

PARDON ME, BUT WHOSE GENES ARE THOSE ANYWAY?: EXAMINING ROYALTY COLLECTION FOR 21ST CENTURY LIVESTOCK

*S. Brett Offutt**

INTRODUCTION

Welcome to the 21st Century, Planet Earth! Forget Dolly; the next round of the biotech revolution is upon us. Genetic engineering of animals has developed into a major world industry for both medical/pharmaceutical and agricultural products. Patents are issued for genetically engineered animals.¹ New animal cloning techniques are developed before most people grasp the impact of earlier techniques.² Biotech corporations develop overnight and, when faced with fierce competition, disappear just as quickly. Technological advances are promising increased and more efficient production of livestock and livestock products.³ Before long researchers will expect better and more predict-

* B.S., 1989, Kutztown University of Pennsylvania; J.D., 1998, South Texas College of Law; LL.M., 1999, University of Arkansas School of Law.

¹ NEIL D. HAMILTON & J. W. LOONEY, NATIONAL CTR. FOR AGRIC. LAW RESEARCH AND INFO., PRODUCER BULLETIN NO. 44, LEGAL ASPECTS OF LIVESTOCK PRODUCTION AND MARKETING: EMERGING LEGAL ISSUES-ANIMAL RIGHTS AND ANIMAL PATENTS (May 1994).

² See Michael D. Lemonick, *Dolly, You're History*, TIME, Aug. 3, 1998; Rachel K. Sobel, *Copying a Multitude of Mice: Cloning is No Fluke; Woolly Mammoths Next?* U.S. NEWS, Aug. 3, 1998.

³ Sidney L. Spahr & Ephraim Maltz, *Advanced Herd Management Technology—Outlook and Reality* (visited Dec. 15, 1998) <[http://www.aces.uiuc.edu/\(ansystem/dairyrep96/Spahr.html\)](http://www.aces.uiuc.edu/(ansystem/dairyrep96/Spahr.html))>. Spahr and Maltz discuss the continued implementation of the computer in the dairy industry. Initial steps to an increased yield include computerizing data on cows' "size, daily milk yield, stage of lactation, body condition score, and inherent lactation persistency" Information is assessed to develop "a least-cost ration of appropriate nutrient density" The authors note efforts to implement

able profits from their contribution to the revolution.

The biotech revolution is not without its drawbacks, however. Ethical considerations alone will provide writers and critics with fuel for the fire for many years to come.⁴ As technology advances at record speeds, other hurdles must be overcome, as well. This article addresses one such hurdle: how can the developers of new technology best benefit from their efforts? Focusing on the narrow issue of genetically engineered livestock, the pages that follow examine the case of ownership interests in the offspring of such livestock, how the industry reached this point, and a proposal for royalty collection systems to solve the problem of funding biotechnological research in livestock. While providing sufficient financial resources to research facilities is of great concern, equally important is the financial and legal protection of farmers, breeders, and other companies who place genetically engineered animals in the stream of commerce.

The bottom line on this issue rests heavily on speculation. This author is merely offering one potential solution to a problem that has yet to fully develop. Currently there is very little genetic engineering taking place in the beef cattle industry.⁵ No transgenic⁶ farm animals are

electronic identification systems into routine commercial use for permanent identification and for linking to sensors such as milk meters. *Id.*

⁴ See generally Geri J. Yonover, *What Hath (Not) Chakrabarty Wrought: From the Mouse that Roared to Hello Dolly and Beyond*, 32 VAL. U. L. REV. 349 (1998); Paul Tully, *Dollywood is Not Just a Theme Park in Tennessee Anymore: Unwarranted Prohibitory Human Cloning Legislation and Policy Guidelines for a Regulatory Approach to Cloning*, 31 J. MARSHALL L. REV. 1385 (1998); Thomas A. Shannon, *Religious, Philosophical, and Ethical Perspectives on Cloning: Examining Religious and Ethical Issues*, 32 VAL. U. L. REV. 773 (1998); Michael Broyde, *Cloning People: A Jewish Law Analysis of the Issues*, 30 CONN. L. REV. 503 (1998); Ted M. Sichelman, Book Note, *Improving Nature?: The Science and Ethics of Genetic Engineering*, 10 HARV. J.L. & TECH. 707 (1997); Andrew Trew, *Regulating Life and Death: The Modification and Co-modification of Nature*, 29 U. TOL. L. REV. 271 (1998).

⁵ Letter from Jim Gibb, Vice President, Center for Quality, National Cattlemen's Beef Association to S. Brett Offutt (Nov. 9, 1998) (on file with author and with the Graduate Agricultural Law Program, University of Arkansas School of Law, Fayetteville) [hereinafter Gibb Letter].

⁶ News release from Jennifer Cannon, Extension News Editor, The University of Georgia Cooperative Extension Service, to Editor (Oct. 29, 1998) (on file with the *San Joaquin Agricultural Law Review*).

Transgenesis is the process of adding or removing genetic material from the genome of an individual. The process is made more efficient through nuclear transplantation cloning, leading to the usefulness of the technology for animal production. The resulting embryo from the process is im-

in commercial production.⁷ The technology required is very expensive and researchers are still perfecting the science.⁸ Corporations and organizations with the knowledge, resources, and desire to implement a system for royalty collection must take the next steps to turn this theory into reality.

I. ILLUSTRATION

A practical examination of the importance of property rights in the progeny of genetically engineered livestock may best be illustrated through a hypothetical example. The parties involved include (1) Farmer Brown, operator of a standard cow/calf operation; (2) R & D Inc. (R&D), which buys calves from Farmer Brown for research and develops clones with desirable traits for resale into the agricultural community; and (3) Bigger Beef, a feedlot which purchases cloned calves from R&D, holds some until they reach an optimal size, and sells to a packing plant, Packers, Inc. Bigger Beef also employs an animal scientist to select those animals exhibiting the best traits and sells those to breeders and other research companies. Packers, Inc. sells its meat products to several wholesalers, who in turn sell to many retailers. Consumers across the nation purchase beef products from retailers.

By their very nature, the above described transactions are expected to generate profits for each seller of cattle or beef product. Similarly, the profits generated by each seller should be proportional to costs incurred at each level. For purposes here, it is assumed that R&D experiences the largest cost burden in producing cloned calves for resale. R&D should, therefore, realize the greatest profits from sale of the cloned calves. Attempts to recover costs through the initial sale could impose restrictive cost burdens on Bigger Beef and its buyers. A better option for R&D would be to incorporate a system in which a portion

planted into the uterus of a recipient female who nurtures it to birth, similar to classical embryo transfer.

Id.

⁷ Electronic mail from Dr. Steven Stice, Georgia Research Alliance Eminent Scholar in Animal Reproductive Physiology, The University of Georgia, Animal and Dairy Science Department, to Brett Offutt (Nov. 10, 1998) (on file with author and with the Graduate Agriculture Law Program, University of Arkansas School of Law, Fayetteville). Dr. Stice is nationally and internationally recognized for the January 1998 birth of a pair of bulls cloned from fetal calf cells and altered genetically.

⁸ See Gibb Letter, *supra* note 5.

of its profits is recovered from each subsequent sale of animal or animal product.

R&D may be concerned that it will not recover expected profits from the animals that Bigger Beef resells to breeders and researchers. It could require a higher return from Bigger Beef's sales to breeders and researchers. Alternatively, it could track sales generated from Bigger Beef's buyers and collect a portion of those sales revenues. Respected commentators have suggested that managing intellectual property rights (IPR) through several generations of livestock would be unprofitable using known technology.⁹ Borrowing ideas, practices, and technologies from other disciplines and industries may provide a workable answer for livestock agriculture.

II. CONCERNS ASSOCIATED WITH GENETIC ENGINEERING IN ANIMALS

Many concerns surround the prospect of genetically engineered animals. Marty Strange refers to the patenting of life as "something as perverse to agriculture as anything that has ever been."¹⁰ A bulk of the concerns surround religious, moral, and ethical problems with technology, such as cloning, and the potential for its use in humans. Such concerns are addressed in a countless number of law review and other periodical articles.¹¹ Additional concerns surround animal rights issues, including the creation of "animal freaks"; environmental issues such as an accidental introduction of dangerous mutants into the biosphere, and a loss of genetic diversity; and the subject of this article, agricultural issues including exorbitantly high royalties on the purchase of patented livestock. Another serious concern surrounds the breadth of the patent issued for the Harvard mouse.¹² The mouse patent covers "any nonhuman animal into which has been implanted any oncogene or sequence of DNA that induces cancer in the animal."¹³ The patent covers the process, "the animals themselves and all future generations."¹⁴

⁹ William Lesser, *Royalty Collection for Patented Livestock*, 10 Eur. Intell. Prop. Rev. 441, 444 (1994).

¹⁰ Marty Strange, Lecture at the University of Arkansas, Contemporary Agricultural Policy Lecture Series (Nov. 19, 1998).

¹¹ See sources cited *supra* note 4.

¹² U.S. Patent No. 4,736,866, issued Apr. 12, 1988.

¹³ *Animal Patents-The Controversy* (visited Oct. 8, 1998) <<http://www.library.ubc.ca/patscan/maus.html>>.

¹⁴ *Id.*

Loss of genetic diversity could be avoided by systems ensuring that breeding companies produce a limited number of clones of each genotype and then restrict the number of each of the clones that could be sold to any one farmer. “[S]ome farmers’ herds might consist entirely of cloned animals”; however, since they would be “clones of different elite animals,” the “genetic diversity on some farms” may actually increase.¹⁵

Cloning may provide new methods for genetic conservation. Many indigenous breeds adapted to local conditions are in danger of being wiped out as more and more imported breeds are raised in intensive farming operations. Since local breeds could contain valuable genes that allow the animal to tolerate local weather and/or disease conditions, there is a need to prevent their extinction. Current methods of storing frozen semen and embryos are much more time consuming and costly than the cloning alternatives.¹⁶

III. HISTORICAL PERSPECTIVES

The issues surrounding property rights in the offspring of genetically engineered livestock are not new. Ten years ago, the Washington Post published an article examining the ownership of offspring from genetically altered livestock.¹⁷ The article, written by Malcolm Gladwell, summarizes the views of legislators, environmentalists, farmers, and the biotech industry as they existed in the late 1980s. Gladwell posed a hypothetical situation involving a biotech company producing “leaner, more fertile pigs,” in turn providing farmers with the potential for larger profits.¹⁸

The biotech industry expected that patent laws would grant it ownership of the “superpig’s” offspring. It claimed that farmers who buy genetically altered livestock should not be able to sell any offspring they raise without paying royalties to the inventor. Biotech firms likened the situation to the protection a software patent affords computer firms in preventing the “unauthorized duplication or sale of their programs”¹⁹

¹⁵ John Woolliams, *Cloning in Farm Animal Production* (visited Oct. 8, 1998) <http://www.ri.bbsrc.ac.uk:8080/cloning/cloning_uses.html>.

¹⁶ *Id.*

¹⁷ Malcom Gladwell, *Genetically Altered Livestock: Who Owns Their Offspring?; Debate Rages Between Scientists, Farmers*, WASH. POST, Oct. 9, 1988, at A01.

¹⁸ *Id.*

¹⁹ *Id.*

At the time the article was written, environmentalists and farmers were pushing for legislation to exempt farmers from the normal provisions of patent law. Their desire was to allow farmers to “free[ly] . . . use or sell offspring of genetically engineered animals for any purpose without infringing on the patent of the company that engineered the animal”²⁰ Biotech firms stressed the problem of trying to recoup their research and development costs in the agriculture industry. Livestock production is a commodity business “where significant markups to cover millions of dollars in laboratory work are unheard of.”²¹

To illustrate the problem, Gladwell described “a hog . . . engineered so that it saves the farmer \$15 in feed costs over . . . its life[time].”²² If the animal were male, it could sire 800 piglets in one year, thus saving a farmer \$12,000 in cost of feed.²³ Generally, “producers of improved [agricultural] strains split the proceeds from any cost-saving innovation equally with the farmer.”²⁴ Researchers acknowledge that no farmer would pay \$6,000 for one pig.²⁵ To cover costs, the industry must rely “on lower margins on higher volume sales.”²⁶ That is where patent protection comes in. To prevent an unlimited number of competitors, the industry needs patent protection and the ability to collect royalties on those 800 piglets, unless the farmer uses them for his own purposes, such as “slaughter, or . . . replace[ment of] original breeding stock.”²⁷

Without patent protection, breeders would be forced to protect their inventions by dealing with only a few centralized vertically integrated livestock producers. Small farmers would be “squeeze[d] out.”²⁸ “Small farmers are . . . least likely to have access to . . . new varieties under [a] contract law system.”²⁹ Vertical integrators would profit from long-term deals with breeders. Likewise, breeders would be in a better position to ensure that their inventions were not being pirated.³⁰

²⁰ *Id.*

²¹ *Id.*

²² *Id.*

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ *Id.* (referring to comments made by Professor William Lesser of Cornell University). See generally electronic mail from Dr. Steven Stice to Brett Offutt, *supra* note 7.

²⁹ Gladwell, *supra* note 17.

³⁰ *Id.*

In his 1988 article, Gladwell quoted Larry McKenzie, assistant director of national affairs for the American Farm Bureau, who stated, “[w]e are in favor of the biotech industry and we’re in favor of patent protection We want to keep these animals available to all producers and don’t want to encourage them to go to large producers, who will vertically integrate.”³¹ McKenzie urged that much further study was still necessary.³²

Another farmers’ groups viewed things differently. Howard Lyman, director of legislative affairs for the National Farmer’s Union, commented “that waiving patent rights for offspring [would not] result in small farmers being denied access to transgenic livestock.”³³ Lyman doubted “that breeders would deliberately limit their own market to major producers.”³⁴ Lyman stated, “If you’re actually producing an animal that is patentable and salable, you’ll do much better with a market of 2.4 million farmers.”³⁵

In 1988, another genetic researcher, Kevin Guise of the University of Minnesota, issued statements regarding royalty payments for the offspring of genetically engineered animals. Guise was “one of a team of . . . scientists . . . working [on] develop[ing] a breed of fish that [would] grow faster and larger than its predecessors.”³⁶ Although Guise hoped to protect his new fish with a patent, he commented that there would be very little change in the way animal genetics are marketed.³⁷ Typically, “breeders control the reproductive capacities of their animals by charging stud fees or controlling the brood stock.”³⁸ Guise commented:

[if] a genetically engineered animal is patented, I think it will be handled in much the same way. Royalty payments for successive generations of animals would not be feasible in my opinion. Products of genetic engineering would be worked into existing brood stocks. Therefore, no substantial change would occur in how a bloodline is marketed.³⁹

Guise anticipated little change for farmers. The cost of breeder’s

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ *Id.*

³⁵ *Id.*

³⁶ Martin Moen, *Animal Patent Ruling Won't Have Much Affect on Farmers*, News Release, Mar. 3, 1988.

³⁷ *Id.*

³⁸ *Id.*

³⁹ *Id.*

services is controlled by the marketplace.⁴⁰ “If a company has a genetically superior animal and charges too much for its services, farmers will go elsewhere. Any increase in price would have to be based on what the organism could offer, which could be either increased growth rates or increased efficiency in production or food consumption.”⁴¹

A. A Brief History of Genetic Engineering in Animals

Genetic engineering of animals is not a new idea. The technology has changed, but the desired effects continue to closely resemble the goals of genetic engineering throughout our country’s history. For years, farmers sought bigger beef cattle and hogs, higher producing dairy cattle, and faster horses. By carefully observing livestock and mating animals with specific characteristics, traits could be replicated in offspring.

Research in cattle breeding has produced numerous breakthroughs for years. “Artificial insemination . . . genetically advanced the cattle industry through the use of frozen semen.”⁴² In 1953 the first calf was born in the United States from frozen semen.⁴³ Later, liquid nitrogen transportation systems allowed for long distance delivery of frozen semen.⁴⁴ Long-term potential for producing cattle from frozen semen was realized in 1984 when a calf was born from semen collected in 1954.⁴⁵ Embryo splitting in the mid-1980s brought the advent of cloning research and experimentation to agriculture.⁴⁶

B. Cloning

Cloning made headlines worldwide in early 1997 with the announcement from Scotland that a sheep named Dolly had been cloned from adult cells.⁴⁷ “[E]arlier clones were made from fetal cells, which have no specialized function but carry the potential to turn into” any type of cell, tissue or organ the body needs.⁴⁸ Adult, or differentiated

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Cloning Technology in the Dairy and Beef Industries* (visited Jan. 6, 1999) <<http://www.infigen.com/tech-beef.htm>>.

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ *Id.*

⁴⁷ Lemonick, *supra* note 2.

⁴⁸ *Id.*

cells, are already specialized.⁴⁹ In adult cells some genes are turned “on” and others are turned “off” to create heart, liver, brain, or other cells.⁵⁰ Until Dolly, no one had ever succeeded in reprogramming the “off” genes to return cells to an “undifferentiated state suitable for cloning.”⁵¹ This breakthrough allows researchers to choose adult individuals with desirable traits for cloning.⁵²

1. A Sheep Named Dolly . . . and Beyond

Ian Wilmut created Dolly using “cells taken from the udder of a 6-year-old Finn Dorset ewe”⁵³ Wilmut used “electric shocks to coax . . . adult cell[s] into merging with . . . host egg[s] whose nucle[i] had been removed.”⁵⁴ Twenty nine eggs containing nuclei “from the original adult ewe . . . were . . . implanted into surrogate Blackface ewes.”⁵⁵ Dolly resulted from the only egg in Wilmut’s experiment to become an embryo, and then a full-term fetus.⁵⁶ Dolly was born 148 days after implantation.⁵⁷

Shortly after Dolly’s introduction to the world, cloning technology was rewritten by a Japanese researcher at the University of Hawaii.⁵⁸ Teruhiko Wakayama presented a litter of cloned mice.⁵⁹ Wakayama “succeeded in cloning the cumulus cells that surround the egg in [a mouse’s] ovary.”⁶⁰ Wakayama injected an “adult nucleus into a nucleus-free host” cell.⁶¹ Three percent of his clones survived.⁶² “[T]he cloned mice were perfectly normal”⁶³ They can mate, give birth, and be cloned themselves.⁶⁴ Clones of clones may also be cloned.⁶⁵ By mid-1998, Wakayama had produced three generations of identical

⁴⁹ *Id.*

⁵⁰ *Id.*

⁵¹ *Id.*

⁵² *Id.*

⁵³ Woolliams, *supra* note 15.

⁵⁴ Lemonick, *supra* note 2.

⁵⁵ Woolliams, *supra* note 15.

⁵⁶ *Id.*

⁵⁷ *Id.*

⁵⁸ Lemonick, *supra* note 2.

⁵⁹ *Id.*

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ *Id.*

mice.⁶⁶ Researchers are currently working on using Wakayama's technique with larger animals.⁶⁷

Other prominent researchers are aggressively working on cloning livestock. The University of Georgia College of Agricultural and Environmental Sciences, (UGA) recently appointed Dr. Steven Stice to a \$1.5 million endowed research chair.⁶⁸ Stice expects "to develop new technologies" while at UGA "which will combine transgenesis and cloning to efficiently produce livestock with superior characteristics at a faster pace than traditional breeding programs."⁶⁹ Stice's efforts are expected "to accelerate tremendously the genetic improvement of food animals and ultimately the safety and quality of animal food products."⁷⁰ Farmers should benefit from Stice's work with "genetically improved, more robust livestock."⁷¹ Consumers will find "meat products with the characteristics [they] demand in a competitive world market."⁷² Animals developed through Dr. Stice's work may be sold to farmers as breeding stock, or may be marketed through traditional artificial insemination or embryonic transfer.⁷³

C. *The Emergence of Animal Patents*⁷⁴

Before 1980, the Patent and Trademark Office (PTO) refused to issue patents on nonplant living organisms.⁷⁵ "[M]ethod[s] of breeding living things by [traditional] breeding techniques" did not constitute a process.⁷⁶ Something occurring in nature was not patentable "because it was [not] a machine, manufacture or a composition of matter."⁷⁷ "Early patent applications on living things were . . . rejected" outright.⁷⁸ The amount of bioengineering involved in the creation of an organism was irrelevant to its patentability.⁷⁹ The PTO relied heavily

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ Cannon, *supra* note 6.

⁶⁹ *Id.*

⁷⁰ *Id.*

⁷¹ *Id.*

⁷² *Id.*

⁷³ *Id.*

⁷⁴ See Matthew McGovern, *Biotechnology and the Patenting of Living Organisms*, 3 ANIMAL L. 221 (1997).

⁷⁵ HAMILTON & LOONEY, *supra* note 1, at 4.

⁷⁶ *Id.* at 3.

⁷⁷ *Id.*

⁷⁸ *Id.*

⁷⁹ McGovern, *supra* note 74, at *222.

on the “products of nature” doctrine in support of its ban on “living things” patents.⁸⁰ Novelty is one of the requirements for issuance of a patent.⁸¹ Because “things . . . produced by, and found in, the natural world . . . are not new,” the PTO historically determined that the novelty requirement was not met.⁸²

Patenting of multicellular life, however, has occurred for nearly seventy years. In 1930 Congress passed the Plant Patent Act.⁸³ Plant patents were limited under the initial act to only asexually propagated plant varieties.⁸⁴ The Plant Variety Protection Act of 1970, though not a part of the patent system, expanded the protections available to include the propagation and sale of a sexually propagated plant variety which is distinct from existing varieties, uniform and stable.⁸⁵

The early history of animal patents included an unsuccessful attempt to patent a dwarf, egg-laying chicken produced by a breeding process that exploited a sex-linked recessive dwarfism gene.⁸⁶ The patent application on the selective breeding process was rejected for “fail[ing] to distinctly claim the invention and due to its obviousness in light of prior art.”⁸⁷ The 1980 Supreme Court decision in *Diamond v. Chakrabarty*, involving a bacteria strain, held that an invention could not be treated as unpatentable simply because it was comprised of living matter.⁸⁸ In 1987, the Patent and Trademark Office’s Board of Ap-

⁸⁰ *Id.*

⁸¹ 35 U.S.C. § 102. “A person shall be entitled to a patent unless— (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent,”

⁸² McGovern, *supra* note 74, at *222.

⁸³ Plant Patent Act of 1930, 35 U.S.C. §§ 161-164 (1999). The driving force behind the passage of the Plant Patent Act was the previously unpatented work of horticulturist Luther Burbank. Stephen A. Bent, *Issues and Prospects in the USA*, in ANIMAL PATENTS: THE LEGAL, ECONOMIC AND SOCIAL ISSUES, (William H. Lesser ed., 1989) at 5.

⁸⁴ 35 U.S.C. § 161 (2000).

⁸⁵ 7 U.S.C. §§ 2321-2585 (2000).

⁸⁶ *In re Merat*, 519 F.2d 1390, 1391 (C.C.P.A. 1975).

⁸⁷ HAMILTON & LOONEY, *supra* note 1, at 5.

⁸⁸ *Diamond v. Chakrabarty*, 447 U.S. 303, 303 (1980); *see also* Kevin W. O’Connor, *Congressional Perspectives*, in ANIMAL PATENTS: THE LEGAL, ECONOMIC AND SOCIAL ISSUES (William H. Lesser ed., 1989) at 39. The five-to-four ruling “held that a live, human-made microorganism is patentable subject matter as a ‘manufacture’ or ‘composition of matter.’ [T]he Court noted that arguments against patentability based on potential hazards that may be generated by genetic research should be addressed to the Congress and the executive for regulation or control, not to the judiciary.” *Id.*

peals upheld the patentability of a genetically altered form of Pacific oyster.⁸⁹ The PTO commissioner then issued a formal pronouncement of the patentability, in principle, of non-human multicellular organisms that are not naturally occurring.⁹⁰

⁸⁹ *Ex parte Allen*, 2 USPQ2d 1425 (Bd. App. & Int. 1987).

⁹⁰ Donald J. Quigg, Assistant Secretary and Commissioner of Patents and Trademarks issued the following statement on April 7, 1987:

A decision by the Board of Patent Appeals and Interferences in *Ex parte Allen*, ___USPQ___ (Bd. App. & Int. April 3, 1987), held that claimed polyploid oysters are nonnaturally occurring manufactures or compositions of matter within the meaning of 35 U.S.C. 101. The Board relied upon the opinion of the Supreme Court in *Diamond v. Chakrabarty*, 447 U.S. 303, 206 USPQ 193 (1980) as it had done in *Ex parte Hibberd*, 227 USPQ 443 (Bd. App. & Int., 1985), as controlling authority that Congress intended statutory subject matter to "include anything under the sun that is made by man." The Patent and Trademark Office now considers nonnaturally occurring non-human multicellular living organisms, including animals, to be patentable subject matter within the scope of 35 U.S.C. 101.

The Board's decision does not affect the principle and practice that products found in nature will not be considered to be patentable subject matter under 35 U.S.C. 101 and/or 102. An article of manufacture or composition of matter occurring in nature will not be considered patentable unless given a new form, quality, properties or combination not present in the original article existing in nature in accordance with existing law. See e.g. *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 76 USPQ 280 (1948); *American Fruit Growers v. Brogdex*, 283 U.S. 1, 8 USPQ 131 (1931); *Ex parte Grayson*, 51 USPQ 413 (Bd. App. 1941).

A claim directed to or including within its scope a human being will not be considered to be patentable subject matter under 35 U.S.C. 101. The grant of a limited, but exclusive property right in a human being is prohibited by the Constitution. Accordingly, it is suggested that any claim directed to a non-plant multicellular organism which would include a human being within its scope include the limitation "non-human" to avoid this ground of rejection. The use of a negative limitation to define the metes and bounds of the claimed subject matter is a permissible form of expression. *In re Wakefield*, 442 F.2d 897, 164 USPQ 636 (CCPA 1970).

Accordingly, the Patent and Trademark Office is now examining claims directed to multicellular living organisms, including animals. To the extent that the claimed subject matter is directed to a non-human "non-naturally occurring manufacture or composition of matter - a product of human ingenuity" (*Diamond v. Chakrabarty*), such claims will not be rejected under 35 U.S.C. 101 as being directed to nonstatutory subjected matter.

IV. INTELLECTUAL PROPERTY RIGHTS IN ANIMALS

Developers of genetically engineered livestock may claim rights to their work in several ways. The most protective and probably most sought after is the patent. Through patent law, IPR holders can grant licenses to use the genetics and can collect royalties from the sale of animals or genetic material. Copyright and trademark may also offer some benefit and protection.

A. *Benefits of Owning IPR in Livestock*

In other industries, intellectual property provides huge profits to companies. Researchers developing cloning technology for agriculture anticipate great promise for profits as well.⁹¹ Infigen, Inc.⁹² expects that its developing cloning technology could allow dairy producers to “better manage cows of the same genetic structure through feeding and breeding, since all cows will respond similarly to nutrition and the environment.”⁹³ Cloned cows allow for improvement in milk production, “uniformity in milk quality and consistency in the content of milk.”⁹⁴

Researchers stress that the main advantage of cloning is the ability to more rapidly disseminate genetic information from elite herds to the commercial farmer. Cloning techniques would replace current practices of artificial insemination, which provide only half of the offspring’s genes, and embryo transfer. In the future, farmers will receive embryos that are clones of the most productive cows of elite herds. Within one generation, the farmer’s herd performance level would rise considerably.⁹⁵

The dairy industry’s future could include farmers “select[ing] cows that produce milk yielding the best mozzarella cheese, [and] then clon[ing] these animals so the herd is identified for that purpose. [Similarly, farmers] could . . . select and clone cows that produce nutrient enhanced milk for babies . . . [B]eef producers . . . can clone a bull

⁹¹ *Cloning Technology in the Dairy and Beef Industries*, *supra* note 42.

⁹² *ABS Global and Infigen Announce Developments in Cloning Technology Research* (visited Jan. 6, 1999) <http://www.infigen.com/1298_1news.htm>. “Infigen, Inc., is a biotechnology company commercializing applications of its cloning and related technologies in both human health and agricultural fields. The company has existing collaborations with ABS Global in the cattle breeding field and Pharming, N.V., for the production of pharmaceuticals in the milk of transgenic cattle.” *Id.*

⁹³ *Cloning Technology in the Dairy and Beef Industries*, *supra* note 42.

⁹⁴ *Id.*

⁹⁵ Woolliams, *supra* note 15.

with specific desirable traits, register the clones, and then use multiple bulls to produce semen with the same genetic makeup. Animals with similar or the same genetic [makeups] will perform consistently in the feedlot and produce meat with desirable nutritional and eating qualities for specific markets and customer demands."⁹⁶

"[C]loning technology [will] help [the] dairy and beef [industries] improve the efficiency and profitability of their operation[s]. The consumer will benefit from . . . product[s] that [are] more uniformly and cost effectively produced."⁹⁷

Beyond benefiting the dairy and beef industries, cloning can benefit those involved in other areas of agricultural research. "[R]esearch in feed efficiency and other important economic traits" is particularly improved through use of cloned animals.⁹⁸ Cloned animal use "eliminates genetic variability and focuses the results on the [specific] factors . . . tested."⁹⁹ The overall number of animals needed for research projects is decreased.¹⁰⁰

Cows and sheep are now being genetically engineered to produce valuable human proteins. Pig organs are altered to remove proteins that trigger rejection after transplant operations. Through cloning technology, these animals can be mass produced with ease. The potential applications for humans include anti-cancer and anti-aging treatments. Researchers also speculate that, for example, "a human with a failing liver could have a new one grown from . . . a cell taken out of his bone marrow."¹⁰¹

B. Patent Protection

A patent issued by the PTO grants its holder the "right . . . to exclude others from making, using or selling an invention that is described in the patent specification and delimited by the language of [the] patent claim."¹⁰² Patent holders "may seek redress [in federal district court] for an alleged unauthorized use of technology"¹⁰³ Patents do not permit their holders "to do anything with the claimed

⁹⁶ *Cloning Technology in the Dairy and Beef Industries*, *supra* note 42.

⁹⁷ *Id.*

⁹⁸ *Id.*

⁹⁹ *Id.*

¹⁰⁰ *Id.*

¹⁰¹ Lemonick, *supra* note 2; *see also* Woolhams, *supra* note 15.

¹⁰² Bent, *supra* note 83, at 7; *see also* O'Conner, *supra* note 88, at 41.

¹⁰³ Bent, *supra* note 83, at 7.

invention which [they] could not do” previously.¹⁰⁴ The existence of a patent on an invention likewise does not automatically mean that others will exploit it. Patented inventions must compete in the market on their merits and against outside economic forces.¹⁰⁵

1. Views on Patenting Livestock and Royalty Collection

The National Cattlemen’s Beef Association¹⁰⁶ (NCBA) has created policy for animal patenting.¹⁰⁷ The NCBA is opposed to applying current patenting laws and royalty payment to the future offspring of patented transgenic animals. NCBA cites legal and financial obligations that could carry on for several generations as its main challenges.¹⁰⁸

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *National Cattlemen’s Beef Association*, (visited Jan. 6, 1999) <<http://www.beef.org/ncba.htm>>. The NCBA was formed in 1898 and serves as a marketing organization and trade association

for America’s one million cattle farmers and ranchers NCBA is a consumer-focused, producer-directed organization representing the largest segment of the nation’s food and fiber industry [Its vision is a] dynamic and profitable beef industry, which concentrates resources around a unified plan, consistently meets consumer needs and increases demand NCBA coordinates state-national efforts to build demand for beef [M]ore than 230,000 cattle breeders, producers and feeders,

including 27 national breed associations and 46 state cattle associations, are represented by NCBA. NCBA members believe strongly in the “humane treatment of farm animals, the wise stewardship of natural resources and the implementation of good husbandry practices.”

Id.

¹⁰⁷ The NCBA’s policy on Animal Patents was issued in 1995 and reads as follows:

WHEREAS, NCBA supports biotechnology and genetic engineering research that can improve beef production efficiency, develop disease resistant and product enhancement traits, and provide humanitarian benefits, and

WHEREAS, the beef industry supports the principle of patenting the techniques and the processes of genetic engineering and accepts the Supreme Court ruling allowing the patenting of transgenic animals, and

WHEREAS, beef producers recognize the impracticalities of maintaining traceable records of offspring derived from patented transgenic animals, and they are unwilling to participate in potential trade resulting in monopolistic, legalistic, federal regulation with greatly increased personal liabilities,

THEREFORE BE IT RESOLVED, that NCBA does not support the application of current patenting laws and royalty payments to the future offspring of patented transgenic animals.

¹⁰⁸ See Gibb Letter, *supra* note 5.

The American Farm Bureau Federation¹⁰⁹ (AFBF) has also issued policy on biotechnology.¹¹⁰ AFBF supports patenting “animals to allow biotechnology companies to recover the costs of research and development of transgenic animals for agriculture [AFBF urges that any] royalties from patents on transgenic animals must be structured [to allow] producers a clear understanding of their obligations and [cannot] disrupt the existing livestock marketing system.”¹¹¹ Generally, AFBF is looking at patents and royalties on a practical basis. If a royalty collection system “is too complicated, producers will be much less likely to . . . purchase transgenic animals [Producers prefer to have] something that will work within their traditional marketing system [F]or a company to be successful, [AFBF] encourage[s] them to seek ways of [recovering research and development costs] that do not place undue burdens on producers.”¹¹²

C. Copyright

It is arguable that the chromosomal “recipe” for a genetically engineered animal could be protected under copyright law. To be protected under United States copyright law a work must be (1) within the constitutional and statutory definitions of a work of authorship, (2) fixed in a tangible medium of expression, and (3) original.¹¹³ The individual sequence of amino acids in an animal’s DNA is easily analogized to the makeup of computer programs. Computer programs can be protected under copyright law.¹¹⁴

¹⁰⁹ *This is Farm Bureau* (visited Jan. 6, 1999) <<http://www.fb.com>>. The American Farm Bureau Federation was founded in Chicago in 1919 and is the nation’s largest farm organization, counting 4.7 million families in 50 states and Puerto Rico as members. It “is a voluntary organization of member families joining together to solve common problems.” The Farm Bureau is politically active, but strives to be nonpartisan. It “seeks to further its members’ goals. It is involved in local, state, national and international issues that affect its members.” As early as 1920 the Farm Bureau issued the following statement of purpose: “The purpose of Farm Bureau is to make the business of farming more profitable, and the community a better place to live. Farm Bureau should provide an organization in which members may secure the benefits of unified efforts in a way which could never be accomplished through individual effort.” *Id.*

¹¹⁰ Electronic mail from Kenneth E. Olson, Dairy And Animal Health Specialist, American Farm Bureau Federation, to S. Brett Offutt (Nov. 9, 1998) (on file with *San Joaquin Agricultural Law Review*).

¹¹¹ *Id.*

¹¹² *Id.*

¹¹³ 17 U.S.C. § 102(a) (2000).

¹¹⁴ 1 P. GOLDSTEIN, COPYRIGHT: PRINCIPLES, LAW AND PRACTICE § 2.15.2 (1989).

For copyright protection to apply, works must be original.¹¹⁵ They cannot be copies of existing works.¹¹⁶ A copyrightable work must possess “at least some minimal degree of creativity,” however, “even a slight amount will suffice.”¹¹⁷ Originality is not a stringent standard.¹¹⁸

A work is original if it is the independent creation of its author. A work is creative if it embodies some modest amount of intellectual labor. A work is novel if it differs from existing works in some relevant respect. For a work to be copyrightable, it must be original and creative, but need not be novel.¹¹⁹

Later works may be copyrightable so long as they are neither directly nor indirectly derived from a prior work. This concept is described in an often-quoted passage from Judge Learned Hand:

[I]t is plain beyond peradventure that anticipation as such cannot invalidate a copyright. Borrowed the work must indeed not be, for a plagiarist is not himself pro tanto an “author,” but if by some magic a man who had never known it were to compose anew Keats’s Ode on a Grecian Urn, he would be an “author,” and, if he copyrighted it, others might not copy that poem, though they might of course copy Keats’s But though a copyright is for this reason less vulnerable than a patent, the owner’s protection is more limited, for just as he is no less an “author” because others have preceded him, so another who follows him, is not a tort-feasor unless he pirates his work If the copyrighted work is therefore original, the public demesne is important only on the issue of infringement; that is, so far as it may break the force of the inference to be drawn from likenesses between the work and the putative piracy. If the defendant has had access to other material which would have served him as well, his disclaimer becomes more plausible.¹²⁰

Even if the genetic information contained in a genetically engineered farm animal is protectable under copyright law, the protection offered appears limited. The creation of an animal having certain desirable traits involves developing amino acid chains within the animal’s DNA which produce those traits. It is the amino acid chain which could theoretically be protectable under copyright law. Problems arise for the researchers who discover the proper sequences. Later researchers may change just one amino acid in the chain from the copyrighted amino acid sequence and still create the same desired trait in

¹¹⁵ Feist Publications, Inc. v. Rural Tel. Serv. Co., 449 U.S. 340, 345 (1991).

¹¹⁶ *Id.*

¹¹⁷ *Id.*

¹¹⁸ *Id.*

¹¹⁹ Baltimore Orioles, Inc. v. Major League Baseball Players Ass’n, 805 F.2d 663, 668 n.6 (7th Cir. 1986).

¹²⁰ Sheldon v. Metro-Goldwyn Pictures Corp., 81 F.2d 49, 53-54 (2d Cir. 1936), *aff’d*, 309 U.S. 390 (1940).

an animal.¹²¹

D. Trademark

Researchers and developers of genetically engineered animals could potentially benefit from trademark protection. If, for example, a researcher developed a genetic line of superior beef cattle, the researcher could establish a trademark to distinguish its line of cattle from those of other cattle producers. Trademark law prevents others from using the same or similar marks that create a likelihood of confusion, mistake, or deception.¹²² A researcher may identify his superior line of beef cattle as "Better Beef." The trademark "Better Beef" informs consumers of the product's identity and its origin.

Merchants, manufacturers, and service providers can use any word or mark on goods or services unless the use violates another's trademark rights or is contrary to law. The essence of trademark law is the right to exclude others from using marks. A researcher or developer of genetically engineered livestock could seek protection under both state common law and through federal trademark property rights law. The Lanham Act¹²³ is the federal legislation providing trademark protection.¹²⁴

V. ROYALTIES

IPR holders may best benefit through some system of royalty tracking and collection. In order for such a system to work, several factors must exist. First, consumers must be willing to pay the additional costs in return for the benefit received through purchase of a genetically improved product. Second, researchers, developers, farmers, and producers must be willing to put forth any extra efforts required to maintain a royalty collection system. Third, the system itself must work efficiently and effectively without great detriment to existing livestock marketing structures.

¹²¹ Christina Dougherty, Ph.D., Presentations to Biotechnology Course at University of Arkansas School of Law (Fall 1998).

¹²² 15 U.S.C. § 1052(d) (2000).

¹²³ 15 U.S.C. §§ 1051-1127 (2000).

¹²⁴ See generally ROBERT C. DORR & CHRISTOPHER H. MUNCH, PROTECTING TRADE SECRETS, PATENTS, COPYRIGHTS, AND TRADEMARKS § 3 (2d ed.1995); DONALD A. GREGORY ET AL., INTRODUCTION TO INTELLECTUAL PROPERTY LAW 4 (1994); DONALD S. CHISUM & MICHAEL A. JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY LAW § 5 (1992) (providing detailed information on the extent of trademark law, protections, and available remedies).

A. Licenses and Royalties

A license is nearly the equivalent of renting property. The owner of rights to intellectual property, such as the genetic information encoded in an animal, transfers a portion of the rights to another person in exchange for a determined fee. The arrangement is contractual; all terms should be specified in the lease.¹²⁵

Licensing may pose an advantage for operations seeking to market their livestock to smaller or start-up farms and companies. Capital investment is less since the livestock and genetics do not need to be purchased. Long-term commitments are not required. IPR owners retain some rights and control over the property.¹²⁶

Disadvantages exist with licensing as well. The IPR owner does lose some rights in the property for a period of time. Licensees may create problems for the IPR owner by breaching contract terms, filing bankruptcy, violating environmental laws, or suffering financial difficulties. This may result in the IPR owner being unable to reap any benefit from the property for some time.¹²⁷ Problems with licensees may end up costing the IPR owner a substantial sum of additional money. Poorly drafted licenses may grant the licensee more rights than anticipated. Finally, licensees may gain enough knowledge during the licensing period to become a competitor of the IPR owner.¹²⁸

“Royalties are monetary payments made by a licensee to a licensor in consideration of the license.”¹²⁹ Royalties may be set by the terms of a licensing agreement.¹³⁰ Typically the amount of royalty to be paid is a pre-determined portion of gross or net profits, but can be a single up-front lump-sum royalty payment for a paid-up license.¹³¹ A number of factors must be considered before setting a royalty payment rate. Smith & Parr provide five such factors in their book:

¹²⁵ GORDON V. SMITH & RUSSELL L. PARR, *INTELLECTUAL PROPERTY: LICENSING AND JOINT VENTURE PROFIT STRATEGIES* 63-64 (1993).

¹²⁶ *Id.* at 64.

¹²⁷ *Id.*

¹²⁸ *Id.* at 65.

¹²⁹ Gregory, *supra* note 124, at 297.

¹³⁰ *Id.* at 297-98.

¹³¹ *Id.* Lump-sum royalty payments are not well suited to genetically engineered livestock. As indicated previously, farmers and producers would be less likely to purchase a genetically engineered animal if the purchase required paying a large royalty payment up front. A running royalty system providing payments at the time of sale or at the time offspring or other genetic material is sold has more potential for success in agricultural markets.

1) Investment rates of return available from alternative forms of investment possessing comparable elements of risk. 2) The value of the intellectual property that is the subject of the licensing. 3) The amount of complementary monetary and tangible assets required to commercialize the intellectual property. 4) The relative investment risk associated with the complementary monetary and tangible assets. 5) The investment risk associated with the intellectual property introduced by factors such as advancing and competing technology, industry economics, governmental regulations, and other factors.¹³²

B. Will Consumers Support Increased Prices?

For a royalty system to be workable, each buyer in the chain must be willing to pay an increased price to cover royalty payments made to breeders/researchers. While some experts do not foresee dramatic changes in the way genetically engineered livestock are marketed, a number of breeders are already capitalizing on better genetics.¹³³

In 1997, Joe Elliott, an Adams, Tennessee Angus breeder, recognized that his customers were paying him more money to get better genetics in their cattle. The customers, however, only realized a benefit through "having more weight to sell [at market price] and better replacement heifers."¹³⁴ The breeder "set out to change that" by hosting a customer calf sale.¹³⁵ Only calves sired by the breeder's bulls were eligible for sale. Such sales allow buyers access to detailed information on the calves' genetic history and carcass data. Buyers benefit from having a large group of cattle with similar genetic makeup offered at one time. Through the special sale, the breeder's customers were able to bring in anywhere from \$3-\$8/hundredweight (cwt.) over the market price for steers and \$10-\$25/cwt. over market price for heifers.¹³⁶ Several Kansas and Georgia breeders implementing similar sales strategies have experienced the same results.¹³⁷

¹³² SMITH & PARR, *supra* note 125, at 125.

¹³³ Becky Mills, *Making Customer Genetics Pay: Filling Commercial Customers' Needs Means Doing More Than Just Selling Bulls*, Angus J., (June 1998) (visited Oct. 24, 1998) <http://www.angus.org/journal/98_06hre/value.htm>.

¹³⁴ *Id.*

¹³⁵ *Id.*

¹³⁶ *Id.*

¹³⁷ *Id.* Ken Stielow's Bar S Ranch in Paradise, Kansas and Fink Beef Genetic Systems of Manhattan, Kansas reported average sales of \$3 to \$9 over market price for their customer only sales; see also Ed Bible, *Feeder-Calf Sales Capitalize on Angus Genetics*, Angus J. (Aug. 1998) (visited Oct. 24, 1998) <http://www.ccp.com/~angus/journal/98_08aug/feeder.htm>.

A number of entities are currently engulfed in genetic research revolving around consumer demands for beef. The NCBA's Carcass Merit Traits project began in 1998 and is expected to last for forty-two months. "Five universities and 16 breed associations are [working with] NCBA on [the] project."¹³⁸ Past research indicated that:

[C]onsumers are demanding a more consistent beef product in the retail case. [A] consumer market exists for a product that "guarantees" tenderness. [B]eef flavor and tenderness are the primary drivers for consumer satisfaction. [T]he greatest improvements in beef quality and consistency can be made through the genetic selection for economically important carcass traits.¹³⁹

The current project's goal "is to provide the tools and mechanisms to genetically identify superior animals in the U.S. beef population which will produce progeny with the greatest potential for meeting the demands of [today's] consumers" as well as the consumers of tomorrow.¹⁴⁰ At the close of the project, "validated markers will be . . . commercially available to the industry,"¹⁴¹ and breed associations will have extensive databases to aid in developing important carcass traits within each breed.¹⁴²

"Approximately 12,000 progeny will be evaluated in the study."¹⁴³ Ten DNA sires from each breed will individually produce a minimum of fifty progeny. Over ninety percent of the beef cattle seedstock in the United States will be represented in the project. "The [Expected Progeny Differences (EPDs)] and DNA selection tools developed from the project will have a major impact on the beef industry."¹⁴⁴ "The use of DNA markers by producers will greatly reduce the time and cost of testing sires for the critical carcass traits Genetic change will . . . be greatly accelerated [T]he beef industry will be more dynamic in meeting consumers needs."¹⁴⁵

¹³⁸ *The Carcass Merit Traits Project: "Fitting the Pieces Together"*, 4 NCBA Q. RES. UPDATE (July-Sept. 1998).

¹³⁹ *Id.*

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.*

¹⁴⁴ *Id.*

¹⁴⁵ *Id.*

C. Managing IPR in Livestock

The world was awakened to the realities of cloning when Dolly was exposed to the world in 1997.¹⁴⁶ Dolly's creators have suggested potential commercial applications of the technology employed with Dolly. Cloned embryos for high quality beef bulls or dairy cows could be marketed to farmers through a catalogue describing each embryo's desirable traits. Farmers could then choose, for example, the sex of the embryo (male for beef and female for milk).¹⁴⁷ Cloned embryos would be delivered to the farmer in a way similar to the method of delivery for semen straws today.¹⁴⁸

Especially where beef bulls are concerned, farmers will likely be passing the purchased genes on to a second generation of cattle. Ethical concerns will be stronger against the development of a "terminator gene" that renders second generations sterile.¹⁴⁹ According to Marty Strange, "sterilizing an end product means putting an end to the heart of what is agriculture."¹⁵⁰ How do the original embryo creators get compensated for the benefit passed on to subsequent generations?¹⁵¹ As previously mentioned in this article, the initial price could be set high enough to protect rights in later generations.¹⁵² A disadvantage to this method is its cost prohibitiveness to buyers. The cost required to protect the seller's interest may be so high as to eliminate some or all of the market. Sellers may wish to set a more reasonable fee for their services and profit from their established record of good will.

¹⁴⁶ *Scientists at the Roslin Institute Publish Scientific Breakthrough, ability to clone sheep through nuclear transfer from somatic cells*, Roslin Institute Online News Release (Feb. 24, 1997) (visited Jan. 6, 1999) <<http://www.2.ri.bbsrc.ac.uk/library/press/pn97-01.htm>>.

¹⁴⁷ Woolliams, *supra* note 15.

¹⁴⁸ *Id.*

¹⁴⁹ See generally *New Technology "Terminates" Food Independence: Seed Sterilization Has Profound Implications*, (visited Jan. 6, 1999) <http://thewinds.org/archive/newworld/terminator_seeds04-98.html>.

¹⁵⁰ Marty Strange, *supra* note 10.

¹⁵¹ See Ralph T. King, Jr. & Gautam Naik, *Science: Tiny Company Could Emerge A Big Winner*, WALL ST. J., Feb. 25, 1997 (reporting that in the case of Dolly, scientists do not expect to individually earn much income from royalties. Dr. Ian Wilmut, Dolly's creator, earns a government salary near \$60,000 and may eventually collect royalty payments for Dolly totaling \$16,181.) Such income seems inadequate for a man whose fame has caused his name to be mentioned along with science greats including Charles Darwin and Albert Einstein. See generally Michael Specter & Gina Kolata, *After Decades and Many Missteps*, SACRAMENTO BEE, Mar. 9, 1997, at F01.

¹⁵² GREGORY, *supra* note 124, at 298.

1. Royalty Collection Mechanisms for Patented Livestock¹⁵³

The ability and means of royalty collection available varies according to the livestock involved.¹⁵⁴ Several proposals for royalty collection methods have been offered, including (1) a qualified sales process; (2) registration; and (3) pooled royalties.¹⁵⁵ Each has distinct advantages and disadvantages for livestock. The answer may lie in a combination of the methods and the addition of newer technology.

The qualified sales proposal was actually offered as an amendment to the United States Patent Act.¹⁵⁶ “[A]uthorized seller(s) . . . market animals for which [a] patent holder has waived the right to sue farmers for infringement when used for breeding.”¹⁵⁷ The system is voluntary.¹⁵⁸ Professor Lesser suggests that “[t]he only reasonable business explanation for waiving royalty rights is the anticipation of higher profits using qualified sales”¹⁵⁹ Trait-carrying brood animals carry a higher price to recover research and development costs. Producers would only be willing to pay the higher premium until the specific trait is spread throughout a herd. After that there would be no need to expend extra funds, as the benefits can be had from the existing herd.¹⁶⁰ The providers of brood stock would necessarily have to recoup their costs along with enough profit to make a comfortable income.

2. Data Collection

The beef industry may already have the answer to the complex record keeping required to manage IPR in livestock.¹⁶¹ Texas cattle producers have implemented technology to lower costs and increase profits.¹⁶² One such solution is a small plastic tag attached to each cow's ear containing a radio-frequency transponder.¹⁶³ When cows pass under a reader, the transponder sends that cow's identification (ID) number

¹⁵³ See Lesser, *supra* note 9.

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ *Id.*

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ *Id.*

¹⁶¹ See Leigh Buchanan, *From Steer to Eternity*, INC., Mar. 15, 1998, at 66.

¹⁶² *Id.*

¹⁶³ *Id.*

to a computer.¹⁶⁴ The process works much like the bar code readers located at nearly every grocery check-out in America.¹⁶⁵

The industry term for this type of auditing system is “source verification and performance-data tracking.”¹⁶⁶ Spreadsheets for each cow contain information on nearly every event in the animal’s life, including a history of previous owners and health and vaccine information.¹⁶⁷

The dairy industry has implemented similar technology. Some dairy producers are using “electronic identification collars.”¹⁶⁸ Each cow “wears an electronic collar around her neck. When she enters the milking parlor, a device over the door reads the number off her collar and she is assigned to a stall.”¹⁶⁹ Computers “record[] milking time and milk weight. All of [the] information, including health, feed intake and medical treatment, is sent to [the producer’s computer where a database has been created] to analyze each cow.”¹⁷⁰ It seems only a small step to use the same technology to record genetic information for each animal and compute royalty payments due to IPR holders.

Electronic technology for identifying livestock has been in use since the early 1980s.¹⁷¹ Its first application was to automatically dispense feed to animals. Producers were later able to “record information coming from the milking meters.”¹⁷² Similar systems have evolved into widespread electronic identification of livestock. Large organizations, such as the Holstein Association, use electronic ID systems to register cattle. The swine industry has also implemented electronic ID systems. Collars were first used “to automatically feed specified amounts of feed to gestating sows.”¹⁷³ The industry quickly moved to using ear tags to reduce costs¹⁷⁴ and increase reliability. Electronic ID allows producers “to track their animals all the way to the packing plant [and] “may help guarantee export buyers that they can track the

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*; see also Bible, *supra* note 137.

¹⁶⁸ JoAnn Wilcox, *Positive ID: Livestock Producers Are Using Space-age Tools Just Like Their Crop-farming Neighbors*, SUCCESSFUL FARMING ONLINE (visited Nov. 16, 1998) <<http://www.agriculture.com/sfonline/sf/1998/may/id/index.html>>.

¹⁶⁹ *Id.*

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

¹⁷² *Id.*

¹⁷³ *Id.*

¹⁷⁴ *Id.* In 1998, “ear tags, ear buttons and implants cost from \$3 to \$13 each. The collars cost from \$45 to \$55 each.” *Id.*

animal to the original owner.”¹⁷⁵

This technology itself is rapidly advancing. Newer technology eliminates the need for an animal to pass under a scanning device to have electronic information read from its ear tag or other tracking device. Radio Frequency Identification (RFID) eliminates “the need for . . . unobstructed line-of-sight or physical contact between the [tracking device] and the reader.”¹⁷⁶ RFID information “can be read quickly and accurately in milliseconds through a variety of non-metallic materials such as dirt, paint and cement.”¹⁷⁷ RFID technology identifies a tracking device through use of radio frequencies. Microchips embedded in ear tags or injected under the skin of animals emit radio frequencies which are read and translated for various applications.¹⁷⁸

Electronic ID systems using injected microchips are widely used in Europe. Companion animals there must be identified and often animal passports are required for crossing borders. Other areas of the world use electronic identification systems voluntarily to track lost pets, for example. Researchers have used electronic identification for years when tracking salmon in migratory studies.¹⁷⁹

The automation and computerization of the livestock and meat packing industries has brought about a need for data acquisition systems. Producers have implemented automated record keeping and inventory controls supported by microchip technology to replace the more labor intensive tattooing and ear clipping systems. International trade of meat products can benefit, as well, from electronic identification to trace diseases or drug residues that could affect meat sales. Outbreaks of “mad cow disease,” swine fever, and foot and mouth disease in livestock can be limited and human food safety increased through effective electronic identification of animals.¹⁸⁰

Microchips operating as passive¹⁸¹ electronic devices work in combi-

¹⁷⁵ *Id.*

¹⁷⁶ Destron Fearing Corp., *Electronic Identification* (visited Dec. 1, 1998) <<http://www.destronfearing.com/elect/elect.html>>. Destron Fearing Corporation manufactures and markets a variety of animal identification products and may be contacted through its website or at 490 Villaume Avenue, South St. Paul, MN 55075-2445.

¹⁷⁷ Y-TEX Corp., *Quality Livestock Identification & Pest Control Systems RFID Electronic Identification* (visited Dec. 1, 1998) <<http://www.y-tex.com/rfid.html>>. Y-TEX Corporation has been in the livestock ear tag business for over 30 years. Y-TEX can be contacted through its website or at PO Box 1450, Cody, WY 82414.

¹⁷⁸ Destron Fearing Corp., *supra* note 176.

¹⁷⁹ *Id.*

¹⁸⁰ *Id.*

¹⁸¹ *Id.* Microchips are inactive in an animal’s body until a scanner sends a low radio frequency signal to the chip. The signal provides enough power for the microchip “to

nation with reading and scanning systems. When scanned by a compatible electronic identification scanner,¹⁸² the microchip provides the animal's unique identification number. "Scanners generate a magnetic field that is intercepted by the microchip [M]icrochip[s] use[] the energy . . . to power [themselves] and transmit a return signal" ¹⁸³ The return signal provides the animal's alpha-numeric identification code and "is displayed on a video display or can be relayed via computer interface to other equipment [I]dentification number[s] can be linked with data about the . . . animal" in addition to verifying its identity.¹⁸⁴

The chips currently "rang[e] in size from 11 to 28 millimeters in length and 2.1 to 3.5 millimeters in diameter."¹⁸⁵ During manufacture "each microchip is individually [programmed] to store a unique, permanent, 10 to 15 digit alphanumeric identification code."¹⁸⁶ Microchips and their antenna are sealed in inert glass capsules.¹⁸⁷

send its unique code back to the scanner and positively identify the animal." By "powering up" only when read by a scanner, microchips easily last the lifetime of the animal. *Id.*

¹⁸² *Id.* Scanners are available to suit the needs of any size operation. Portable and mini-portable hand held readers are available in addition to stationary scanners. Stationary scanners are often used where tagged animals move through a passageway. "Stationary scanners are usually coupled to other equipment, or fiber optic lines to transmit data directly to a remote data collection site." *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.* Just as genetic engineering and cloning face outspoken opponents, microchip technology has its critics as well. One group, whose internet site focuses much attention to UFOs and alien life on earth, includes discussion of implantable biochips. The concern, or perhaps forewarning, is that this type of technology will next be directed toward tracking humans. It compares implantable biochips in humans to the "Mark of the Beast," and includes the following Ralph Nader quote: "Is there a number or a mark planned for the hand or forehead in a new cashless society? Yes, and I have seen the machines that are now ready to put it into operation." The website describes biochip applications for pet identification and livestock tracking. It suggests that humans are next and describes a concept system called KIDSCAN which never materialized. KIDSCAN involves implanting biochips under childrens' skin which would transmit a signal to a satellite. "The satellite would then relay the child's location to police via a map on a computer monitor" According to the website article, local ACLU chapters in Arizona objected to the plan. The ACLU claimed that the "police could use the system to enforce curfew laws or trace the movements of teen-agers who had not agreed to such scrutiny." *Implantable Biochips* (visited Dec. 28, 1998) <<http://www.parascope.com/mx/1096/beast2.htm>>.

¹⁸⁷ Destron Fearing Corp., *supra* note 176.

Microchips are typically implanted into an animal within hours of birth using a syringe in “a procedure similar to a routine vaccination [T]he device remains [implanted under the animal’s skin] for life.”¹⁸⁸ Implantation of a microchip under an animal’s skin decreases the chance of it being lost or altered. Companies developing implantable microchips have developed additional technology to prevent chips from migrating. When a microchip migrates, it could become difficult to detect and may be easily missed when an animal is scanned. RFID microchips are covered with “a porous polypropylene polymer sheath” to prevent migration within animal tissue.¹⁸⁹ The covering increases retention in tissue “by promoting the development of fibrocytes and collagen fibers around the implant, thus inhibiting movement within the animal.”¹⁹⁰

Injectable microchips received Food and Drug Administration (FDA) approval in 1996 for use in livestock. Equipment used in electronic identification of livestock must also comply with the Federal Communications Commission (FCC) Part 15 Regulations for Electromagnetic Emissions.¹⁹¹ Some state laws have already been affected by microchip electronic identification systems. Washington State includes in its Brand Laws a definition for “microchipping.”¹⁹² Washington has enacted statutes making it a gross misdemeanor to remove microchips implanted in horses or re-implant microchips into different horses to defraud subsequent purchasers.¹⁹³

3. Royalty Collectives

The obvious problem with royalty collection for genetically engineered livestock is the resulting wide dispersment of specific genes in

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ *Id.*

¹⁹¹ *Id.*

¹⁹² “Microchipping” is defined in WASH. REV. CODE § 16.57.010(13) (2000) as: the implantation of an identification microchip or similar electronic identification device to establish the identity of an individual animal: (a) In the pipping muscle of a chick ratite or the implantation of a microchip in the tail muscle of an otherwise unidentified adult ratite; (b) In the nuchal ligament of a horse unless otherwise specified by rule of the director; and (c) In locations of other livestock species as specified by rule of the director when requested by an association of producers of that species of livestock.

¹⁹³ WASH. REV. CODE § 16.57.405. (2000).

a short time.¹⁹⁴ Potentially, a large number of IPR owners may have relatively small claims to royalty payments. For them the prospect of managing IPR records and collecting payments is not economically feasible.

In the world of copyrights, organizations exist whose purpose is to administer copyrights held by a large number of owners.¹⁹⁵ A similar system could feasibly be implemented to administer intellectual property rights in livestock. One or more organizations could provide centralized administration of property rights in the specific genetics of animals. The result would be a greater collection rate at a cost lower than if each IPR holder was to enforce his rights separately.¹⁹⁶

Royalty collective organizations would best serve small- to medium-size rights holders. Larger operations may find it more economical to employ their own staff and technology to administer royalty rights.¹⁹⁷

a. Structure and Operation

The "source verification and performance-data tracking system"¹⁹⁸ generates periodic¹⁹⁹ reports sent directly to an Internet site accessible by the collective agency.²⁰⁰ The agency calculates payments due to its rights holders, prepares statements showing payments owed by various parties, invoices those parties, retains its administration fees, and distributes payments to rights holders.²⁰¹ By this method, agency repre-

¹⁹⁴ See Lesser, *supra* note 9.

¹⁹⁵ STANLEY M. BESEN & SHEILA NATARAJ KIRBY, COMPENSATING CREATORS OF INTELLECTUAL PROPERTY: COLLECTIVES THAT COLLECT 1 (1989).

¹⁹⁶ *Id.* at 3.

¹⁹⁷ See *id.* (describing " 'small' rights" as "those rights for which the cost of administration is large relative to their value . . . [U]nless [some] collective [organization existed to administer rights,] no market for these rights" would likely exist. Administrative costs would exceed revenues from royalty payments.)

¹⁹⁸ See *supra* text accompanying notes 160-66.

¹⁹⁹ These could be generated hourly, daily, weekly or monthly, depending upon the size of the operation and number of head passing through in a given time. Royalty payments under license agreements are often paid on a quarterly basis. GREGORY ET AL., *supra*, note 124, at 299. Timing of payments would be determined by the IPR holders and the collective agencies.

²⁰⁰ Buchanan, *supra* note 161.

²⁰¹ The potential exists for numerous collective agencies to operate independently of one another. Rights holders would have the opportunity to shop around for the best deal offered by the agencies in a manner similar to that which consumers employ when choosing a long distance telephone carrier. Such a situation would require that each agency initially identify and separate the rights of its clients from the rights other people may have in the same source transmission.

sentatives rarely need to visit actual livestock marketing locations. Periodic inspections would, however, be scheduled. Inspections would verify that equipment is working properly and procedures are followed to ensure that IPR holders are not cheated out of royalty payments.²⁰²

Royalty collection agencies could not exist unsupervised or unregulated.²⁰³ A government body will be necessary to guide resolution of disputes between agencies and their clients or between agencies and those supplying electronic transaction records.²⁰⁴ Disputes may center on fees charged by the agency, the amount of royalty collected or other contractual provisions.²⁰⁵

Governmental regulation is required to prevent agencies from exploiting their market power. Since collective agencies could develop as monopolistic organizations, a government body will have oversight responsibility to intervene and prevent abuses.²⁰⁶

VI. CONCLUSION

Genetic engineering, including cloning, in animals is a reality. The United States Patent and Trademark Office is granting patents for genetically engineered animals. Genetic technology is advancing rapidly in light of the many religious, moral, ethical, and environmental concerns. Developers of new technology must recover their costs in one form or another. Large lump sum payments "up front" prevent small farmers from benefitting from advanced technology.

Consumers have expressed not only an interest in, but a desire for improved agricultural products. With such demand, retail prices may rise with little or no objection from consumers. A system of royalty payments helps spread costs over a wider area and allows small farmers access to advanced technology.

Concerns over the complexity of implementing a royalty system can be eased by expanding technology already in place in the livestock industry. Electronic identification systems already track health and ownership data for many varieties of livestock. Data bases currently in use can record additional genetic information including names and/or identification numbers for holder of intellectual property rights. All information from the electronic identifications and computer data bases may be available for access on the internet.

²⁰² See BESEN & KIRBY, *supra* note 195, at 5.

²⁰³ *Id.* at 64.

²⁰⁴ *Id.*

²⁰⁵ *Id.*

²⁰⁶ *Id.*

Royalty collectives remove much of the additional labor required for managing royalties. Without ever coming into contact with livestock animals, collectives can access required information from the internet or through direct computer networking and determine which owners of intellectual property rights are owed royalty payments and from whom they are owed. Royalty collectives manage the system through billing and dispersal of royalty payments. The collectives are supported through fees subtracted from royalty checks sent to IPR holders.

Royalty systems for livestock will not evolve overnight. Participants from several sectors must be willing to work together to get a system up and running. The task may lie on the shoulders of some of the largest livestock integrators in the country to begin the process.

Regardless of who takes the first step and develops a royalty collection system for genetically engineered livestock, the end result for consumers will be a higher quality, safer food product.