

ASSOCIATION FOR MOLECULAR PATHOLOGY V. MYRIAD GENETICS, INC.: WHAT ARE THE EFFECTS ON CLONING EXTINCT ANIMALS AND AGRICULTURE NOW THAT CDNA IS PATENTABLE?

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Animal cloning has been debated for many years. It is a new technological process, and the long-lasting effects must be considered.¹ Due to the possible ramification of cloning animals, the decision from the United States Supreme Court in *Association for Molecular Pathology v. Myriad Genetics Inc.* must be examined closely.² Specifically, the effects on the issue of cloning extinct animals and livestock must be analyzed because cDNA is used in the process of cloning.³ The Court also determined that an isolated DNA strand involving a naturally recurring piece of DNA prevents patentability.⁴ This additional decision will have legal ramifications related to cloning animals. Now that a part of the cloning process is patentable, but organisms that are naturally occurring are not, how will this affect the environment and the agricultural industry's introduction of cloned animals? The cloning process and the consequences of the Court's decision on extinct animals and agriculture will be analyzed in this Note.

This Note will provide an overview of the possible effects the decision in *Myriad* will have on the cloning of extinct and livestock animals. First, the case

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1. See Andrew B. Perzigian, *Genetic Engineering and Animal Rights: The Legal Terrain and Ethical Underpinnings*, ANIMAL LEGAL & HISTORICAL CTR. (2003), <http://www.animallaw.info/articles/ddusgeneticengin.htm> (providing examples of what could result from cloning).

2. *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2111, 2119 (2013).

3. See *Isolation and Use of cDNA Clones*, http://www-users.med.cornell.edu/~jawagne/cDNA_cloning.html (last visited Sept. 8, 2015).

4. *Myriad*, 133 S. Ct. at 2111.

will be summarized to provide the background for the issue, as well as an explanation of a recent case that supported the *Myriad* decision. Second, the actual process of cloning will be described. Third, both sides of the patentability of cloned animals' will be delved into. Then, the ethical issues that may arise from this issue will be analyzed. Finally, this note will address what may be the repercussions, both positive and negative, of cloning animals, and how the now patentable cDNA and un-patentability of naturally occurring animals may influence those repercussions.

Multiple plaintiffs, including researchers and patients, challenged Myriad Genetics and the Patent and Trademark Office on the patent registration in the original case.⁵ The patent was for DNA sequences associated with breast and ovarian cancer, and for the diagnostic methods.⁶ The Court determined that naturally occurring cells, such as human cells, are not patentable subject matter.⁷ However, in considering cDNA, the Court determined it was patentable.⁸

The Court explains cDNA results from an exons-only molecule that does not naturally occur in nature.⁹ Lab technicians create something new and different when cDNA is made because it is distinct from the DNA it originated from and falls under section 101.¹⁰ Section 101 states a person may receive a patent when he or she "discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement . . ." ¹¹ The Court determined cDNA fell underneath this definition because it was different enough from the original DNA due to the methods conducted on it, that it was to be considered an item that does not naturally occur in nature.¹²

The recent case, *In re Roslin Institute (Edinburgh)*, supports the *Myriad* decision and involves the most famous cloned animal, Dolly the Sheep.¹³ The case was brought on appeal to the United States Court of Appeals, Federal Circuit, from the Patent and Trial and Appeal Board decision that the actual cloned animal, Dolly the Sheep, was not patentable material.¹⁴ The court agreed with the

5. See *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 702 F. Supp. 2d 181, 186-92 (S.D.N.Y. 2010), *aff'd in part, rev'd in part* 133 S. Ct. 107 (2013).

6. *Myriad*, 133 S. Ct. at 2112.

7. *Id.* at 2111.

8. *Id.* at 2111, 2119.

9. *Id.* at 2119.

10. *Id.*

11. 35 U.S.C. § 101 (2012).

12. *Myriad*, 133 S. Ct. at 2119.

13. *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333, 1334 (Fed. Cir. 2014).

14. *Id.*

Board's decision that for an item to be patentable it must not be the exact same as the animal that was cloned and that there needs to be a substantial enough of a change.¹⁵ While supporting the *Myriad* decision, it also clarifies actual cloned animals are un-patentable subject matter.¹⁶ Now that we know what the judicial system thinks of patenting cloned animals, how does this issue even reach the higher courts?

I. WHAT IS THE CLONING PROCESS?

As previously stated, the cloning process is a new technology that is rapidly increasing and receiving a great deal of attention. A clone is an organism descended from one single common ancestor and genetically identical to that ancestor.¹⁷ There are two main types of cloning: embryo splitting and nuclear transfer.¹⁸ Embryo splitting is when a technician bisects multicellular-embryos in the early stages in order to generate twins, which is done naturally in the laboratory.¹⁹ The other type, and more common, is nuclear transfer.²⁰ Nuclear transfer occurs when the scientists take the genetic material from one cell and place it into an unfertilized, genetically changed egg.²¹ The cells used are retrieved by a skin biopsy.²² The cell is then fused with the egg from the female of the same species and then scientists stimulate the egg, which causes the cell to divide.²³ After the pregnancy, the recipient of the cloned cell gives birth to the identical twin of the genetic donor.²⁴

cDNA is another process of cloning commonly used. cDNA cloning is the isolation of a homogeneous genetic strain of an organism.²⁵ It is created when a self-replicating organism is isolated and amplified.²⁶ cDNA is created by an enzyme reverse transcriptase which uses the information from RNA to generate

15. *Id.* at 1336.

16. *Id.* at 1338.

17. Alison L. Van Eenennaam, *Animal Cloning*, ANIMAL BIOTECHNOLOGY: UC DAVIS, <http://animalscience.ucdavis.edu/animalbiotech/biotechnology/cloning/> (last updated Jan. 7, 2013).

18. *Id.*

19. *Id.*

20. *Process of Cloning*, CLONESAFETY.ORG, <http://www.clonesafety.org/cloning/facts/process/> (last visited Sept. 8, 2015).

21. Van Eenennaam, *supra* note 17.

22. *Process of Cloning*, *supra* note 20.

23. *Id.*

24. *Id.*

25. *Isolation and Use of cDNA Clones*, *supra* at note 3.

26. *Id.*

complimentary DNA, which is cDNA.²⁷

The test subjects for cloning are often animals.²⁸ Many of the cells come from mammals.²⁹ Mammals were first cloned in the early 1980s, which is almost thirty years after frogs were successfully cloned.³⁰ The cells used are from pre-implantation embryos from a list of animals such as: “mice, rats, rabbits, pigs, goats, sheep, cattle, and . . . rhesus monkeys.”³¹ The world-renowned Dolly the Sheep was the first animal cloned by nuclear transfer.³² While there have been successes in cloning adult tissues in cattle, pigs, cats, etc., cloned living offspring from nuclear transfer have been less successful.³³ The proportion of adult cells that actually develop into live offspring after egg transfer is very low.³⁴ The scientists have found high rates of abortion in many stages of the pregnancies.³⁵ There has been abnormalities found in cloned cows and mice after they are born, which scientists concluded were likely from the type of tissue that was used.³⁶ These abnormalities and abortions are some of the issues why many anti-cloning groups oppose cloning animals.³⁷

Now that cDNA is considered patentable,³⁸ is the cloning of extinct animals and livestock even patentable material? Is this process even considered patentable subject matter? Does it fall within the definition of patentable subject matter as set out in 35 U.S.C. Section 101 or does it fall short? To be a valid patent, the item or process must fulfill the requirements of patentable subject matter, utility, novelty, nonobviousness, and enablement.³⁹ Many support the patentability, but the most recent Supreme Court case disagrees with this, showing the trend courts are moving towards.⁴⁰ Patentable subject matter, utility and novelty will be the only requirements that will be elaborated on in this Note since they pertain the most to the issue of cloning extinct animals and livestock.

27. *Id.*

28. *See* Van Eenennaam, *supra* note 17.

29. *Id.*

30. *Id.*

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.*

35. *Id.*

36. *Id.*

37. *See id.*

38. *Myriad*, 133 S. Ct. at 2111.

39. 35 U.S.C. §§ 101, 102(a), 103 (2012).

40. *See, e.g., Myriad*, 133 S. Ct. at 2119, 2120.

II. THE PATENTABILITY OF CLONED ANIMALS

First, to receive a patent the Patent and Trademark Office must consider an item patentable subject matter.⁴¹ Organisms in nature that occur naturally are not considered patentable subject matter.⁴² However, anything manmade is potentially patentable.⁴³ Interestingly, cloning animals combines both of these rules. Sometimes cloning takes naturally occurring organisms and alters them through manmade processes and ingenuity, which can often substantially alter them enough to be patentable.⁴⁴ Many argue that the ingenuity of the scientists to create the cell makes the clones patentable material because the scientist devises conditions in the laboratory and alters the DNA of the original animals.⁴⁵ Similarly, in *Diamond v. Chakrabarty*, the United States Supreme Court found the patentee had produced new bacterium significantly different than anything else in nature because of the scientist's own methods and processes, not nature's.⁴⁶ The experimentation of human ingenuity and effort of a higher organism can create patentable material.⁴⁷ Thus, it could be argued this would include cloned animals, because to create a clone a scientist must manipulate the gene and alter the structure. However, under *Myriad* and *In re Roslin* the courts have disagreed, deciding actual animals are not patentable.⁴⁸ The Federal Circuit in *In re Roslin* rejected the scientists' arguments that Dolly was not part of nature's process, but was from their own ingenuity.⁴⁹ The court states cloned animals are exact replicas of the animals they were cloned from and do not possess substantial differences from the animals that occur in nature.⁵⁰ While many advocate for cloned animals to be considered a construct of human ingenuity, at least for now, cloned animals are considered part of nature.⁵¹ Regenerated organisms are in the grey area of being patentable material, but lean towards being patentable according to some scientists.⁵² However, it is likely those theories would run into the same

41. 35 U.S.C. § 101 (2012); *see, e.g.*, *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980).

42. *Chakrabarty*, 447 U.S. at 309.

43. *Id.* at 313.

44. *See id.*

45. *See id.* at 310 (holding the bacterium developed in the laboratory by scientists was a human-made invention).

46. *Id.*

47. *Id.* at 313.

48. *Myriad*, 133 S. Ct. at 2107; *In re Roslin Institute* (Edinburgh), 750 F.3d 1333 (Fed. Cir. 2014).

49. *In re Roslin*, 750 F.3d at 1337.

50. *Id.*

51. *Id.*

52. *See generally* Ryan Hagglund, *Patentability of Cloned Extinct Animals*, 15 GEO.

issue that currently living animals face.

The second requirement is utility.⁵³ The potential patent needs to be useful, and it will not be precluded if they have practical or specific utility.⁵⁴ The cloning of extinct animals could possibly lead towards ecological and environmental benefits.⁵⁵ Those animals could provide new information or new knowledge the world may be lacking since they became extinct.⁵⁶ Now that the world is facing many environmental and ecological issues, it could be a way to help restore some of the balance.⁵⁷ Comparably, cloned livestock could provide healthier foods for consumers.⁵⁸ Herds that are resistant to illness could be extremely valuable for economic reasons for both farmers and meat for consumers.⁵⁹ For these reasons, many scientists argue patents for cloned animals would be considered useful.

Third, the potential patent must be novel.⁶⁰ Novelty is a difficult issue discussing cloning animals. Section 102 explains novelty is “available to the public before the effective filing date of the claimed invention; or . . . described in a patent . . .”⁶¹ Courts have not considered novelty for extinct animals since they determined living animals are not patentable material; however, they could be considered novel under section 102 according to some scientists.⁶² The in-depth analysis of whether extinct animals are considered novel will not be analyzed here, but it is believed extinct animals could be considered patentable under the Lost Art Doctrine.⁶³ The Lost Art Doctrine would consider an extinct animal to

MASON L. REV. 381, 404-05 (2008).

53. 35 U.S.C. § 101 (2012).

54. *Id.*

55. Jeffrey Yule, Editorial, *Cloning the Extinct: Restoration as Ecological Prostheses*, COMMON GROUND 1.2, 6 (2002), available at http://www.globalrestorationnetwork.org/uploads/files/LiteratureAttachments/71_cloning-the-extinct--restoration-as-ecological-prostheses.pdf.

56. See Caroline P. Rogers, Note, *Solution or Stumbling Block?: Biological Engineering and the Modern Extinction Crisis*, 30 GA. J. INT'L & COMP. L. 141, 145 (2001) (noting certain animal that might have been expendable before, now might bring new information to help with diseases and medicine).

57. See, e.g., *id.*

58. See *A Primer on Cloning and Its Use in Livestock Operations*, FDA, available at <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalCloning/ucm055513.htm> (last updated July 28, 2014) (possibilities that could happen because of cloned animals).

59. *Id.*

60. 35 U.S.C. § 102(a) (2012).

61. *Id.*

62. See *id.*

63. Darren M. Jiron, *Patentability of Extinct Organisms Regenerated Through Cloning*, VA. J.L. & TECH. 9, 45 (2001). See generally Hagglund, *supra* note 52.

be a lost art since it has been completely lost from nature and cloning would bring it back.⁶⁴ As extinct animals, cloned livestock will have the same barrier to being patentable because they are being cloned from already existing animals. The barriers made in *Myriad* were made stronger in the *In re Roslin* case where the PTO Board, upheld by the Federal Circuit, explained that Dolly was not considered lost art because she was anticipated and obvious because she was indistinguishable from the animals used in the cloning process.⁶⁵

Many scientists argue their cloned animals should be patented so they can protect their creations. The decision in *Myriad* that cDNA is patentable⁶⁶ could be seen as giving scientists hope because a part of the cloned animal can be patented, does that mean that the whole animal can be? Do not parts of the sum make the whole? However, I believe they will have an uphill battle trying to get the courts to decide in their favor.

III. WHAT TYPES OF EXTINCT ANIMALS CAN BE CLONED?

While there have been many livestock animals cloned, such as Dolly, there are not many cases of cloned extinct animals.⁶⁷ The ethical issues and effects on extinct animals and agriculture from the now patentable cDNA will be analyzed later.⁶⁸ First, the possibility of cloning extinct animals will be examined. When people hear extinct animals they automatically think of dinosaurs, saber-tooth tigers, and woolly mammoths. Many questions arise surrounding whether we will see T-Rexes in the Amazon or woolly mammoths roaming the Great Plains. However, with today's science these kinds of extinct animals may not be the type scientists will be able to clone.⁶⁹ Rather, science indicates that more recently extinct animals are more likely possibility.⁷⁰ With the current technology for nuclear DNA, the animal's genome must be in nearly perfect condition, which means the genome must be almost completely whole.⁷¹ Genome degradation is

64. *Id.*; see generally Hagglund, *supra* note 52.

65. *In re Roslin Institute* (Edinburgh), 750 F.3d 1333, 1336-37 (Fed. Cir. 2014).

66. *Myriad*, 133 S. Ct. at 2111, 2119.

67. Van Eenennaam, *supra* note 17.

68. See *Myriad*, 133 S. Ct. at 2111.

69. Yule, *supra* note 55.

70. *Id.*; see e.g., Sarah Griffiths, *The End of Extinction? Scientists are Close to 'Cloning' an Australian Frog that no Longer Exists—and There are Plans to Resurrect More Dead Species*, MAILONLINE (Sept. 3, 2013), <http://www.dailymail.co.uk/sciencetech/article-2409838/The-end-extinction-Scientists-close-cloning-Australian-frog-longer-exists—plans-resurrect-dead-species.html>.

71. See Carl Zimmer, *Bringing Them Back to Life: The Revival of an Extinct Species is no Longer a Fantasy. But is it a Good Idea?*, NAT'L GEOGRAPHIC (Apr. 2013), <http://ngm.nationalgeographic.com/2013/04/125-species-revival/zimmer-text>. See generally

caused by the passage of time, the more time passed, the more degradation.⁷² No meaningful genetic information can be preserved in most geological environments longer than 10,000 years.⁷³ This would rule out dinosaurs, which became extinct around sixty-five million years ago.⁷⁴ Cloning more recent animals is a much better prospect.⁷⁵ However, the Pyrenean ibex was the first time an extinct animal had been cloned, although it died “shortly after birth.”⁷⁶ But, scientists believe more recent extinctions would be more viable because their genomes would not be as degraded; however, there are still hurdles technology has to face.⁷⁷

The prospect of cloning recently extinct animals has faced many difficulties; nevertheless, some believe they are close to being able to bring back certain extinct animals. For example, if a woolly mammoth were to be cloned it would have to be born from its closest relatives—the African or Asian elephants.⁷⁸ Ancient mammoths became endangered around 10,000 years ago and became extinct 4,000 years ago, which is recent enough for possible recoverable genomes.⁷⁹ One way to get around the fragmented DNA of an ancient mammoth is to alter a living elephant’s chromosomes at every 400,000 sites where they differ from mammoths’.⁸⁰ Once the genomes are linked together and each of the missing sites are modified, the cloned organism would then be implanted into a living el-

Tanya Lewis, *De-Extinction Experts See Benefits in Resurrecting Extinct Animals, But Critics Abound*, HUFFINGTON POST (Aug. 26, 2013, 9:05 AM), http://www.huffingtonpost.com/2013/08/26/de-extinction-extinct-animals-life_n_3816271.html.

72. See Zimmer, *supra* note 71 (discussing how the farther back a creature became extinct the less likely they will be able to reconstruct the genome).

73. Yule, *supra* note 55.

74. *Id.*

75. *Id.*; Zimmer, *supra* note 71.

76. Richard Gray & Roger Dobson, *Extinct Ibex is Resurrected by Cloning*, THE TELEGRAPH (Jan. 31, 2009, 9:00PM), <http://www.telegraph.co.uk/news/science/science-news/4409958/Extinct-ibex-is-resurrected-by-cloning.html>.

77. See generally Yule, *supra* note 55.

78. Tom Mueller, *Recipe for a Resurrection, Bringing Extinct Species Back to Life is no Longer Considered Science Fiction. But is it a Good Idea?*, NAT’L GEOGRAPHIC (May 2009), http://ngm.nationalgeographic.com/2009/05/cloned-species/mueller-text?rptregcta=reg_free_np&rptregcampaign=20131016_rw_membership_r1p_us_se_w#close-modal.

79. See *Why Did the Woolly Mammoth Die Out?*, NAT’L GEOGRAPHIC WILD, <http://natgeotv.com.au/tv/waking-the-baby-mammoth/why-did-the-woolly-mammoth-die-out.aspx> (last visited Sept. 8, 2015) [hereinafter *Mammoth*].

80. Mueller, *supra* note 78.

ephant and a mammoth would be born.⁸¹ Cloning mammoths have received a recent boost of excitement from a discovery made in the Siberian permafrost.⁸² A preserved mammoth trunk has been found that has been incredibly preserved.⁸³ The trunk was described as looking like red animal meat that had been freshly killed.⁸⁴ Long extinct animals, such as the dinosaurs, may be out of reach to bring back, but more recent animals could be cloned and one day repopulate the world.

IV. CLONING OF AGRICULTURAL ANIMALS

On July 5, 1996, the first ever mammal was successfully cloned in Scotland, this animal was known as Dolly the sheep.⁸⁵ Dolly was cloned via somatic cells nuclear transfer and lived until 2003.⁸⁶ Another example of an agricultural animal being cloned is on a cattle farm in Oklahoma called Pollard Farms, run by neurosurgeon Barry Pollard.⁸⁷ Pollard Farms contains some four hundred Black Angus cattle and twenty-two of those cattle are clones.⁸⁸ These two examples show that there has been a history of cloned livestock. In addition to these examples, scientists have been able to clone cattle, pigs, sheep, goats, mules, and horses.⁸⁹

Some argue cloning of livestock is a simple progression from current practices.⁹⁰ Many livestock farmers use assisted reproductive technologies for breeding, such as artificial insemination and embryo transfer.⁹¹ These practices have been used to decrease the chances of injury or diseases that might occur during

81. *Id.*

82. Anna Liesowska, *Scientists Discover World's 'Best-Preserved Woolly Mammoth Trunk*, SIBERIAN TIMES (Sept. 23, 2013), <http://siberiantimes.com/science/casestudy/news/scientists-discover-worlds-best-preserved-woolly-mammoth-trunk/>.

83. *Id.*

84. *Id.*

85. 1997: *Dolly the Sheep is Cloned*, ON THIS DAY, BBC HOME, http://news.bbc.co.uk/onthisday/hi/dates/stories/february/22/newsid_4245000/4245877.stm (last visited Sept. 8, 2015).

86. David Stocum, *Somatic Cell Nuclear Transfer (SCNT)*, ENCYCLOPEDIA BRITANNICA, <http://www.britannica.com/science/somatic-cell-nuclear-transfer> (last visited Sept. 8, 2015).

87. Karl Plume, *Welcome to the Clone Farm*, REUTERS (Fri. Nov. 13, 2009, 7:38 AM) <http://www.reuters.com/article/2009/11/13/us-food-cloning-idUSTRE5AC07V20091113>.

88. *Id.*

89. *A Primer on Cloning and Its Use in Livestock Operations*, *supra* note 58.

90. *Id.*

91. *Id.*

the mating process.⁹² It seems mating is not much easier for animals than it is for humans. These practices could be seen as precursors to the newer technology of cloning. The somatic cell nuclear transfer process is used to clone the majority of livestock.⁹³ As stated before, nuclear transfer is combining the nucleus from the egg, which is combined with a donor nucleus.⁹⁴ They then implant the embryo into the uterus of the chosen specimen and the clone is born through that surrogate.⁹⁵ Livestock were some of the first animals that cloning was tested on and there is obvious evidence cloning of livestock is alive and well.

V. ETHICAL ISSUES OF CLONING ANIMALS

Now that we have determined extinct animals and livestock can be cloned, the next step is to analyze the ethical issues that arise from cloning animals. After reading multiple sources about cloning animals, it seems that ethical issues and animal cloning go hand-in-hand. There are as many arguments for patentability of cloning animals as there are against it. Both of these viewpoints will be analyzed in this section.

First, animal rights and animal welfare is one of the main arguments against cloning. Opponents argue genetic modification, such as cloning, poses a new and frustrating threat to animal welfare.⁹⁶ Animal welfare supporters fear that cloning presents unforeseen results.⁹⁷ There are many possible results from cloning that pose harm to animals. Some of those include: mutation in genes, deprivation of nutrients for the developing animal due to the placenta not forming properly, or serious and painful diseases.⁹⁸ Due to the varying possibilities of results, animal rights activists are concerned because they do not know what to expect and how to fight it.⁹⁹ Another concern is the success rate of cloned animals. There is a small portion of cloned animals which actually survive past birth.¹⁰⁰

92. *Id.*

93. *Id.*

94. *Id.*; *Process of Cloning*, *supra* note 20.

95. *A Primer on Cloning and Its Use in Livestock Operations*, *supra* note 58; *Process of Cloning*, *supra* note 20.

96. JAY RUTOVITZ & SUE MAYER, GENETICALLY MODIFIED AND CLONED ANIMALS. ALL IN A GOOD CAUSE?, GENEWATCH UK 24 (April 2002), available at <http://www.genewatch.org/uploads/f03c6d66a9b354535738483c1c3d49e4/GMAnimalsA4.pdf>.

97. *Id.*

98. *Id.*

99. *See id.*

100. *Animal Welfare*, AM. ANTI-VIVISECTION SOC'Y, <http://www.endanimalcloning.org/animalwelfare.shtml> (last visited Sept. 8, 2015) [hereinafter *Animal Welfare*].

Cloned livestock tend to have more problems than their natural counterparts and die more often.¹⁰¹ Additionally, due to the fact that cloning requires such a large number of animals because of the high possibility of failures, it unnecessarily uses more animals than it should.¹⁰² Finally, there is the concern cloned animals will contain genetic mutations that affect the standard of living for these animals.¹⁰³ There are examples of mice that have suffered fusion deformities or the absence of bones, and some of these mutations may never be found because the animal dies from the mutations.¹⁰⁴ These undetected abnormalities concern animal welfare proponents because it undermines the actions they can take against cloning because these abnormalities cannot be detected.¹⁰⁵ Some abnormalities believed to occur are early or late-term abortions and shorter lifespans.¹⁰⁶ For opponents of cloning, the welfare of the animal is one of most disconcerting issues for them.

Besides animal welfare, opponents argue a variety of other concerns. One of those arguments is animal integrity.¹⁰⁷ Animal integrity is the concept animals have some sort of natural worth, like humans do.¹⁰⁸ GeneWatch UK, a group in the United Kingdom, argued when animals are cloned, it fundamentally alters the genome.¹⁰⁹ This does not just affect the individual animal's lifetime, but affects future generations.¹¹⁰ The integrity of the animal could be affected many years down the road, and possibly end up changing the animal's inherent characteristics.¹¹¹ Also, animal rights activists argue there is the possibility people will create cloned animals and will not feel pain or will be senseless to the research process, which would take away the animal's inherent integrity of being living and

101. *A Primer on Claiming and Its Use in Livestock Operations*, *supra* note 58.

102. See Elisabeth H. Ormandy, Julie Dale & Gilly Griffin, *Genetic Engineering of Animals: Ethical Issues, Including Welfare Concerns*, CAN. VET. J. 52(5) 544 (2011), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078015/> (multiple examples of how many test animals are used in the process of cloning).

103. See, e.g., *id.*

104. RUTOVITZ & MAYER, *supra* note 96.

105. See generally *id.*

106. See U.S. FOOD AND DRUG ADMINISTRATION, CHAPTER V: ANIMAL HEALTH RISKS, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalCloning/ucm124840.htm> (last visited Sept. 8, 2015).

107. See, e.g., Bart L.J.E. Rutgers, *The Use of the Reflective Equilibrium Method in Teaching Animal Ethics and Veterinary Ethics*, UTRECHT UNIV., <http://web04.univ-lorraine.fr/ENSAIA/marie/bioethics/workshop/pdf/Rutgers.pdf> (last visited Sept. 8, 2015).

108. See RUTOVITZ & MAYER, *supra* note 96.

109. *Id.*

110. *Id.*

111. See *id.*

feeling creatures.¹¹²

Another question is whether humans have the “right” to clone animals. Who or what gives humans the right to control what kind of animal is created or to inflict possible harm onto an innocent animal? These are the questions many animal rights activists ask when it comes to cloning. Many accuse scientists of playing God.¹¹³ One theory argues patenting life reflects on the disinterest of humans towards animals and their sanctity of life.¹¹⁴ Another theory is referred to as the stewardship theory.¹¹⁵ The theory is based on the definition of steward, which is “a person who acts as the surrogate of another or others” or “the responsible overseeing and protection of something considered worth caring for and preserving.”¹¹⁶ The stewardship theory is guided by the idea that because animals are under human care and protection and humans have the ability to protect them, they should shoulder that task because it protects the circle of life.¹¹⁷ These accusations arise from the belief that cloning interferes with the sanctity of human life and affects humanity’s relationship with the natural world.¹¹⁸ Lastly, if the process of cloning animals can be patented, the possibility of profit could outweigh any potential moral arguments, potentially effecting humanity in a negative way.

Opponents of animal cloning believe that patenting the process of cloning will likely lead to the patenting of genetically engineered human beings.¹¹⁹ However, this outcome faces many barriers before it could happen. First, the Thirteenth Amendment prohibits property rights in humans, which could be deemed as extending to patent law because when a patent is granted to the creator, it gives them rights over the patent and object; thus, patenting a human would be highly improbable.¹²⁰ Second, science is has a long way to go before being able to clone humans, so arguably this would appear to be a moot point.¹²¹ Even

112. Perzigian, *supra* note 1.

113. Keith Schneider, *New Animal Forms Will be Patented*, N.Y. TIMES (April 17, 1987), <http://www.nytimes.com/1987/04/17/us/new-animal-forms-will-be-patented.html>; RUTOVITZ & MAYER, *supra* note 96.

114. David Manspeizer, Note, *The Cheshire Cat, the March Hare, and the Harvard Mouse: Animal Patents Open Up a New, Genetically-Engineered Wonderland*, 43 RUTGERS L. REV. 417, 438 (1991).

115. *Id.*

116. BLACK’S LAW DICTIONARY 1549 (9th ed., 2009).

117. *See* Manspeizer, *supra* note 114.

118. RUTOVITZ & MAYER, *supra* note 96.

119. Manspeizer, *supra* note 114.

120. U.S. CONST. amend XII.

121. *See id.*

though the possibility of patenting cloned humans is extremely remote the fact that the process of cloning can be patented¹²² and that parts of the cloned animal can be patented,¹²³ may give this argument some legs.

The desert rationale is an argument that patenting cloned animals promotes innovation.¹²⁴ The theory states patents protect laborers, or bio-technicians, and their property rights in their inventions when created for social purpose.¹²⁵ These bio-technicians have put in their time and effort to create these innovations and have sacrificed many things for their projects; these property rights would be considered their “just desserts.”¹²⁶ These bio-patents would be providing the scientists with what they are legally and rightfully justified in receiving.¹²⁷ In addition to the dessert rationale, the patenting of animal clones could help the natural world.¹²⁸

Patented cloned animals would be a way for humans to right the wrongs that have occurred due to human interaction.¹²⁹ This particular argument really targets the question of patenting cloned extinct animals.¹³⁰ Supporters of this argument urge cloning extinct animals is an ethical way to preserve and revitalize the ecosystems that have been affected by humans.¹³¹ Also, if extinct animals could be brought back they may provide new information and benefits for humans.¹³²

Thirdly, supporters claim the social utility of bio-patents outweighs the possible ethical issues, and the bio-patents are necessary to the production of in-

122. See *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014).

123. See generally, *Myriad*, 133 S. Ct. at 2107.

124. See Ned Hettinger, *Patenting Life: Biotechnology, Intellectual Property, and Environmental Ethics*, 22 B.C. ENVTL. AFF. L. REV. 267, 240 (1995).

125. *How U.S Patents Hinder Progress in the Tech Industry: Arguments For*, PSU COLLEGE OF INFORMATION SCIENCES AND TECHNOLOGY, <http://faculty.ist.psu.edu/bagby/432Spring08/T5/Arguments%20for%20Patents.html> (last visited Sept. 8, 2015) [hereinafter *Patents*].

126. See generally Edwin C. Hettinger, *Justifying Intellectual Property*, 18 PHIL. & PUB. AFF. 31, 40-43 (1989) [hereinafter *Intellectual Property*].

127. See generally *id.*

128. See Rogers, *supra* note 56.

129. See *id.*

130. See Breanna Draxler, *5 Reasons to Bring Back Extinct Animals (And 5 Reasons Not To)*, DISCOVER MAG. (Apr. 4, 2013, 1:36 PM), http://blogs.discovermagazine.com/d-brief/2013/04/04/5-reasons-to-bring-back-extinct-animals-and-5-reasons-not-to/#.U8gtquPZ_gI.

131. See Rogers, *supra* note 56.

132. Draxler, *supra* note 130.

novation.¹³³ Some possible innovations, such as oil-eating bacteria and leaner, cheaper pigs, are possible patents that could be turned down if biotechnicians are not allowed to patent their projects.¹³⁴ There is also the consideration that if these patents will no longer be issued, then the desire for innovation will decrease.¹³⁵ Additionally with the decisions in *Myriad* and *In re Roslin* rejecting patents that are identical to items in nature, investors may shy away from providing funding, according to one scientist.¹³⁶

Finally, supporters of cloning animals want to make clear that cloned animals are different than transgenic animals. Transgenic animals are produced when there has been the addition or removal of genes, such as injecting the genes of different species into the animal.¹³⁷ An example of this is injecting a goat with insulin and the goat producing the insulin through its milk for diabetics or injecting salmon with growth hormones to make them grow bigger faster.¹³⁸ These animals differ from cloned animals. Cloned animals are produced using biotechnology; they are intended to be exact replicas of the original animal.¹³⁹ They are not meant to biologically change an already existing animal. This difference, according to supporters, needs to be recognized to show cloning is not as unethical as some would argue.¹⁴⁰

VI. POSSIBLE EFFECTS OF PATENTING CLONED EXTINCT AND AGRICULTURAL ANIMALS

There is a multitude of possible effects, negative and positive, that cloning of extinct and agricultural animals could have, but this Note will only focus on the main four: environmental/ecological, agricultural, economic, and human.

First, what are the possible positive effects on the environment that could result from cloning? Cloning may have indirect and direct effects on the envi-

133. Hettinger, *supra* note 124.

134. *Id.*

135. *Id.*

136. See Kelly Servick, *No Patent for Dolly the Cloned Sheep, Court Rules, Adding to Industry Jitters*, AAAS (May 14, 2014, 7:30 AM), <http://news.sciencemag.org/biology/2014/05/no-patent-dolly-cloned-sheep-court-rules-adding-industry-jitters>.

137. Linda Bren, *Cloning: Revolution or Evolution in Animal Production?*, FDA VETERINARIAN NEWSL., (Sept./Oct. 2003) available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/VeterinaryMedicineAdvisoryCommittee/ucm127249.htm>.

138. *Id.*

139. *Id.*

140. See *id.*

ronment. Supporters argue cloning of extinct animals decrease the growing rate of animal extinction.¹⁴¹ The World Wildlife Fund (WWF) estimated that 150-200 species disappear daily.¹⁴² Also, the WWF reported that the main cause is humans, which is another argument for reintroducing extinct species as a way to rectify negative human interactions with the environment.¹⁴³ Cloning could support the endangered species that are housed in zoos and laboratories by providing greater genetic diversity among the species and patents could help facilitate this benefit.¹⁴⁴ Additionally, it could help those species in captivity that have difficulty in breeding.¹⁴⁵ These reintroduced species could provide invaluable information and knowledge to preserve the environment and ecosystem.¹⁴⁶ Many opponents argue the introduction of cloned animals will cause a severe change in the makeup of the animals DNA, but others contend the introduction would be similar to the natural mutations that occur in native species overtime.¹⁴⁷ Overall, supporters claim with the introduction of cloned animals it could benefit the environment in a positive manner because it would help revitalize the environment.¹⁴⁸

Cloning can have inadvertent positive effects, too. For example, cloning grass-fed animals instead of grain-fed animals could reduce erosion caused by crops.¹⁴⁹ Also, because grass does not need fertilizers to survive, those fertilizers used on crops would not get into the water and harm the ecosystem.¹⁵⁰ Additionally, with the availability of these types of bio-patents, it could provide motivation for scientists to regenerate a valuable species that may not have been in existence if those patents would not have been issued.¹⁵¹ While there are possible positive impacts, there are also negative ones too.

First, many conservationists argue cloning endangered species would do little to actually help the root causes of extinction, such as human settlement and

141. See Perzigian, *supra* note 1.

142. *Priority Species*, WORLD WILDLIFE FUND, http://wwf.panda.org/what_we_do/endangered_species/ (last visited Sept. 8, 2015) [hereinafter *Species*].

143. *Id.*

144. Perzigian, *supra* note 1.

145. Jon Cohen, *Can Cloning Help Save Beleaguered Species?*, SCI. VOL. 276 no. 5317, 1329-30 (1997), available at <https://www.sciencemag.org/content/276/5317/1329.full>.

146. See, e.g., Rogers, *supra* note 56.

147. Manspeizer, *supra* note 114.

148. See Bren, *supra* note 137.

149. *Id.*

150. See *id.*

151. See, e.g., Jiron, *supra* note 63 (list of possible extinct animals that could be cloned).

deforestation.¹⁵² Reintroducing an animal does not cause humans to stop what they are doing. This lack of needing patents to facilitate the cloning would make the patent process null-and-void. Second, it could negatively affect the conservation movement because humans would not have to conserve if scientists could simply clone the endangered or extinct animals.¹⁵³ Third, studies have shown there are negative effects on the animals used for cloning, such as issues with reproduction.¹⁵⁴ Further, cloning extinct animals ignores the natural process that occurs between genes and the environment as an animal develops, possibly leading to abnormalities.¹⁵⁵ Fourth, bio-patents give private ownership of the reconstituted species, which gives them sole means to create them and defeats the notion of wild animals as public resources.¹⁵⁶ In summary, opponents argue that the introduction of cloned animals could pose a risk to the environment and greatly affect the ecosystem.¹⁵⁷

The cloning of livestock can have great repercussions in the agricultural world. Many of the proponents of cloning contend farmers would be able to control the quality of their livestock.¹⁵⁸ Farmers would be able to preserve strong genetics so they could select the best animals and predict what type of animal would be produced.¹⁵⁹ Cloning could potentially improve the welfare of the farm animals by eradicating the pain and suffering from diseases.¹⁶⁰ Additionally, cloning could allow farmers to reduce the number of unwanted animals in their herds and select the animals more suitable for climate, quality body type, and fertility, thus creating an environment of survival of the fittest.¹⁶¹ Farmers could also raise cloned animals that could supply organs for human transplantation.¹⁶² The process of cloning animals is patentable; this means farmers could not only

152. Ferris Jabr, *Will Cloning Ever Save Endangered Animals?*, SCIENTIFIC AM. (Mar. 11, 2013), <http://www.scientificamerican.com/article/cloning-endangered-animals/>; see also Lewis, *supra* note 71.

153. See Peter T. Jenkins, *Policy Positions on Wild Animal Cloning, Genetic Engineering, and Patenting*, CTA INT'L CTR. FOR TECH. ASSESSMENT, <http://andrewkimbrell.org/doc/policy%20positions%20-%20animal%20cloning,%20ge,%20&%20patenting.pdf>.

154. See RUTOVITZ & MAYER, *supra* note 96.

155. See *id.*

156. Jenkins, *supra* note 153.

157. See Hettinger, *supra* note 124.

158. See Bren, *supra* note 137.

159. *Id.*

160. *Id.*

161. *Id.*

162. Jennifer Mitol, *How Cloning Could Change Farming*, ABC NEWS (July 16, 2013), <http://abcnews.go.com/Technology/story?id=98410&page=1>.

benefit from the product of their actual animal, but the profit that comes from cloning process.¹⁶³ Cloning livestock would not only benefit farmers, but also consumers and producers looking for nutritious meat that is repeatable and reliable.¹⁶⁴ Opponents argue cloned animals' meat is not the same as natural, but there is no evidence to support that according to the FDA.¹⁶⁵ The FDA explains that the composition of the cloned animals is not any different than naturally produced animals and there is no scientifically based reasoning that says cloned animal meat should include food labels.¹⁶⁶ However, most cloned livestock are used for breeding stock and not consumption.¹⁶⁷

In contrast, many possible negative effects could occur. In some cloned cattle and sheep a disease called Large Offspring Syndrome often occurs. Large Offspring Syndrome refers to when the fetus grows too large for the uterus, causing problems for the surrogate and the fetus.¹⁶⁸ Cloning could also reduce the genetic diversity.¹⁶⁹ Furthermore, some farmers may feel the heavy burden of cloned livestock, and costs could increase because farmers would be forced to buy high- priced patented animals.¹⁷⁰ They may also lose profits because consumers may prefer the genetically engineered animals.¹⁷¹ Small farms would be greatly affected by cloning because they would not have the money or means to compete with larger patented animal farms.¹⁷² However, they could affect agriculture by introducing new predators or creating an overabundance of predators

163. See *In re Roslin Institute (Edinburgh)*, 750 F.3d 1333 (Fed. Cir. 2014) (holding the process of cloning can be patentable, but the actual animal is not).

164. Mitol, *supra* note 162.

165. See U.S. FOOD & DRUG ADMIN., CONSUMER HEALTH INFORMATION, ANIMAL CLONING & FOOD SAFETY, (Jan. 15, 2008) available at <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm148768.htm> [hereinafter ANIMAL CLONING].

166. *Id.*; U.S. DEP'T OF HEALTH & HUMAN SERV., FDA GUIDANCE FOR INDUSTRY: USE OF ANIMAL CLONES AND CLONE PROGENY FOR HUMAN FOOD AND ANIMAL FEED, (Jan 12, 2008), available at <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052469.pdf> [hereinafter FDA GUIDANCE].

167. ANIMAL CLONING, *supra* note 165.

168. *A Primer on Claiming and Its Use in Livestock Operations*, *supra* note 58 (possibilities that could happen because of cloned animals).

169. See generally *Cloned Animals a "Threat to Genetic Diversity"*, ECOLOGIST (Aug. 4, 2010), http://www.theecologist.org/News/news_round_up/555115/cloned_animals_a_threat_to_genetic_diversity.html.

170. *Animal Leg. Def. Fund v. Quigg*, 932 F.2d 920, 932 (Fed. Cir. 1991).

171. See *id.*

172. *Id.*

that could kill off herds.¹⁷³

Along with agricultural effects, there are possible economic ones too. Cloned livestock could help boost the farming industry by letting farmers determine the best animals, which would lead to higher-quality meat.¹⁷⁴ Also, it would help farmers meet the demands of consumers who want high-quality meat continuously and quickly.¹⁷⁵ Introducing cloned animals into the environment could help poorer countries that are not able to dedicate money to conservation efforts.¹⁷⁶ However, cloning is a huge monetary endeavor. The cloning industry would be drawing money out of already stretched funds of conservation efforts.¹⁷⁷ Finally, it would give patent owners huge amounts of money that could create monopolies.¹⁷⁸ Those patent incentives could motivate certain people to eradicate all endangered species just so they could receive the monetary gain that comes with patents.¹⁷⁹

Finally, the possible effects cloning may have on humans. Additionally, the possible effects on human health must be considered. With the reintroduction of cloned extinct animals or endangered animals there is the possibility these animals could help treat human diseases.¹⁸⁰ These animals that have been extinct could provide humans with life-saving information that was previously present because those species were no longer on the planet.¹⁸¹ New species could also provide new medicines and useful knowledge that could lead to breakthroughs in cancer treatment and other diseases.¹⁸²

VII. CONCLUSION

Now that the Supreme Court has determined cDNA is patentable material, the possible consequences must be deliberated.. Even though cloned animals are not patentable subject material, the fact that part of a cloned animal may be,¹⁸³

173. Draxler, *supra* note 130.

174. Bren, *supra* note 137.

175. *Id.*

176. Jiron, *supra* note 63.

177. Jenkins, *supra* note 153.

178. *See, e.g.,* Eli Lilly & Co. v. Premo Pharmaceutical Laboratories, Inc., 630 F.2d 120, 137 (3rd Cir. 1980) (explaining the pharmaceutical patent could create a monopoly that would harm other companies).

179. Jiron, *supra* note 63.

180. Lauren Pecorino, *Animal Cloning: Old MacDonald's Farm is Not What it Used to Be*, ACTIONBIOSCIENCE (Sept. 2000), <http://www.actionbioscience.org/biotechnology/pecorino.html>.

181. Draxler, *supra* note 130.

182. *See* Rogers, *supra* note 56.

183. *Myriad*, 133 S. Ct. at 2111.

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could lead down a very interesting road for the patent and scientific fields. The discussion on cloning animals is a large and impressive topic that has gone on for many years. These discussions are now turned toward the future with the possibility of cloning endangered animals. This discussion will undoubtedly grow and expand and touch many areas of science, ethics, and the environment. However, one thing is sure, now that cDNA is patentable, and as of a current federal court decision cloned animals themselves are not patentable, it could open the doors to new and unexplored areas of animal ecology and even humanity.