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Technology and Nonhumans

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Technology and Nonhumans

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Animal Law

Cases and Materials

FOURTH EDITION

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the Animal Welfare Act and the 1970 act that first included animal exhibitions within the AWA confirms that Congress acted with the public's interest in mind." *Animal Legal Defense Fund, Inc. v. Glickman*, 332 U.S. App. D.C. 104, 154 F.3d 426, 444 (D.C. Cir. 1998). The Act was designed to benefit the public at large rather than specific individuals.

Second, the matter must be fundamental, substantial, and well-established at the time of the wrongful discharge. The Act and its accompanying regulations are fundamental. The statement of policy accompanying the Act states that it is "essential" to regulate how animals are treated in interstate commerce. 7 U.S.C. §2131. The statute is substantial in that it sets out a broad-based statutory and regulatory framework for the treatment of animals used in research facilities, for exhibition purposes, and for pets. It is the "core federal statute regulating animal use and abuse." *United States v. Thompson*, 118 F. Supp. 2d 723, 724 (W.D. Tex. 1998). The public policy embodied in the statute of treating animals humanely is well-established; the statute was originally passed in 1966. Its requirements were made applicable to exhibitors, such as circuses showcasing animals, in 1970. Pub. L. 91-579 (1970), as codified in 7 U.S.C. §2131. Defendant has been on notice since that time of the policy purpose of the Act.

In sum, plaintiff has presented a prima facie case of wrongful discharge under California law. As alleged, he was fired after complaining to management about violations of a federal statute. A colorable state law claim has been made, and the court DENIES defendant's motion to dismiss the wrongful discharge claim....

Notes

1. The *Hagan* court also considered plaintiff's claim for intentional infliction of emotional distress. Under California's Labor Code, if the employee's physical or emotional injury, or both, occurred during the "normal course of the employment relationship," the state's workers' compensation system generally provides the sole remedy and the plaintiff would not be entitled to damages for emotional distress. *Hagan*, 365 F. Supp. 2d at 710. The court noted that "[t]he defendant's conduct itself may have been abnormal and inhumane, making the circumstances surrounding Clyde's death distasteful or outrageous," but the "acts constituting defendant's misconduct all occurred during the normal course of the employment relationship." *Id.* at 711. On that basis, the court dismissed plaintiff's emotional distress claim.

2. It appears that Frank Hagan asserted only claims of wrongful discharge and infliction of emotional distress against Feld/Ringling Bros. Looking back to the *ALDF v. Glickman* opinion on standing excerpted in Chapter 5, section 1, do you think he had standing to sue for violation of the AWA?

C. Technology and Nonhumans

This Section provides a summary of the legal history and current status of transgenic animals, animal patents and animal cloning, and examines many of the ethical and legal questions that these and related technologies raise.

1. Transgenic Animals

Transgenic animals are those animals whose genetic structure has been altered by adding at least one additional gene from another breed or species of animal, including hu-

mans. All living beings have a basic genetic makeup that represents the building blocks for that being. Each species has the same genetic makeup, although each individual's combination of the genes involved is unique. Transgenic animals have been created by scientists interested in combining the qualities of different species into a completely new animal with genetic components of two or more species. A transgenic animal's genetic structure is altered, potentially changing his or her attributes.

Cloning, on the other hand, is the process by which genetically identical biotic materials are produced. A cloned animal is not a "new" creation, but rather a genetic "carbon copy" of one that already exists. Further, there are two types of cloning: reproductive cloning, which creates a new animal and allows him or her to live and grow, and therapeutic cloning, which results only in the reproduction of cells, not actual animals. Stem cell research relies on therapeutic cloning and is seen as an alternative to the use of animals in biomedical research; reproductive cloning has been more controversial with respect to both animals and humans. Robin McKie, *Rival Ways to Send in the Clones...*, Observer, Mar. 20, 2005, at 6 (News Pages). For more information on the intersection between stem cell research and animal testing, *see* Maneesha Deckha & Yunwei Xie, *The Stem Cell Debate: Why Should it Matter to Animal Advocates?*, 1 Stan. J. Animal L. & Pol'y 69 (2008).

Transgenic animals have received substantial attention both from the scientific and legal communities, which have analyzed and in some instances criticized the failure of governmental agencies to establish meaningful rules and regulations relating to the development and marketing of genetically engineered plants and animals. *See, e.g.*, Gregory N. Mandel, *Gaps, Inexperience, Inconsistencies, and Overlaps: Crisis in the Regulation of Genetically Modified Plants and Animals*, 45 Wm. & Mary L. Rev. 2167 (2005) (criticizing regulatory structure involving multiple statutes and agencies leading to problems of enforcement and interpretation that results in inappropriately shoehorning biotechnology regulation into existing statutes that were never intended to regulate transgenic plants and animals). If the controversial practice of genetic transfer is to continue, more focused agency approach to the unique and new problems raised by this area will need to be implemented. *See also* Rebecca M. Bratspies, *Glowing in the Dark: How America's First Transgenic Animal Escaped Regulation*, 6 Minn. J. L. Sci. & Tech. 457 (2005); Rekha K. Rao, *Mutating Nemo: Assessing the Environmental Risks and Proposing the Regulation of the Transgenic Glofish*, 57 Admin. L. Rev. 903 (2005); Sheryl Lawrence, *What Would You Do with a Glowing Green Pig?: How Novel Transgenic Products Reveal Flaws in the Foundational Assumptions for the Regulation of Biotechnology*, 34 Ecology L. Q. 201 (2007).

In response to increasing concern and criticism over transgenic work, on January 15, 2009 the federal Food and Drug Administration ("FDA") released what it termed final "Guidance" for industry on genetically engineered animals. FDA Center for Veterinary Medicine, *Guidance for Industry: The Regulation of Genetically Engineered Animals Containing Heritable Recombinant DNA Constructs* (2009), available at *http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM113903.pdf*. The Guidance sets forth the regulatory framework that allows animals to be genetically altered to produce drugs, model human disease, produce industrial or consumer products or to be improved as food. The Guidance requires the FDA to subject genetically engineered animals to considerable testing before being placed on the market. However, it does not regulate animals intended to be companion animals and it is unclear whether it applies to other categories of animals not meant for the market. The Guidance also contains guidelines for manufacturers regarding their responsibilities and requirements under the National Environmental Policy Act ("NEPA") (regarding the po-

tential need for environmental assessments and environmental impact statements) and other statutes. Although some consumers have expressed concern about eating genetically altered animals, the Guidance does not require any special labeling for meat coming from transgenic animals.

Before the Guidance was published, several high profile transgenic animals and products were developed for use in biotechnology, including a transgenic glow-in-the-dark cat known as "Mr. Green Genes." John Pope, *Glowing Cat May Shed Light on Disease-Fighting Strategy*, Times-Picayune (New Orleans), Oct. 20, 2008, Transgenic chickens were also produced. *"Lab Chickens" Challenge Lab Mice*, Seed Magazine, June 12, 2006. The transgenic Glofish was also made available for purchase as a pet in 2003.[m] The FDA's refusal to regulate Glofish because they were neither food nor drug sparked a lawsuit. *See Int'l Center for Tech. Assessment v. Thompson*, 421 F. Supp. 2d 1 (D.D.C. 2005), which was dismissed because the court determined that the FDA's action did not trigger NEPA reporting requirements. For further information on the Glofish, *see* U.S. Patent No. 7,135,613 (filed Nov. 14, 2006).

In 2009, scientists were planning on breeding Mr. Green Genes with another transgenic cat to determine whether the glow-in-the-dark gene is inheritable. At the same time, ATryn, an antithrombin drug isolated from a transgenic goat, was approved by the FDA. Approval came less than a month after the FDA final Guidance was published principally because it was fast-tracked under the FDA's orphan drug system, which supports development of drugs to treat rare diseases that affect small populations. The speed with which this drug was approved, however, was not without its critics. "'FDA did a poor environmental impact statement, had virtually no transparency in its process, and had questionable statistics for the approval of ATryn,' says Jaydee Hanson, policy director at the nonprofit International Center for Technology Assessment." *See* Britt Erickson, *FDA Approves Drug From Transgenic Goat Milk*, Chemical & Engineering News, Feb. 16, 2009, at 9.

2. Animal Patenting

The U.S. Constitution grants Congress the power to enact patent laws "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." U.S Const. art. I, §8, cl. 8. The U.S. Patent Act, 35 U.S.C. §§1–376 (2006), establishes basic conditions that an invention must meet to qualify for patent protection: it must be useful, novel, and nonobvious. The invention must also be "a process, machine, manufacture or composition of matter, or any new and useful improvement thereof." 35 U.S.C. §101. "Products of nature" are not patentable. *See, e.g., Gen. Elec. Co. v. De Forest Radio Co.*, 28 F.2d 641 (3d Cir. 1928). "A patent confers the right to exclude others from making, using, or selling the claimed invention in the United States for a term of seventeen years from the issue date. A patent owner may file a civil suit for infringement against anyone who, without authority, makes, uses or sells the patented invention." 1 Donald S. Chisum, *Chisum on Patents* §1, OV-2 (2004).

Prior to 1980, it was generally assumed that naturally occurring living things were not patentable. *See, e.g., Guaranty Trust Co. of N.Y. v. Union Solvents Corp.*, 54 F.2d 400 (D.

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m. Glowing creatures made international news in late 2008 when the Nobel Prize in Chemistry was awarded to three scientists who had discovered the "glow gene" through their work with jellyfish. They used the gene's "enhanced green fluorescence protein" to develop a way to observe processes within an organism that were otherwise invisible. *See Glowing Jellyfish Earns Noble Prize*, CNN, Oct. 8, 2008, *http://www.cnn.com/2008/TECH/science/10/08/nobel.chemistry/index.html.*

Del. 1931), *aff'd*, 61 F.2d 1041 (3d Cir. 1932); *In re Mancy*, 499 F.2d 1289 (C.C.P.A. 1974) (U.S. Court of Customs and Patent Appeals). This was the case despite the fact that both the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act extended patent protection to some asexually and sexually reproducing plants. In 1972, microbiologist Ananda Chakrabarty filed for a patent for a human-made, genetically engineered bacterium which was designed to consume and digest oil slicks, a property that no naturally occurring bacterium possessed. The patent examiner who considered his claim rejected it, stating that (1) microorganisms were products of nature, and thus not patentable, and (2) because the bacterium was a living thing, it was not patentable subject matter. The Patent Office Board of Appeals affirmed the examiner on the second ground.

Chakrabarty appealed, and the case reached the U.S. Supreme Court, which examined the question of whether the genetically altered bacterium constituted a "manufacture" or "composition of matter" within the meaning of the Patent Act. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). The Court relied on legislative history indicating that Congress intended section 101 to be construed broadly, including as patentable "'anything under the sun that is made by man.'" *Id.* at 309, *quoting* 1952 Committee Reports. By a 5–4 vote, the Court held that Chakrabarty's bacterium was patentable because it was "markedly different ... from any found in nature" and was a product of his, not nature's, handiwork. *Id.* at 310. "[T]he relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions." *Id.* at 313. The commercial potential for patenting new life forms is significant, and *Chakrabarty* ensured that value to inventors.

The Board of Patent Appeals was faced with the question of whether multicellular animals could be patented under the *Chakrabarty* rule in *Ex parte Allen*, 2 U.S.P.Q.2d 1425 (Bd. Pat. App. & Interf. 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988). A patent application was filed for "polyploid oysters" which were created by a mechanical process and were designed to foster year-round edibility. The examiner denied the application, finding that (1) the oysters were "obvious," and thus unpatentable, and (2) because the oysters were "living entities," they were not within the subject matter of section 101.

The Board of Patent Appeals upheld the denial, agreeing with the examiner that because polyploidy had been induced in other species of oysters previously, the present invention "would have been obvious to one of ordinary skill in the art [of inducing] polyploidy." *Id.* at 1427. However, the Board specifically held that *Chakrabarty* made it clear that section 101 includes man-made life forms. Thus, the examiner's finding that the oysters were "living entities" was not controlling because the key issue was instead "whether that subject matter is made by man. If the claimed subject matter occurs naturally, it is not patentable...." *Id.* at 1426–27. Therefore, the Board stated that the "claimed polyploid oysters are non-naturally occurring manufactures or compositions of matter within the confines of patentable subject matter under 35 U.S.C. 101." *Id.* at 1427.

Shortly after *Allen*, the U.S. Patent and Trademark Office ("PTO") issued a Notice ("PTO Rule") in its Official Gazette announcing that nonnaturally occurring, nonhuman, multicellular organisms, including animals, would be patentable subject matter. *Policy Statement on Patentability of Animals*, 1077 Off. Gaz. Pat. Office 24 (Apr. 21, 1987). To be patentable, however, an animal had to be "given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law." *Id.* The PTO Rule expressly excluded humans, stating that "the grant of a limited, but exclusive property right in a human being is prohibited by the Constitution." Commentators have interpreted this provision to mean that patents on human beings might violate the Thirteenth Amendment's prohibition against slavery. *See, e.g.*, Eliza-

beth Joy Hecht, Note, *Beyond Animal Legal Defense Fund v. Quigg: The Controversy over Transgenic Animal Patents Continues*, 41 Am. U.L. Rev. 1023, 1024 (1992); Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 Berkeley Tech. L.J. 443 (1999).

The issuance of this PTO Rule did not go unnoticed by animal advocates. It was the impetus behind *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (1991), discussed later in this Section. As the Humane Society of the United States' ("HSUS") position statement issued in response to the PTO Rule explained, the fear was that the new policy would result in

> a dramatic increase in animal experimentation for agricultural, biomedical and other industrial purposes.... In many instances, animals will ... be abnormal at birth, and generations of animals will suffer.... [P]atenting could result in monopoly of genetic stock and predominance of certain genetic lines of animals over others, with an ultimate loss of genetic diversity within species [resulting in] adverse social, economic and ecological consequences.... In conclusion, if the patenting of genetically altered animals is permitted, the wholesale industrialized exploitation of the animal kingdom will be sanctioned, protected and intensified. This could, in fact, signify the end of the natural world.

33 Pat. Trademark & Copyright J. (BNA) No. 827, at 664–65 (Apr. 23, 1987). Despite these protests, the PTO opened its doors to the receipt of animal patent applications. To date, more than 660 patents on animals have been granted. Links to the official patents for some of these animals can be viewed on the Animal Anti-Vivisection Society website at *http://www.stopanimalpatents.org/examples.html.*

In 1988, the PTO granted its first patent for a multicellular organism, now known as the "Harvard Mouse." The patent went to researchers at Harvard University for an "oncomouse," a mouse who had been genetically altered and now had an oncogene—a piece of DNA that made him highly susceptible to, and thus a research model for studying, cancer. These mice are different from the altered oysters that were at issue in *Allen* because they are "transgenic"—genetically engineered animals that have had at least one additional gene introduced into their cells.

The patent that was issued covered not just mice, but all mammals, and specifically covered the progeny of the animals that first received the oncogene. As noted earlier in this section, however, the grant of a patent gives its holder property rights in the actual patent, and the right to exclude others from using the same process, but no positive rights in the "invention" itself. Thus, the current holder of the license to these oncomice creates and sells them to various research institutions, and can exclude others from doing the same thing, but the patent does not give the holder any more right to own the mice themselves than he or she would have without the patent.

Canada's Supreme Court later denied a patent for the same "Harvard Mouse," holding that the mouse does not qualify as an invention under Canada's patent law. *Harvard College v. Canada (Commissioner of Patents)*, [2002] 4 S.C.R. 45, 2002 S.C.C. 76, 99, (Can.) ("The act in its current form fails to address many of the unique concerns that are raised by the patenting of higher life forms.").

After the Harvard Mouse patent, many other transgenic animals were patented, including sheep, pigs, and rabbits. *See, e.g.*, Hammer et al., *Production of Transgenic Rabbits, Sheep, and Pigs by Microinjection*, 315 Nature 680 (1985); Rick Weiss, *Patent Sought on Making Of Part-Human Creatures*, Washington Post, Apr. 2, 1998, at A12. The reality of animal patenting drew its share of critics and supporters, who expressed their views during Congressional hearings in 1987, and later in 1989, before a House Judiciary Sub-

committee. *Statement in Patents and the Constitution: Transgenic Animals, Hearings before the Subcomm. on Courts, Civil Liberties and the Administration of Justice of the Comm. on the Judiciary*, 100th Cong. (1st Sess. 1987); *See also* Daniel J. Kevles, *Patenting Life: A Historical Overview of Law, Interests, and Ethics* 24 (Dec. 20, 2001) (prepared for Legal Theory Workshop, Yale Law School).

During these hearings, disagreement arose as to whether patent protection should be extended to the offspring of transgenic farm animals. The biotechnology sector's ideas clashed with those of farmers. Bills were proposed that would have exempted farmers from restraints as to what they did with these offspring, so long as they did not sell the "germ cells, semen, or embryos of a patented transgenic farm animal," and expressly stated that human beings could not be patented. Transgenic Animal Patent Reform Act, H.R. 4970, 100th Cong. (1988); Transgenic Animal Patent Reform Act, H.R. 1556, 101st Cong. (1989); Patent Competitiveness and Technological Innovation Act, H.R 5598, 101st Cong. (1990).

In *Animal Legal Defense Fund v. Quigg*, 932 F.2d 920 (Fed. Cir. 1991), animal advocacy organizations, individual farmers, and animal husbandry groups challenged the 1987 PTO Rule which stated that nonnaturally occurring, man-made living microorganisms, including animals, are patentable subject matter. Plaintiffs asserted that the PTO Rule was promulgated in violation of Administrative Procedure Act ("APA") because the U.S. Patent and Trademark Commissioner failed to allow for public notice and comment and exceeded his authority under the APA. As relief for these violations, plaintiffs sought "a declaration that 'animals' are not patentable subject matter under section 101 and an injunction against the issuance of any 'animal' patents." *Id.* at 931.

The case was dismissed because the court held plaintiffs lacked standing, and thus did not reach the merits of the claim or address whether section 101 in fact covered animals as "patentable subject matter." The injury asserted by the farmers was that the promulgated PTO rule would increase their "costs of operation, by forcing them to pay royalties to purchase patented, genetically altered animals, and ... will render [them] less able to compete in the production of uniform and predictable traits and products, thereby lowering their" profits. *Id.* at 932. The court held that these claims were speculative, and thus the causation prong of the standing requirements was missing.

The animal advocacy groups had asserted that they were injured by the PTO Rule based on their general interest in preventing cruelty to animals, and that the Rule would effectively result in the need for them to expend more money on organizational activities. The court held, however, that this did not sufficiently distinguish most of them from any other member of the public with a concern and conviction for protecting animals. Further, for those groups that did make out injury, the court found causation lacking, as the injury alleged could not be attributed to the Commissioner's interpretation of section 101.

In December of 1997, Dr. Stuart Newman, a professor and cellular biologist at New York Medical College, and Jeremy Rifkin, a well-known critic of biotechnology, filed a patent application with the PTO for the production of an animal-human "chimera" that would contain up to fifty percent human genetic material. *See* Valerie J. Phillips, *Half-Human Creatures, Plants & Indigenous Peoples: Musings on Ramifications of Western Notions of Intellectual Property and the Newman-Rifkin Attempt to Patent a Theoretical Half-Human Creature*, 21 Santa Clara Computer & High Tech. L.J. 383 (2005); Thomas A. Magnani, *The Patentability of Human-Animal Chimeras*, 14 Berkeley Tech. L.J. 443 (1999). Newman and Rifkin filed their patent application to prevent others from producing human-ani-

mal chimeras and, in turn, to spark debate about such a process. According to one news source at the time, Dr. Newman stated that

> he has not created such creatures and never intends to. Indeed, he said, although the hybrids could be extremely useful in medical research, his goal is to stop the technology from being used by anyone—and to force the U.S. Patent and Trademark Office and the courts to reexamine this country's 18-year history of allowing patents on living creatures, which he considers unethical and immoral.

Rick Weiss, *Patent Sought on Making Of Part-Human Creatures*, Washington Post, Apr. 2, 1998, at A12. In response to this application, the PTO issued an advisory statement in which it stated:

> [C]ourts have interpreted the utility requirement to exclude inventions deemed to be "injurious to the well being, good policy, or good morals of society." *Lowell v. Lewis*, Fed. Cas. No. 8568 (C.C. Mass. 1817) (Story, J.) ... It is the position of the PTO that inventions directed to human/non-human chimera could, under certain circumstances, not be patentable because, among other things, they would fail to meet the public policy and morality aspects of the utility requirement.

PTO Media Advisory, *Facts On Patenting Life Forms Having A Relationship To Humans*, Apr. 1, 1998, *http://www.uspto.gov/web/offices/com/speeches/98-06.htm*.

The "moral utility" doctrine was first described in *Lowell*. In that case, the court upheld a patent, finding that it satisfied the utility requirement of the Patent Act:

> All that the law requires is, that the invention should not be frivolous or injurious to the well-being, good policy, or sound morals of society. The word "useful," therefore, is incorporated into the act in contradistinction to mischievous or immoral. For instance, a new invention to poison people, or to promote debauchery, or to facilitate private assassination, is not a patentable invention.

Lowell v. Lewis, 15 F. Cas. 1018, 1019 (D. Mass. 1817). Although this doctrine had been out of use for many years, it was invoked again just before the 1998 PTO advisory regarding the chimera was issued. *See Tol-O-Matic, Inc. v. Proma Produkt-Und Mktg. Gesellschaft m.b.H.*, 945 F.2d 1546, 1552–53 (Fed. Cir. 1991), *overruled on other grounds by Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995) (upholding a patent and citing *Lowell* for the proposition that section 101 has "been interpreted to exclude inventions deemed to be immoral").

In 1999 the PTO rejected the chimera patent application, not on moral utility grounds, but in part because the "invention" was too much like a human to be patentable: it "'embrace[d]' a human being." Rick Weiss, *U.S. Ruling Aids Opponent of Patents for Life Forms*, Washington Post, June 17, 1999, at A02. In its rejection, however, the PTO failed to specifically address how much human genetic material is necessary for something to be "too human" to be patented. *Id.*; *see also* Valerie J. Phillips, *supra*, at 389. After the denial, Newman and Rifkin immediately appealed the decision, hoping still to force the courts and Congress to reassess the policy of allowing patents on living beings. *Id.*

On February 11, 2005, the PTO again denied the chimera patent application, and this time Newman and Rifkin decided not to appeal. Rick Weiss, *U.S. Denies Patent for a Too-Human Hybrid*, Washington Post, Feb. 13, 2005, at A03. Based on a reading of the denial letter itself, as well as the Washington Post's description of its contents, it appears that the PTO again made its decision not on any moral utility grounds, but because the chimera was deemed to be too human. According to the article:

> One rationale in the documents sent to Newman is that such a patent would be "inconsistent with the constitutional right to privacy." After all, the office wrote, a patent allows the owner to exclude others from making the claimed invention. If a patent were to issue on a human, it would conflict with one of the Constitution's core privacy rights—a person's right to decide whether and when to procreate. Patents on humans could also conflict with the 13th Amendment's prohibition against slavery. That is because a patent permits the owner to exclude others from "using" the invention. Because "use" can mean "employ," officials wrote, a patent holder could prevent a person from being employed by any other—which "would be tantamount to involuntary servitude."
>
> Finally, the office noted that it is illegal to import products that are made abroad using processes patented in the United States. To show how that could cause a problem in a world where people are patentable, it gave an example in which a person goes overseas and undergoes one of the many surgical procedures patented by U.S. doctors. Simply by returning to the United States, the office said, that "surgically altered human being" could be guilty of patent infringement for illegally importing herself.

Id.

Thus, the PTO has concerned itself more with the human component than that of animals, concluding, in essence: patenting of nonhuman animals is acceptable, patenting of human animals is not. The question that still remains, however, is "what is human"? Though this was a final PTO decision, because the applicants decided not to further appeal the ruling, no binding precedent or case law was created. Thus, the fact still remains that the U.S. Supreme Court has only once addressed the question of whether life could be patented, and that was twenty-five years ago in a case involving microorganisms. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

There are many questions still to be answered with respect to this science. Human genes have been inserted into animals, creating patentable transgenic animals. Do they become humans (and therefore not patentable) at some point? Likewise, at what point do we recognize a robot with organic material integrated into it as a living thing in its own right? *See, e.g.*, *Rat-Brain Robot Aids Memory Study*, BBC News, Aug. 13, 2008, *http://news.bbc.co.uk/2/hi/ technology/7559150.stm.*

3. *Animal Cloning*

Serious dialogue about animal cloning is a bit newer than that regarding animal patenting, though every bit as, if not more, controversial. The debate over cloning humans is still in its relatively early stages, with most of the Congressional and academic attention focused on that topic, as opposed to animal cloning. *See, e.g.*, *Biotechnology and the Ethics of Cloning: How Far Should We Go?: Hearing Before the Subcomm. on Technology of the H. Comm. on Science*, 105th Cong. 20–21 (1st Sess. 1997). However, as of 2009, no federal legislation existed barring human cloning.

Although cloning has been a staple of science fiction stories for some time, the reality of cloning first entered the public consciousness with the 1997 reported "creation" of a sheep named Dolly. *See, e.g.*, I. Wilmut et al., *Viable Offspring Derived from Fetal and Adult Mammalian Cells*, 385 Nature 810 (1997) ("Wilmut"); Stacy Ratner, Note, *Baa, Baa, Cloned Sheep, Have You Any Law? Legislative Responses to Animal Cloning in the European Union and United States*, 22 B.C. Int'l & Comp. L. Rev. 141 (1999) ("Ratner").

Scottish researchers from the Roslin Institute announced the creation of their famous clone in a 1997 Nature article. *See* Wilmut, *supra*; Ratner, *supra*. Although Dolly is by far the world's most famous cloned animal, she was not the first; but she was the first mammal to have been cloned from an adult cell, as opposed to an embryo. Wilmut, *supra*; Ratner, *supra*; Tim Friend, *Cloning Animals for Healthier Humans*, USA Today, Feb. 25, 1997, at 6D. As soon as the news of this cloning spread, ethical and moral questions were raised, both by commentators and legislators. *Id.*; H.R. 922, 105th Cong. (1997); H.R. 923, 105th Cong. (1997); S. 368, 105th Cong. (1997) (discussed in detail below). Most of this commentary focused on the benefits humans would derive from cloned animals, as well as concerns about the "obvious" next step, cloning humans, as opposed to the ethical issues surrounding the cloning of the animals themselves. Several articles at that time pointed out this glaring omission. *See, e.g.*, Anjay Elzanowski & Derek M. Brown, Editorial Letter, *Animals, Not Humans, Should Be the Focus of the Ethics Debate on Cloning*, Washington Times, June 19, 1997, at A18 ("[H]umans have received all the attention while the impact on animals, which will carry the burden of this new technology, was ignored."); Dave Brett Wasser, Editorial Letter, *Cloning Raises Question of Whether We Have the Right to Exploit Animals*, Washington Times, Mar. 2, 1997, at B2 ("[N]ews programs have trotted out one ethics authority after another. Each one says the same thing. Namely, the cloning of animals is fine as long as we don't try cloning humans."); *see also* Robert F. Blomquist, *Cloning Endangered Animal Species*, 32 Val. U. L. Rev. 383, 384 (1998).

Within one week of the article in Nature discussing Dolly's creation, three cloning-related bills were proposed in Congress, though none of them passed. This effort has been made several times since 1997, but no federal laws have been passed regarding cloning. The legislative history behind the enactment of House Bill 922, 105th Cong. (1997) stated, in part, "the sheep cloning raised the prospect of a similar procedure for humans. Although major hurdles still exist before human cloning can become a reality, this theoretical ability to clone humans has raised strong objections and profound moral, ethical, religious, and psychological concerns throughout the world." H.R. Rep. No. 105-239, pt. 1, at 2 (1998).

In response to the mammal cloning news, and at the behest of President Clinton, the National Bioethics Advisory Commission ("NBAC") prepared a report and recommendation on cloning human beings. NBAC Report, *Cloning Human Beings*, June 1997, available at *http://bioethics.georgetown.edu/nbac/pubs/cloning1/cloning.pdf*. The executive summary of this report stated that "research on cloning animals ... does not raise the issues implicated in attempting to use this technique for human cloning, and its continuation should only be subject to existing regulations regarding the humane use of animals and review by institution-based animal protection committees." *Id.* at iv. This is ironic because, as addressed below, the animals who have been the most often used in cloning experiments are those who are afforded the least protection under current "humane treatment" laws.

Human cloning has been the focus of all attempts at legislation. In 1998, House Bill 3133, 105th Cong. (Jan. 28, 1998) would have prohibited the expenditure of federal funds to conduct or support research on human cloning, but expressly exempted from the Act's restrictions the use of "cloning technologies to clone molecules, DNA, cells other than human embryo cells, or tissues; or ... to create animals other than humans." Likewise, Senate Bill 1602, 105th Cong. (Feb. 3, 1998), made the distinction that "cloning animals ... does not raise the same issues implicated in attempting to use the technique to create a child," and acknowledged that animal cloning "may have many applications for biotechnology, livestock productions, and new medical approaches including the pro-

duction of pharmaceutical proteins and prospects for repair, regeneration, or transplant of human tissues or organs." The bill also expressly exempted from restriction cloning "techniques to create nonhuman animals." Like their predecessors, these bills failed to make it out of their respective houses.

Because of the lack of federal regulation on cloning, some states have enacted bans, though none prohibit animal cloning. As of January 2008, fifteen states had enacted laws relating to human cloning. *See* Alissa Johnson, *Attack of the Clones,* State Legislatures, April 2003 and chart update, available at the National Conference of State Legislatures, *http://www.ncsl.org/programs/health/genetics/rt-shcl.htm.* California was the first state to ban reproductive cloning in 1997. Cal. Bus. & Prof. Code §§16004, 16105 (2009); Cal. Health & Safety Code §§24185–24187, 125115–125117 (2009). Once again, the legislative history reveals that the concern was not with the ethical implications of animal cloning, but of the progression to human cloning. *See* Senate Floor Analysis for S.B. 1344 (1997) ("The human egg develops much more quickly than does a sheep egg, which will make human cloning technically much more difficult. However, the successful cloning of a large animal has initiated a broad debate on the ethics of human cloning."). In 2005, California passed "Proposition 71," 2004 Cal. Legis. Serv. Prop. 71 (West), which permits funding of research involving therapeutic, but not reproductive, cloning. Karen Kaplan, *With Clones Come Complex Concerns,* L.A. Times, May 21, 2005, at A19.

Those in favor of animal cloning tend to overlook the ethical questions it raises, apparently having concluded that any arguable potential benefit to humans justifies its impact on nonhumans. This is consistent with the general view of researchers regarding most testing and research using nonhuman animal subjects. For example, researchers claim that the use of animals provides distinct benefits in the area of pharmaceutical production. Scientists can transgenically modify nonhuman animals so they produce human proteins in their bodily fluids, such as milk and blood; and then clone them. "In essence, barnyard animals such as sheep, goats, cows and pigs will be made into living factories for producing a variety of vital human proteins that, when missing in a person, cause disease." Tim Friend, *Cloning Animals for Healthier Humans, supra,* at 6D. This "living factory" concept highlights the role of animals as property and tools to be used for human benefit, and holds especially true for farm animals, as discussed below.

In line with the "treatment for humans" benefits of animal cloning is "xenotransplantation"—the use of animal organs for transplant into humans. Ray Moseley & Jeremy Manier, *Another First in Animal Cloning: Pigs,* Chi. Trib., Mar. 15, 2000, at N3. Both the United States and the United Kingdom originally banned xenotransplants, not because of any ethical or moral concerns, but due to fears of animal viruses being transmitted to human recipients.[n] *Id.* Scientists claim, however, that cloning provides a level of precision, apart from genetic engineering alone, that is needed to produce nonhuman animals who are compatible with the human immune system. Specifically, pigs appear to be the cloned animal of choice for researchers involved with xenotransplantation, who intend to use them primarily for spare parts. *Id.* ("In addition to having fewer disease risks than primates, pigs would be a more ethically acceptable source of organs because they already are bred for food, researchers say.").

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n. Until April of 2005, the Secretary's Advisory Committee on Xenotransplantation, Department of Health and Human Services, was accepting comments on its then most recent draft reports on xenotransplantation. 70 Fed. Reg. 14705-06 (Mar. 23, 2005). The draft report discussed the state of the science of xenotransplantation, focusing mainly on potential harm to human recipients. As of mid-2005, it appeared any U.S. ban had been lifted, at least in part, and clinical trials were underway.

Another claimed benefit of cloning animals is that it allows for reproduction of those animals who have proven to be "best" in their specific industry. This includes cloning prizewinning cows to create more of the "perfect" steak, cloning sheep with top quality wool, or cloning a prize racehorse. *See, e.g.*, Ian Sample, *Idaho Gem, the World's First Cloned Mule*, Guardian, May 30, 2003. Some commentators also have discussed cloning endangered species as a means of replenishing them. *See, e.g.*, Robert F. Blomquist, *Cloning Endangered Animal Species*, 32 Val. U.L. Rev. 383 (1998); Caroline P. Rogers, Note, *Solution or Stumbling Block?: Biological Engineering and the Modern Extinction Crisis*, 30 Ga. J. Int'l & Comp. L. 141 (2001). Critics of this idea assert that it might reduce the motivation to protect endangered habitat, which is key if the cloned endangered species are to thrive. *See, e.g.*, Blomquist, *supra*, at 411–14. In addition, others have asserted benefits to the nonhuman animals themselves, because researchers can "select" for disease-resistant animals, and can ensure the creation of a specific gender, thereby eliminating excess male calves who end up as veal. Linda Bren, *Cloning: Revolution or Evolution in Animal Production?*, FDA Consumer Magazine, Vol. 37, May–June 2003.

With respect to the dangers of, and arguments against, cloning animals, one of the concerns is that the process—in line with the "animals as property" doctrine—is exploitative. Others are opposed to animal cloning for purely ethical reasons. For example, cloning causes suffering in cloned animals and those who birth them. Even the FDA, in a report addressed below, found that cloned animals whose organs are removed suffer, and that cloned animals have many problems, such as advanced aging and physical deformities. *See, e.g.*, 149 Cong. Rec. H1402 (Feb. 27, 2003) ("the horror stories are too many to mention here of deformed mice and deformed sheep developing from cloned embryos") (statement of Rep. Stupak). Others are concerned that cloning will further reduce the genetic diversity of livestock which is already compromised due to inbreeding. It is noteworthy that one of the main fears associated with the cloning of humans—that it raises the spectre of eugenics—does not appear to be a concern with respect to the cloning of nonhuman animals.

One reason the creation of cloned animals is permitted is that farmed animals have very little legal protection, and thus are viewed by many as merely a source of food or clothing. The Animal Welfare Act ("AWA") regulates the living conditions and other aspects of the lives of farmed animals only if those animals are used in research. Specifically, it states, "regulation of animals and activities ... is necessary ... to insure that animals intended for use in research facilities ... are provided humane care and treatment." 7 U.S.C. §2131 (2006). The AWA does not define "humane," but it does define "animal" as

> any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation ... but such term excludes (1) birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research, (2) horses not used for research purposes, and (3) other farm animals, such as, but not limited to livestock or poultry, used or intended for use as food or fiber, or livestock or poultry used or intended for use for improving animal nutrition, breeding, management, or production efficiency, or for improving the quality of food or fiber.

7 U.S.C. §2132(g). Thus, so long as it can be said that farm animals, whom scientists wish to turn into the living factories, are being used to improve the agribusiness industry, be it through cloning for efficient grain conversion, better wool, or more milk, they may be exempt from protection under the AWA. As such, they are unregulated cloning research subjects. *See* Ratner, *supra*, at 144, 148. One could argue, however, that those cloned

animals whose only function is the improvement of *human* nutrition or health are not exempted under the AWA and, thus, research conducted upon them must be done "humanely." Of course, without any non-discretionary definition for what such "humane" treatment entails, this is a very vague directive. *See* Ratner, *supra*, at 147 n.54 ("This purposeful vagueness stems from Congressional desire to provide researchers, particularly medical ones, with maximum autonomy. As the Committee on Agriculture put it, this legislation 'establishes by law the human ethic that animals should be afforded the basic creature comforts,' but also 'recognizes the responsibility and specifically preserves the necessary domain of the medical community.... [It] in no manner authorizes the disruption or interference with scientific research or experimentation.... The research scientist still holds the key to the laboratory door.' [Citation omitted.]").

In January of 2008, the FDA released the results of an independent analysis "assessing the health of clones and their progeny ... or food consumption risks resulting from edible products from these animals." FDA Center for Veterinary Medicine, *Animal Cloning: A Risk Assessment* (2008) ("Risk Assessment"), available at *http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalCloning/ucm055489.htm*. The Risk Assessment addresses not only the safety of consuming milk and meat from cloned animals and their offspring, but also the risk to the nonhuman animals who are involved in the cloning process. The results "indicated that significant adverse health outcomes have been reported for cattle and sheep clones and their surrogate dams" and that although "goats and swine appear to develop without significant abnormalities ... [t]he incidence of adverse outcomes in cattle and sheep clones ... appears to be higher than in other forms of ARTs [assisted reproductive technologies]." *Id.* at 328. The Risk Assessment does not address the ethical concerns of such hazards, but it does acknowledge that such concerns exist. As noted in its preface, "cloning raises many ethical and economic concerns [that] may be important to members of the public, however, they are not within the FDA's mission and therefore not within the purview of this Risk Assessment." *Id.* at ii–iii.

The most common adverse development outcomes (observed in cattle and sheep) stem from a class of problems known as Large Offspring Syndrome ("LOS"). "Newborn animals with LOS tend to be bigger than average..., may show edema or other abnormalities of the lungs and other parts of the body, and exhibit cardiovascular and respiratory problems." *Id.* at 328. The causes of LOS were still unknown at the time of the Risk Assessment, but "may be related to *in vitro* culture conditions." *Id.* at 182. If the animal clone can survive the perinatal period, however, most "*appear* to grow and develop normally." *Id.* at 328 (emphasis added). LOS may also pose a health hazard to the surrogate mother if she is unable to completely expel the fetus and its associated membranes, but such complications generally arise in "mid- and late-term spontaneous abortions." *Id.* at 181. "Losses due to defects in the embryo or failure to implant do not pose a hazard to the dam in early stages of pregnancy." *Id.* Overall, the Risk Assessment concluded that there is an "increased frequency of health risks to animals involved in the cloning process" but that these risks "do not differ qualitatively from those observed in other ARTs or natural breeding." *Id.* at 15. Furthermore, "the risk of morbidity and mortality appears to decrease with age, ..." and progeny of animal clones are "reported as normal and healthy." *Id.*

As to the food safety issue, the Risk Assessment found that "there are no biological reasons, based on empirical data and underlying biological assumptions, to indicate that consumption of edible products from cattle, pigs, or goat clones poses a greater risk than consumption of those products from their non-clone counterparts." *Id.* at 320. The Risk Assessment did not attempt to assign quantitative values to estimates of risk or safety, concluding only that food products from animal clones pose "no additional risk" or—in

other words—"are as safe as foods we eat every day." The first comprehensive assessment of the nutritional value of food from clones, completed in spring 2005, came to similar conclusions, finding no significant difference between the composition of milk and meat derived from cloned and non-cloned cattle. Rick Weiss, *Cloned Cows' Milk, Beef Up to Standard*, Washington Post, Apr. 12, 2005, at A03.

In December 2004, a company called "Genetic Savings & Clone" created "Little Nicky," a kitten cloned to replace a woman's deceased cat, at the price of $50,000, and sparked the controversy of the public sale of cloned animals.[o] Rick Weiss, *Pet Clones Spur Call For Limits*, Washington Post, Feb. 17, 2005, at A03 ("*Pet Clones*"). The main opposition to such a practice is that, with tens of millions of animals killed in shelters each year, the pet cloning industry seems to be "frivolous" at best. More recently, a Brahmin bull and pet Labrador retriever were cloned for their owners. *See,* Russell Goldman, *Cloned Pets: Looks Can Be Deceiving*, ABC News, Jan 30, 2009, *http://abcnews.go.com/Technology/AmazingAnimals/story?id=6762235&page=1.*

Animal advocates and activists have attempted to stop these companies. The American Anti-Vivisection Society petitioned the U.S. Department of Agriculture to regulate pet-cloning companies in the same way it does other animal research labs under the AWA. Weiss, *supra.* As of publication of this edition, the USDA has not regulated pet cloning

In 2005, California lawmakers rejected a bill that would have banned the sale of cloned or genetically modified pets. Steve Lawrence, *Assembly Committee Rejects Ban on Cloned Pets*, Associated Press, May 3, 2005 (LEXIS News). The legislation (A.B. 1428, introduced May 3, 2005, by Assembly member Lloyd E. Levine (D)), was rejected as being premature, or better left to Congress. For the informative analysis that accompanied this bill, *see http://www.leginfo.ca.gov/pub/05-06/bill/asm/ab_1401-1450/ab_1428_cfa_20050502_091221asm_comm.html.*

Notes

1. The extra-judicial ethical implications of genetic engineering, even as they relate solely to nonhuman animals, are beyond the scope of this casebook—yet animals' status as property is a central precept of any such discussion. As science progresses, human/nonhuman distinctions may become genetically blurred and ancient precepts become arguably irrelevant. For further discussion of these issues, *see, e.g.*, Barry S. Edwards, "... *And On His Farm He Had a Geep*," 2001 Minn. Intell. Prop. Rev. 3 (2001).

2. What are the different considerations raised by cloning (1) companion animals, (2) farmed animals and (3) animals used for biomedical and cosmetics research?

3. Why do you think Congress has not enacted a ban on cloning humans? What, if any, implication does this lack of action have on the future of animal cloning?

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o. A related topic is the sale of transgenic pets. "Without regulation we have seen the invention of a transgenic glowing rabbit solely for display as a piece of art (France, 2003) and the mass manufacture of transgenic glowing fish (Florida, 2003) solely for the viewing pleasure of consumers who want to spice up their home aquariums." Cal. Assembly Committee on Bus. & Prof., Analysis—Comment & Purpose of A.B. 1428 (2005).