
DOES DOLLY DESERVE DEFENSE? AN ANALYSIS OF THE PATENTABILITY OF CLONED LIVESTOCK

Andrew Clark*

I. Introduction

“The real value of cloning... lay in the potential to engineer animals to produce medications, and even transplantable organs, for use by human beings. Those prospects, too, have so far remained largely unrealized.” Dr. Keith Campbell¹

Rapid developments in the biotechnology industry have made cloning a once futuristic idea a reality, leaving the United States Patent laws in a perplexing position: can the longstanding patent system adequately protect products of unforeseen technologies, or are the technologies themselves the only patentable subject matter? The term “clone” was first coined by J.B.S. Haldane, a British biologist, in a speech he gave in 1963.² The science of cloning has rapidly developed since the 19th century, with the first major advances occur-

* J.D. Candidate, Suffolk University Law School, 2015.

¹ See Margalit Fox, *Keith Campbell, Cloner of Sheep, Dies at 58*, N.Y. TIMES (Oct. 12, 2012), archived at <http://perma.cc/G4SK-7QK5> (expounding on the life and legacy of Dr. Keith Campbell). Dr. Keith Campbell was born on May 23, 1954 in Birmingham, England. He received his bachelor’s degree in Microbiology from the University of London in 1978, and his doctorate degree from the University of Sussex in 1986. Dr. Campbell was credited with developing the idea to clone Dolly. See *id.*

² See *History of Cloning*, BASIC SCI. P’SHIP HARVARD MED. SCH., archived at <http://perma.cc/0eAe58kaSBV> hereinafter *History of Cloning*] (illustrating the timeline of cloning).

ring in the 1970s.³ The biggest event in cloning history, the successful cloning of Dolly the sheep, was revealed in 1997.⁴ Dr. Keith Campbell,⁵ a cell biologist, and Dr. Ian Wilmut,⁶ a developmental biologist, were responsible for cloning Dolly at the Roslin Institute in Scotland in 1996.⁷ The field of cloning has continued to develop with other milestones along the way, including the cloning of fifty mice by scientists at the University of Hawaii and the successful cloning of an endangered guar (wild ox) by scientists at Advanced Cell Technology, Inc.⁸

This note suggests that the United States Patent and Trademark Office should no longer deny patents to genetically cloned animals, in particular livestock. Patent laws should no longer consider cloned animals to be unpatentable subject matter, rather the laws should include animals that are not a product of natural reproduction.⁹ Parts II and III describe the evolution of United States Patent laws.¹⁰ Part IV will provide a background of the development and uses of the science of cloning.¹¹ Part V will propose facts that pre-

³ See Allison Royal, *The History of Cloning Humans and Animals*, COSMOS UC DAVIS (July, 27, 2009), archived at <http://perma.cc/0oGKp1Quv8N> (discussing the history and development of the science of cloning).

⁴ See *id.* at 1 (highlighting the creation and existence of Dolly).

⁵ See Fox, *supra* note 1 (expanding upon the biography and legacy of Dr. Keith Campbell).

⁶ See Kara Rogers, *Sir Ian Wilmut*, ENCYCLOPÆDIA BRITANNICA (Oct. 30, 2013) archived at <http://perma.cc/37AL-B7T3> (detailing the career and life of Sir Ian Wilmut). Sir Ian Wilmut was born on July 7, 1944 in Hampton Lucy, Warwickshire, England. At the age of twenty-two Wilmut graduated from the University of Nottingham, during his studies at Nottingham, he was able to perform reproductive research at the University of Cambridge. The research Sir Wilmut performed at Cambridge encouraged him to pursue a doctorate, which he received in 1971 from Darwin College, Cambridge. After receiving his doctorate Sir Wilmut was appointed senior scientific officer at Roslin Institute, the laboratory where he and Dr. Campbell would successfully clone Dolly twenty-four years later. Sir Ian Wilmut, accepted a position at University of Edinburgh in 2005, and was knighted in 2007. See *id.*

⁷ See *id.* at 3 (discussing further the history and creation of Dolly the sheep).

⁸ See History of Cloning, *supra* note 2 (describing successes in cloning since the cloning of Dolly the sheep by Campbell and Wilmut in 1996).

⁹ See *infra*, at Part VI (analysis section).

¹⁰ See *infra*, at Part III (history of patent laws section).

¹¹ See *infra*, at Part IV (history of cloning, and its uses).

sent unique considerations for patent law.¹² Part VI will propose an expanded application of Patents to incorporate products of animal cloning.¹³

II. Current State of United States Patent Law

The United States Congress has the right to develop and enact patent laws under Article I, § 8, cl. 8 of the United States Constitution.¹⁴ The creation of patent laws, and the interpretation of patentable subject matter have drastically changed since the first patent statutes were enacted.¹⁵ The most recent modification of United States Patent Law was enacted on September 16, 2011.¹⁶ The biggest change brought by the 2011 revision is the change to a first-to-file system rather than the first-to-invent system that was previously in place.¹⁷ The Patent and Trademark Office made this change in order to “result in greater transparency, objectivity, predictability, and simplicity in patentability determinations.”¹⁸ This change to a first-to-file system puts the United States on a similar patent system as the

¹² See *infra*, at Part V (describing the facts considered when writing this piece).

¹³ See *infra*, at Part VI (analysis section).

¹⁴ See *Pennock v. Dialogue*, 27 U.S. 1, 16-17 (1829) (discussing the Constitutional language that grants Congress the right to enact patent laws and regulate patents through the enactment of those laws).

¹⁵ See *infra*, at Part III (describing the historical progression of patent law from its first inception in 1970 to the modern day patent regime).

¹⁶ See Andrew Beckerman-Rodau, *Problems/Questions/Notes: Patent Law*, I. Background/Overview of Patent Law, 1 (on file with author) (examining the changes in US patent law over time culminating in the most recent revision in 2011).

¹⁷ See *id.* at 5 (contrasting the previous first-to-invent system with the newly enacted first-to-file system). Professor Beckerman-Rodau discussed the former first-to-invent system, which differed from that employed by the patent laws of the rest of the world. Using the first-to-invent system the “inventor is determined according to the date of creation of the invention.” The first-to-file system became effective March 16, 2013; however, the first-to-invent system still applies to any patent application filed before March 16, 2013. See *id.*

¹⁸ DONALD S. CHISUM, 1-SA02 CHISUM ON PATENTS § 3 (Matthew Bender ed., 2013) (providing the rationale of the Patent and Trademark office for switching to the first-to-file system rather than the first-to-invent system that was previously in place).

rest of the world.¹⁹ Using this system, a patent is granted to the first inventor to file a patent application in contrast to the old system that granted a patent to the first person to invent.²⁰ In the current patent system there are five requirements of patentability.²¹ It is undisputed that a patent right is a property right.²² The property right granted by patents is a negative right that allows the holder of a patent to exclude others from making the invention.²³ However, the negative property right does not ensure the right of inventor to make or sell his patented invention.²⁴ It is important to note that patent rights, like property rights, are transferrable.²⁵

¹⁹ See *id.* (reaffirming the importance of the first-to-file system because it makes United States patent law cohesive with the rest of the world).

²⁰ See *id.* (contrasting the grant of patents to those first to file for a patent application rather than the previous method of granting patents to the first to create the invention).

²¹ See Beckerman-Rodau, *supra* note 16 (enumerating the five requirements of patentability as: 1. Patentable Subject Matter; 2. Usefulness 3. Novelty 4. Non-obviousness 5. Enablement). Beckerman-Rodau then describes each condition of patentability in detail. *Id.*

²² See Adam Mossoff, *Exclusion and Exclusive Use in Patent Law*, 22 HARV. J.L. & TECH. 321, 322 (2009) (observing that the idea that patent rights are property rights is a fundamental thread through patent cases heard by the Supreme Court). The Supreme Court was instrumental in solidifying the rights granted by a patent as property rights. “If patents are defined solely by the right to exclude, and the Supreme Court has declared the right to exclude to be ‘one of the most essential sticks in the bundle of rights that are commonly characterized as property,’ then patents are property.” *Id.* at 326.

²³ See *id.* (explaining the right granted by patent holders as a negative right to exclude). The right to exclude does not afford the patent holder the right to make or sell their invention. See *id.* at 327. The premise of a negative right to exclude has been held by the Federal Circuit to be “elementary.” See *Bio-Tech. Gen. Corp. v. Genetech, Inc.*, 80 F.3d 1553, 1559 (Fed. Cir. 1996) (guaranteeing the right to exclude as a fundamental patent right conferred upon an inventor for his invention).

²⁴ See DONALD S. CHISUM, 5 CHISUM ON PATENTS § 16.02 (Matthew Bender ed., 2013) (explaining the rights conferred on the holder of a patent). The right to exclude others does include the right to prohibit others from making using and selling the patented invention. See *id.*

²⁵ See *General Information About 35 U.S.C. 161 Plant Patents*, UNITED STATES PATENT AND TRADEMARK OFFICE, (Feb. 13, 2007), archived at <http://perma.cc/4D97-BE4H> (affirming that patent rights are transferrable by the patent holder). “A plant patent is granted by the Government to an inventor (or the inventor’s heirs or assigns) who has invented or discovered and asexually reproduced a distinct and new variety of plant...” the emphasis on heirs and assigns demonstrates the transferability of patents. *Id.*

A. Types of Patents

The modern patent system has three main types of patents.²⁶ The three types of patents available to inventors in the United States are: 1. a utility patent; 2. a design patent; and 3. a plant patent.²⁷ This section discusses each type of patent in detail. The type of patent that an inventor files is dependent upon the subject matter or type of invention.²⁸

1. Utility Patent

The most commonly filed patent type is the utility patent.²⁹ Approximately 90% of all patent applications that have been filed in the last few years have been utility patents.³⁰ A utility patent is granted to the inventor for the invention of “a new and useful process, machine, manufacture, or composition of matter.”³¹ There is also a grant of a utility patent for a sufficiently useful improvement of an existing patented invention.³² The utility patents require various conditions of patentability, which are discussed below.

²⁶ See UNITED STATES PATENT AND TRADEMARK OFFICE, TYPES OF PATENTS, (Oct. 3, 2013), *archived at* <http://perma.cc/U8NG-KHBF> [hereinafter TYPES OF PATENTS] (summarizing the three types of patents available to patent applicants in the United States).

²⁷ See *id.* (explaining the characteristics of the three different types of patents in regards to the kinds of protection and subject matter each cover).

²⁸ See Beckerman-Rodau, *supra* note 16, at 5 (discussing how to determine which type of patent is appropriate to the invention).

²⁹ See Beckerman-Rodau, *supra* note 16, at 5 (observing that utility patents are the most commonly filed patent type of the three varieties of patents).

³⁰ See TYPES OF PATENTS, *supra* note 26 (demonstrating the overwhelming number of utility patent applications and grants as compared to plant and design patents).

³¹ See TYPES OF PATENTS, *supra* note 26 (describing broadly the inventions that can be classified or filed under a utility patent).

³² See TYPES OF PATENTS, *supra* note 26 (discussing the grant of a utility patent for a useful improvement upon an already existing patent).

a. Patentable Subject Matter

The scope of patentable subject matter for a utility patent is defined by 35 U.S.C. § 101.³³ The patentable subject matter is described in broad terms as “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”³⁴ Therefore, patentable subject matter can be said to be any machine, manufacture, composition of matter and process.³⁵ In terms of patentable subject matter a machine is described as “the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.”³⁶ It is important to note that manufacture implies a change to a product or item, but not every change is considered to be manufacture.³⁷ Therefore, manufacture should yield a new good, one that has been transformed with a distinctive character, name or use.³⁸ Composition of matter as specified in § 101 can simply be put as all “compositions [made up of] two or more substances.”³⁹ An expan-

³³ See 35 U.S.C. §101 (2014) (providing the criteria for an invention to be patentable).

³⁴ *Id.*

³⁵ See Beckerman-Rodau, *supra* note 16, at 3 (highlighting that machines, manufactures, compositions of matter and processes are known as statutory subject matter).

³⁶ See *American Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11 (1931) (defining the term manufacture as expressed in § 101 and applying it to a patent for a method of treating fresh oranges to prevent the growth of blue mold).

³⁷ See *Hartranft v. Weigmann*, 121 U.S. 609, 615 (1887) (“The application of labor to an article, either by hand or by mechanism, does not make the article necessarily a manufactured article...”); see also *Anheuser-Busch Assn. v. United States*, 207 U.S. 556, 562 (1908) (clarifying that just because something was the result of labor and manipulation it does not mean that it is automatically patentable subject matter).

³⁸ See *American Fruit Growers, Inc.*, 283 U.S. at 13 (opining that a transformation needs to take place when manufacturing a good for it to be considered sufficiently patentable subject matter).

³⁹ See *Shell Development Co. v. Watson*, 149 F. Supp. 279, 280 (1957) (qualifying what inventions or claims by inventors are encompassed by the language “composition of matter” in § 101). The Court in *Shell Development Co.* goes on to further define composition of matter to “includes all composite articles, whether they be results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids.” See *id.* See also Beckerman-Rodau, *supra* note 16 at 3

sion of the interpretation of composition of matter occurred when the United States Supreme Court heard *Diamond v. Chakrabarty*.⁴⁰ The *Chakrabarty* Court held that a genetically manufactured bacterium was in fact patentable subject matter.⁴¹ 35 U.S.C. § 100 clarifies the meaning of process by stating that “process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.”⁴² On occasion, the Supreme Court has been tasked to decide whether a new invention is sufficient subject matter to warrant a grant of a patent; yet after considering these various cases there is still no settled interpretation of § 101 and the subject matter it includes.⁴³ “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.”⁴⁴

b. Usefulness

Once it is determined that an invention is of a sufficient patentable subject matter another condition of patentability is useful-

(quoting the Court in *Shell Development Co.* and further describing the definition of “compositions of matter”).

⁴⁰ See *Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980) (reconsidering whether a microbiologist was entitled to a patent for his human-made genetically engineered bacteria, which was created to clean up oil spills).

⁴¹ See *id.* at 310 (holding that “the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility”); see also Beckerman-Rodau *supra* note 16 at 3 (discussing the holding of *Chakrabarty* and its impact on patentable subject matter).

⁴² See 35 U.S.C. § 100 (2014) (defining the term process as it pertains to 35 U.S.C. § 101). 35 U.S.C. § 100 also defines other key words found throughout the patent statutes. “The term patentee includes not only the patentee to whom the patent was issued but also the successors in title to the patentee.” See *id.* “The term “claimed invention” means the subject matter defined by a claim in a patent or an application for a patent.” “The term “inventor” means the individual or, if a joint invention, the individuals collectively who invented or discovered the subject matter of the invention.” *Id.*

⁴³ See Beckerman-Rodau, *supra* note 16 at 2 (indicating that there is no clear interpretation of § 101 leaving the Supreme Court to decide the scope of patent eligibility on a case by case basis).

⁴⁴ Ryan Hagglund, *Patentability of Cloned Extinct Animals*, 15 GEO. MASON L. REV. 381, 386 (2008).

ness. As stated in § 101 of the Patent Act, “Whoever, invents or discovers any new and useful process, machine, manufacture, or composition of matter, may obtain a patent therefore . . .”⁴⁵ The standard of usefulness is a very low threshold.⁴⁶ Therefore, any invention that has a minimal degree of usefulness will sufficiently fulfill this requirement.⁴⁷ Inventions that lack any usefulness or are otherwise inoperable are inventions that are said to have not fulfilled the usefulness threshold.⁴⁸

c. Novelty

In addition to an invention being useful and patentable subject matter, the invention must also satisfy a novelty requirement. The novelty requirement of patentability is governed by 35 U.S.C. § 102.⁴⁹ Section 102 statute states that:

A person shall be entitled to a patent unless—

(1)The claimed invention was patented, described in a printed publication, or in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention; or

(2)The claimed invention was described in a patent issued under section 151 [35 USCS § 151], or in an application for patent published or deemed published under section 122(b) [35 USCS § 122(b)], in which the patent or application, as the case may be, names another inventor and was effectively filed before the effective filing date of the claimed invention.

⁴⁵ See 35 U.S.C § 101 (2014); see also Beckerman-Rodau, *supra* note 16 at 4 (discussing the usefulness requirement of the Patent Act).

⁴⁶ See Beckerman-Rodau, *supra* note 16, at 4 (defining the very low threshold of usefulness that a potential patentable invention must meet).

⁴⁷ See Beckerman-Rodau, *supra* note 16, at 4 (noting that the low threshold of usefulness opens the door to any invention that has a “reasonable degree of usefulness”).

⁴⁸ See Beckerman-Rodau, *supra* note 16, at 4 (providing examples of inventions that would not reach the level of usefulness sufficient to warrant the issuance of a patent).

⁴⁹ See 35 U.S.C. § 102 (2014) (defining novelty as it pertains to patentability and providing exceptions to the novelty requirement).

Section 102 focuses on the prior art of the invention that was in existence before the patent application filing date.⁵⁰ In the above quoted language subsection (1) of § 102 highlights that an invention lacks novelty if it was previously in public use or available to the public.⁵¹ Courts examining patent eligibility disputes have defined disclosure in public by an inventor to occur when he discloses the invention in a printed document.⁵² “To constitute a publication, within the meaning of the statute, the invention must be described sufficiently to impart to a person with ordinary skill and knowledge of the prior art the information needed to devise the invention without further genuine inspiration or undue experimentation.”⁵³ Some examples of the applicable document have been held to include: “slides and drawings,⁵⁴ microfilm,⁵⁵ photographs, or [material published] in technical or popular journals.”⁵⁶ There is a “critical date” one-year grace period that allows an inventor up to one year to file for a patent after he has engaged in public or commercial activity involving the invention.⁵⁷

⁵⁰ See Beckerman-Rodau, *supra* note 16, at 4 (highlighting the fact that the novelty of an invention is void if the invention was present in prior art of similar inventions).

⁵¹ See 35 U.S.C. § 102 (2014) (emphasizing the presence of the invention in the public sector as a reason to deny a patent to an invention); see also Beckerman-Rodau, *supra* note 16, at 4 (describing the effect of public knowledge of use of an invention that is in the process of obtaining a patent).

⁵² See Beckerman-Rodau, *supra* note 16, at 4 (offering an example of public disclosure that would render an invention unpatentable).

⁵³ See *Regents of Univ. of Cal. v. Howmedica, Inc.*, 530 F. Supp. 846, 859 (D. N.J. 1981) (declaring what is sufficient publication under § 102 and which will result in a denial of a patent application) (citing *Seymour v. Osborne*, 78 U.S. 516, (1871)).

⁵⁴ *Howmedica*, 530 F. Supp. at 860 (stating that the use of slides in a presentation can constitute printed publication; however, in this case the court found the slides did not violate the publication stipulation found in § 102).

⁵⁵ See *In re Wyer*, 655 F.2d 221, 224 (1981) (declaring that micro film, specifically microfilm filed in another country's patent office and publicly accessible, is considered publication, thus voiding the patent application).

⁵⁶ See *Torin Corp. v. Philips Industries, Inc.*, 625 F. Supp. 1077, 1090 (1985) (stipulating that photographs, in particular ones that pertain to visual devices, are sufficient disclosure of the invention to invalidate patentability of the invention).

⁵⁷ See *Howmedica*, 530 F. Supp. at 858 (defining what the “critical period” is as it pertains to disclosure and the potential negating of novelty through disclosure).

d. Non-obviousness

A third condition of patentability for a grant of a United States patent is the requirement that the nature of the subject matter of the invention is non-obvious. The condition for an invention to be non-obvious is found in 35 U.S.C. § 103, which provides:⁵⁸

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102, if the differences between the claimed invention and the prior art are such that the claimed invention as a whole would have been obvious before the effective filing date of the claimed invention to a person having ordinary skill in the art to which the claimed invention pertains. Patentability shall not be negated by the manner in which the invention was made.⁵⁹

The statute considers non-obviousness subject matter as it pertains to a person skilled in the normal art of the invention; therefore, if the invention would have been obvious to someone of average skill in that specific field, then the invention does not fulfill the non-obviousness requirement.⁶⁰ When considering a challenge to a patent based on obviousness, the court starts with a presumption of validity, and the burden of proving the invention was obvious rests upon the party

⁵⁸ See Beckerman-Rodau, *supra* note 16, at 4 (asserting that non-obviousness is another requirement of a patentability); see also 35 U.S.C. § 103 (2014) (providing the specific language of the Patent Act requiring an invention to be non-obvious).

⁵⁹ See 35 U.S.C. § 103 (2014) (providing the statutory language requiring the subject matter of the invention to be non-obvious to those skilled in the art for which the invention is claimed).

⁶⁰ See *Howmedica*, 530 F. Supp. at 860 (highlighting how the court will examine non-obviousness as it pertains to a new proposed invention); see also *Graham v. John Deere Co.*, 383 U.S. 1, 14 (1966) (proposing different considerations that should be given to the invention and the prior art when determining non-obviousness). “Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or non-obviousness of the subject matter is determined.” *Id.* at 17.

challenging the patents.⁶¹

e. Specifications of the Invention

The last condition of patentability is that of enablement. This provision is stated in 35 U.S.C. § 112.⁶² The first specification under § 112 states that the application should contain a written description of the invention with sufficient detail to enable “any person skilled in the art to which it pertains...to make and use the [invention.]”⁶³ The next specification required for patentability is disclosure of the “best mode,” which is the best mode in which the inventor has found to make the invention.⁶⁴ Lastly, the provision states that the patent application should include claims of the patented invention that clarifies the subject matter that the inventor is relying on.⁶⁵

2. Design Patent

Design patents do not present any application to the patentability of cloned livestock,⁶⁶ therefore, the following is only a brief overview. A design patent is available to someone who develops an original or new “ornamental” design of a useful manufactured good.⁶⁷ Congress enacted 35 U.S.C. § 171, which formally estab-

⁶¹ See *Howmedica*, 530 F. Supp. at 860 (outlining the way in which a court examines a patent challenge based upon obviousness, which the patent is looked at with a presumption of validity).

⁶² See 35 U.S.C. § 112 (2012) (describing the degree of specification required in the patent application for a patent to be granted).

⁶³ See *id.* (outlining the enablement principle required of inventions seeking patent protection).

⁶⁴ See *id.* (explaining that the best mode required when applying for a patent on an invention or discovery is not necessarily the best mode possible of making the invention).

⁶⁵ See *id.* (discussing the need for claims in the patent application and the various types of claims that can be relied on). “The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.” *Id.*

⁶⁶ See DONALD S. CHISUM, 1-23 CHISUM ON PATENTS § 23.01 (Matthew Bender ed., 2014) (presenting the application of design patents without an inference to livestock).

⁶⁷ See *id.* (providing an introduction and brief overview of design patents).

lished design patents.⁶⁸ There is a drastic difference between the subject matter of design patents and utility patents.⁶⁹ The subject matter of utility patents, useful functional products or processes, is contrary to subject matter of design patents prohibiting any functional aspects.⁷⁰ Once granted design patents allow the patent holder to exclude other from making, using or selling a product with the patented design for a period of fourteen years.⁷¹ Unlike utility patents that present claims for the various functions of the invention, design patents present only one claim, which is the full disclosure of the design through a drawing.⁷² Design and utility patents do share similar requirements of non-obviousness and novelty.⁷³

3. Plant Patent

The United States Patent and Trademark Office may grant a plant patent to an inventor who has invented an asexually reproduced distinct new variety of plant.⁷⁴ The Plant Patent Act was adopted in

⁶⁸ See DONALD S. CHISUM, 1-23 CHISUM ON PATENTS § 23.03 (Matthew Bender ed., 2014) (providing the statutory grant for design patents). “A design, consisting of the configuration or surface ornamentation of an article of manufacture, is patentable if it meets the general requirements of novelty, originality and non-obviousness and is ornamental.” *Id.* See also 35 U.S.C. § 171 (2014) (permitting the issuance of patents based on the ornamental nature or design of an object).

⁶⁹ See CHISUM, *supra* note 68 (differentiating between the subject matter of utility patents, embodying a useful invention, and design patents, covering the ornamental appearance of a useful item).

⁷⁰ See CHISUM, *supra* note 68. (contrasting the subject matter under which a utility patent is granted and the subject matter under which a design patent is granted). “A design need not meet the requirement of utility and indeed will not be patentable if its form is dictated solely by considerations of function.” See Chisum, *supra* note 68.

⁷¹ See TYPES OF PATENTS, *supra* note 26 (outlining the statutory period that entitles the design patent holder to exclude others from making, using, or selling the design).

⁷² See CHISUM, *supra* note 66 (examining the claims required to obtain a design patent, which is only a drawing of the aesthetic look of the product.)

⁷³ See CHISUM, *supra* note 68 (discussing the requirements for non-obviousness and novelty, which are similar for utility patents).

⁷⁴ See UNITED STATES PATENT AND TRADEMARK OFFICE, *supra* note 25 (setting forth the initial definition of a plant patent and what inventions they are intended to cover).

1930.⁷⁵ A plant patent lasts 20 years from the date of filing the patent application.⁷⁶ An inventor who holds a plant patent is granted the right to exclude others from “asexually reproducing, selling, or using the plant so reproduced.”⁷⁷ Title 35 United States Code, Section 161 provides for the statutory grant of plant patents.⁷⁸ Section 161 states:

Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefore, subject to the conditions and requirements of title.⁷⁹

The general requirements of patentability for a plant patent are similar to that of both utility and design patents.⁸⁰ The development of a

⁷⁵ See W. Lesser, *Bowman v. Monsanto and Self-Replicating Seeds; David v. Goliath or Don Quixote v. Windmills?*, 13. J. HIGH TECH. L. 508, 511 (2013) (describing the development and implications of the Plant Patent Act).

⁷⁶ See UNITED STATES PATENT AND TRADEMARK OFFICE, *supra* note 25 (stating the length, in years, of time that a plant patent gives the inventor the right to exclude others from making, using and selling the patented plant).

⁷⁷ See UNITED STATES PATENT AND TRADEMARK OFFICE, *supra* note 25 (summarizing the exclusive rights granted to a plant patent holder). See also 35 U.S.C. § 163 (defining the grant of the exclusive rights afforded to the plant patent holder).

⁷⁸ See UNITED STATES PATENT AND TRADEMARK OFFICE, *supra* note 25 (providing the statute that grants the right to obtain a patent for an asexually developed plant).

⁷⁹ 35 U.S.C. § 161 (2014).

⁸⁰ See UNITED STATES PATENT AND TRADEMARK OFFICE, *supra* note 25 (providing the general requirements for an inventor to file a plant patent application and receive a plant patent). The plant must have been invented or discovered, and the discovery must have been made in a cultivated area. The plant must also not be excluded by statute, specifically “where the part of the plant used for asexual reproduction is not a tuber food part.” The person or persons who are filing the application actually have discovered or invented the claimed plant. The plant that is being patented must not have been sold or released in the United States of America. Another requirement of plant patentability is that the “plant must not have been enabled to the public.” “That the plant be shown to differ from known, related plants by at least one distinguishing characteristic which is more than a difference caused

new plant through asexual reproduction means that a plant is multiplied without the use of genetic seeds.⁸¹ There is another protection available for protecting invented plants called the Plant Varieties Protection Act of 1970.⁸² The Plant Variety Protection Act extends protection to the development of sexually reproduced plants and expanded coverage to most commercial agricultural crops.⁸³

III. History and Development of Patent Law

United States patent laws have evolved, since the first enactment in 1790, to correspond with current technological advancements. “To promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.”⁸⁴ Congress relied on the above quoted language when they enacted their first patent statute in 1790.⁸⁵ The statute entitled “An Act to promote the progress of useful Arts” stated that:

[H]e, she or they, hath or have invented or discovered an useful art, manufacture, engine, machine, or device or any improvement therein not before known or used, and praying that a patent may be granted therefore... [the] Secretary

by growing conditions or fertility levels, etc.” Similar to utility patents, the invention must not have been obvious to someone skilled in the art. *See id.*

⁸¹ *See* UNITED STATES PATENT AND TRADEMARK OFFICE, *supra* note 25 (describing what constitutes asexual reproduction to fulfill the statutory requirements of § 161). The following are examples of models of asexual reproduction: Rooting Cutting; Apomictic Seeds; Division; Layering; Runners; Tissue Culture; Grafting and Budding; Bulbs; Slips; Rhizomes; Corms; and Nucellar Embryos. *See id.*

⁸² *See* David G. Scalise & Daniel Nugent, *International Intellectual Property Protections for Living Matter: Biotechnology, Multinational Conventions and the Exceptions for Agriculture*, 27 CASE W. RES. J. INT’L L. 83, 93 (1995) (describing an alternative protection for newly developed plants that were developed through sexual means rather than asexual means).

⁸³ *See id.* at 88 (explaining the Plant Variety Protection Act, which was developed in 1970 and became “more valuable for commercial agricultural because the bulk of commercial crops are sexually reproduced...”).

⁸⁴ U.S. CONST. art. I, § 8, cl. 8.

⁸⁵ *See* DONALD S. CHISUM, 1-OV CHISUM ON PATENTS § 2 (Matthew Bender ed., 2013) (explaining the development of the foundational patent laws).

of State, the Secretary for the department of war, and the Attorney General, or any two of them if they shall deem the invention or discovery sufficiently useful and important, to cause letters patent to be made out in the name of the United States...granting to such petitioner or petitioners, his, her or their heirs, administrators or assigns for any term not exceeding fourteen years, the sole and exclusive right and liberty of making, constructing, using and vending to others to be used the said invention or discovery....⁸⁶

The 1790 statute states an inventor seeking a patent, must include in their letter “a description, accompanied with drafts or models, and explanations and models...” that sufficiently describe their invention or discovery.⁸⁷ Congress’ 1790 patent legislation was only in effect for three years before Congress replaced it with the 1793 act.⁸⁸ The 1793 act omitted the word “important” thus stating “any useful art, machine, manufacture, or composition of matter, or any new and useful improvement [thereon], not known or used before the application...” could obtain a patent.⁸⁹ There are principals and concepts that were included in the 1790 and 1793 and explained in subsequent patent cases that are still prominent parts of United States patent law.⁹⁰ One concept that is still relied on in modern day United States patent law would be the

⁸⁶ See 7 Stat. 110 (1790).

⁸⁷ See *id.* (detailing the language used by the First Congress of the United States when enacting patent legislation to protect ideas and inventions).

⁸⁸ See CHISUM, *supra* note 85 (describing the repeal of the 1790 patent act, and the replacement with the newly enacted 1793 act).

⁸⁹ See 11 Stat. 318 (1793) (highlighting the removal of the term “important” from the 1790 patent statute allowing any new or useful invention or discovery to be patented).

⁹⁰ See CHISUM, *supra* note 85 (identifying some fundamentals of United States patent law that were formed in the 1790s and are still relied upon today in modern patent law).

four categories of patentable subject matter explained in the 1793 patent act.⁹¹ The four categories from the 1793 Patent Act that are still relied on today are: art, machine, manufacture or composition of matter.⁹² Another concept that was included in the 1793 Patent Act is “the distinction between *lack of novelty*, meaning discovery by others before the inventor’s invention, and *loss of right*, meaning public use or sale by the inventor before applying for a patent.”⁹³

The next major changes in United States patent laws came in 1836 when Congress enacted sweeping revisions of the 1793 act.⁹⁴ One of the most significant changes to the patent laws was the creation of a Patent Office, which included a system of examiners who would read the patents and determine their patentability.⁹⁵ Another change to the patent law was the introduction of “a statutory requirement of clear claiming,” which required an inventor to “distinguish” his invention and provide full disclosure of the discovery.⁹⁶ The 1836 act also changed the public use and sale provision to add a two-year grace period.⁹⁷ The Supreme Court played a vital role in the mid-19th century of establishing funda-

⁹¹ See 11 Stat. 318 § 1 (detailing the four categories Congress provided to determine if an invention or discovery would be patentable); see also CHISUM, *supra* note 85 (explaining one of the fundamental concepts that was incorporated in the 1793 patent act is still relied upon in modern patent law).

⁹² See 11 Stat. 318 (explaining what subject matter of invention or discovery would qualify for patent protection under the 1793 Patent Act).

⁹³ CHISUM, *supra* note 85.

⁹⁴ See CHISUM, *supra* note 85, § 3 (proposing the changes to United States patent law that took place with the Congressional revision of the 1793 Patent Act).

⁹⁵ See CHISUM, *supra* note 85, § 3. (highlighting the creation of the United States Patent Office by the 1836 Congressional revision of patent law).

⁹⁶ See CHISUM, *supra* note 85, § 3 n.11 (explaining requirement for inventor to distinguish and disclose his invention).

⁹⁷ See CHISUM, *supra* note 85, § 3 (discussing the change to the public use and sale provision). The public use and sale provision would negate the patentability of an invention or discovery if the said invention had been in use by the public or for sale. See CHISUM, *supra* note 85 at § 3 (clarifying that an inventor’s discovery may not be in public use or for sale prior to filing its patent application).

tent law concepts.⁹⁸ The 1850 Supreme Court case *Hotchkiss v. Greenwood* illustrated one of these concepts, establishing the obviousness standard of the patentability of new inventions.⁹⁹ The standard described an invention as unpatentable if it would have been obvious to a person of ordinary skill in the specific art.¹⁰⁰ Congress replaced the 1836 Act thirty-four years later through the codification of the 1870 Act; however, the new act retained the provisions and requirements of the 1836 Act.¹⁰¹ Two changes were included by Congress: first congress added a clause that a description of an invention in a printed publication prior to patenting would result in loss of patentability; and second that violation of the public use or sale clause must take place in the United States.¹⁰²

The year 1952 brought about a new patent act when Congress passed an addition to the United States Code.¹⁰³ The 1952 act created standards that “stated in statutory form matters previously recognized only in court decisions and Patent Office practice.”¹⁰⁴ Many of the statutory additions and provisions found in 35 U.S.C. are still in effect today.¹⁰⁵

⁹⁸ See CHISUM, *supra* note 85, § 3 (highlighting the Supreme Court’s role in interpreting the patent statute and creating standards of assessing patent infringement cases).

⁹⁹ See CHISUM, *supra* note 85, § 3 (noting the impact of the Supreme Court’s interpretation of the patent act).

¹⁰⁰ See *Hotchkiss v. Greenwood*, 52 U.S. 248, 267 (1917) (describing the obviousness standard that the Court relied on).

¹⁰¹ See CHISUM, *supra* note 85, § 3 (describing Congress’ enactment of the 1870 Act and what changes were included).

¹⁰² See Patent Act of 1870, ch. 230, 16 Stat. 198-217 (1870) (detailing the language and the changes included by Congress in the 1870 Patent Act); see also CHISUM, *supra* note 85, § 3 (expanding on the changes Congress included in the enactment of the 1870 Patent Act).

¹⁰³ See 35 U.S.C. § 103 (1952) (stating the language and statutory provisions included in the 1952 Patent Act). 35 U.S.C. included two parts: Part I detailed the United States Patent and Trademark Office, and Part II regarded Patentability of Inventions and Grant of Patents. See also CHISUM, *supra* note 85, § 6 (describing the development of the United States Code Title 35).

¹⁰⁴ See CHISUM, *supra* note 85, § 6 (addressing what Congress accomplished by enacting the Patent Act of 1952).

¹⁰⁵ See CHISUM, *supra* note 85, § 6 (explaining several of the provisions that Congress included in the 1952 act).

IV. History and Development of the Science of Cloning

The term cloning can be used to “describe a number of different processes that can be used to produce genetically identical copies of a biological entity.”¹⁰⁶ If that is cloning, then what exactly is a clone? A clone is an animal that has “the [exact] same genetic makeup as the original” donor animal.¹⁰⁷ The science of cloning is a relatively young process compared to most sciences with its first real breakthrough occurring in the late 1800s.¹⁰⁸

A foundational concept for cloning occurred in 1894 by Hans Dreisch when he discovered that blastomeres,¹⁰⁹ a cell produced during cleavage of a fertilized egg, could develop into small sea urchin larvae.¹¹⁰ In 1901, Hans Spemann, a German embryologist, successfully “split a 2-cell salamander embryo into two parts, which developed into two complete organisms. This result showed that early embryo cells retain all genetic information necessary to develop into a new organism.”¹¹¹ Walter Sutton hypothesized in 1902 that “chromosomes hold the genetic information in the nucleus,” twelve years later Hans Spemann was able to perform the first successful nuclear transfer¹¹² experiment.¹¹³ Nuclear transfer is an essential process that

¹⁰⁶ *Cloning*, NAT’L HUMAN GENOME RESEARCH INST. (Oct. 25, 2013), archived at <http://perma.cc/LE29-R4CR>.

¹⁰⁷ *See id.* (defining a “clone”).

¹⁰⁸ *See* Royal, *supra* note 3, at 1 (recounting the cloning of a sea urchin in 1885 as the first instance of cloning).

¹⁰⁹ *Blastomere Definition*, MERRIAM-WEBSTER.COM, archived at <http://perma.cc/SC23-2R84> (last visited Sept. 23, 2014).

¹¹⁰ *See History of Cloning*, *supra* note 2 (noting how Dreisch, to challenge the theories of cloning posited by his peers, proved blastomeres from sea urchin embryos could develop into small larvae).

¹¹¹ *History of Cloning*, *supra* note 2.

¹¹² *See* Christen Brownlee, *Nuclear Transfer: Bringing in the Clones*, *Proceedings of the National Academy of Sciences of the United States of America*, PROCEEDINGS OF THE NATIONAL ACADEMY OF SCIENCES OF THE UNITED STATES OF AMERICA (Oct. 31, 2013), archived at <http://perma.cc/9HJD-3NQG> (defining the term nuclear transfer). Nuclear Transfer is “a two-part process: first, scientists remove the nucleus from an egg, and second, they replace it with the nucleus of an older donor cell.” This process is used to create clones. *See id.*

is still used by scientists to create clones today.¹¹⁴ In 1938 Hans Spemann published the results of his 1928 nuclear transfer experiments in a book entitled *Embryonic Development and Induction*.¹¹⁵ In 1962, John Gurdon was the first to claim that he had cloned South African frogs from the nucleus of differentiated adult intestinal cells.¹¹⁶ That following year in 1963 J.B.S. Haldane, a British biologist, was the first to use the word “clone” when describing Gurdon’s work.¹¹⁷ In 1964, F.E. Steward was the first person to use differentiated cells to grow a cloned carrot plant, from differentiated cells.¹¹⁸ The following developments in the field of biological sciences were essential techniques in the progression of modern day cloning. In 1969, James Shapiro and Jonathan Beckwith, Harvard Medical School researchers, developed the first of these essential techniques of isolating a single gene.¹¹⁹ The next technique, developed by Paul

¹¹³ See *History of Cloning*, *supra* note 2 (distinguishing the significant dates of nuclear transfer research).

¹¹⁴ See Brownlee, *supra* note 112 (highlighting the development of nuclear transfer in creating a cloned genetic copy of the donor animal).

¹¹⁵ See *History of Cloning*, *supra* note 2 (indicating Hans Spemann’s 1928 publication educating the public on his methodology). In his book, *Embryonic Development and Induction*, Spemann proposed “a fantastical experiment to transfer one cell’s nucleus into an egg without a nucleus, providing the basis for subsequent cloning experiments. See *id.*

¹¹⁶ See *History of Cloning*, *supra* note 2 (highlighting a monumental achievement in cloning by John Gurdon, a scientist at Oxford University).

¹¹⁷ See *History of Cloning*, *supra* note 2 (pointing to the first time that the word clone was used to describe an animal that was developed through artificial means).

¹¹⁸ See *History of Cloning*, *supra* note 2 (summarizing the first time in which a differentiated cell was able to be used to clone any multicellular organism). Differentiated cells are created through a process called cell differentiation. See Rabiah Choudhary, *Glossary*, UNIV. N. CAROLINA CHAPEL HILL (last visited Sept. 23, 2014) archived at <http://perma.cc/QHY6-S76U>. “Cell differentiation is a process in which a generic cell develops into a specific type of cell in response to triggers from the body or the cell itself. This is the process which allows a single celled zygote to develop into a multicellular adult organism that can contain hundreds of different types of cells.” *Id.*

¹¹⁹ See *History of Cloning*, *supra* note 2 (discussing the research done by Shapiro and Beckwith to isolate a single gene). The Harvard Crimson stated “[t]his new technique will allow geneticists to study the detailed operation of a single gene without chemical interference from neighboring genes. It may also encourage the development of genetic engineering—the artificial control of animal and plant characteristics by manipulating genes.” Mark W. Oberle, *Harvard Team Isolates The*

Berg in 1972, was a method of creating the first recombinant DNA molecules.¹²⁰ In 1983, Kary Mullis developed the polymerase chain reaction, an important foundational techniques used in cloning.¹²¹ The past 30 years have seen the greatest developments and achievements in the field of cloning.¹²² This revolution in cloning began in 1984 when Danish scientist Steen Willadsen successfully cloned a sheep from embryonic cells.¹²³ Willadsen's successful cloning was so monumental because it marked the first confirmed case of mammalian cloning.¹²⁴ Two years later, Willadsen was again in the spot-

Gene, THE HARVARD CRIMSON, November 24, 1969 *archived at* <http://perma.cc/2NAC-QSKJ>.

¹²⁰ See *History of Cloning*, *supra* note 2 (highlighting the research done by Paul Berg resulting in the creation of recombinant DNA). Taking a strand of one DNA molecule and combining it with another strand of DNA creates recombinant DNA. See Matthew Kuure-Kinsey and Beth McCooley, *The Basics of Recombinant DNA*, RENSSELAER POLYTECHNIC INSTITUTE (2000) *archived at* <http://perma.cc/SAG8-7HK9> (describing the basic science of DNA). "By combining two or more different strands of DNA, scientists are able to create a new strand of DNA." *Id.* Kuure-Kinsey and McCooley believed that recombinant DNA was going to have a large impact on the future. See *id.* Wilmut and Campbell used recombinant DNA when they cloned a sheep containing a human gene. See *History of Cloning*, *supra* note 2.

¹²¹ See *History of Cloning*, *supra* note 2 (acknowledging the importance of polymerase chain reaction in the development of cloning). "[Polymerase chain reaction] allows the rapid replication of designated fragments of DNA. The technique greatly facilitated every aspect of molecular biology." *Id.*

¹²² See *History of Cloning*, *supra* note 2 (acknowledging the developments in cloning since 1984 that have given current scientists the ability to clone live animals).

¹²³ See *History of Cloning*, *supra* note 2 (acknowledging the first cloning of a mammal).

¹²⁴ See *1984: Willadsen Clones a Mammal*, ORACLE THINKQUEST *archived at* <http://perma.cc/JAZ4-TQ2X> (describing the implications of Willadsen's scientific discoveries). "Willadsen fused a cell from an eight-cell lamb embryo with an unfertilized egg whose nucleus had been removed. Traditionally, scientists had used fertilized eggs in the nuclear transfer process. Willadsen found that unfertilized eggs more easily received the transplanted nucleus. The egg was then tricked into thinking it had been fertilized." Then the fertilized embryos were coated in agar and placed into the oviducts of sheep where they grew for a short period of time. After about a week of growing in the oviducts, Willadsen extracted the embryos of placed each into a uterus of a surrogate mother. From the experiment, two lambs died at birth, and another survived to be the first cloned mammal by the nuclear transfer method. Willadsen's feat had only months ago been referred to as biologically possible." See *id.*

light when he successfully cloned a cow from differentiated cells.¹²⁵ That same year Neal First, Randal Prather, and Willard Eyestone of the University of Wisconsin were able to successfully clone a cow from an embryonic cell further substantiating the authenticity of Willadsen's technique.¹²⁶ In 1995, Ian Wilmut and Keith Campbell of the Roslin Institute in Scotland, successfully cloned two sheep, Megan and Morag, from differentiated embryos.¹²⁷ The world-renowned sheep, Dolly, was born on July 5, 1996, due to the work of Wilmut and Campbell.¹²⁸ Dolly was cloned using cells from an adult sheep.¹²⁹ The cloning of Dolly is one of the most important milestones in the history of animal cloning, as it proves that cloning using cells from an adult animal was possible.¹³⁰ The health and reproductive functionality of Dolly was confirmed when she gave birth to 3 healthy lambs.¹³¹ Evidence that the cloning technique has been perfected and is available for public use can be seen through development of cloning laboratories offering their services to the public.¹³²

V.Facts

¹²⁵ See *History of Cloning*, *supra* note 2 (expanding upon Willadsen's achievements in the field of cloning).

¹²⁶ See *History of Cloning*, *supra* note 2 (offering another example of successful livestock cloning using the same technique explored by Willadsen).

¹²⁷ See *History of Cloning*, *supra* note 2 (introducing Wilmut and Campbell, into the historical timeline of cloning).

¹²⁸ See Shantile Vos, *Dolly and the Clone Wars* (April 2004) archived at <http://perma.cc/94UL-BWCR> (describing the history of Dolly the sheep and all of the research done by Wilmut and Campbell); see also *History of Cloning*, *supra* note 2 (discussing the cloning of Dolly the sheep, and where it fits in the time line of cloning).

¹²⁹ See Vos, *supra* note 128 (describing the methods used to successfully clone Dolly the sheep).

¹³⁰ See Vos, *supra* note 128 (highlighting the importance of the successful birth and cloning of Dolly); see also, *History of Cloning*, *supra* note 2 (illustrating the importance of the birth of Dolly the sheep).

¹³¹ See *History of Cloning*, *supra* note 2 (acknowledging that Dolly the sheep had three baby lambs; therefore, indicating that she was a healthy normal adult sheep).

¹³² See *Viagen's History*, VIAGEN, archived at <http://perma.cc/32QC-JHKA> (providing the history and development of the company evidencing the capacity of cloning as a modern business).

The science of cloning has presented the world with numerous possible benefits; one major benefit would be to clone livestock for agricultural use and food consumption.¹³³ Farming is a vital industry, of which “prosperous animal agriculture [was] historically [a] mark of a strong, well developed nation.”¹³⁴ A farmer typically raises livestock to obtain meat, milk or other useful products such as, wool, from the animals.¹³⁵ Traditionally animals classified as livestock are beef and dairy cattle, pigs, sheep, goats, and horses.¹³⁶ Livestock farms occupy about thirty percent of the planet’s “ice-free terrestrial surface area” with a staggering global value of 1.4 trillion.¹³⁷ Developed and developing nations rely heavily on livestock farming with 600 million people relying on farming in developing nations.¹³⁸ Rapid growth in the world population has translated to increased demand for livestock products as well as an increase in the number of livestock farmers.¹³⁹ In order to fulfill this increased demand farmers try to isolate and breed for desired characteristics such as lean meat, high milk yield or increased fertility.¹⁴⁰ Farmers aim to incorporate high quality traits into their herds through breeding animals with desired traits, hoping they pass on the desired traits to their

¹³³ See Heather Smith Thomas, *Should Cloned Animals Be Used As A Food Source?*, CATTLE TODAY archived at <http://perma.cc/D3SF-XDUH> (discussing the use of cloning for food necessity).

¹³⁴ Wesley Patterson Garrigus & Palmer J. Holden, *Livestock Farming*, ENCYCLOPÆDIA BRITANNICA (Nov. 7, 2013), archived at <http://perma.cc/D8R2-Q2UG>.

¹³⁵ See *id.* (observing the practice of livestock farming).

¹³⁶ See *id.* (expanding upon the practice of livestock farming, and describing the various animals that constitute livestock).

¹³⁷ See Philip K. Thornton, *Livestock Production: Recent Trends, Future Prospects*, 365 PHIL. TRANS. R. SOC. B. 2853, 2853 (2010) archived at <http://perma.cc/YU5U-JQG9> (highlighting the vast impact that livestock has both on global land use and the global economy).

¹³⁸ See *id.* (expounding upon the impact livestock farming has in developing nations).

¹³⁹ See *id.* (analyzing the connection between the steady growth in world population with the increased demand in livestock products).

¹⁴⁰ See Thornton, *supra* note 137, at 2858 (describing the reasoning for farmers to isolate desired characteristics).

offspring.¹⁴¹ Selective breeding is a slow way of incorporating a desired genetic trait into the farmer's overall herd.¹⁴²

Cloning livestock can prove to be a vital tool for farmers and breeders to "dramatically change livestock production."¹⁴³ Clones are born just like other animals, however, they have the identical genetic makeup of the original donor.¹⁴⁴ This allows a farmer to identify certain animals that have desired traits, or that generate more income than others and use that animal's genetic makeup to bolster their herds.¹⁴⁵ "Cloning gives the farmer complete control over the offspring's inherited traits."¹⁴⁶ The clones are then incorporated into a farmer's traditional breeding program.¹⁴⁷ Incorporating clones into a traditional breeding program allows farmers to know in advance that the offspring will contain the desired genetic traits.¹⁴⁸ There are

¹⁴¹ See Thornton, *supra* note 137, at 2858 (describing the use of traditionally breeding livestock to respond to increased demand).

¹⁴² See Thornton, *supra* note 137, at 2858 (recognizing the slow nature of selective breeding used by farmers in attempt of incorporating a beneficial trait into their herd). "Genetic changes typically [occur in pigs and chickens in the range of] 1-3% per year...genetic change achieved in national beef cattle and sheep populations are often substantially lower..." *Id.*

¹⁴³ Thornton, *supra* note 137, at 2858; see also U.S. FOOD AND DRUG ADMIN., *A Primer on Cloning and Its Use in Livestock Operations* (Oct. 29, 2009), archived at <http://perma.cc/0QZjNMaNTrT> (exposing the benefits that a farmer or breeder would receive from cloning their livestock). Transgenic livestock is engineered to carry genes from other species. See Thornton, *supra* note 137 at 2858 (advocating for the use of transgenic livestock to benefit food production). Some benefits of transgenic live stock are sheep that grow larger producing more wool and cows that produce insulin in their milk. See *id.*; see also Endang Tri Margawati, *Transgenic Animals: Their Benefits To Human Welfare*, ACTION BIOSCIENCE (Jan 2003), archived at <http://perma.cc/0rJ7ZCznj5n> (highlighting potential benefits from inserting genes into livestock).

¹⁴⁴ See U.S. FOOD AND DRUG ADMIN., *supra* note 143 (highlighting the benefit of a clone having the same genetic makeup as the original animal). "They are similar to identical twins, only born at different times. Just as twins share the same DNA, clones have the same genes as the donor animal." *Id.*

¹⁴⁵ See U.S. FOOD AND DRUG ADMIN., *supra* note 143 (describing the great benefits farmers can receive by selectively picking the genes of their herd).

¹⁴⁶ U.S. FOOD AND DRUG ADMIN., *supra* note 143.

¹⁴⁷ See U.S. FOOD AND DRUG ADMIN., *supra* note 143 (noting that the clones will eventually end up in a traditional breeding program).

¹⁴⁸ See U.S. FOOD AND DRUG ADMIN., *supra* note 143 (discussing the benefit a farmer receives from using clones with desired traits in their traditional breeding program). See also *Satisfied Purebred Seed Stock Producers*, Viagen, archived at

various benefits of selecting genetic traits to introduce into a herd such as: disease resistance; suitability to climate; quality body type; fertility; and market preference.¹⁴⁹

The current United States Patent Regime has been weary to grant patents to multicellular living organisms.¹⁵⁰ The Court in *Chakrabarty* was the first to grant a patent on a single celled living organism.¹⁵¹ In 1984 the Court expanded the holding of *Chakrabarty* to multicellular organisms when it granted a patent to Harvard University on their genetically engineered “oncomouse.”¹⁵² The Patent and Trademark Office acknowledged, “[that] it now considered ‘nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope’ of 35 U.S.C. § 101.”¹⁵³ This article will propose the issuance of patents on cloned livestock, to allow farmers the exclusive right to their cloned livestock.

VI. Analysis

“A patent claiming a living organism, like all patents, must claim statutory subject matter and meet the statutory requirements for patentability including novelty, non-obviousness, and utility.”¹⁵⁴

<http://www.perma.cc/Q42U-EDR6> (providing an account by satisfied Longhorn breeders). “We’re breeders first and foremost...[b]ut if we clone a top cow, we can mate the clones to several different bulls each breeding season to find out which bulls work best. Within a few short years we can find out what used to take a cow’s entire lifetime to figure out: what bulls work best with her! From that point on we can work smarter instead of harder.” *Id.*

¹⁴⁹ See U.S. FOOD AND DRUG ADMIN., *supra* note 143 (listing the traits that farmers will select).

¹⁵⁰ See Linda J. Demaine & Aaron Xavier Fellmeth, *Reinventing the Double Helix: A Novel and Nonobvious Reconceptualization of the Biotechnology Patent*, 55 STAN. L. REV. 303, 318 (2002) (acknowledging that the first patent granted to a multicellular organism was not until the beginning of 1980).

¹⁵¹ See *id.* (discussing the Supreme Court’s grant of a patent on a living single cell organism).

¹⁵² See *id.* (acknowledging the U.S. Patent and Trademark Office’s controversial grant of a patent to a multicellular animal).

¹⁵³ *Id.* at 319.

¹⁵⁴ Hagglund, *supra* note 44, at 404.

A. Patent Requirements

1. Utility

The PTO states, "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 on the invention or discovery."¹⁵⁵ The invention must have a practical use, or a specific real world utility to fulfill the usefulness requirement.¹⁵⁶ There is a relatively low threshold to surpass in order to meet the usefulness requirement.¹⁵⁷ "An invention is 'useful' under section 101 if it is capable of providing some identifiable benefit."¹⁵⁸

A cloned livestock animal satisfies the utility requirement for patentability¹⁵⁹. Cloned livestock animals would be useful in developing a breeding program or furthering a specific genetic trait.¹⁶⁰ For example, farmers can use clones with desirable traits such as resistance to disease or high milk production in conventional breeding programs to upgrade the quality of their herds.¹⁶¹ In 2001 the FDA acknowledged the use of cloned animals as a "commercial venture to improve quality of herds."¹⁶² This acknowledgement by the FDA prompted a 5-year study by the Center for Veterinary Medicine, which resulted in finding that "clones...and the offspring of clones

¹⁵⁵ 35 U.S.C § 101.

¹⁵⁶ See *In re Miguel F. Brana*, 51 F.3d 1560, 1564 (Fed. Cir. 1995) (highlighting the implications of the usefulness requirement found in § 101); see Utility Examination Guidelines, 66 Fed. Reg. 1092, 1094 (stating that "[t]he utility requirement, as explained by the courts, only requires that the inventor disclose a practical or real world benefit available from the invention, i.e., a specific, substantial and credible utility.").

¹⁵⁷ See *Juicy Whip, Inc. v. Orange Bang*, 185 F.3d 1364, 1366 (Fed. Cir. 1999) (stating that the threshold for meeting the usefulness requirement is relatively low compared to the other patent requirements).

¹⁵⁸ *Id.* at 1366.

¹⁵⁹ See *Beckerman-Rodau*, *supra* note 16, at 4 (defining the utility requirement for patentability).

¹⁶⁰ See *Animal Cloning and Food Safety*, FDA, CONSUMER HEALTH INFORMATION, archived at <http://perma.cc/A54E-RZWW> (highlighting the potential uses of cloned animals as it relates to benefits to society).

¹⁶¹ See *id.* (noting the use of clones in upgrading a famers herd).

¹⁶² See *id.* (stating one of the potential uses identified by the FDA for cloned livestock animals).

from any species traditionally consumed as food are as safe to eat as a food from conventionally bred animals.”¹⁶³ Therefore, cloned animals, as a food source is another way of fulfilling the utility requirement of patentability.¹⁶⁴

2. Novelty

The novelty requirement of a patent application is tougher hurdle to surpass, however it seems that cloned livestock do meet this mark.¹⁶⁵ Section 102 requires that an invention be novel.¹⁶⁶ The provision states that an invention is not patentable 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.”¹⁶⁷ Prior art must enable a person of the ordinary skill in the art to make or possess the invention.¹⁶⁸ However, printed publications or description of livestock would not enable others to use or create that animal.¹⁶⁹ The presence of the original animal that is being cloned or a description of it does not enable replication.¹⁷⁰ It is also arguable that the existence of one animal does not make the animal readily available to the public.¹⁷¹ Unless the genome of the livestock being cloned was publicized it seems that an animal could be viewed like an invention that was never disclosed, thus not violating the novelty agreement.¹⁷² It is

¹⁶³ *Id.*

¹⁶⁴ *See id.* (describing the possible beneficial use of cloned animals as a food source).

¹⁶⁵ *See* Beckerman-Rodau, *supra* note 16, at 4 (describing the novelty requirement for patent applications).

¹⁶⁶ *See* 35 U.S.C. § 102 (providing the novelty requirement of the patent act).

¹⁶⁷ *Id.*

¹⁶⁸ *See* Hagglund, *supra* note 44, at 411 (describing the novelty requirement and the implications it has if the requirement is not fulfilled).

¹⁶⁹ *See* Hagglund, *supra* note 44, at 411 (stating that “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”).

¹⁷⁰ *See* Hagglund, *supra* note 44, at 412 (noting that a description of an animal does not violate the novelty requirement of § 102).

¹⁷¹ *See* Hagglund, *supra* note 44, at 412 (discussing the novelty of an animal, even though it is present in the public).

¹⁷² *See* Hagglund, *supra* note 44, at 412 (arguing for the novelty of an animal, due to the lack of prior art allowing for duplication).

important to note that even if the presence of the animal could violate the public disclosure provision of § 102, there is a one-year grace period to file for a patent, which could be used to allow for patenting livestock.¹⁷³

3. Non-obviousness

Non-obviousness is another patent requirement contained in 35 U.S.C. § 103. Section 103 states that, “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 same time the invention was made to a person having ordinary skill in the art to which the subject matter pertains.”¹⁷⁴ Farmers seeking a patent on their cloned livestock are doing so because of a desired trait that the livestock possess, which they received from the original animal.¹⁷⁵ The desired trait is not apparent to the naked eye; it takes years of breeding to determine what traits are passed on from one animal to another.¹⁷⁶ Applying this analysis to the isolating of genes or trait carrying animals for cloning, leads to the conclusion that cloned livestock are not obvious because a farmer skilled in the art would not be readily able to determine what cows carry what desired traits.¹⁷⁷

B. Product of Nature Doctrine

The Product of Nature Doctrine prohibits the patenting of anything that occurs in nature; however, this does not prohibit the pa-

¹⁷³ See *Howmedica*, 530 F. Supp. at 859 (describing the grace period afforded inventors to file for a patent after public disclosure).

¹⁷⁴ See Hagglund, *supra* note 44 at 421 (discussing the statutory requirement, of non-obviousness, found in section 103).

¹⁷⁵ See U.S. FOOD AND DRUG ADMIN., *supra* note 143 (describing the desire to pass on positive traits as the reasoning behind farmers cloning their livestock).

¹⁷⁶ See Thornton, *supra* note 137 (discussing the slow process of standard breeding to incorporate a specific desired trait into a farmer’s herd).

¹⁷⁷ See Hagglund, *supra* note 44, at 422-23 (noting non-obviousness requires that 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).

tenting of cloned livestock¹⁷⁸. The Supreme Court applies the product of nature doctrine in a “conclusory manner” without elaboration.¹⁷⁹ The differentiation can be found in the fact that those seeking protection of clones are not seeking to patent the original animal, which did occur in nature, but are seeking to patent all the subsequent cloned animals.¹⁸⁰ Therefore, the clones are not naturally occurring, rather they are man-made, similar to the microorganisms in question in *Chakrabarty*.¹⁸¹ The court in *Chakrabarty* made an important distinction when considering the product of nature doctrine, by differentiating between the creations of the organism in question.¹⁸²

C. Chakrabarty & Other Patent Grants to Multicellular Organisms

Chakrabarty was a landmark decision that greatly expanded the patentable subject matter of living organisms.¹⁸³ The Court in *Chakrabarty* held that a living microorganism that does not occur in nature is sufficient patentable subject matter.¹⁸⁴ The *Chakrabarty* court contemplated Congress’s intent when drafting the patent laws.

¹⁷⁸ See Hagglund, *supra* note 44, at 388 (explaining under the product of nature doctrine, that a patent cannot be awarded for a discovery or of nature).

¹⁷⁹ See Hagglund, *supra* note 44, at 388 (describing the manner in which the Supreme Court applies the product of nature doctrine).

¹⁸⁰ See Hagglund, *supra* note 44, at 388 (stating that an article derived from nature is patentable if it experiences a degree of refinement or improvement resulting in characteristics different from those given by nature).

¹⁸¹ See Hagglund, *supra* note 44, at 388-89 (noting that the product of nature doctrine is seeking to prohibit the grant of exclusive rights over a naturally occurring thing to a single person). “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;’” however, clones are not produced by the hands of nature rather they are made by the ingenuity of men. *See id.*

¹⁸² See *Chakrabarty*, 447 U.S. at 309 (discussing the way in which the Supreme Court applied the product of nature doctrine).

¹⁸³ See Hagglund, *supra* note 44, at 387 (describing the implications of the holding of *Chakrabarty*).

¹⁸⁴ See Hagglund, *supra* note 44, at 387 (highlighting the holding of the Court in *Chakrabarty*).

¹⁸⁵ The court reasoned that, “Congress intended statutory subject matter to include anything under the sun that is made by man.”¹⁸⁶

In *Ex parte Allen*, the Board of Patent Appeals was forced to face the issue of whether animals were patentable subject matter.¹⁸⁷ When considering the patentability of polyploidy oysters the Board concluded that “a nonnaturally occurring animal made by man was patentable subject matter.”¹⁸⁸ The board held that because the oysters did not occur without the assistance of man, then they were not naturally occurring.¹⁸⁹ Applying this rationale to the patentability of cloned livestock, it is clear that the clones are not naturally occurring.¹⁹⁰ Cloned livestock do not occur in nature, and only result from the work of scientists and geneticists; therefore they are not naturally occurring.¹⁹¹

VII. Conclusion

Patents should be granted to cloned livestock that possess unique traits that are beneficial to farmers and the public. Cloned livestock animals represent patentable subject matter because they would not occur in nature if it were not for their creation by man. Furthermore, cloned livestock animals also constitute the requisite level of utility, novelty and non-obviousness and required by the USPTO. In addition to meeting the patentability requirements, a grant of a patent for livestock seems to further the intent of the Supreme Court based upon their broad holding in *Chakrabarty*.

¹⁸⁵ See Hagglund, *supra* note 44, at 389 (stating the reasoning behind the Court’s holding in *Chakrabarty*).

¹⁸⁶ *Chakrabarty*, 447 U.S. at 309.

¹⁸⁷ See *Ex parte Allen*, 2 USPQ2d 1425, 1427 (Bd. Pat. App. & Inter. 1987), *aff’d sub nom. In re Allen*, 846 F.2d 77 (Fed. Cir. 1988) (concluding that the Patent Office established prima facie obviousness for polyploidy oysters, which because they are sterile have increased body weight which is not used up in reproduction).

¹⁸⁸ See Hagglund, *supra* note 44, at 402 (describing the rationale of the board of patent appeals in *Ex parte Allen*).

¹⁸⁹ See Hagglund, *supra* note 44, at 402 (highlighting the rationale of the board of patent appeals).

¹⁹⁰ See Hagglund, *supra* note 44, at 402 (inferring from the rationale of the board of patent appeals in *Ex parte Allen* that clones are not naturally occurring).

¹⁹¹ See Hagglund, *supra* note 44, at 402 (explaining that non-naturally occurring animals are man-made).