

A striking example of this manipulation is the Supreme Court's decision in *American Fruit Growers, Inc. v. Brogdex Co.*¹⁰³ In *American Fruit*, the Court determined that impregnating orange rinds with borax, rendering the oranges resistant to destructive blue mold decay, did not produce an article that "possesse[d] a new or distinctive form, quality, or property" that was not present in naturally-occurring oranges.¹⁰⁴ The Court reasoned that the added substance only protected the natural article against deterioration by inhibiting the growth of extraneous spores on the rind and did not alter the "name, appearance, or general character of the fruit" or create any additional uses for the orange.¹⁰⁵ Thus, the Court held that the impregnated oranges were not patentable subject matter. This decision appears contrary to the product of nature analysis that the *American Fruit* Court purported to follow, and has been maligned by commentators.¹⁰⁶ "The borax-impregnated orange" was not found in nature and "undeniably possessed a

⁹⁸ *Funk Bros.*, 333 U.S. at 131.

⁹⁹ *Id.*

¹⁰⁰ See Scalise & Nugent, *supra* note 40, at 90.

¹⁰¹ *Id.*

¹⁰² *Id.*

¹⁰³ 283 U.S. 1 (1931).

¹⁰⁴ *Id.* at 11.

¹⁰⁵ *Id.* at 11-12.

¹⁰⁶ *E.g.*, Scalise & Nugent, *supra* note 40, at 90-91 ("The Court's analysis seemed indefensible . . ."); Edmund J. Sease, *From Microbes, to Corn Seeds, to Oysters, to Mice: Patentability of New Life Forms*, 38 *DRAKE L. REV.* 551, 555 (1989) ("[T]here was little logic in the decision.").

new and distinct quality . . . that change[d] the general character of the fruit” inasmuch as “it was resistant to the ruinous blue mold decay.”¹⁰⁷ Thus, the impregnated orange appeared not to be an unpatentable product of nature under the product of nature doctrine as the patentee’s treatment resulted in characteristics different than those that were the product of nature.

One might attempt to explain the *American Fruit* decision as narrowly construing a ‘change in character’ to necessarily require the creation of a new use. This suggestion, however, conflicts with the Court’s statement that patentability of an article derived from nature requires a transformation entailing “a new and different article . . . having a distinctive name, character, or use.”¹⁰⁸ If a change in character entailed a new use, the Court would not have separately enumerated character and use in listing the differences required to render a product derived from nature an invention outside of the product of nature doctrine. Thus, *American Fruit* can be considered an example of a manipulation of the product of nature doctrine to exclude a product derived from a living thing and capable of giving rise to a living thing, an orange tree, from the scope of patentability despite the fact that the resistant orange did not occur in nature and this additional characteristic was the handiwork of man.

Another area where courts had evinced their hostility toward patentability of living organisms is the purified microorganism context. Courts have long permitted patents for purified forms of natural products if sufficiently different from the nonpurified or natural form as to otherwise meet the requirements for patentability.¹⁰⁹ For instance, in *Parke-Davis & Co. v. H.K. Mulford Co.*,¹¹⁰ the Circuit Court for the Southern District of New York upheld a patent for a purified form of adrenaline purified from the suprarenal glands of living animals.¹¹¹ In *Parke-Davis*, the circuit court held that the purified adrenaline became a new thing commercially and therapeutically when it was removed from the dried gland tissue in which it was found.¹¹² The purified adrenaline was a new substance, rather than merely the dried gland tissue in a purer state.¹¹³ Unlike the dried gland tissue, the patentee’s purified adrenaline was not dangerous for intravenous use.¹¹⁴ Thus, the court found that the patentee was the first to make the purified form of adrenaline available for any use by extracting it from the gland

¹⁰⁷ Scalise & Nugent, *supra* note 40, at 91; *see also* Sease, *supra* note 106 (describing the Supreme Court’s ruling in *American Fruit*).

¹⁰⁸ *Am. Fruit Growers, Inc. v. Brogdex*, 283 U.S. 1, 13 (1931).

¹⁰⁹ *See, e.g., Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103, 115 (C.C.S.D.N.Y. 1911) (Hand, J.) *aff’d in part, rev’d in part on other grounds*, 196 F. 496 (2d Cir. 1912); MUELLER, *supra* note 38, at 185.

¹¹⁰ 189 F. 95 (C.C.S.D.N.Y. 1911) (Hand, J.).

¹¹¹ *Id.* at 103, 115.

¹¹² *Id.* at 103.

¹¹³ *Id.*

¹¹⁴ *See id.* at 115.

tissue.¹¹⁵ Thus, an “extracted product without change” may be patentable subject matter.¹¹⁶

In contrast, courts have demonstrated much more hostility to patents for living microorganisms purified from naturally-occurring materials such as soil. In *In re Mancy*,¹¹⁷ the Court of Customs and Patent Appeals concluded that a purified strain of bacteria isolated from soil samples that produces a specific antibiotic “is not new [and is thus] a product of nature.”¹¹⁸ Like purifying adrenaline from gland tissue, purifying microorganisms from soil samples produces a new thing commercially and therapeutically and is not merely soil in a purer state. Soil cannot be used to manufacture antibiotics like purified bacterial can. Thus, under the reasoning of *Parke-Davis*, the purified bacterial strain is patentable even though it was merely extracted and was naturally-occurring in a sense. This is another example of a court concluding that a living thing was not patentable in the face of established precedent or doctrine indicating that it should have been.

However, the Court of Customs and Patent Appeals reconsidered its conclusion that a biologically pure culture of a microorganism was not patentable when it decided *In re Bergy*¹¹⁹ in 1977. In *Bergy*, the court found that its conclusion in *Mancy* “was ill-considered.”¹²⁰ The court held that purified microorganisms were patentable subject matter under § 101 as manufactures or compositions of matter.¹²¹ The court compared purified bacterial cultures with chemical compounds purified from natural sources, such as the one held patentable in *Parke-Davis*.¹²² The court stressed that it reached this conclusion because “the [relevant] biologically pure culture of [bacteria] clearly does not exist in [and] is not found in [nature].”¹²³ Such purified microorganisms are “manmade and can be produced only under carefully controlled laboratory conditions.”¹²⁴ Therefore, the court concluded that such purified microorganisms are not products of nature.¹²⁵

¹¹⁵ *Id.* at 103.

¹¹⁶ *Parke-Davis*, 189 F. at 103

¹¹⁷ 499 F.2d 1289 (C.C.P.A. 1974).

¹¹⁸ *Id.* at 1294.

¹¹⁹ 563 F.2d 1031 (C.C.P.A. 1977), *vacated sub nom.* Parker v. Bergy, 438 U.S. 902 (1978) (mem.), *aff'd on remand sub nom. In re Bergy*, 596 F.2d 952 (C.C.P.A. 1979), *aff'd sub nom.* Diamond v. Chakrabarty, 447 U.S. 303 (1980).

¹²⁰ *Id.* at 1036.

¹²¹ *See id.* at 1038.

¹²² *Id.*

¹²³ *Id.* at 1035.

¹²⁴ *Id.* This reasoning is also used to support the patentability of genes and DNA sequences. *See* MERGES & DUFFY, *supra* note 62, at 103-04. The theory is that isolated genes do not exist in nature and can be produced only in the laboratory environment by man. The genes are seen as purified or extracted from the organism or tissue and are an entirely new thing.

¹²⁵ *Bergy*, 563 F.2d at 1035.

However, the court was careful to note that its holding applied only to purified microorganisms and did not apply to animals, plants, or insects.¹²⁶

The *Bergy* decision holding that purified microorganisms are patentable subject matter is consistent with the product of nature doctrine as previously articulated by the courts. Although purified microorganisms are not technically made by man, the purification process “requires [the patentee’s] ingenuity to devise [the appropriate] laboratory conditions in which to isolate and culture the microorganisms.”¹²⁷ In contrast, the court correctly noted that its reasoning did not apply to “naturally-occurring [] plants and animals that are large enough that their identification and isolation does not require [the patentee’s] ingenuity in developing experimental culture conditions.”¹²⁸

B. *Diamond v. Chakrabarty—Patentability of Microorganisms as Living Subject Matter*

While *Bergy* permitted the patenting of purified microorganisms, it did not address the patentability of the microorganism or living things in general other than microorganisms purified from natural sources. In *Chakrabarty*, the Supreme Court directly addressed the question of whether living things that did not occur in nature were patentable subject matter independent of purification. The patentee created a genetically engineered bacterium capable of degrading crude oil by introducing certain plasmids, encoding genes conferring the ability to break down multiple components of crude oil, into a naturally-occurring strain of bacteria which had no capacity to degrade crude oil.¹²⁹ The Court held that a living nonnatural microorganism was patentable subject matter under § 101.¹³⁰ Also, the Court noted that in choosing terms such as “manufacture” and “composition of matter,” Congress contemplated that patent laws be given wide scope based on the common usages of these terms.¹³¹ This was consistent with the legislative history of the Patent Act indicating that “Congress intended statutory subject matter to include anything under the sun that is made by man.”¹³² For instance, the Court adopted the broad definition of “manufacture” it articulated but erroneously applied in *American Fruit* as an article “produc[ed] . .

¹²⁶ *Id.* at 1038.

¹²⁷ Mark L. Rohrbaugh, *The Patenting of Extinct Organisms: Revival of Lost Arts*, 25 AIPLA Q.J. 371, 384-85 (1997).

¹²⁸ *Id.* at 385.

¹²⁹ *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980). Plasmids are circular pieces of DNA which encode bacterial genes and function as hereditary units that are physically separate from the bacterial chromosome. *Id.* at 305 n.1.

¹³⁰ *See id.* at 318.

¹³¹ *See id.* at 308.

¹³² *Id.* (internal quotation omitted).

. for use from raw or prepared materials by giving these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.”¹³³ Similarly, the Court defined “composition of matter” to include “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.”¹³⁴ The genetically engineered bacterium in the case plainly met both of these definitions as it had different properties than the naturally-occurring bacterium, which served as a raw material in its production, and it was a composition of the original bacterium and the plasmids. Thus, the Court concluded that the bacterium was patentable subject matter because it was a nonnaturally-occurring manufacture or composition of matter—“a product of human ingenuity having a distinctive name, character, and use” from the natural bacterium from which it was synthesized.¹³⁵ The Court distinguished *Funk Bros.*, where it rejected the patentability of a mixture of naturally-occurring bacteria used for natural characteristics, by noting that the genetically engineered bacterium was “a new bacterium with markedly different characteristics from any found in nature.”¹³⁶ The Court also rejected the argument that Congress needed to expressly authorize protection for this new subject matter because it was not contemplated when the patent laws were enacted, reasoning that it was encompassed by the broad scope of the statutes that Congress already had authorized precisely because inventions are often unforeseeable.¹³⁷ A rule that unanticipated inventions cannot be patented “would conflict with the core concept of patent law that anticipation undermines patentability.”¹³⁸ Therefore, the Court concluded that the non-naturally-occurring genetically engineered bacterium did not constitute an unpatentable product of nature because its creation was the patentee’s rather than “nature’s handiwork.”¹³⁹

The Court also rejected the argument that Congress had impliedly excluded living organisms from patentability by enacting the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act (collectively “Plant Acts”), both of which provided for intellectual property protection for plants but not other living things, based on an evaluation of the legislative history of these acts because these acts would have been unnecessary if living things, such as plants, were patentable.¹⁴⁰ Nothing in the language of legislative history of these acts suggested that Congress enacted them be-

¹³³ *Id.* (quoting *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)).

¹³⁴ *Chakrabarty*, 447 U.S. at 309 (quoting *Shell Dev. Co. v. Watson*, 149 F. Supp. 279, 280 (D.D.C. 1957)).

¹³⁵ *Id.* at 309-10 (internal quotation marks omitted).

¹³⁶ *Id.* at 310.

¹³⁷ *See id.* at 314-15.

¹³⁸ *Id.* at 316.

¹³⁹ *Id.* at 310.

¹⁴⁰ *See Chakrabarty*, 404 U.S. at 313.

cause it believed that § 101 did not include living things.¹⁴¹ The Court noted that Congress believed that the work of the plant breeder in aid of nature was patentable invention and that these acts were passed to ensure intellectual property protection for plants in the face of two factors that were impairing the patenting of plants: (1) the belief that plants, even artificially bred ones, were products of nature evinced by the PTO; and (2) the fact that plants were thought not to be amenable to the written description requirement of the patent law.¹⁴² Furthermore, the legislative history indicated that Congress acknowledged that a plant discovery resulting from artificial breeding that is not repeated in nature or reproduced by nature unaided by man is different than the discovery of a product of nature, such as a mineral, which is created wholly without the assistance of man.¹⁴³ Therefore, the Court concluded the Plant Acts draw a distinction between products of nature, whether living or not, and man-made inventions rather than between living and inanimate things.¹⁴⁴ Since genetically engineered bacteria are the result of human ingenuity and research, the Plant Acts do not support the conclusion that they are not patentable.¹⁴⁵

Finally, the Court rejected arguments against patentability of genetically engineered microorganisms that claimed “that genetic research . . . may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life.”¹⁴⁶ The Court reasoned Congress was better suited to make such policy determinations.¹⁴⁷

The Court’s decision in *Chakrabarty* was a seminal event in the evolution of patent law. The Court repudiated the rationales previously employed to reject patents claiming living things. Furthermore, the Court’s broad language permitting patents for any living thing created by man seemed to permit patents for all living things, including larger organisms such as plants, animals, and even humans.

C. *Extension of Chakrabarty to Multicellular Organisms*

1. Plants

In 1985, the Board of Patent Appeals and Interferences applied the Supreme Court’s reasoning in *Chakrabarty* in holding that an artificially

¹⁴¹ *Id.*

¹⁴² *Id.* at 311-12.

¹⁴³ *Id.* at 313.

¹⁴⁴ *See id.*

¹⁴⁵ *See id.*

¹⁴⁶ *Chakrabarty*, 404 U.S. 303, 316-17 (1980).

¹⁴⁷ *Id.* at 317.

bred corn plant that contained abnormally high levels of the amino acid tryptophan was patentable subject matter under § 101.¹⁴⁸ The Board reasoned that in light of *Chakrabarty*, the scope of § 101 encompassed “man-made life forms, including plant life.”¹⁴⁹ Furthermore, the Board noted that the *Chakrabarty* Court’s analysis of the Plant Acts makes it clear that the legislative intent of these acts was to extend intellectual property protection to plant breeders who were stymied in procuring patents and that it did not evince an intent to limit the scope of patentable subject matter under § 101.¹⁵⁰ Thus, the availability of plant-specific protection did not foreclose the availability of patent protection for manmade plants.¹⁵¹

In 2001, the Supreme Court adopted the Board’s position and explicitly held that artificially developed plant breeds were patentable subject matter under § 101 in *J.E.M. Agricultural Supply, Inc. v. Pioneer Hi-Bred International, Inc.*¹⁵² The Court reaffirmed its conclusions in *Chakrabarty* that the Plant Acts were to be given wide scope considering the broad language Congress employed in § 101 and that “the relevant distinction [in determining the patentability of a living thing i]s not between living and inanimate things, but between products of nature, living or not, and [man]made inventions.”¹⁵³ Thus, the Court concluded that artificially bred plants were patentable subject matter because they fall within the broad terms of § 101 that include manufactures and compositions of matter.¹⁵⁴ Furthermore, the Court adopted the Board’s conclusion that the Plant Acts do not limit the scope of patentable subject matter under § 101 because Congress did not give any indication that it intended to do so and thus that such statutes do not foreclose the patentability of artificially bred plants.¹⁵⁵ Given these decisions, the patent office now routinely grants patents on manmade plants.¹⁵⁶

2. Animals

In contrast to plants, neither the Supreme Court nor the Federal Circuit have squarely faced the issue of whether nonnaturally-occurring animals developed by man are patentable, although they appear to be encompassed by the *Chakrabarty* Court’s broad language in a published decision. Indeed, in the wake of *Chakrabarty*, the PTO refused to grant patents for multicol-

¹⁴⁸ See *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443, 444-47 (B.P.A.I. 1985).

¹⁴⁹ *Id.* at 444.

¹⁵⁰ See *id.* at 445.

¹⁵¹ See *id.* at 446.

¹⁵² 534 U.S. 124, 145-46 (2001).

¹⁵³ See *id.* at 130 (quoting *Diamond v. Chakrabarty*, 404 U.S. 303, 313 (1980)).

¹⁵⁴ See *id.* at 131-32.

¹⁵⁵ See *id.* at 145-46.

¹⁵⁶ Sease, *supra* note 106, at 563.

lular animals on the ground that it required explicit judicial authorization to do so.¹⁵⁷

In 1987, the Board of Patent Appeals and Interferences squarely faced this issue when it decided *Ex parte Allen*.¹⁵⁸ In *Allen*, the patentee sought to patent polyploid oysters on the basis that their polyploidy was induced by the application of pressure on oyster zygotes by the patentee.¹⁵⁹ The Board noted that under *Chakrabarty*'s holding that § 101 included manmade life forms, "the issue . . . in determining whether the claimed subject matter is patentable . . . is simply whether that subject matter is made by man."¹⁶⁰ Thus, the Board concluded that a nonnaturally occurring animal made by man was patentable subject matter.¹⁶¹ As the claimed oysters did not occur naturally without the intervention of man, the Board held that they were nonnaturally-occurring manufactures or compositions of matter and thus were patentable subject matter.¹⁶² *Allen* also extends *Chakrabarty* inasmuch as it stands for the proposition that a living thing need not be genetically engineered to be patentable since, unlike the genetically engineered bacteria in *Chakrabarty*, the oysters were simply altered by environmental pressures.¹⁶³ This extension is consistent with the Court's broad definitions of manufacture and composition of matter as well as the product of nature doctrine as the alteration of the oysters engendered properties not found in naturally-occurring oysters.

Only four days after the Board delivered its decision in *Allen*, the PTO issued a notice stating that the PTO considered nonnaturally occurring, nonhuman, multicellular, living organisms patentable subject matter as compositions of matter or manufactures.¹⁶⁴ The PTO also indicated that a

¹⁵⁷ See *Patents and the Constitution: Transgenic Animals: Hearing Before the Subcomm. on Courts, Civil Liberties and the Admin. of Justice of the H. Comm. on the Judiciary*, 100th Cong. 160 (1987); Paul Blunt, Note, *Selective Breeding and the Patenting of Living Organisms*, 48 SYRACUSE L. REV. 1365, 1369 (1998). Given the power of Congress to define the scope of patentable subject matter, the PTO would surely have granted patents in the absence of explicit judicial authorization had Congress expressly authorized the issuance of patents for multicellular animals. Of course, if Congress were to amend the patent laws to include such an express statement, the federal courts or the Board of Patent Appeals and Interferences would have surely provided the express judicial authorization the PTO claimed it needed. Of course, without congressional action, in *Ex parte Allen*, 2 U.S.P.Q.2d (BNA) 1425 (B.P.A.I. 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988) (unpublished table decision), the Board provided the PTO with the judicial authorization it said that it required to grant patents for multicellular animals. Blunt, *supra*, at 1369; see also *infra* notes 158-63 and accompanying text.

¹⁵⁸ 2 U.S.P.Q.2d (BNA) 1425, 1426-27 (B.P.A.I. 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988) (unpublished table decision).

¹⁵⁹ *Id.* at 1426.

¹⁶⁰ *Id.*

¹⁶¹ *Id.* at 1427.

¹⁶² *Id.*

¹⁶³ *Id.* at 1426.

¹⁶⁴ Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks, Policy Announcement, in 69 J. PAT. & TRADEMARK OFF. SOC'Y 328 (1987).

manufacture or composition of matter occurring in nature, such as an animal, would not be patentable unless “given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law.”¹⁶⁵ In essence, the PTO’s notice indicated that it would issue patents permitted by *Chakrabarty*, an approach consistent with the product of nature doctrine.¹⁶⁶

After the announcement, various animal rights groups, animal husbanders, and farmers challenged the PTO’s notice by filing a lawsuit claiming it was not properly promulgated under the Administrative Procedure Act.¹⁶⁷ The Federal Circuit held that the suit should be dismissed because the plaintiffs lacked standing.¹⁶⁸ However, it suggested in dicta that it considered nonnaturally-occurring animals patentable subject matter as it noted that the *Chakrabarty* Court held that all manmade life forms were patentable.¹⁶⁹ Also, the court affirmed the Board’s decision in *Allen*, which expressly included animals in the realm of patentable subject matter, albeit in a summary unpublished opinion.¹⁷⁰

In April 1988, the PTO issued the first patent for a multicellular animal.¹⁷¹ The patent was issued to Harvard University for a transgenic mouse, a mouse in which at least one additional gene has been introduced into the germ cells of the animal.¹⁷² Harvard researchers introduced a gene into the mouse that made it particularly disposed to cancer.¹⁷³ Since 1988, the PTO has granted numerous patents for animals not occurring in nature, including other transgenic animals, and a rabbit infected with the HIV virus.¹⁷⁴

¹⁶⁵ *Id.*

¹⁶⁶ Although the *Chakrabarty* Court’s language suggests that manmade humans might be patentable, the PTO’s statement excluded humans from the scope of patentable subject matter because including them would be unconstitutional, presumably under the Thirteenth Amendment. *See id.* In 1999, the PTO rejected a patent for a human-animal chimera concluding that the claims encompassed a full human being and that despite the broad scope of patentable subject matter which might include humans as articulated by the *Chakrabarty* Court, Congress did not intend to authorize the patenting of humans in § 101. *Patent Application Is Disallowed as ‘Embracing’ Human Being*, 58 Pat. Trademark & Copyright J. (BNA) 203 (June 17, 1999) (quoting the PTO’s office action on the application). Neither the Supreme Court nor the Federal Circuit has hitherto addressed this issue.

¹⁶⁷ *Animal Legal Def. Fund v. Quigg*, 932 F.2d 920, 922 (Fed. Cir. 1991).

¹⁶⁸ *Id.* at 924-25.

¹⁶⁹ *Id.* at 927-28.

¹⁷⁰ *In re Allen*, 846 F.2d 77 (Fed. Cir. 1988) (unpublished table decision); *see also* *Animal Legal Def. Fund*, 932 F.2d at 927-28 (citing *Allen*, 846 F.2d 77).

¹⁷¹ U.S. Patent No. 4,736,866 (filed June 22, 1984) (issued Apr. 12, 1988); Keith Schneider, *Harvard Gets a Mouse Patent, A World First*, N.Y. TIMES, Apr. 13, 1988, at A1.

¹⁷² Warren D. Woessner, *The Evolution of Patents on Life—Transgenic Animals, Clones and Stem Cells*, 83 J. PAT. & TRADEMARK OFF. SOC’Y 830, 830, 832 (2001).

¹⁷³ *See id.*

¹⁷⁴ *Id.* at 833.

II. PATENTING CLONED EXTINCT ANIMALS

As an extinct animal has never been cloned, it is not surprising that courts and the PTO have not hitherto addressed the patentability of such an animal. However, given the attempts to clone extinct animals currently under way, the courts and the PTO may have to face this issue in the near future. Several unique issues arise in assessing the patentability of regenerated organisms that were once extinct.¹⁷⁵ A patent claiming a living organism, like all patents, must claim statutory subject matter and meet the statutory requirements for patentability including novelty, nonobviousness, and utility. This Part explores the issue of whether a patent claiming a cloned extinct animal may meet these requirements for validity. Analysis of both the relevant statutes and case law addressing the patentability of other biotechnological inventions suggests that cloned extinct animals are patentable subject matter and that they may meet the patentability requirements of novelty, nonobviousness, and utility. This Part also shows that the patentability of cloned extinct animals promotes the goals of the patent system. Finally, it examines the related question concerning the patentability of cloned animals when cloning is used to prevent a nearly extinct animal from actually becoming extinct and suggests that the patenting of such animals is foreclosed by the product of nature doctrine.

A. *Cloned Extinct Animals Are Patentable Subject Matter*

Extinct organisms that are cloned or otherwise regenerated by man straddle the boundary between nonnaturally-occurring organisms patentable under *Chakrabarty* and unpatentable products of nature because they are identical to an animal that formerly occurred in nature but no longer does at the time of the cloning. However, under the Supreme Court's product of nature doctrine, they are not products of nature and thus fall within the broad scope of § 101 as patentable subject matter.

After an animal becomes extinct, it no longer occurs in nature. Indeed, by definition, "extinct" means "no longer existing or living."¹⁷⁶ The Supreme Court's articulation of the product of nature doctrine in *Chakrabarty*, which indicates that a living thing "found in the wild" is not patentable subject matter, suggests that for the purposes of the doctrine, the Court defines a naturally-occurring living thing as one that is present in nature at the purported time of invention.¹⁷⁷ An extinct animal, which once occurred in nature but no longer does, cannot be said to be "found in the wild." Further-

¹⁷⁵ Perhaps, this is the reason that this still hypothetical question has already been addressed by at least two commentators. See Jiron, *supra* note 34; Rohrbaugh, *supra* note 127.

¹⁷⁶ THE AMERICAN HERITAGE DICTIONARY OF THE ENGLISH LANGUAGE 465 (1982).

¹⁷⁷ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

more, the Court considers an invention not to be an unpatentable product of nature if it is a “new and different article” as distinguished from what occurs in nature and has a “distinctive name, character, or use.”¹⁷⁸ Under this standard, a cloned extinct animal is not an unpatentable product of nature because it is obviously different from existing animals in both character and name. Also, because the animal was not present in nature at the time it is cloned, it may be considered new. Thus, there is a compelling argument that a cloned extinct animal does not constitute a product of nature.

Moreover, the Court considers the scope of patentable subject matter to be very broad and to include “anything under the sun made by man.”¹⁷⁹ A cloned extinct animal is “the result of human ingenuity and research” inasmuch as the patentee must devise cloning methods, including the selection of a species of existing animal for use as the donor of enucleated eggs and as the surrogate mother.¹⁸⁰ Thus, an extinct animal does not exist naturally without the intervention of man. In *Allen*, the Board of Patent Appeals and Interferences held that the fact that an animal does not exist naturally without the intervention of man was enough to render an animal patentable subject matter as a manufacture or composition of matter.¹⁸¹ This holding is consistent with the Court’s broad language in *Chakrabarty* indicating that any man-made living thing that does not occur in nature is patentable subject matter. Therefore, a fair application of *Chakrabarty* suggests that a cloned extinct animal, like the bacteria in *Chakrabarty*, is the patentee’s handiwork rather than nature’s and thus is patentable subject matter.

While this relatively straightforward analysis is appealing on the surface, the patentability of extinct animals raises unique and complicated issues that play no role in the analysis involving other living things. These complications stem from the fact that an extinct animal formerly occurred in nature. Thus, in a sense, cloned extinct animals are products of nature insofar as they once existed in nature. As compared to the extinct natural species, a cloned extinct animal is not new or different. The clone is exactly the same as the animal that once occurred in nature in terms of name, character, and use. Thus, if a court compares a cloned extinct animal to a realm of all animals that have ever naturally existed in lieu of one containing only those animals existing in nature at the time of the cloning, the necessary conclusion is that the animal is an unpatentable product of nature under the Court’s product of nature doctrine. Thus, whether a cloned extinct animal is patentable subject matter or not comes down to whether the scope of animals said to be naturally-occurring includes animals that once existed in nature as living creatures but exist only as remains at the time of cloning.

¹⁷⁸ See *Am. Fruit Growers v. Brogdex Co.*, 283 U.S. 1, 13 (1931); see also *supra* notes 46-48 and accompanying text.

¹⁷⁹ *Chakrabarty*, 447 U.S. at 309.

¹⁸⁰ *Id.* at 313.

¹⁸¹ *Ex Parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1427 (B.P.A.I. 1987).

There are tenable arguments supporting the conclusion that a cloned extinct animal is an unpatentable product of nature. The remains used to clone an extinct animal were derived from a naturally-occurring animal. When a naturally-occurring organism dies, some components of it, its remains, are still present in nature. Indeed, an extinct animal's remains must be available, and its nuclear DNA must be preserved for it to be cloned.¹⁸² Such remains are products of nature. Thus, one might argue that an extinct animal itself exists in nature because its remains do.¹⁸³ A related argument is that even if an extinct animal itself is no longer naturally-occurring, the remains themselves are products of nature and that the process of regenerating them does not involve sufficient inventive activity to render the regenerated organism patentable subject matter. Unlike cases such as *Chakrabarty* and *Allen* where the patentee's handiwork resulted in a new organism with characteristics markedly different than those of any organism that had ever appeared in nature, the patentee of a cloned extinct animal merely reverse-engineers nature's handiwork and reproduces the organism as it once appeared in nature. Indeed, in contrast to the microorganism context where a wholly natural microorganism that exists only in an unpurified state in nature is patentable in a purified form, neither the PTO nor any court has approved a patent for a higher animal or plant that did not possess novel properties that did not previously exist in nature.¹⁸⁴ A patentee's labor and effort are insufficient to render a claimed invention patentable subject matter if the claimed invention represents only the handiwork of nature and acquires no new uses or properties.¹⁸⁵ A cloned extinct animal is characterized by the same uses and properties as the original naturally-occurring animal. Thus, one might consider the patentee's efforts in regenerating an extinct animal akin to the patentee's unpatentable mixture of natural bacterial strains in *Funk Bros.*, which gave the strains no properties beyond their natural ones, inasmuch as the patentee's efforts do not improve the animal or create a new organism that has never appeared in nature. Rather, the patentee's efforts merely revive a creature with properties and uses identical to those conferred by nature.

Although the above arguments supporting the conclusion that a cloned extinct animal is an unpatentable product of nature have considerable merit, a conclusion that the realm of patentable subject matter encompasses cloned extinct animals is more consistent with Supreme Court precedent. First, the

¹⁸² See, e.g., Yule, *supra* note 17.

¹⁸³ See Jiron, *supra* note 34, ¶ 26.

¹⁸⁴ See Rohrbaugh, *supra* note 127, at 385. Unlike microorganisms, "naturally occurring higher plants and animals are large enough that their identification and isolation does not require [the patentee's] ingenuity in developing experimental culture conditions." *Id.* Thus, "[a] higher organism constitutes statutory subject matter only when the organism itself results from . . . human ingenuity or effort, rather than from the routine cultivation of a free living organism, which is insufficient to render it patentable. *Id.*

¹⁸⁵ See *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 131 (1948).

conclusion that an extinct animal still occurs in nature because its remains are present in nature is questionable at best. A living animal has vastly different properties and uses than its remains. Furthermore, the patent sought is on the animal, not the remains, and the very fact of extinction means that the animal itself is no longer present in nature. Second, the conclusion that the process of regenerating the extinct animal does not involve sufficient inventive activity to render the regenerated organism patentable subject matter is also debatable in light of several cases. The Court's statements of the product of nature doctrine in cases such as *American Fruit* consider an article a product of nature if it does not possess "a new or distinctive form, quality, or property" from articles that currently exist in nature.¹⁸⁶ The Court has never suggested that an article that did not exist in nature constituted a product of nature, even if that article existed in nature at one time. In other words, the Court has never indicated that in applying the product of nature doctrine, the scope of examination is broader than the universe of articles that currently exist in nature.

The facts of *Allen* indicate that the law does not require absolute proof that a living organism does not or has never existed in nature to constitute statutory subject matter.¹⁸⁷ In *Allen*, the Board of Patent Appeals and Interferences held that polyploid oysters do not occur naturally without the intervention of man and thus were patentable subject matter.¹⁸⁸ However, it did not seem relevant to the Board that polyploid oysters might have existed in nature at some point in the past.¹⁸⁹ Rare events in nature lead to the generation of polyploid oysters.¹⁹⁰ While *Allen* might be dismissed as wrongly decided, it can also be explained as standing for the proposition that the possibility of an occasional or rare event in nature engendering an organism does not defeat its patentability and that an organism only constitutes an unpatentable product of nature if it occurs in nature in the ordinary course of things and not due to an aberrant natural event. Thus, if polyploid oysters are patentable subject matter although they have occurred in nature in the past, the fact that an extinct animal existed in the past does not render it a product of nature. In fact, the argument for patentability is much stronger in the cloned extinct animal context because the chances of an extinct animal reappearing are less than those of the natural occurrence of a polyploid oyster which might be present somewhere in nature at any given time. Thus, extinct animals do not occur in nature for purposes of the product of nature doctrine because they do not *currently* occur in nature.

Furthermore, cloning is sufficient inventive activity to render the regenerated organism patentable subject matter. It is undeniable that remains

¹⁸⁶ *Am. Fruit Growers v. Brogdex Co.*, 283 U.S. 1, 11 (1931).

¹⁸⁷ *See* Rohrbaugh, *supra* note 127, at 385 n.63, 386.

¹⁸⁸ *Ex Parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1427 (B.P.A.I. 1987).

¹⁸⁹ Rohrbaugh, *supra* note 127, at 385 n.63.

¹⁹⁰ *Id.*

of an extinct animal found in nature are naturally-occurring. This fact does not defeat the patentability of a living animal generated from them. Cloning of an extinct animal from its remains can only occur under controlled conditions devised by the patentee. The living cloned extinct animal would not exist but for human ingenuity in devising a cloning process which successfully can produce the animal. In this respect, the cloned extinct animal is identical to the completely new organisms held to be patentable subject matter in *Chakrabarty, Allen, J.E.M., and Hibberd*. Thus, only through the intervention of man do living creatures of the extinct species exist. Furthermore, this situation parallels cases such as *Bergy* and *Parke-Davis* where courts held that microorganisms purified from their natural environment and adrenaline purified from natural gland tissue respectively were patentable.¹⁹¹ *Bergy* held that purified microorganisms were patentable subject matter because they were manmade as they did appear in nature in a purified form and could only be produced from natural sources under carefully controlled laboratory conditions.¹⁹² As discussed above, this reasoning applies with equal force to cloned extinct animals as they do not exist in nature in a living form. Likewise, in *Parke-Davis*, purified adrenaline was held patentable because it was an entirely new substance in a purer state than the gland tissue.¹⁹³ A living animal cloned from remains of an extinct species is an entirely new and different entity than inanimate natural remains. The *Parke-Davis* court concluded that “an extracted product without change” may be patentable subject matter.¹⁹⁴ Thus, a natural substance or microorganism which is intermingled with other substances in nature is patentable if it is purified away from the other substances even if the substance or microorganism is exactly the same as it was in the intermingled state. An argument that such substances and microorganisms are naturally-occurring would not be spurious as they do exist in nature, albeit in an intermingled state. If the contemporaneous existence of the exact same substance or microorganism in nature, albeit intermingled with other substances, does not render the purified form a product of nature and defeat patentability, the fact that a cloned extinct animal previously existed in nature should not render it an unpatentable product of nature because the living form was not in existence at the time of the invention.

Furthermore, a cloned extinct animal derived from natural remains is not a product of nature and is sufficiently “new and different” to constitute

¹⁹¹ *In re Bergy*, 563 F.2d 1031, 1038 (C.C.P.A. 1977); *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 115 (C.C.S.D.N.Y. 1911) *aff'd in part, rev'd in part on other grounds*, 196 F. 496 (2d Cir. 1912).

¹⁹² 563 F.2d at 1035. The PTO has extended this reasoning and issued a patent for prehistoric microorganisms purified from amber between twenty-five and forty million years old. *See* U.S. Pat. No. 5,593,883 (filed Oct. 28, 1994) (issued Jan. 14, 1997).

¹⁹³ 189 F. at 103, 115.

¹⁹⁴ *Id.* at 103.

patentable subject matter under *Chakrabarty*. A living cloned extinct animal unmistakably is a new and different article with a distinctive name, character, and use from the natural nonliving remains from which a patentee would create it. The differences in character between a living and dead animal are innumerable. Because the manmade living animal that was not present in nature would have characteristics different from the natural remains from which it is derived, a cloned extinct animal is not a product of nature under the product of nature doctrine.¹⁹⁵ A living cloned animal certainly meets the *Chakrabarty* Court's definition of "manufacture" as an article produced from raw or prepared materials by giving them new forms, qualities, properties or combinations. A living thing has different forms, properties, and qualities from remains of a like living thing. Likewise, a cloned animal can be considered a composition of matter in numerous ways including as a composite article consisting of genetic material from the extinct animal and the enucleated egg into which it was introduced.

Given the extreme differences between a living cloned extinct animal, which is created from natural remains by man and does not occur in nature, and the remains themselves, the cloned extinct animal context is readily distinguished from cases like *Funk Bros.* where the patentee's efforts effected no change in the character or properties of the bacteria involved. Rather, a cloned extinct animal is more like the totally new organisms held to be patentable subject matter in *Chakrabarty* and *Allen*. A cloned extinct animal possesses markedly different characteristics from the natural remains from which it is created just as the manmade organisms in these cases are different from the naturally-occurring animals from which they were generated. *Chakrabarty* and *Allen* turned on the fact that "the patentee has produced a new [organism] with markedly different characteristics from any found in nature"¹⁹⁶ A cloned extinct animal meets this criterion as extinct animals are no longer found in nature.¹⁹⁷ Nothing in this language, these cases, or any other case suggests that an organism that does not appear in nature is not patentable subject matter because it previously had done so. Therefore, while a cloned extinct animal is derived from natural remains, the animal itself is not a product of nature because the intervention of man is required to generate it. Thus, a cloned extinct animal derived from natural remains is patentable subject matter.¹⁹⁸

¹⁹⁵ See *supra* Part I.A.

¹⁹⁶ *Diamond v. Chakrabarty*, 447 U.S. 303, 310 (1980).

¹⁹⁷ In contrast, a cloned extant animal does not likely constitute statutory subject matter because it is not a new organism and exists in nature without the intervention of man.

¹⁹⁸ Artificially preserved biological materials, including remains of extinct animals, are patentable subject matter when their existence or form results primarily from inventive activity. See Rohrbaugh, *supra* note 127, at 387. The application of inventive methods of preservation render remains different in form or character and thus patentable subject matter when they extend the viability or form of these materials beyond that which they would have in nature. See *id.* Thus, cells preserved in liquid nitrogen

This conclusion is consistent with the justification of the product of nature doctrine as protecting a special quality inherent in the handiwork of nature as opposed to articles created by humans.¹⁹⁹ As discussed above, a cloned extinct animal is created from natural starting materials by humans. Thus, it does not possess the special quality inherent in articles “produced by the spontaneous hand of nature” that renders them unpatentable because human intervention is required to produce a living cloned extinct animal that otherwise would not exist.²⁰⁰ Accordingly, cloned extinct animals cannot fairly be said to be produced spontaneously by nature.

Even if a court were to consider an extinct animal itself naturally-occurring, Supreme Court precedent suggests that a living clone of that animal would not be a product of nature for the purposes of § 101 and thus would constitute patentable subject matter for related reasons. As discussed above, the courts have held that microorganisms and chemical substances purified from nature are patentable because the purified microorganism or substance did not exist in nature. The purified forms function as a new substance or microorganism as some of its properties are not manifested or it is not capable of being put to certain uses in the unpurified form. However, purification works no change on the substance or microorganism themselves—they remain the same in terms of structure and inherent properties. Even though the purified product is naturally-occurring in the sense that it exists in nature with the same properties, albeit in an unpurified form such that these properties cannot be harnessed, and it is “an extracted product without change,” it is patentable because purification entails human ingenuity.²⁰¹ Likewise, if an extinct animal exists in nature in the form of remains, the ingenuity and handiwork of man is required to convert it from an inanimate form to a living form. This conversion is akin to purification as it transforms the natural creature from remains, the form it exists in naturally, into a new and different form that is not present in nature. Indeed, the living creature has properties that are not manifested by remains, much like purified adrenaline and microorganisms have properties that cannot be harnessed in their natural unpurified states. Even though the living form of an extinct animal once existed naturally, it no longer does so, and the intervention of man is required for it to exist. Thus, if an extinct animal itself exists in nature in the form of remains, the fact that human intervention is necessary to transform it into a living form that is not present in nature, which is new and different as compared to the remains, renders the living form patentable.

in a special medium are not products of nature. *See id.* Accordingly, a cloned extinct animal derived from such cells is not derived from nature and is not a product of nature.

¹⁹⁹ *See supra* notes 55-59 and accompanying text.

²⁰⁰ LOCKE, *supra* note 58, at 286-87.

²⁰¹ *Parke-Davis & Co. v. H.K. Mulford Co.*, 189 F. 95, 103 (C.C.S.D.N.Y. 1911) *aff'd in part, rev'd in part on other grounds*, 196 F. 496 (2d Cir. 1912).

A possible counterargument is that neither courts nor the PTO have hitherto applied the reasoning employed in purification cases holding organisms existing in nature patentable in a purified form to higher eukaryotic organisms, such as animals, and have insisted that higher animals must be different from organisms known to exist in nature to be patentable.²⁰² The reason for this is that, unlike microorganisms, naturally-occurring living plants and animals are large enough such that their isolation does not require the patentee's ingenuity in devising conditions for isolation.²⁰³ In contrast to animals that are living in nature, isolating a living extinct animal requires the ingenuity of man. Thus, the reasoning applicable to purified microorganisms is equally germane in the cloned extinct animal context.

B. *Novelty*

Section 102 contains the novelty provisions of the patent law.²⁰⁴ Because the Supreme Court has held that living things that occur in nature are not patentable subject matter,²⁰⁵ courts have not had the occasion to consider the novelty of such organisms under the language of § 102. This Part examines whether the provisions related to novelty relevant to the patentability of a cloned extinct animal, § 102(a), § 102(f), and § 102(g), foreclose patentability and concludes that they do not.²⁰⁶ Even if one of these provisions precludes patentability, a cloned extinct animal is likely still patentable under the lost art doctrine. Thus, although a cloned extinct animal is not novel, intuitively speaking, inasmuch as the animal previously existed in nature, it is not unpatentable for want of novelty under the legal definition of novelty.

1. Section 102(a)

Section 102(a) states that an applicant is not entitled to a patent if “the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country” before the applicant's invention.²⁰⁷ To demonstrate lack of novelty, the prior art must anticipate the claimed invention.²⁰⁸ To anticipate an invention, a single prior art reference must: (1) teach all elements of the claimed invention, either

²⁰² See *supra* note 184 and accompanying text.

²⁰³ See *id.*

²⁰⁴ 35 U.S.C. § 102 (2000).

²⁰⁵ See *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

²⁰⁶ Other provisions of § 102 are not discussed here because they do not raise issue unique to cloned extinct animals.

²⁰⁷ § 102(a).

²⁰⁸ See *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631 (Fed. Cir. 1988).

expressly or inherently²⁰⁹ and (2) enable a person of ordinary skill in the art to make or possess the invention.²¹⁰

In the case of cloned animals that are known to be extinct, printed publications including a description of the animal and possibly pictures will likely exist and at least some American scientists probably know of the animal.²¹¹ However, these sources of anticipatory art for a cloned extinct animal do not enable the invention. A living organism is unique subject matter inasmuch as “a written description, photograph, or awareness of public use alone does not enable one to recreate it.”²¹² An individual “must obtain a sample of the living organism such as a microorganism culture, cell line, seed, or living animal” in order to reproduce the invention.²¹³ Indeed, courts have held that a reference must describe or provide the manner in which one can obtain either the living organism or a biological sample that may be used to create the organism without undue experimentation to enable the invention.²¹⁴ Thus, neither a printed publication describing an organism before or after its extinction nor public knowledge or use of the organism in the United States before extinction enables one to create the living organism.²¹⁵ When an animal is extinct, no enabling living organism

²⁰⁹ See *id.*

²¹⁰ See *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 555 (1870) (“Patented inventions cannot be [anticipated] unless the descriptions and drawings [in the reference] contain and exhibit a substantial representation of the patented improvement in such full, clear, and exact terms as to enable any person skilled in the art or science to which it appertains to make, construct and practice the invention”); *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994); *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985) (citing *In re Borst*, 345 F.2d 851, 855 (C.C.P.A. 1965)) (holding that disclosure and description of an invention in a printed publication is insufficient to anticipate an invention if the description is not enabling); *Dewey & Almy Chem. Co. v. Mimex Co.*, 124 F.2d 986, 989 (2d Cir. 1942) (Hand, J.) (“No doctrine of the patent law is better established than that a prior patent or other publication to be an anticipation must bear within its four corners adequate directions for the practice of the patent invalidated.”); *Van Heusen Prods., Inc. v. Earl & Wilson*, 300 F. 922, 930 (S.D.N.Y. 1924) (indicating that a prior art reference “must tell you how you can get with certainty the result you are after” to be anticipatory).

²¹¹ See *Jiron*, *supra* note 34, ¶ 35.

²¹² *Rohrbaugh*, *supra* note 127, at 391.

²¹³ *Id.*

²¹⁴ See, e.g., *In re Lundak*, 773 F.2d 1216, 1218 (Fed. Cir. 1985) (indicating that a written description of a human cell line is not enabling without a deposit in a public depository unless the cell line is known and readily available to the public); *In re LeGrice*, 301 F.2d 929, 939 (C.C.P.A. 1962) (concluding that a description of a flower is not prior art for plant patents because it does not enable one to obtain or create the flower).

²¹⁵ *Rohrbaugh*, *supra* note 127, at 391. Likewise, this analysis applies to the 102(b) statutory bar as well since 102(b) prior art must also be enabling. See, e.g., *Donohue*, 766 F.2d at 533 (indicating that a reference must be enabling to constitute § 102(b) prior art). For instance, a printed publication describing an extinct animal cannot trigger a § 102(b) statutory bar.

One might argue that description of an extinct animal in a printed publication prior to its extinction might constitute prior art because at the time the animal was described, it was naturally occurring and reproducing and thus enabling at the time of the publication. Even a bare description of the animal

may be obtained. DNA and other biological remains of the organism that are present as remains in nature or are preserved by man are not enabling because the current state of technology is such that no person of ordinary skill in the art can reproduce the living organism.²¹⁶ Therefore, at first blush, it appears that because there is no source of enabling prior art for a cloned extinct animal, §102(a) poses no barrier to its patentability.

However, while the case law invariably requires that a printed publication or patent must be enabling to constitute prior art,²¹⁷ some case law indicates that public use or knowledge of an invention in the United States need not be enabling to defeat patentability so long as it is public.²¹⁸ Under this rule, knowledge of an extinct animal by American scientists or use of the animal for food or other purposes in the United States prior to its extinction appear to render a regeneration of it by cloning unpatentable regardless of the fact that the knowledge and prior use are not enabling and do not

itself without any information concerning breeding would be enabling because a person skilled in the art would likely be able to breed the animals without undue experimentation (or with no experimentation as animals can mate without human intervention). A court would likely reject such an argument as courts evaluating whether a reference is enabling looks to whether the reference is enabling to one of ordinary skill in the art as of the date of the invention or other critical date rather than the date of the reference itself. See *Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1379 (Fed. Cir. 2001); *In re Samour*, 571 F.2d 559, 562-63 (C.C.P.A. 1979); cf. *Schering Corp. v. Geneva Pharms., Inc.*, 339 F.3d 1373, 1380 (Fed. Cir. 2003); *Donohue*, 766 F.2d at 533-34; *In re Collins*, 462 F.2d 538, 542 (C.C.P.A. 1972); *LeGrice*, 301 F.2d at 936. Furthermore, the Federal Circuit's requirements for a deposit of a living organism or biological material to be enabling in the context of 35 U.S.C. § 112 suggest that it would not consider use of an extinct animal before it disappeared from nature enabling. For such a deposit to be enabling, the deposit must be in "a depository affording permanence and ready [sic] accessibility thereto to the public." *Lundak*, 773 F.2d at 1219. A deposit that does not meet this permanence requirement and ceases to be available to the public is not enabling even though at one time, enabling individuals might have existed and been used by humans. See *id.* at 1218-19. Likewise, when an animal becomes extinct and ceases to be available to the public, prior knowledge, use, or descriptions of the animal can hardly be considered enabling. Indeed, no one possesses information sufficient to enable an extinct animal in the absence of the cloner's efforts. Finally, even if a court were to hold that knowledge or use of an extinct animal prior to extinction constituted enabling prior art (even though at the time the animal was cloned it was no longer enabling) that anticipated the cloned extinct animal, the cloned extinct animal would still be patentable under the lost art doctrine because all knowledge of its reproduction had been lost prior to the work of the cloner. See *infra* Part II.B.4.

²¹⁶ *Jiron*, *supra* note 34, ¶ 36.

²¹⁷ See *Seymour v. Osborne*, 78 U.S. (11 Wall.) 516, 555 (1870); *In re Epstein*, 32 F.3d 1559, 1568 (Fed. Cir. 1994); *In re Donohue*, 766 F.2d 531, 533 (Fed. Cir. 1985) (citing *In re Borst*, 345 F.2d 851, 855 (C.C.P.A. 1965)); *Dewey & Almy Chem. Co. v. Mimex Co.*, 124 F.2d 986, 989 (2d Cir. 1942) (Hand, J.); *Van Heusen Prods., Inc. v. Earl & Wilson*, 300 F. 922, 930 (S.D.N.Y. 1924).

²¹⁸ See *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1570 (Fed. Cir. 1997); *In re Epstein*, 32 F.3d 1559, 1567-68 ("Beyond this "in public use['] . . . there is no requirement for an enablement-type inquiry."); DONALD S. CHISUM, 1-3 CHISUM ON PATENTS § 3.05 (2007); MERGES & DUFFY, *supra* note 62, at 389-90, 473 ("Where the anticipatory reference is a product actually in public use, some case law suggests that the enablement standard simply does not apply—The product constitutes prior art even if the knowledge needed to produce the product is not publicly available.")

convey how the animal can be reproduced.²¹⁹ However, it is not at all clear that a court would apply this rule in the cloned extinct animal context. The cases articulating this rule contemplate an invention that is known by or used by the public but such knowledge or use of the invention does not disclose to the public how to build and/or practice the invention while someone does have such enabling knowledge and is keeping it secret.²²⁰

In contrast, at the time of cloning, nothing, knowledge or otherwise, exists anywhere that can enable an extinct animal, as the animal cannot be reproduced, either naturally or by way of human intervention, short of cloning.²²¹ Thus, unlike the conventional case, where an individual possesses enabling knowledge and the capability to produce the invention and has provided the public with at least some exposure to it, there is no chance that enabling information for an extinct animal could ever be communicated to the public or that the animal could be generated again in the absence of cloning. Therefore, the policy behind the patent system and novelty rules of promoting public access to inventions and preventing patentability where it would cause withdrawal of an invention from the public more strongly favors permitting patentability in the case of nonenabling use or knowledge of an extinct animal than in the run-of-the-mine case where public knowledge and use of the invention is not enabling. Furthermore, even if a court were chary to create an exception to the rule that nonenabling public knowledge and use could defeat patentability in the extinct animal context, as discussed below in Part II.B.4, a cloned extinct animal would still be patentable despite the rule under the judicially-created lost art doctrine, which prescribes that prior use and knowledge of an invention does not render the invention unpatentable when all knowledge of its reproduction has been lost.²²² Therefore, since an extinct animal constitutes a lost art because its methods of reproduction have been lost, the lost art doctrine renders the rule that nonenabling public use or knowledge can defeat pat-

²¹⁹ Indeed, the use of an animal for purposes such as food by humans can be a major factor leading to its extinction, as was the case with the dodo. *See Raphus Cucullatus*, <http://extinctanimals.petermaas.nl>. Of course, many extinct animals are not indigenous to the United States and have become extinct without ever being present in the United States while alive, much less used by humans in the United States. However, it is likely that at least some American scientists will know of such extinct animals.

²²⁰ *See Lockwood*, 107 F.3d at 1570.

²²¹ Even nature herself cannot reproduce an extinct animal.

²²² *Infra* Part II.B.4. The discussion in this paragraph and the preceding one also applies to public use and offers for sale under § 102(b), which case law indicates need not be enabling to create a statutory bar. *See Lockwood*, 107 F.3d at 1570; *Epstein*, 32 F.3d at 1567-68; DONALD S. CHISUM, 1-3 CHISUM ON PATENTS § 3.05 (2007); *see also* J.A. La Porte, Inc. v. Norfolk Dredging Co., 787 F.2d 1577, 1583 (Fed. Cir. 1986).

entability effectively nugatory and the cloned extinct animal patentable despite public knowledge or use of the animal before it became extinct.²²³

Another possible counterargument is that the level of ordinary skill contemplates cloning as a viable way to regenerate living animals of extinct species without undue experimentation.²²⁴ The first animal was cloned in 1996, and those skilled in the art have cloned numerous animals from preserved materials, including some using interspecies surrogate mothers, as would be required for cloning an extinct animal.²²⁵ However, there is no evidence that the state of cloning technology permits cloning of an extinct animal without undue experimentation. No researchers have hitherto cloned an extinct animal successfully. Recent efforts to clone the bucardo have failed, and scientists have suspended attempts to clone the Tasmanian tiger after failing to secure undegraded DNA suitable for cloning.²²⁶ Cloning an extinct animal entails technological hurdles not present in other types of cloning. There may be greater difficulty in selecting an interspecies surrogate mother or the species of enucleated eggs to use in cloning an extinct animal that is no longer present in nature. Also, DNA samples of extinct animals are irreplaceable and less likely to be free of degradation to the point that they are suitable for cloning given current methods. Thus, current cloning technology does not provide a biologist of ordinary skill with a tool to recreate extinct animals without undue experimentation.

2. Section 102(f)

Section 102(f) precludes an applicant from obtaining a patent if “he did not himself invent the subject matter sought to be patented.”²²⁷ To invalidate a patent for derivation of invention, a party must demonstrate that the patentee “acquired knowledge of the claimed invention from another, or at least so much of the claimed invention as would have made it obvious to one of ordinary skill in the art”²²⁸ and that “the invention was previously conceived by another person and that the complete conception was communicated to the patentee.”²²⁹ The knowledge communicated to the patentee must be able to “enable an ordinary mechanic, without exercise of any in-

²²³ In the conventional nonenabling use case where an individual has constructed an invention which has been known and used in public and such knowledge and use did not disclose to one skilled in the art how to produce the invention, the lost art doctrine is not applicable because all knowledge of the reproduction of the invention has not been lost—the individual responsible for the nonenabling use has enabling knowledge that he has kept secret. *See infra* Part II.B.4.

²²⁴ Jiron, *supra* note 34, ¶ 35.

²²⁵ *Id.* ¶ 37 & n.61.

²²⁶ Recently Extinct Animals, Cloning Extinct Animals, *supra* note 13.

²²⁷ 35 U.S.C. § 102(f) (2000).

²²⁸ *New England Braiding Co. v. A.W. Chesterton Co.*, 970 F.2d 878, 883 (Fed. Cir. 1992).

²²⁹ *Pentech Int'l v. Hayduchok*, 18 U.S.P.Q.2d (BNA) 1337, 1343 (S.D.N.Y. 1990).

geniety and special skill on his part, to construct the [invention] and put [it] in successful operation.”²³⁰

While courts’ language suggests that derivation can only occur when the patentee acquires knowledge of the invention from another person and not nature, which is not a person, an extinct animal previously existing in nature might be said to be “conceived and reduced to practice by natural forces.”²³¹ Even if a court were to adopt this construction, an extinct animal’s prior existence in nature does not foreclose patents on a clone derived from its remains under § 102(f). While the patentee would obtain general knowledge of the animal from nature by way of analysis of remains or accounts or actual viewing of the animal in nature before it became extinct, such information is insufficient to enable an ordinary mechanic or person of ordinary skill in the art to construct the living creature from naturally available remains without the exercise of ingenuity and special skill in cloning it. Cloning an extinct animal is not obvious to one skilled in the biotechnology art.²³²

3. Section 102(g)

In relevant part, § 102(g)(2) forecloses a patent if “the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it” before the patentee invented it.²³³ Although one commentator has suggested that § 102(g)(2) might defeat a patent for a cloned extinct animal,²³⁴ its applicability in this context is questionable at best. Such an argument assumes that nature, a nonhuman inanimate force, is an inventor as § 102(g)(2) requires that the invention be made by an inventor, not merely exist. No court has ever suggested that nature constitutes an inventor. The Federal Circuit speaks of inventors as persons,²³⁵ and the patent statute itself refers to inventors as “persons.”²³⁶ To be an inventor, an individual must invent the invention meaning that she must both conceive it

²³⁰ *Agawam Co. v. Jordan*, 74 U.S. (7 Wall.) 583, 602-03 (1869).

²³¹ Rohrbaugh, *supra* note 127, at 394. No court has hitherto addressed whether information acquired from nature can defeat patentability under § 102(f). The Federal Circuit defines conception as “the formation, in the mind of the inventor of a definite and permanent idea of the complete and operative invention, as it is thereafter to be applied in practice.” *Coleman v. Dines*, 754 F.2d 353, 359 (Fed. Cir. 1985). Nature does not have a mind and does not formulate ideas in the ordinary sense. Thus, nature might be incapable of conception.

²³² *See supra* Part II.B.1.

²³³ 35 U.S.C. § 102(g)(2).

²³⁴ Rohrbaugh, *supra* note 127, at 396.

²³⁵ *E.g.*, *Dow Chem. Co. v. Astro-Valcour, Inc.*, 267 F.3d 1334, 1340-41 (Fed. Cir. 2001).

²³⁶ 35 U.S.C. § 116 (2000).

and reduce it to practice.²³⁷ Furthermore, to conceive an invention for the purposes of § 102(g), the prior inventor “must . . . recognize[] and appreciate . . . the new form” that constitutes the invention.²³⁸ As discussed above, nature does not appear to be capable of conception, at least in the ordinary sense of the term.²³⁹ Also, nature cannot fairly be said to recognize and appreciate a new animal that evolved. Thus, a court would likely hold that nature is not an inventor for the purposes of § 102(g) and thus that § 102(g)(2) does not preclude an extinct animal patent.

This conclusion is supported by the fact that in § 102(a), Congress used language foreclosing a patent for prior use, knowledge, or description in a printed publication that readily encompasses natural objects. Thus, Congress knew how to deny patents on the basis of prior art other than invention including presence in nature. In § 102(g), Congress expressly restricted the class of prior art that precludes a patent for an invention made prior to the patentee’s invention of it resulting from invention by an inventor.²⁴⁰ If Congress had meant to give § 102(g) broader scope to include articles in existence or made that were not invented by humans, such as natural animals, it could have easily done so and would not have limited § 102(g) prior art to the work of inventors, requiring a strained interpretation of invention and conception.

Even if a court were to hold that nature were an inventor under § 102(g) and that it previously made an extinct animal, the clone of that animal is not necessarily unpatentable. First, the animal must have evolved, or have been made or reduced to practice by nature, in the United States.²⁴¹ Many extinct animals, such as the bucardo and Tasmanian tiger, were never native to the United States. Second, the function and purpose of § 102(g) is to incorporate an earlier inventor’s secret knowledge into the prior art capable of defeating a patent so long as it is not abandoned, suppressed, or concealed.²⁴² Such knowledge, although secret, is enabling.²⁴³ In contrast, na-

²³⁷ See 35 U.S.C. § 102(g)(2) (2000); *Dow Chem.*, 267 F.3d at 1340-41; MERGES & DUFFY, *supra* note 62, at 472.

²³⁸ *Dow Chem.*, 267 F.3d at 1341 (quoting *Silvestri v. Grant*, 496 F.2d 593, 599 (C.C.P.A. 1974)).

²³⁹ See *supra* note 231 and accompanying text.

²⁴⁰ See § 102(g)(2) (“A person shall be entitled to a patent unless . . . before such person’s invention thereof, the invention was made in this country by another *inventor* who had not abandoned, suppressed, or concealed it.” (emphasis added)).

²⁴¹ This requirement of § 102(g)(2) raises several interesting issues. First, an animal may have evolved outside the United States and have been transported to the United States by man where it reproduced naturally. If nature were said to be an inventor, it probably would be “made” in the United States by nature under § 102(g) even though nature first “invented” it elsewhere. Second, animals may have naturally occurred in the territory that became the United States before the country was founded or even colonized. Because the Patent Act defines “this country” as “the United States of America, its territories, and possessions” without mention of its geographic territory, 35 U.S.C. § 100 (2000), a court would likely consider such animals to fall outside the scope of § 102(g).

²⁴² MERGES & DUFFY, *supra* note 62, at 473.

²⁴³ See *id.*

ture cannot be said to be in possession of enabling knowledge in the extinct animal context because nothing that can be learned from nature would enable someone with ordinary skill in biotechnology to reproduce an extinct animal. Thus, as a reference must be enabling to constitute prior art,²⁴⁴ one might argue that the previous “making” of an extinct animal by nature does not constitute prior art and thus does not foreclose patentability.²⁴⁵

Finally, an animal might be considered abandoned, suppressed, or concealed when it becomes extinct.²⁴⁶ This issue raises the question of whether a court would consider an animal abandoned, suppressed, or concealed after it has freely occurred in nature where it is accessible to the public.²⁴⁷ Courts consider noninforming public access to and use of an invention, which is not enabling (while the inventor has enabling information), to foreclose a finding of abandonment, suppression, or concealment.²⁴⁸ Thus, the noninforming presence of an extinct animal in nature before it became extinct might also be said to preclude such a finding because the public has been exposed to the animal. However, the rationale for this rule is that a noninforming use gives the public the benefit of the invention and its use and that the public may uncover the invention’s secret if exposed to it.²⁴⁹ However, these reasons are not present in the extinct animal context where, unlike the noninforming use context, the public is no longer exposed to the living animal. The public derives no benefit from an extinct creature and is unable to uncover the secret of regenerating it save for use of inventive skill. Thus, even though an extinct animal was once present in nature, it totally disappeared from nature upon extinction.²⁵⁰ Extinction thus effects complete suppression of an animal. Consequently, a court would probably extend abandonment, suppression, and concealment to the extinct animal context.²⁵¹

²⁴⁴ See *supra* Part II.B.1.

²⁴⁵ A possible counterargument here is that the § 102(g) requirement that an inventor make an invention is less amenable to the judicially-created enablement requirement than use, knowledge, or description in a printed publication.

²⁴⁶ See Rohrbaugh, *supra* note 127, at 396.

²⁴⁷ This issue has never been decided by the courts. See *id.*

²⁴⁸ *E.g.*, Dunlop Holdings Ltd. v. Ram Golf Corp., 524 F.2d 33, 37 (7th Cir. 1975).

²⁴⁹ See *id.*

²⁵⁰ Indeed, barring the most aberrant of evolutionary events where an extinct animal gradually re-evolves from existing species, nature is wholly unable to engender new individuals of an extinct species.

²⁵¹ This situation is different than that involving the subsequent cloning of a nonnatural transgenic animal patentable under *Chakrabarty* after all specimens of the animal have died out. In that case, prior art describing the construction of the transgenic animal could be enabling and thus defeat patentability under § 102(a). In addition, the original animal was made with enabling information in the mind of the original inventor and thus is not patentable under § 102(g)(2).

4. The Lost Art Doctrine

However, if a court were to determine that any of the novelty provisions precluded a patent for an extinct animal based on prior art derived from the animal's previous existence in nature, a cloned extinct animal would likely still be patentable because a court would likely consider an extinct animal a lost art. Thus, the animal's original appearance in nature would not foreclose the patent.

In 1850, the Supreme Court created the lost art doctrine in *Gayler v. Wilder*,²⁵² holding that prior knowledge and use of an invention does not preclude a second, independent inventor from procuring a patent for the same invention where the original invention has been completely lost.²⁵³ The *Gayler* Court articulated two requirements for a second inventor to obtain a patent: (1) that the invention "pass[] away from the memory of [the inventor], and of those who had seen it [such that] the knowledge of the [invention] was as completely lost as if it had never been discovered"; and (2) that the second inventor make his invention by his own efforts without any knowledge of the original invention and that his invention be new and unknown at the time it was made.²⁵⁴ A patent for the second invention could not be defeated if the second invention caused the first inventor to recall the invention.²⁵⁵ The lower courts have interpreted *Gayler*'s complete loss requirement to mean that the invention "must at least have been so far forgotten that its inventor . . . or others who may have witnessed its use [or had knowledge of it] would not be able to recall it to memory and reproduce it without the assistance of the . . . subsequent discovery."²⁵⁶ This interpretation is consistent with language in *Gayler* indicating that the reinvention of an art was patentable when "the fruits of [the art] have come down to us [from the original invention], but the means by which the work was accomplished are at this day unknown."²⁵⁷ The policy behind the lost art doctrine is that "when an earlier invention is inaccessible, a later, independent inventor restores to the public the benefit of the invention" and is thus entitled to patent protection.²⁵⁸

²⁵² 51 U.S. (10 How.) 477 (1850).

²⁵³ *Id.* at 497-98.

²⁵⁴ *Id.* at 498. Since *Gayler*, the Supreme Court has only discussed the lost art doctrine once in *Coffin v. Ogden*, 85 U.S. (18 Wall.) 120, 124-25 (1873). Although the *Coffin* Court did not question the validity of the lost art doctrine, it questioned *Gayler*'s test relying on the memory of the original inventor. *Id.* at 125.

²⁵⁵ See *Gayler*, 51 U.S. at 498.

²⁵⁶ *Mason v. Hepburn*, 13 App. D.C. 86, 92 (D.C. Cir. 1898); *accord Rich v. Lippincott*, 20 F. Cas. 672, 675 (C.C.W.D. Pa. 1853) (No. 11,758) (concluding that the second inventor would not be entitled to a patent if the invention and its mode of construction were in the memory of the first inventor or in the knowledge or use of others before they were recalled by the second patent).

²⁵⁷ *Gayler*, 51 U.S. at 497.

²⁵⁸ *Id.* at 497-98; see also Rohrbaugh, *supra* note 127, at 398 (citing *Gayler*).

Under these standards, an extinct animal qualifies as a lost art. Nature, which might be viewed as the first inventor, no longer provides the animal to the public.²⁵⁹ Although the animal may not be completely forgotten in the literal sense because knowledge of it is still available from fossils or other remains in nature or from previous knowledge and printed descriptions if the animal is recently extinct, none of these types of prior art would permit one with ordinary skill in the art to reproduce the living animal, by way of breeding for instance, without reliance on the ingenuity embodied in the second invention. Thus, an extinct animal is completely lost as interpreted by the lower courts, and suggested by *Gayler* itself, and accordingly satisfies the first *Gayler* requirement.

However, one commentator has argued that the phrase “completely lost” in *Gayler* should be literally construed to mean that all knowledge of an invention, including that which is insufficient to enable reproduction of the invention, must be lost to meet the first *Gayler* requirement.²⁶⁰ The public undoubtedly retains such nonenabling knowledge of an animal after extinction that can be gleaned from books, photographs, fossils, preserved specimens and other remains.²⁶¹ Thus, since all knowledge of the animal is not completely lost as the knowledge need not be enabling, an extinct animal is not a lost art under this reasoning.²⁶² While this reasoning has some appeal, it conflicts with lower courts’ interpretation of *Gayler*’s complete loss requirement, as well as statements by the *Gayler* Court itself, indicating that an invention is deemed completely lost when all knowledge of its *reproduction* is lost even though some nonenabling knowledge of the invention might remain.²⁶³

The second *Gayler* requirement is also met. A cloned extinct animal is new and unknown at the time it is made because the living organism has not been present in nature since the time of extinction. Furthermore, the cloner of an extinct animal makes his invention by his own efforts in devising a method to clone the animal and does so without any knowledge of the evolutionary process by which nature originally generated the animal or replicating it. A valid counterargument here is that cloning employs genetic material taken from the remains of the live animal, and thus, that the cloner had knowledge of and relied on nature’s original invention of the animal in making his invention. However, having knowledge of the remains or even using them is not the same thing as having knowledge of the living organism or how it was created. As discussed above, transformation of remains into a living animal by cloning requires invention beyond knowledge that can be obtained from remains or by knowing of the animal’s previous exis-

²⁵⁹ Rohrbaugh, *supra* note 127, at 404.

²⁶⁰ Jiron, *supra* note 34, ¶ 55.

²⁶¹ *See id.*

²⁶² *See id.*

²⁶³ *See supra* notes 256-57 and accompanying text.

tence. This fact also cuts against the related counterargument that the cloner of an extinct animal undoubtedly has knowledge that the animal previously existed as well as at least some knowledge about the animal itself. While this knowledge is not enabling, one might argue that it is sufficient to defeat application of the lost art doctrine because it is knowledge of the invention by the second inventor. However, the *Gayler* Court's language suggests that the second inventor may still obtain a patent if he has knowledge of the fruits of the original invention, but not if he has knowledge of the means by which it was accomplished.²⁶⁴ Thus, knowledge of the fruits of nature's handiwork, the living animal, does not foreclose a patent for a cloned extinct animal because this knowledge does not permit reproduction of the animal without an inventive step by the cloner.

Finally, extending the lost art doctrine to extinct animals furthers the policy considerations underlying the doctrine. The inventor who clones an extinct animal regenerates an animal that has been totally lost from nature. Thus, he "confers knowledge and use of [the animal] to the public that it would not otherwise enjoy."²⁶⁵ Accordingly, an inventor who provides a benefit to the public by reviving an extinct animal should be rewarded by the patent system.²⁶⁶

C. *Nonobviousness*

Under 35 U.S.C. § 103(a), an invention is not patentable "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which [the] subject matter pertains."²⁶⁷ In *Graham v. John Deere Co.*,²⁶⁸ the Supreme Court provided analytical guidance for determining the issue of nonobviousness under § 103.²⁶⁹ The Court articulated four criteria to be weighed in analyzing nonobviousness: (1) the scope and content of the prior art; (2) the differences between the prior art and the claimed invention; (3) the level of ordinary skill in the art; and (4) secondary considerations that are objective indicia of nonobviousness including commercial success, long felt but unsolved needs, and failure of others.²⁷⁰ In the recent case of *KSR International Co. v. Teleflex Inc.*,²⁷¹ the Supreme Court reaf-

²⁶⁴ *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 497 (1850).

²⁶⁵ Rohrbaugh, *supra* note 127, at 404 (citing *Gayler*, 51 U.S. at 497).

²⁶⁶ *See id.*

²⁶⁷ 35 U.S.C. § 103(a) (2000).

²⁶⁸ 383 U.S. 1 (1966).

²⁶⁹ *Id.* at 17-18; *accord KSR Int'l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1734 (2007).

²⁷⁰ *Graham*, 383 U.S. at 17-18; *accord KSR*, 127 S. Ct. at 1734.

²⁷¹ 127 S. Ct. 1727 (2007).

firmed this framework.²⁷² In assessing the obviousness of an invention, the prior art references are combined, and the entire prior art is compared to the invention as a whole.²⁷³ Thus, while a single reference is required to anticipate an invention, the combination of multiple prior art references can render an invention obvious although no single one of them does. In combining prior art references, a court must be careful to “avoid aggregating pieces of prior art through hindsight which would not have been combined absent the inventor[‘s] insight.”²⁷⁴ The obviousness inquiry is highly fact specific making formulation of specific rules difficult.²⁷⁵ However, in this nonobviousness analysis, the Federal Circuit considers two factors: “(1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device . . . and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success.”²⁷⁶

The Federal Circuit has evaluated these factors in determining the obviousness of a recombinant microorganism.²⁷⁷ When the prior art suggests that an invention should be made and/or the use of a technique to make an invention, but does not convey to those of ordinary skill in the art a reasonable expectation of doing so by suggesting how to create the invention using the technique and providing evidence that this could be accomplished successfully, the invention is not obvious.²⁷⁸ Thus, when this is the case, both factors must be fulfilled for an invention to be obvious as prior art; only meeting the first one is defective as it serves merely as an invitation to try to create the invention.²⁷⁹ Such prior art shows it was obvious to try to create an invention, not that the invention was obvious.

²⁷² *Id.* at 1734.

²⁷³ *See, e.g.,* *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1383 & n.6 (Fed. Cir. 1986); *McNeil-PPC, Inc. v. Perrigo Co.*, No. 05 Civ. 1321 (WHP), 2007 U.S. Dist. LEXIS 50255, at *14-16 (S.D.N.Y. July 3, 2007) (decided after *KSR*) (“The claimed invention as a whole must be compared to the prior art as a whole.”).

²⁷⁴ *McNeil-PPC*, 2007 U.S. Dist. LEXIS, at *15 (following *KSR*); *see also KSR*, 127 S. Ct. at 1242-43; *Graham*, 383 U.S. at 36; *L & A Prods., Inc. v. Britt Tech Corp.*, 365 F.2d 83, 87 (8th Cir. 1966); *cf. Interconnect Planning Corp. v. Feil*, 774 F.2d 1132, 1143 (Fed. Cir. 1985).

²⁷⁵ *See In re Brouwer*, 77 F.3d 422, 425 (Fed. Cir. 1996); *cf. KSR*, 127 S. Ct. at 1739.

²⁷⁶ *In re Vaeck*, 947 F.2d 488, 493 (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 (Fed. Cir. 1988)).

²⁷⁷ *See Vaeck*, 947 F.2d at 493.

²⁷⁸ *See Hybritech*, 802 F.2d at 1380 (holding an invention nonobvious when the prior art suggested it but “[d]id not suggest how that end might be accomplished”); Rohrbaugh, *supra* note 127, at 409-10.

²⁷⁹ *See Rohrbaugh*, *supra* note 127, at 409-10 (citing *Hybritech*, 802 F.2d at 1380). Nothing in *KSR* alters this analysis. In *KSR*, the Court rejected the Federal Circuit’s “teaching, suggestion or motivation test,” under which a claimed invention was nonobvious in the face of a combination of prior art references unless “some motivation or suggestion to combine the prior art teachings can be found in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art.” 127 S. Ct. at 1734 (internal quotation marks omitted); *see also id.* at 1739, 1741-43. Thus even in the absence of a suggestion that prior art teachings should be combined, the combination is not necessarily nonobvious.

Applying this analysis to an extinct animal leads to the conclusion that a cloned extinct animal is not obvious. The relevant prior art includes remains and/or fossils of the extinct animal and possibly printed descriptions or pictures if the animal is recently extinct as well as the state of cloning technology. As discussed above, the prior art also includes materials related to cloning. Numerous animals have been cloned since the first cloned animal was described in 1996, and those skilled in the art are capable of producing clones from preserved biological materials.²⁸⁰ Furthermore, several existing species have been cloned using interspecies surrogate mothers.²⁸¹

The analysis articulated in the cases cited in this discussion does not concern whether the prior art suggested or taught that prior art references be combined but rather whether there was a suggestion in the prior art that the invention should be made and whether the prior art revealed that one making it would have a reasonable expectation of success.

Nothing in *KSR* suggested that it altered or repudiated the Federal Circuit's analysis of obviousness in situations beyond the combination of prior art elements. Although, in the context of combinations of known prior art elements, the *KSR* Court stated that it was wrong to conclude that a patent claim cannot be proved obvious merely because it was obvious to try the combination, the Court also noted that the fact that a combination was obvious to try might render it obvious under circumstances where a person of ordinary skill in the art pursues known options from a finite universe of identified predictable solutions to a problem, for which there was a design need or market pressure for a solution, and achieves anticipated success. *Id.* at 1742. The Court reasoned that it is likely that such actions are the product of ordinary skill and common sense as opposed to innovation. *See id.* Although the Court did say that it was error to conclude that a patent claim cannot be proved obvious merely by showing that a combination of prior art elements was obvious to try, the Court in no way indicated that this pronouncement applied outside of the situation where a person of ordinary skill in the art achieves anticipated success as a result of pursuing known options from a finite universe of particular solutions. Thus, *KSR* does not prescribe that the fact that it was obvious to try a combination is sufficient to render it obvious when the combination is not a known option drawn from a finite universe of predictable solutions or its success is surprising rather than anticipated. Therefore, like the approach employed by the Federal Circuit outside of the combination of prior art elements described in this discussion, which looks to whether the prior art suggested to try to build the invention and whether the prior art revealed a reasonable probability of success, the *KSR* Court's approach in combination cases is bipartite inasmuch as it has components addressing both obviousness to try and the degree of anticipated success created by the prior art.

In the run-of-the-mine case, a suggestion in the prior art to build an invention is insufficient to render the invention obvious because it is merely an invitation to construct the invention, but does not create a reasonable expectation of doing so. Also, it provides no evidence that it can be constructed successfully and thus is defective. *See Hybritech*, 802 F.2d at 1380; Rohrbaugh, *supra* note 127, at 409-10. Thus, a suggestion to try is insufficient to enable one of ordinary skill in the art to construct the invention. In contrast, in the situation contemplated by *KSR*, where the prior art suggests a combination and a person of ordinary skill in the art pursues known options from a finite universe of identified predictable solutions to achieve anticipated success in addressing a known problem, the suggestion to try the combination is enabling because the suggestion alone allows the inventor to create the invention by using common sense and ordinary skill without innovation. Therefore, even if the precepts articulated in *KSR* were held to apply beyond the combination of prior art context, they would not alter the analysis in situations, such as the cloned extinct animal context, where the mere suggestion to build an invention does not enable one skilled in the art to construct the invention without further innovation.

²⁸⁰ *See Jiron*, *supra* note 34, ¶ 37.

²⁸¹ *See id.* ¶ 9 & n. 35.

Several important differences exist between cloning an extinct animal and existing animals because the extinct animal is no longer present in nature. First, selecting an interspecies surrogate mother or the species of enucleated eggs to use in cloning an extinct animal may be more difficult in the extinct animal context as the relatedness of an extinct animal to existing ones may be harder to determine. Second, DNA samples of extinct animals are irreplaceable and likely to be degraded to an extent, such that the samples are unsuitable for cloning given the current methods.²⁸² Also, DNA in remains of extinct animals naturally or artificially preserved is present in much lesser concentrations than in tissues or cells extracted from living species.²⁸³ The prior art also includes extant naturally occurring animals, including related species. However, an extinct animal is markedly different from even a related one. For instance, there are physical and behavioral differences between species and individuals of an extinct species cannot be reproduced by mating or breeding of a related species. These differences suggest that a cloned extinct animal is not obvious from the prior art.

In the extinct animal context, a court probably would consider the prior art to have suggested to those of ordinary skill in the art that they should clone an extinct animal. Unlike a recombinant bacterium, a cloned extinct animal has previously existed in nature. Furthermore, endangered animals have been successfully cloned using interspecies surrogate mothers.²⁸⁴ There are numerous references in articles and papers discussing cloning and suggesting that it be applied to extinct animals.²⁸⁵ The Federal Circuit has held that such explicit references in the prior art constitute suggestion for the purposes of nonobviousness.²⁸⁶

While an argument that an extinct animal is obvious because it has previously existed in nature might seem intuitive, it neglects the requirement that the prior art engender a reasonable expectation of success in making the invention in a person of ordinary skill in the art. This requirement is not met in the extinct animal context. For a cloned extinct organism to be obvious, the prior art must provide a reasonable likelihood of success by specifically suggesting how to employ existing biological materials, such as remains or preserved remains, to regenerate the organism and must provide evidence that this could be accomplished successfully.²⁸⁷ As discussed above, cloning an extinct animal poses difficulties not present in cloning an existing animal for reasons such as degradation of DNA and selection of the

²⁸² Current cloning technology requires DNA that is in nearly perfect condition, meaning that it is nearly free of degradation. *See* Recently Extinct Animals, Cloning Extinct Animals, *supra* note 13.

²⁸³ *See* Mecklenborg, *supra* note 16.

²⁸⁴ *See, e.g.,* *Scientists Close to First Successful Cloning of Extinct Animal*, CNN.COM, Oct. 9, 2000, <http://archives.cnn.com/2000/NATURE/10/09/ox.cloning.ap>.

²⁸⁵ *See, e.g.,* Yule, *supra* note 17; Lanza et al., *supra* note 4; Recently Extinct Animals, Cloning Extinct Animals, *supra* note 13; Mecklenborg, *supra* note 16.

²⁸⁶ *See In re O'Farrell*, 853 F.2d 894, 901 (Fed. Cir. 1988).

²⁸⁷ *See* Rohrbaugh, *supra* note 127, at 410.

species to use for an interspecies surrogate mother.²⁸⁸ Nothing in the prior art of cloning indicates a reasonable likelihood of success in applying conventional cloning techniques to generate an extinct animal or suggests how difficulties specific to cloning extinct animals may be overcome. Existing techniques are unable to solve the problem of DNA degradation faced in cloning many extinct animals. Furthermore, as discussed above, an extinct animal has never been successfully cloned, and several serious well-funded attempts have failed.²⁸⁹ This secondary factor militates in favor of finding nonobviousness under *Graham* and also is strong evidence that there is no reasonable likelihood of success of cloning an extinct animal using techniques in the prior art.

Also, at least one commentator has noted that evidence that scientists find the results unpredictable and difficult to obtain when adapting biological techniques from one species to another suggests that application of a known technique to a different species is not obvious.²⁹⁰ While a suggestion in the prior art to adapt techniques used with one species to a closely related species is more likely to provide a reasonable likelihood of success than when species are divergent,²⁹¹ efforts to clone goats could not be successfully adapted to clone the bucardo, an extinct animal related to goats.²⁹² Thus, the successful cloning of an existing species does not suggest a reasonable likelihood of cloning an extinct species closely related to it. Therefore, a court will likely hold that cloning an extinct animal is not obvious in light of the prior art.

Likewise, one might argue that the existence of living animals, especially close relatives of the extinct species renders an extinct animal obvious. Indeed, the continued existence of related or similar animals would suggest to those of ordinary skill in the art that they should attempt to regenerate an extinct animal. However, an animal of a species other than an extinct one, even one of a closely related species, does not engender a reasonable expectation of success in regenerating the extinct animal in a person of ordinary skill in the art as any prior art related to a surviving animal neither suggests how an extant species can be used to regenerate an extinct one nor provides any evidence whatsoever that this could be accomplished

²⁸⁸ See *supra* notes 282-83 and accompanying text.

²⁸⁹ See *supra* notes 13-14, 24-28 and accompanying text.

²⁹⁰ Rohrbaugh, *supra* note 127, at 411 (“Scientists adapting the technique from one species to another may often find the results unpredictable and difficult to obtain. Such failure or others to adapt a technique serves as a secondary consideration to suggest that the invention is nonobvious.”).

²⁹¹ *Id.* (“A suggestion in the prior art to apply techniques used with one variety to another closely related variety or species is, as in *Allen*, more likely to provide a reasonable expectation of success. Conversely, the further the organism diverges genetically from a given species to another, as in *Vaack*, the less likely techniques can be adapted in any predictable manner.”).

²⁹² See *Cloning Extinct Animals*, *supra* note 13; *Cloning Goats*, <http://www.crystalinks.com/cloninggoats.html> (last visited Dec. 4, 2007).

successfully. Thus, existing animals do not render a cloned extinct animal obvious.

D. *Utility*

Section 101 requires that an invention be useful in order to be patentable.²⁹³ Courts require patentable inventions to possess practical or specific utility, meaning some real world use.²⁹⁴ Also, early U.S. judicial decisions required moral or beneficial utility rendering inventions “injurious to the well-being, good policy, or sound morals of society” unpatentable,²⁹⁵ but the Federal Circuit has rejected the relevancy of these decisions and has suggested that the modern standard for utility not to attempt to judge the morality of an invention.²⁹⁶ The utility requirement does not preclude the patentability of cloned extinct animals as they have practical or specific utility and are not rendered unpatentable by notions of moral or beneficial utility.

1. Practical or Specific Utility

In contrast with novelty and nonobviousness requirements, the substantive threshold for satisfying the utility requirement is relatively low.²⁹⁷ An invention “is useful . . . if it is capable of providing some identifiable benefit.”²⁹⁸ Although an invention need not have more than one use, that use must be credible to a person of ordinary skill in the art.²⁹⁹ The Supreme Court requires that an invention have substantial utility or a real world use.³⁰⁰ Use as a research tool or scientific curiosity does not qualify as a substantial use and thus does not satisfy the utility requirement.³⁰¹ However, an invention inciting amusement in the public possesses the requisite utility to be patentable.³⁰² The PTO Utility Examination Guidelines state the stan-

²⁹³ 35 U.S.C. § 101 (2000) (mandating that patentable inventions must be “new and useful” among other things).

²⁹⁴ See *In re Brana*, 51 F.3d 1560, 1564 (Fed. Cir. 1995); MUELLER, *supra* note 38, at 156.

²⁹⁵ *Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568).

²⁹⁶ *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366-68 (Fed. Cir. 1999).

²⁹⁷ See MUELLER, *supra* note 38, at 155.

²⁹⁸ *Juicy Whip*, 185 F.3d at 1365; accord *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1571 (Fed. Cir. 1992) (“To violate § 101 the claimed device must be totally incapable of achieving a useful result.”).

²⁹⁹ See, e.g., *Brana*, 51 F.3d at 1566; see also *Rohrbaugh*, *supra* note 127, at 388 & n.80 (collecting cases).

³⁰⁰ *Brenner v. Manson*, 383 U.S. 519, 534 (1966).

³⁰¹ See *id.* at 534-35.

³⁰² See *Callison v. Dean*, 70 F.2d 55, 57-58 (10th Cir. 1934) (“[A] device which may be used for innocent amusement possesses utility.”); see also, e.g., U.S. Pat. No. 5,523,741 (filed Aug. 19, 1994)

dard in a similar manner and require a “specific and substantial” utility and exclude “‘throw-away,’ ‘insubstantial,’ or ‘nonspecific’ utilities, such as the use of a complex invention as landfill, as a way of satisfying the utility requirement.”³⁰³

A cloned extinct animal satisfies the utility requirement. A cloned extinct animal would likely have a function to amuse and would be popular attractions at zoos and carnivals.³⁰⁴ Given the attention given to the possibilities of cloning extinct animals and the large number of websites devoted to them, extinct animals are of interest to the public and members of the public would likely observe them at zoos for amusement purposes.³⁰⁵ A related possible use is an educational one. Observing actual living animals would be the best way to inform the public about animals that formerly lived in the wild. There are many potential uses for cloned extinct animals that are species specific. An extinct animal may have commercial value as breeding stock for animal breeders.³⁰⁶ Depending on the species, other possible commercial uses include: agricultural uses as a source of food, wool, fur, or other by-products; pharmaceutical uses as a source of particular drugs or biologicals; domestic uses as pets; or as a source for genetic materials to improve existing animals.³⁰⁷

Since the asserted utility must be credible, an applicant may have greater difficulty asserting more speculative uses.³⁰⁸ For instance, assertion

(issued June 4, 1996) (patenting a “Santa Claus detector” that is useful for “providing children reassurance that their good behavior has . . . been rewarded by Santa Claus” by “providing selective illumination to signal the arrival of Santa Claus”).

³⁰³ Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (Jan. 5, 2001). Such a “throw away” use in the cloned extinct animal context would be to claim a cloned extinct animal to be used as snake food. See MERGES & DUFFY, *supra* note 62, at 249 (using this example in the transgenic animal context). This use is neither specific because any animal of comparable size could be used as snake food nor substantial because using a cloned extinct animal which would be rare and expensive to produce as snake food is not a real world context of use. *Id.*

³⁰⁴ An amusement function for extinct animals was contemplated in the novel *Jurassic Park* and the blockbuster movie based on it. JURASSIC PARK (MCA 1993); MICHAEL CRICHTON, JURASSIC PARK (1990). *Jurassic Park* described a fictional theme park where cloned dinosaurs could be observed by the public. The fictional dinosaurs in Jurassic Park were recombinant animals containing both dinosaur and frog DNA and had properties that natural dinosaurs likely did not have such as the inability to synthesize the amino acid lysine. Thus, unlike a true clone, they differed from the extinct animal. As these creatures never occurred in nature and were made by man, they clearly constitute patentable subject matter under *Chakrabarty* and do not raise some of the issues raised by exact clones of extinct animals.

³⁰⁵ See, e.g., Grant Holloway, *Cloning to Revive Extinct Species*, CNN.COM, May 28, 2002, <http://archives.cnn.com/2002/WORLD/asiapcf/auspac/05/28/aust.thylacines>; *Scientists Close to First Successful Cloning of Extinct Animal*, *supra* note 284; <http://extinctanimals.petermaas.nl> (listing links to eighteen websites related to extinct animals); <http://www.extinctanimal.com>; <http://www.thylacines.net> (describing the recent extinction of the Tasmanian tiger).

³⁰⁶ Rohrbaugh, *supra* note 127, at 388; cf. *In re Magerlein*, 602 F.2d 366 (C.C.P.A. 1979) (holding intermediates in the production of an improved series of biologically active compounds patentable).

³⁰⁷ Rohrbaugh, *supra* note 127, at 388-89.

³⁰⁸ *Id.* at 389.

of a pharmaceutical utility may require support from an appropriate experimental model system.³⁰⁹ Some scientists have suggested that the primary uses of cloned extinct animals include restoring ecological environments and maintaining biodiversity.³¹⁰ A possible difficulty with this use is that one species alone is unlikely to restore an ecological environment, although restoring even a single species slightly increases biodiversity, and thus it may not be possible to describe the ecological benefit in concrete terms as having a substantial or real world value.³¹¹ The PTO might consider such uses too speculative and not credible to someone with ordinary skill in the art. This problem is obviated if the applicant provides concrete evidence of a particular benefit to the environment and thus to the public from the reintroduction of an extinct animal.³¹²

2. Moral Utility

Early U.S. judicial decisions recognized a morality component within the utility requirement restricting utility to inventions with “some beneficial use in society” and rendering those that were injurious to the well-being, good policy, sound morals, health, or good order of society unpatentable.³¹³ Applying this standard, courts invalidated patents on gambling devices and patents on inventions designed to be deceptive in the early twentieth century.³¹⁴ However, the Federal Circuit has noted that this “principle . . . has not been applied broadly in recent years.”³¹⁵ In 1977, the Board of Patent Appeals and Interference upheld the patentability of a slot machine reasoning that it could not find any basis in § 101 to hold that gambling machines were unpatentable for want of utility although some consider gambling immoral and injurious to public order.³¹⁶ In 1999, the Federal Circuit held that an arguably deceptive product, which was designed to appear to be something it is not, is patentable, reasoning that cases invalidating patents on deceptive products on moral utility grounds “do not . . . represent[] the cor-

³⁰⁹ *Id.* (citing *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995)).

³¹⁰ *E.g.*, Rohrbaugh, *supra* note 127, at 389; Yule, *supra* note 17, at 7.

³¹¹ Rohrbaugh, *supra* note 127, at 389.

³¹² *See id.* An example is a situation where a predator that went extinct due to hunting is reintroduced into its natural habitat which became overpopulated by its prey leading to adverse ecological effects or migration of the prey into agricultural areas where it competed with livestock for food.

³¹³ *Bedford v. Hunt*, 3 F. Cas. 37, 37 (C.C.D. Mass. 1817) (No. 1,217); *see also Lowell v. Lewis*, 15 F. Cas. 1018, 1019 (C.C.D. Mass. 1817) (No. 8,568) (stating that inventions “injurious to the well-being, good policy, or sound morals of society” are unpatentable).

³¹⁴ *E.g.*, *Scott & Williams, Inc. v. Aristo Hosiery Co.*, 7 F.2d 1003 (2d Cir. 1925); *Brewer v. Lichtenstein*, 278 F. 512 (7th Cir. 1922); *Rickard v. Du Bon*, 103 F. 868 (2d Cir. 1900).

³¹⁵ *See Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1366-67 (Fed. Cir. 1999).

³¹⁶ *See Ex Parte Murphy*, 200 U.S.P.Q. (BNA) 801, 802 (B.P.A.I. 1977).

rect view of the doctrine of utility.³¹⁷ Thus, although the Federal Circuit did not expressly disclaim moral utility entirely, it suggested that the modern standard of utility does not attempt to judge the morality of an invention.³¹⁸ The Court reasoned that the PTO is not the proper arbiter of whether an invention is moral, deceptive or illegal, as this is the realm of Congress and other agencies such as the FDA.³¹⁹ Congress is free to declare classes of inventions unpatentable and has done so in the case of inventions useful solely in connection with certain nuclear materials and atomic weapons.³²⁰ Lower courts have followed Federal Circuit precedent on moral utility, and held that radar detectors, which are used only to circumvent the law, are patentable.³²¹ However, the moral utility doctrine is not completely dead as lower courts have recited it as the standard for utility without applying it,³²² and the PTO suggested that patents on human-animal chimeras and human beings are void on moral utility grounds in a press release.³²³ Thus, since the PTO has suggested that that the moral utility doctrine might apply to defeat patents for one type of biological invention raising ethical issues, there is a possibility that the doctrine might be advanced as a reason to foreclose the patentability of a cloned extinct animal, which, as discussed below, also raises ethical concerns.

Given the vestigial state of the moral utility doctrine, a court would not likely employ it to defeat the patentability of a cloned extinct animal. This is especially so given the acceptance of courts and the PTO of the patentability of living things and animals and the Supreme Court's statements in *Chakrabarty* that whether ethical concerns and dangers associated with genetic engineering should foreclose patentability of living things is a question for Congress to decide.³²⁴ Cloning extinct animals is not illegal, does not raise ethical issues of a significant magnitude greater than those raised by other nonhuman living things, and does not implicate the weighty ethical concerns surrounding human cloning. Furthermore, even if a court contemplated applying the moral utility doctrine, cloned extinct animals have multiple beneficial uses in society as discussed above and accordingly have moral utility.

³¹⁷ *Juicy Whip*, 185 F.3d at 1367.

³¹⁸ *See id.*; MUELLER, *supra* note 38, at 165.

³¹⁹ *See Juicy Whip*, 185 F.3d at 1367-68.

³²⁰ *Id.* at 1368 (citing 42 U.S.C. § 2181(a) (2000)).

³²¹ *Whistler Corp. v. Autotronics, Inc.*, 14 U.S.P.Q.2d (BNA) 1885, 1886 (N.D. Tex. 1988).

³²² *E.g., Geneva Pharms., Inc. v. Glaxosmithkline PLC*, 213 F. Supp. 2d 597, 610 (E.D. Va. 2002).

³²³ *See Media Advisory*, Pat. and Trademark Off. (Apr. 1, 1998), <http://www.uspto.gov/web/offices/com/speeches/98-06.htm>. However, in rejecting a patent for a chimera, the PTO concluded that human hybrid creatures were not patentable subject matter and did not address moral utility. *See MERGES & DUFFY*, *supra* note 62, at 225-26.

³²⁴ *Diamond v. Chakrabarty*, 447 U.S. 303, 316-18 (1980).

However in addition to the general concerns about patenting living things dismissed by the *Chakrabarty* Court,³²⁵ there are several policy arguments specific to extinct animals advanced against their patentability. As indicated in *Chakrabarty*, Congress is in a better position to assess these arguments than courts or the PTO. Also, these arguments do not warrant a finding that cloned extinct animals have no moral utility. One such argument is that because of the potential monetary value of the uses of some animals and the monopoly granted to a patent owner, the patentability of cloned extinct animals would create perverse incentives for inventors to eradicate all remaining natural members of a species to clear the way for a patent on the cloned animal allowing the inventor to exploit any commercial value of the animal.³²⁶ However, laws protecting endangered species could effectively prevent this conduct. Indeed, courts hold that the role of patent laws is not to displace the police power of the state.³²⁷ Furthermore, this possibility is quite speculative.

Also, some scientists argue that investments in experimental cloning, which would be encouraged by patentability, would divert funding from demonstrated methods of conservation, such as preservation of habitat.³²⁸ Thus, additional natural species might become extinct because resources were expended on cloning a few species. A related argument is that the possibility of regeneration of extinct animals by cloning will cause the public to take conservation less seriously because any species lost could be regenerated by cloning.³²⁹ However, it is not clear that cloning will deplete conservation funding since much funding for cloning comes from independent sources. Furthermore, progress in cloning could bring more press coverage to conservation efforts and bolster the morale of conservationists by showing that human errors can be corrected.³³⁰

These are precisely the types of high issues that the *Chakrabarty* Court concluded that the legislature is more competent to address by balancing competing interests after investigation, examination, and study that courts cannot do.³³¹ Permitting patents for cloned extinct animals might provide the incentive necessary to ensure that scientists perform this expensive and complicated work to preserve biodiversity. However, as extinction is often caused by habitat destruction, many cloned animals cannot be reintroduced into their natural habitat and will live out their lives in captivity in zoos.³³² Educating people about conservation by exposing them to extinct animals

³²⁵ *Id.* at 316-17.

³²⁶ See Jiron, *supra* note 34, ¶ 62.

³²⁷ *E.g.*, *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1368 (Fed. Cir. 1999) (citing *Weber v. Virginia*, 103 U.S. (13 Otto) 344, 347-48 (1880)).

³²⁸ Yule, *supra* note 17, at 6-7.

³²⁹ *Id.* at 7.

³³⁰ *Id.*

³³¹ *Diamond v. Chakrabarty*, 447 U.S. 303, 317 (1980).

³³² See *Recently Extinct Animals, Cloning Extinct Animals*, *supra* note 13.

might not justify regenerating extinct animals only for them to live out their lives in captivity with no chance of reintroduction into the wild, although medical and biological research appears to do so in the transgenic animal context. Finally, one might argue that cloning extinct animals tampers with nature by reintroducing animals that failed in nature. However, tampering with nature is not enough to defeat patentability, as recombinant organisms that have never appeared in nature are routinely patented.

E. *The Patentability of Cloned Extinct Animals Furthers the Goals of the Patent System*

The patenting of cloned extinct animals ultimately furthers the goals of the patent system.³³³ One goal is to encourage inventive activities and the unveiling of new articles for public use by granting inventors the right to exclude others from making, selling, or using the invention for a limited period of time.³³⁴ At the same time, the patent system strives to maximize the benefit to society and minimize potential harms by preventing inventors from removing articles from the public domain.³³⁵ Furthermore, such principles permit the award of a patent to an inventor who has conferred the benefit of a lost art to the public even though the invention had previously existed because it is not in the public domain.³³⁶

Since extinction is a serious concern, both scientifically and economically, regeneration of extinct organisms by cloning is worthy of encouragement by the patent system. The benefits of recovering extinct organisms inure to the public in that the extinct organisms may serve as potential sources for novel pharmaceutical agents, agriculturally valuable animals and crops, and new genetic materials that may be used to improve domesticated species via genetic engineering.³³⁷ Allowing pioneers in this art to obtain broad patent protection for entire organisms provides a stronger incentive to vigorously invest their time and money in this effort than a rule permitting only narrower claims to methods of regenerating extinct animals or using them.³³⁸ Furthermore, permitting patents on cloned extinct animals

³³³ Rohrbaugh, *supra* note 127, at 411.

³³⁴ *See, e.g.*, *Eli Lilly & Co. v. Premo Pharm. Labs., Inc.*, 630 F.2d 120, 137 (3d Cir. 1980).

³³⁵ *See, e.g.*, *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 497 (1850).

³³⁶ *See, e.g.*, *Converse v. Matthews*, 58 F. 246, 249 (C.C.D. Mass. 1893).

³³⁷ Rohrbaugh, *supra* note 127, at 412.

³³⁸ *Id.* While claims to the process of regeneration would be valuable, product claims for the actual animal produced by the process would be more valuable intellectual property. *Id.* at 412-13. Once the extinct animal is cloned and regenerated, use of the organism or production of it in other ways may not necessarily infringe on the patented regeneration technique whereas they would infringe on a patent for the organism itself, which confers broad rights over all uses of the animal as well as individuals generated by any method. *See id.* at 413.

does not withdraw something to which the public had access to previously. While the public may have access to knowledge of extinct animals through written accounts, photographs, and remains, by definition, the public does not have access to living animals of an extinct species. The cloner of an extinct animal restores the benefit of the animal, which was lost to the public as a result of the animal's extinction, to the public in a manner analogous to the conventional restoration of a lost art to the public. In other words, the public had once been able to access the creature, but would no longer be able to, but for the handiwork of the patentee. Thus, the goals of the patent system are promoted by allowing the cloner of an extinct animal to obtain a patent for it.

F. *Patentability of Near-Extinct Animals*

A discussion of the patentability of cloned extinct animals raises the question of whether a cloned animal of a species about to become extinct is patentable if the species would have become extinct but for the intervention of man by cloning it. Although the patentability of such cloned near-extinct animals that would have become extinct but for the patentee's cloning efforts appears to promote the goals of the patent system discussed above, the product of nature doctrine, as currently envisioned by the Supreme Court, appears to foreclose the patentability of such animals.

It may be argued that from a policy perspective, a process patent for a method of cloning an extinct animal provides sufficient incentive for inventors to clone extinct animals. While the debate over whether allowing broad product patents for living things or restricting patent rights to narrow process patents best promotes innovation in biotechnology and should be the approach followed is beyond the scope of this article, it is worth noting that the answers to these questions have no bearing on whether a particular living thing, here a cloned extinct animal, constitutes an unpatentable product of nature or meets the other statutory requirements for patentability. Congress has elected to promote innovation through the patent system by allowing broad product patent protection for inventions that constitute patentable subject matter and meet the novelty and nonobviousness requirements. As is the case with run-of-the-mill inventions, the public gains access to a cloned extinct animal because of the inventor's handiwork. Thus, if as the analysis presented in this Article concludes, a cloned extinct animal is patentable subject matter, and if it otherwise meets the statutory requirements for patentability, the patent system will reward the cloner of an extinct animal with a broad product patent.

Likewise, a use patent only encompasses that particular use. Others could use the animal for different purposes (and even patent those uses) without infringing on a use patent. If the cloner of an extinct animal is able to obtain a product patent for the animal, later inventors who claim new uses can only claim new methods of use and can only practice them if they obtain a license from the holder of the product patent who cloned the animal. *Id.* at 412. Furthermore, "if the method of using a [cloned extinct] organism is not patentable, such as growing the organism as a farm crop or using it for food, the only patent incentive available for the regeneration of the organism is a product claim for the organism itself." *Id.*

1. The Product of Nature Doctrine Forecloses Patentability of Near-Extinct Animals, Including Those That Are Certain to Become Extinct Without Cloning

The cloning of a near-extinct animal to prevent its extinction preserves public access to the living animal that extinction would otherwise ablate. Thus, patentability would encourage inventors to take action by cloning to allow the public to continue to have access to the animal. This is consistent with the goals of the patent system to encourage inventors to unveil new inventions to the public and to restore lost arts to the public. Nominally speaking, patent protection for a near-extinct animal would deprive the public from access and use of the few natural individuals still in existence, but the totality of harm to the public in permitting patentability of cloned near-extinct individuals is little or none because absent the cloner's activities, the public would soon completely lose access to living individuals of the species when the species became extinct. Although cloning an animal about to become extinct does not actually restore the animal to the public because a few individuals exist in the public domain, it obviates the necessity for restoration by preventing the loss of the animal in the first place. Such preservation of public access to the animal is consistent with the policy underlying the patent system and the lost art doctrine of encouraging inventors to bring new or lost inventions into the realm of public access by ensuring that an animal that would fall out of public access without human intervention no longer does so. Furthermore, denying patent protection to cloners of near-extinct animals while allowing it for cloners of extinct animals creates perverse incentives for those skilled in cloning technology to wait until an animal actually becomes extinct before cloning it, so they can obtain patent protection for it. While cloning a near-extinct animal ensures that it will not disappear from public access, waiting until it becomes extinct to clone it ensures that the animal will disappear from the earth, and thus from the public, for some time until cloning can be successfully accomplished. Given the difficulty scientists have had in cloning certain species, the animal might be unavailable to the public for a period of years or possibly indefinitely if the animal proved extremely difficult or impossible to clone. Allowing patents for cloned near-extinct animals would encourage individuals skilled in cloning technology to begin cloning near-extinct animals as soon as it becomes apparent that the animal would become extinct, and would minimize the period of time that the animal would be absent from the Earth and the public.³³⁹ Thus, permitting patentability of cloned near-

³³⁹ One complication raised by the issue of patentability of near-extinct animals is that courts would need to develop a standard for when an animal is sufficiently close to extinction to warrant patentability. To best serve the goals of the patent system, a cloned near-extinct animal should not be patentable unless the animal were wholly incapable of reproducing naturally and was certain to become extinct but for human intervention by cloning. A less stringent standard, one encompassing endangered

extinct animals to prevent their extinction would promote the goals of the patent system.

Despite these considerations, the product of nature doctrine forecloses patentability of an article if it does not possess “a new or distinctive form, quality, or property” from articles that currently exist in nature, thereby indicating that a near-extinct animal that is about to become extinct is a product of nature and thus is not patentable subject matter.³⁴⁰ The Supreme Court considers an invention not to be a product of nature if it is a new and different article from those that occur in nature and has a “distinctive name, character and use.”³⁴¹ An animal that is about to become extinct exists in nature. A clone of it would be the same animal, identifiable by the same name, and would not have any new or distinctive forms, qualities, or properties that the naturally-occurring animal did not possess.

However, in applying the product of nature doctrine, courts have held that living things that: (1) do not occur in nature; and (2) do not exist but for the intervention of man are patentable subject matter.³⁴² An argument could be made that a cloned near-extinct animal that would become extinct but for its being cloned by man is patentable subject matter because it would cease to exist but for the intervention of man by cloning. This argument is intuitively appealing and, as discussed above, is consistent with policy considerations driving the patent system. However, it still runs afoul of the first requirement of the product of nature doctrine excluding articles present in nature from the scope of patentable subject matter. As discussed above, the Court has determined that an invention does not occur in nature when it is

animals, for instance, would deprive the public of an animal to which it has access to and will not certainly lose access to. This does not serve the goals of the patent system as the harm to the public is greater than when the animal is sure to become extinct as the grant of monopoly power does not necessarily promote activity that ensures public access as public access might never be destroyed. If it is not certain that a near-extinct animal will actually become extinct, its cloning no longer can be viewed as a proactive measure to remedy the extinction situation. Generally speaking, when only one individual of a species remains or all remaining individuals are of the same sex, the species will become extinct but for extraordinary human intervention, such as cloning. However, the latter is not a complete certainty because animals of some species have been known to change sexes, especially in single-sex environments. The situation becomes more complicated when very few individuals of both sexes remain. In such cases, a court will have to evaluate their capabilities of breeding. Some animals are very difficult, if not impossible, to successfully breed. Likewise, it is extremely difficult to determine when human efforts short of cloning, such as conservation and breeding programs, could save an animal from certain extinction. Indeed, if an animal's situation were such that such human intervention could save it from extinction, the animal would necessarily be capable of reproducing naturally. Thus, any conclusion that the animal would become extinct with absolute certainty but for this type of human intervention would be suspect at best. At any rate, an animal that could be reproduced, and possibly rescued from extinction, by such methods would not be patentable under the novelty provisions of the patent code because the surviving individuals would be enabling. *See infra* note 374 and accompanying text.

³⁴⁰ *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931)

³⁴¹ *Id.* at 13.

³⁴² *See, e.g., Ex Parte Allen*, 2 U.S.P.Q.2d (BNA) 1425, 1427 (1987).

“a new and different article” from those occurring in nature.³⁴³ The phrase “new and different” indicates that an article must not exist in nature to escape the product of nature doctrine. A cloned near-extinct animal is not new or different with respect to naturally-occurring individuals of the same species, even if those individuals will cease to exist at some point in the future. Only when naturally-occurring individuals cease to exist and that species becomes extinct would a living animal of that species engendered by cloning become different from anything occurring in nature, and thus, cease to be deemed a product of nature under the product of nature doctrine.³⁴⁴ The Court has never suggested that the fact that an article would certainly disappear from nature in the future precludes it from constituting a product of nature while it exists in nature. Rather, the Court has explicitly stated that minerals found in the earth are unpatentable products of nature,³⁴⁵ despite the fact that if a mineral is extracted, natural supplies are certain to be depleted eventually. Under this precedent, future depletion of a product of nature does not render it patentable subject matter when the product is currently present in nature.³⁴⁶ Therefore, the fact that an animal is certain to become extinct does not render it patentable when cloned if naturally-occurring individuals are still alive.

Another argument in favor of a conclusion that a nearly-extinct animal that will become extinct but for human intervention by cloning may constitute patentable subject matter stems from the fact that the product of nature doctrine is not always strictly applied. As discussed above, in *Allen*, the Board of Patent Appeals and Interferences held that polyploid oysters do not occur naturally without human interventions and thus were patentable subject matter.³⁴⁷ However, it did not seem relevant to the Board that polyploid oysters may be and have been engendered by an occasional or rare event in nature.³⁴⁸ Thus, “the mere possibility of an occasional or rare event

³⁴³ *Am. Fruit*, 283 U.S. at 13.

³⁴⁴ *See supra* Part II.A.

³⁴⁵ *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

³⁴⁶ One might argue that for the purposes of the product of nature doctrine, naturally-occurring individuals of a near-extinct species or naturally-occurring minerals might be distinguished from cloned individuals of such a species or synthetically produced minerals. This is not the case because the product of nature doctrine defines the scope of patentable subject matter. An article, such as an animal, that occurs in nature is not patentable subject matter. Thus, the animal is unpatentable, regardless of the source of any given individuals. Thus, if man synthesizes such an animal by cloning, the cloned individuals are not patentable since animals of that species are not patentable subject matter because they occur in nature.

One might also attempt to distinguish the cloned near-extinct animal context from the depletion of minerals. For instance, the time when a near-extinct animal is certain to become extinct is more readily ascertained than that when a mineral will be depleted because animals have finite lifespans. This fact does not change the Court’s suggestion that future depletion from nature alone does not exclude a natural article from the product of nature doctrine.

³⁴⁷ 2 U.S.P.Q.2d (BNA) at 1427.

³⁴⁸ *See Rohrbaugh, supra* note 127, at 385 n.63; *supra* notes 187-88 and accompanying text.

in nature giving rise to a product identical to that claimed . . . does not necessarily defeat its patentability [under the product of nature doctrine].”³⁴⁹ In most cases, a near-extinct animal is necessarily very rare since few are found in nature. Thus, if *Allen* excludes naturally-occurring items that are very rare from the product of nature doctrine, cloned near-extinct animals might be patentable.³⁵⁰

While this argument has some appeal, it also fails. *Allen* was premised on the possibility of an occasional rare event that has been known to produce polyploid oysters. There was no definitive knowledge that any naturally-occurring polyploid oysters were actually in existence. In the near-extinct animal context, there is absolute knowledge that a naturally-occurring specimen of the species exists, especially if the patentee is in possession of one of the animals. Thus, unlike the Board in *Allen*, a court evaluating a near-extinct animal case could be certain that the animal was a product of nature. As the Board noted that it could not be certain that polyploid oysters existed in nature, *Allen* may well have been decided differently if there was definitive proof of their existence.³⁵¹ Therefore, even under an interpretation of *Allen* as standing for the proposition that the possibility of a rare natural event giving rise to an organism would not render it a product of nature and foreclose its patentability, *Allen* does not indicate that an organism that definitively exists in nature is not an unpatentable product of nature, no matter how rare the article or its natural formation may be. Extension of *Allen* to such articles would be in direct and certain contravention of the product of nature doctrine.

Furthermore, the creation of a polyploid oyster in nature is an aberrant event that occurs due to a malfunction of natural processes.³⁵² Thus, an argument can be made that organisms engendered by such malfunctions are

³⁴⁹ Rohrbaugh, *supra* note 127, at 385 n.63.

³⁵⁰ Under this reasoning, cloned individuals would be within the scope of patentable subject matter, but the cloner’s assertion of a patent for the creature would not cover any remaining naturally-occurring individuals. *Allen* confines the realm of patentable subject matter to “subject matter made by man.” 2 U.S.P.Q.2d (BNA) at 1426. This fact raises several thorny issues. Breeding of these natural individuals with cloned ones would constitute infringement on the patent because it entails use of the cloned animal. A court would probably consider an animal with a cloned and a natural parent to fall within the patent because it would not exist but for the handiwork of man. The fact that the small number of remaining naturally-occurring individuals, which will eventually disappear entirely due to death, are excluded from the patent does not render the patentee’s remaining rights, such as the right to prevent others from synthesizing the patented near-extinct organisms, a nullity—“the entire fabric of the patent grant need not be unraveled by clipping one thread.” Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597, 1650 (1993). The reasoning presented here also precludes patentability of a new naturally-occurring animal discovered in nature on the basis of its rarity. Such an animal, although rare, is not made by man. *Allen* can only be fairly read as extending the scope of patentable subject matter to include living things that are made by man and thus only exist but for the intervention of man although they rarely or occasionally occur in nature.

³⁵¹ See Rohrbaugh, *supra* note 127, at 385 n.63 (citing *Allen*, 2 U.S.P.Q.2d (BNA) at 1427).

³⁵² See *supra* Part II.A.

not truly products of nature. However, while the natural occurrence and reproduction of an animal that is nearly extinct might be a rare occurrence, it occurs in nature in the ordinary course of things. Thus, no such argument can be made in this context. If the mere rarity of a naturally-occurring article vitiated the product of nature doctrine, the doctrine would be eviscerated as many naturally-occurring objects that man reproduces artificially are rare.³⁵³ It is much less often that man desires to reproduce an aberrant event in nature. Thus, while nature's missteps are naturally-occurring in the formal sense, permitting the articles resulting from such missteps to be patented does not significantly impinge on the product of nature doctrine, especially since they constitute defective products of nature.

Therefore, while the Board in *Allen* may have desired to carve out a limited exception to the product of nature doctrine for organisms that may occur in nature due to rare aberrant events, the Board likely did not intend to do serious violence to a venerable doctrine, which has been repeatedly reaffirmed by the Supreme Court, by extending such an exception to include things that occur in nature in the ordinary course of things infrequently, such as the mating of rare animals. This is especially so, given that the Board did not even discuss this issue in its opinion. Finally, it is possible that *Allen* was simply an improper application of the product of nature doctrine to the facts of the case and wrongly decided as polyploid oysters may exist in nature.

This analysis is further complicated by the fact that naturally-occurring individuals of a species surely to become extinct will eventually die off even if the species is saved by cloning. Thus, when such an animal is cloned before it becomes extinct, the original naturally-occurring individuals will die, leaving only cloned individuals or offspring between cloned individuals and naturally-occurring individuals. After the death of the last naturally-occurring individual, all remaining individuals would not have existed but for cloning, which is the intervention of man. Thus, an argument can be advanced that, at this point, the animal ceases to be a product of nature and thus is patentable.

While this reasoning may be appealing, it fails in several respects. First, the patent law looks to the state of the prior art at the time an invention is first created by the patentee in determining its patentability. For instance, both novelty and nonobviousness provisions explicitly state that novelty and nonobviousness are determined at the time of invention for the purposes of patent validity.³⁵⁴ At the time a cloner of a near-extinct animal clones and saves it from extinction, the animal is still a product of nature—

³⁵³ A rule permitting a natural article to escape the product of nature doctrine due to rarity would require courts to come up with a standard for the degree of rarity required to overcome the doctrine. Courts would likely be reluctant to do this.

³⁵⁴ See 35 U.S.C. §§ 102(a), 102(g), 103 (2000 & Supp IV 2004).

and therefore unpatentable—as naturally-occurring individuals still exist.³⁵⁵ However, one might argue that unlike novelty and nonobviousness, whether or not an invention constitutes a product of nature is not necessarily determined at the time of invention. The product of nature doctrine forecloses the patentability of an article by excluding products of nature from the realm of patentable subject matter, and § 101, the provision defining patentable subject matter, does not explicitly require analysis of whether an invention is patentable subject matter at the time of invention. Rather, § 101 simply states that “whoever invents . . . [an invention that constitutes patentable subject matter] may obtain a patent therefore.”³⁵⁶ Nonetheless, this provision of a patent to an individual who invents an invention constituting patentable subject matter suggests that the invention must be patentable subject matter at the time that it was invented because it requires that the inventor must invent something that is patentable subject matter to obtain a patent. If an invention is not patentable subject matter at the time it is invented, the inventor cannot be said to be inventing something that constitutes patentable subject matter.

Second, even if a court were to hold that events subsequent to invention could convert an invention that was not patentable subject matter at the time of invention into patentable subject matter, a cloned animal that was cloned when natural individuals of its species were still alive would still be unpatentable under the product of nature doctrine when all natural individuals of the species disappeared. For an invention to be patentable under the product of nature doctrine, it must be “a new and different article” from those articles occurring in nature.³⁵⁷ Once all naturally-occurring individuals of the species died out, the cloned ones would indeed be different from any naturally-occurring animals. However, the cloned animals would not constitute new articles as compared to those existing in nature. Prior to the complete disappearance of the natural individuals, the cloned and natural individuals would have existed contemporaneously. Thus, when the natural individuals die out, the living cloned individuals are not new.³⁵⁸ In contrast, a cloned extinct animal can be said to be new inasmuch as there were no living individuals present in nature when the cloned animal was created or

³⁵⁵ See *supra* notes 342-46 and accompanying text.

³⁵⁶ 35 U.S.C. § 101 (2000).

³⁵⁷ *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 13 (1931).

³⁵⁸ In articulating the product of nature doctrine, the Supreme Court likely meant for “new” and “different” to have unique meanings. This interpretation of the Court’s language is consistent with the canon of statutory interpretation that “no . . . word shall be superfluous, void, or insignificant” if possible. *TRW, Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (quoting *Duncan v. Walker*, 533 U.S. 167, 174 (2001)); see also *supra* note 78 and accompanying text. Although this canon of statutory interpretation might not apply to the interpretation of language in judicial opinions in the same way that it applies to statutes, the Court did not likely intend that “new” and “different” had the same meaning.

at any time contemporaneously with it.³⁵⁹ Therefore, even after the naturally-occurring individuals of a species saved from extinction by cloning have died out, the cloned animal remains unpatentable under the product of nature doctrine.³⁶⁰

Thus, based on the current status of the product of nature doctrine, a court would likely hold that the doctrine excludes cloned near-extinct animals from the scope of patentable subject matter even if the animal would have become extinct but for the efforts of the cloner. Although the product of nature doctrine appears to be consistent with and promote the goals of the patent system in most circumstances,³⁶¹ it is not when applied to prevent the patentability of a cloned near-extinct animal that would become extinct absent cloning. Courts have never had the occasion to address this issue because no animal that has hitherto been cloned was saved from extinction by virtue of being cloned. However, it is feasible that this scenario will arise one day. When it does, it is possible that a court would create this limited exception to the product of nature doctrine since permitting patentability of cloned near-extinct animals would promote the goals of the patent system. Absent patentability of near-extinct animals, a putative cloner may wait to clone such an animal until it becomes extinct, and thus would no longer constitute a product of nature. Thus, this situation differs from a typical attempt to patent a product of nature because the near-extinct animal will certainly become an extinct animal that is not a product of nature and accordingly is patentable. An exception to the product of nature doctrine in this unique situation where a naturally-occurring article will cease to exist but for human intervention will do little, if any, violence to the doctrine because the near-extinct animal will become patentable subject matter after the animal's imminent extinction. As discussed above, allowing patentability before actual extinction promotes the goals of the patent system by creating incentives for those skilled in the art to clone the animal before it becomes extinct and to preserve continuity of public exposure or access to the animal.³⁶² Thus, as this unique exception seems to cause no material sys-

³⁵⁹ One might argue that a cloned extinct animal is not new because it previously existed in nature. However, courts consider a purified substance or microorganism new even though the exact same substance exists in nature in a commingled form because the purified form did not previously exist. *See supra* Part II.A. Thus, if purified substance or microorganism which exists in a different form at the time of invention is considered new for the purposes of the product of nature doctrine, a cloned extinct animal which did not exist at all at the time of the invention would surely be considered new despite the fact it had previously existed. *See id.*

³⁶⁰ The opposite rule would be very difficult for courts to administer. For instance, in a mixed population of natural and cloned animals derived from the natural ones, it would be difficult if not impossible to ascertain when the natural animals die off. The matter is further complicated if breeding is possible.

³⁶¹ *See supra* Part I.A.

³⁶² The situation of an animal that is about to become extinct is readily distinguishable from that of an animal that exists in an extremely small but stable population, such as a species that exists in very

temic harm to the product of nature doctrine, a court might very well adopt it.

However, it is likely that a court would reject an exception to the product of nature doctrine for cloned near-extinct animals, including those that would have become extinct had they not been cloned. While the last surviving individuals of such a species are alive, the animal is naturally-occurring. The animal accordingly occurred in nature at the time it was cloned. Thus, allowing such an exception is at odds with the justification for the product of nature doctrine: products of nature are “free to all men

small numbers only on an isolated island. As very few if any members of the public have access to an animal that only inhabits an isolated island in small numbers, one might say that cloning such an animal and production of clones would bring about public exposure and access to the animal, just as the cloning of a rare animal that is about to become extinct. Thus, one could argue that permitting a patent for such rare animals would further the patent system’s goal of promoting public access. However, allowing a patent in this situation would certainly contravene the product of nature doctrine and is a much greater affront to its underpinnings than allowing patents for animals about to become extinct. Unlike the relatively unique situation where an animal that is sure to become extinct, such as when only one individual remains, the animal will not disappear from nature in this situation. Thus, a patent for a rare animal would give a patentee rights over an animal that would continue to exist and perpetuate itself in nature.

This is much more offensive to the special status accorded nature as apart from human invention and property that undergirds the product of nature doctrine than allowing patent rights for an animal that will certainly cease to occur naturally after a few surviving individuals die out. Furthermore, the gain to the public from encouraging cloning of rare animals via the patent system is less than that from promoting the saving of near-extinct animals from extinction using cloning. The animal that is about to become extinct will totally disappear from the public save for intervention by the cloner while at least some members of the public can access the rare animal, either by exploration or simply going to areas where the animal is known to live. A rare animal could be brought into greater public exposure by conventional means such as breeding programs as well as cloning while an animal about to become extinct will disappear in the absence of the efforts of the cloner.

Thus, the incentive of the monopoly conferred by a patent is less necessary to promote public access to the rare animal for two reasons. First, more people are likely in the position to regenerate naturally-occurring animals by conventional means than are able to clone them. Second, even though it may be difficult, members of the public may access living specimens of a rare animal if they commit enough resources without the use of cloning or other methods to expand its numbers. In contrast, in the absence of the cloner’s efforts, an animal that is about to become extinct will disappear from public exposure completely and permanently. Thus, the incentives to clone provided by the patent system are more important to ensuring public access, and thus to promoting the goals of the patent system, in the case of near-extinct animals than of rare ones. In the case of rare animals and in other situations as well, the product of nature doctrine reflects a policy decision that respect for nature might be worth decreased public access. In the rare animal situation, patentability causes a great affront to the special status of nature and cloning the animal results in only a modest incremental increase in public exposure. In contrast, in the case of near-extinct animals, patentability causes only slight denigration of the respect for nature while cloning the animal is absolutely essential for maintaining public access to the animal. Therefore, the balancing of the sometimes competing considerations of the patent system’s goal of promoting public access and the special status of naturally-occurring articles embodied by the product of nature doctrine cuts much more strongly against permitting the patentability of rare animals that are indigenous to remote places than it does against permitting a narrow exception to the product of nature doctrine and permitting patentability of near-extinct animals.

and reserved exclusively to none” based on a moral imperative that products of nature should be accorded special protections against being monopolized by a patentee because there is something inherently and unidentifiably special about nature’s handiwork.³⁶³ Even natural articles that will disappear from nature were created by it and thus have such special qualities. The Court’s acknowledgement of this might suggest that it considers preventing any monopolization of nature to trump the ordinary goals of the patent system to encourage innovation and unveiling of newly-invented articles to the public. Thus, this respect for nature might be said to justify the possible loss of public access to an animal during the period of time between when it becomes extinct and when an individual incentivized by the patent system clones it as a result of the absence of patent incentives for cloning before the animal becomes extinct.

Furthermore, the product of nature doctrine is easier to administer absent even limited exceptions. Patent law is characterized by rules that tend to promote the goals of the patent system in most cases although they do not promote them in every case. For instance, even obscure prior art references may defeat novelty although they do not inform the public about the invention in any meaningful way and creating a situation where encouraging a second-comer to provide the invention to the public would be beneficial.³⁶⁴ These rules prevent the courts from having to make difficult determinations involving fact and policy that they might not be able to accurately and consistently make, such as whether a prior art reference is sufficiently obscure that it does not meaningfully inform the public about the invention such that the patent system should encourage others to make the invention. Likewise, an exception to the product of nature doctrine for near-extinct animals creates such administrability issues. For instance, a court would have to determine whether it is truly certain that a species will become extinct, which might be difficult, particularly if there are surviving members of both sexes that do not breed readily.³⁶⁵

³⁶³ Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); see Grusd, *supra* note 54, ¶ 12 n.24; see also *supra* notes 52-61 and accompanying text. A rule foreclosing patentability of a cloned near-extinct animal which would have become extinct but for being cloned even once all naturally-occurring individuals have died out and only those derived from clones remain also supports the purpose of the product of nature doctrine. The animal existed in nature at the time it was cloned. Thus, the respect for the special character of nature underlying the product of nature doctrine was abrogated when the animal was cloned.

³⁶⁴ *E.g.*, *In re Hall*, 781 F.2d 897, 897 (Fed. Cir. 1986) (holding that a single copy of an obscure dissertation in a single library in a foreign country defeats patentability).

³⁶⁵ See *supra* note 339.

2. Application of the Statutory Requirements for Patentability in the Near-Extinct Animal Context

If a court were to find that a cloned near-extinct animal that would become extinct but for cloning was patentable subject matter, additional requirements, such as novelty and nonobviousness, must be met.³⁶⁶ These requirements appear to be met in some cases—when the near-extinct animal is unable to reproduce because only one individual remains or all surviving individuals are of the same sex. As discussed above, an obscure reference, such as a single copy of a dissertation, nominally available to the public in an out-of-the-way library defeats novelty.³⁶⁷ Thus, a single known individual of a near-extinct animal or printed publication describing it would appear to defeat novelty under § 102(a).³⁶⁸ However, to anticipate an invention, a prior art reference must enable a person of ordinary skill to make or possess the invention.³⁶⁹ A single copy of a dissertation may very well be an enabling reference that explains how to create an invention. For a biological invention to be enabled, the prior art reference must provide the manner in which one could obtain either the living organism or a biological sample that may be used to create the organism without undue experimentation to enable the invention.³⁷⁰ When only one individual or multiple individuals of the same sex of a near-extinct species remains, the animal may not be reproduced or made by ordinary means such as breeding. The only way such animals may be reproduced is by cloning. Thus, such individuals and printed publications describing them are not enabling because they do not permit an individual of ordinary skill to reproduce the animal without undue experimentation.³⁷¹ Given that scientists have had difficulty adapting

³⁶⁶ The fact that naturally occurring individuals of a species die out after it has been cloned has no bearing on novelty or nonobviousness because these are evaluated at the time of invention, the time the cloned animal was invented here. *See supra* note 354 and accompanying text.

³⁶⁷ *Hall*, 781 F.2d at 897.

³⁶⁸ If researchers are in possession of an individual of a species in order to clone it or there is knowledge of the existence of an individual of the species derived from any source, the animal is certainly “known” for the purposes of § 102.

³⁶⁹ *See supra* note 210 and accompanying text.

³⁷⁰ *See supra* note 214 and accompanying text.

³⁷¹ It is for this reason that written descriptions of such a near-extinct animal do not create a statutory bar under § 102(b). *See In re Paulsen*, 30 F.3d 1475, 1481 n.9 (Fed. Cir. 1994); J. THOMAS MCCARTHY, MCCARTHY’S DESK ENCYCLOPEDIA OF INTELLECTUAL PROPERTY 147 (2d ed. 1995). It is almost certain that written descriptions of near-extinct animals would have existed prior to one year before a cloner of such an animal filed his patent application. However, when the animal is no longer able to reproduce, such prior art is not enabling and is thus defective.

As long as a single breeding pair still exists, a printed publication describing the animal will be enabling because the animal is able to reproduce. The analysis concerning the status of nonenabling knowledge or use of extinct animals presented in Part II.B.1, *supra* notes 217-22 and accompanying text, is equally applicable to near-extinct animals that will become extinct but for the intervention of the cloner. A lone individual or surviving individuals of the same sex may be known and even used by the

the cloning technique to some species, the fact that other species have been cloned does not mean that a given species can be cloned without undue experimentation.³⁷²

A counterargument is that as long as naturally-occurring individuals of a species exist, they may be obtained or possessed and thus are enabling and foreclose patentability. However, in the cell line context, the Federal Circuit has held that for a biological invention that cannot be reproduced by one of ordinary skill in the art without undue experimentation, to be enabled, the organism must be readily available to the public, by means such as a public depository.³⁷³ A near-extinct animal which is unable to reproduce naturally and exists in very small numbers is hardly readily available to the public. Therefore, a court would likely hold that prior art references describing a near-extinct animal and an individual specimen(s) of the animal are not enabling when the animal cannot reproduce in nature because there is only one surviving individual or multiple surviving individuals of the same sex. Thus, § 102(a) would not defeat patentability. However, if the prior art would enable an individual of ordinary skill in the art to reproduce the animal at the time it was cloned, for instance by breeding if individuals of both sexes existed and were competent to breed, it would be unpatentable under § 102(a).³⁷⁴

Likewise, as discussed above, if a court concluded that naturally-occurring animals could defeat patentability under § 102(g),³⁷⁵ a previous “making” of an animal about to become extinct that is unable to reproduce would not constitute prior art and would not foreclose patentability because a reference must be enabling to constitute prior art.³⁷⁶ Also, if a court were to hold that naturally-occurring animals could trigger § 102(f), § 102(f) would not bar the patentability of a cloned near-extinct animal that was unable to naturally reproduce because the presence of individuals in nature would provide insufficient information to enable an ordinary mechanic to

public in the United States, but such knowledge and use is not enabling because it does not provide for reproduction of the animal. Although some case law indicates that nonenabling use or knowledge may foreclose patentability and a court might apply this rule in the extinct animal or near-extinct animal contexts, *see* Part II.B.1, *supra* notes 217-22 and accompanying text, as discussed below, such prior art may be overcome by the lost art doctrine as the doctrine covers a near-extinct animal that is incapable of reproducing and will become extinct but for the intervention of the cloner. *See infra* note 378 and accompanying text.

³⁷² *See supra* notes 290-92 and accompanying text.

³⁷³ *See In re Lundak*, 773 F.2d 1216, 1218 (Fed. Cir. 1985).

³⁷⁴ For this reason, near-extinct animals rescued from extinction by more conventional methods of human intervention, such as conservation efforts and breeding programs, would be unpatentable under § 102(a).

³⁷⁵ *See supra* Part II.B.3.

³⁷⁶ *See supra* note 245 and accompanying text.

construct the living creature without the exercise of ingenuity and special skill in cloning it.³⁷⁷

Application of the lost art doctrine to an animal that still exists seems improper in an intuitive sense. However, in the special case where a near-extinct animal is unable to reproduce because only one individual exists or all remaining individuals are of the same sex, the lost art doctrine as articulated by the Supreme Court appears to apply and permit patentability even if a court were to hold it were foreclosed by the novelty provisions of the patent law. Although the Court has stated that the lost art doctrine permits patentability only if “knowledge of the [invention] was as completely lost as if it had never been discovered,” the Court has indicated that a reinvention of an art is patentable when “the fruits of [the art] have come down to us [from the original invention], but the means by which the work was accomplished are at this day unknown.”³⁷⁸ Thus, the Court considers the lost art doctrine to permit patentability of an invention that might still exist, but can no longer be reproduced or made. An animal that is almost extinct that is no longer able to reproduce in nature fits this description. But for the work of the cloner, it no longer can be made or reproduced although it still exists, at least temporarily. Thus, such an animal qualifies as a lost art. However, a near-extinct animal that still can reproduce does not qualify as a lost art as its reproduction is not completely lost.

Likewise, a cloned near-extinct animal that is unable to reproduce in nature meets the nonobviousness test as well. When the prior art does not engender a reasonable expectation of success in making an invention in a person of ordinary skill in the art, the invention is not obvious.³⁷⁹ Although some of the difficulties inherent in cloning an extinct animal, such as those involving DNA preservation, are not present in the near-extinct animal context, scientists have found results unpredictable and difficult to obtain when adapting biological techniques, including cloning, from one species to another.³⁸⁰ This suggests that successful cloning of one species does not suggest a reasonable likelihood of success in cloning a different species. Thus, a court would likely find that the cloning of a given near-extinct animal is not obvious.

CONCLUSION

Analysis of patentability involves many fact-specific factors that could not be considered here. Nonetheless, the above analysis indicates that cloned extinct animals constitute patentable subject matter because they

³⁷⁷ See *supra* Part II.B.2.

³⁷⁸ *Gayler v. Wilder*, 51 U.S. (10 How.) 477, 497-98 (1850).

³⁷⁹ See *supra* Part II.C.

³⁸⁰ See *supra* notes 290-92 and accompanying text.

would not exist in a living form save for the intervention of man. Furthermore, cloned extinct animals likely meet the novelty, nonobviousness, and utility requirements of the patent law. Thus, a cloned extinct animal may be patented. The cloner of an extinct animal provides knowledge and use of an animal to the public that it would not otherwise enjoy, and cloning an extinct organism requires an inventive act. Thus, the patenting of a cloned extinct animal serves the goals of the patent system of providing incentives to inventors to induce the discovery of new invention while “maximiz[ing] the benefit to society and minimiz[ing] any potential harm by not permitting inventors to remove from the public domain anything to which the public already has access.”³⁸¹ The previous existence of the animal in nature does not alter this conclusion and thus should not foreclose patentability. In contrast, even when an animal present in nature is about to become extinct, and extinction is averted by cloning, under the current state of the product of nature doctrine, it appears not to be patentable subject matter.

A conclusion that cloned extinct animals may be patentable opens the door to further issues that the courts and PTO will have to confront. New technologies will likely arise in the future that will expand the range of extinct organisms that may be cloned. Also, as the extinction rate is increasing,³⁸² it is likely that more attempts to clone extinct animals will arise and force the courts to face the issue of patentability of extinct animals. However, since whether an organism is patentable subject matter turns on if it is actually extinct, courts and the PTO will have to grapple with this difficult factual question. Indeed, proving that an animal is totally extinct is an arduous task, especially given the number of unconfirmed sightings of extinct animals that occur. While some commentators have suggested that the difficulty of this question may be reason to hold cloned extinct animals unpatentable,³⁸³ courts and the PTO routinely face difficult factual questions in patent cases, such as the determination of when an inventor conceived an invention in interference cases. The international standard for extinction is that there be “no reasonable doubt that the last individual has died.”³⁸⁴ This standard replaced one requiring that the animal not be observed in the wild for fifty years and that all specimens in captivity have died.³⁸⁵ Thus, the courts and the PTO would have to craft standards for defining extinction that prevent inventors from patenting rare animals, but also permit patents for *bona fide* extinct animals. Likewise, were courts to adopt an exception to the product of nature doctrine permitting patenting of cloned-near extinct animals when cloning was necessary to prevent extinction, the courts and the PTO would have to wrestle with crafting a standard for determination of

381 Rohrbaugh, *supra* note 127, at 411-12.

382 See Recently Extinct Animals, Cloning Extinct Animals, *supra* note 13.

383 See Jiron, *supra* note 34, ¶ 25.

384 See Recently Extinct Animals, Cloning Extinct Animals, *supra* note 13.

385 *Id.*

when an animal would have become extinct but for cloning. Such a standard must be stringent to prevent inventors from obtaining unnecessary monopolies on living things that do not create significant benefits for the public.

When the Supreme Court decided *Chakrabarty*, it almost certainly did not foresee that the possibility of cloning extinct animals would ever be realized to the point where the question of whether the patent laws applied to it was colorable. Undoubtedly, a holding that cloned extinct animals are patentable will raise unforeseen questions that emerge as the state of biotechnology advances.