Comments

Controlling Biotech Babies Following the Transfer of Self-Replicating Inventions

I. INTRODUCTION

Modern biotechnology allows the production of transgenic animals that have either unique characteristics or that produce a valuable biological product.[1] Transgenic animals are developed by inserting the gene coding for the unique characteristic or valuable product into the genome of an animal.[2] This gene is inserted into the genome of the animal in such a way as to allow that gene to be passed on to that animal's progeny through reproduction.[3] Genes coding for regulators, such as hormones, have been inserted into various mammals causing alterations in the physical characteristics of the resulting

1. Van Brunt, *Molecular Farming: Transgenic Animals as Bioreactor*, 6 BIOTECHNOLOGY 1149-50 (1988).

2. Genes are inserted into a transgenic animal by injecting the gene containing the desired genetic information for a particular trait into an embryo. This gene is then incorporated into the genetic material of the embryo so that the gene is carried along with each cell of the embryo as it divides and grows into a mature animal. For a discussion of the technical aspects of producing transgenic animals, see generally B. HOGAN, F. CONSTANTINI & E. LACY, MANIPULATING THE MOUSE EMBRYO: A LABORATORY MANUAL (1986) [hereinafter B. HOGAN].

Recently, transgenic animals have been produced using a technique that allows the desired gene to be inserted into the genome of an animal at a specific location. *See* Capecchi, *Altering the Genome by Homologous Recombination*, 244 SCI. 1288 (1989).

3. A transgenic animal generally has the useful gene inserted into all of its cells including the germ cells (sperm or eggs). Because the transgenic animal's germ cells contain the gene, sperm or eggs produced from those germ cells also contain the gene, thereby allowing that gene to be passed on to progeny. The progeny would also have the useful gene inserted into all of its cells. *See generally* B. HOGAN, *supra* note 2.

transgenic animals such as growth rate and fat content of the animal's meat.[4] In other transgenic animals, genes coding for a valuable biological product such as tissue plasminogen activator (TPA)[5] have been inserted into transgenic animals in a manner that results in the production of TPA in the milk of that animal.[6]

The first transgenic animals produced by modern biotechnology have only recently been commercialized and widely distributed.[7] Currently only transgenic mice are distributed but recent reports of the production of transgenic cattle indicate that within only a few years wide distribution and commercialization of transgenic cattle will occur.[8]

In a landmark decision, the Supreme Court in *Diamond v. Chakrabarty*[9] laid down the rule that an invention made up of living cells could not be treated as unpatentable subject mater simply because it was made up of living matter. Immediately after this decision the Patent and Trademark Office (PTO) began granting patents covering various organisms including yeasts and bacteria.

After subsequent court cases,[10] the PTO began to allow patents

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4. Palmiter, Brinster, Hamner, Trumbauer, Rosenfeld & Evans, *Dramatic Growth of Mice That Develop from Eggs Microinjected with Metallothionein-Growth Hormone Fusion Genes*, 300 NATURE 611 (1982).

5. Tissue plasminogen activator (TPA) is an enzyme that can dissolve blood clots and is used in treating patients who have had myocardial infarctions (heart attacks). The administration of TPA has been shown to reduce the tissue damage to the heart if administered to patients having an acute myocardial infarction within 8-24 hours of the acute event. *See generally* McNeill, Cunningham, Flannery, Dalzell, Wilson, Campbell, Khan, Patterson, Webb & Adgey, *A Double Blind Placebo Controlled Study of Early and Late Administration of Recombinant Tissue Plasminogen Activator in Acute Myocardial Infarction*, 61 BRIT. HEART J. 316 (1989).

TPA has attracted much interest because it is one of the first genetically engineered products to be widely used. Genetically engineered TPA was commercially developed by Genetech and is sold under the name Activase. *Important New Heart Attack Drug is Patented*, Bus. Wire, Jan. 12, 1991, *available in* LEXIS, NEXIS Library, OMNI File.

6. Pittins, *A Milk Protein Promoter Directs the Expression of Human Tissue Plasminogen Activator cDNA to the Mammary Gland in Transgenic Mice*, 85 PROC. NAT'L. ACAD. SCI. 5874 (1988); *Expression of Heterologous Proteins by Transgenic Lactating Mammals*, Int'l. Pat. App. No. WO 88/01648; *Peptide Production*, Int'l. Pat. App. No. WO 88/00239; Schneider, *Texas Researchers Develop 4 Gene-Altered Calves*, N.Y. Times, June 8, 1990, § A, at 1, col. 2; Ebert, *A Moloney MLV-Ret Somatotropin Fusion Gene Produces Biologically Active Somatotropin in a Transgenic Pig*, 2 MOL. ENDOCRINOL. 277 (1988); Simons & Land, *Transgenic Livestock*, 34 J. REPROD. FERT. SUPPL. 237 (1987).

7. The mice described in Leder & Stewart, *Transgenic Non-Human Mammals*, U.S. Pat. No. 4,736,866 (1988), are currently being marketed by the Dupont Corp. under the tradename Onco-Mouse. The Onco-Mouse contains at least one copy of the myc oncogene making the mouse more susceptible to developing various tumors than normal mice. The Onco-Mouse is used in medical research to screen various compounds for potential carcinogenicity. *See Customizing Animals From a Single Cell*, Newsday, Feb. 25, 1992, at 57.

8. *See, e.g.*, Schneider, *supra* note 6, at col. 2.

9. 447 U.S. 303 (1980).

10. *Ex parte* Hibberd, 227 U.S.P.Q. (BNA) 443 (B.P.A.I. 1985) (holding that the

covering plants and animals.[11] Thus, under current U.S. patent law, any microbe, cell, plant, or animal may be patented as long as it meets the requirements of patentability[12] set forth in title thirty-five of the U.S. Code.[13]

Given that man-made animals can be patented[14] and the rapidly expanding number of both issued patents[15] and patent applications on transgenic animals,[16] the degree of control the patentee may exercise over patented transgenic animals which have been transferred to a third party using a sale,[17] a field of use license,[18] lease,[19] or bailment[20] becomes a critical consideration in deciding which type of transfer to use.[21] If the technology is transferred without sufficient control over the technology's use, patentees risk losing all of their research and development efforts expended to develop the technology.

To determine which type of transfer to use, one must consider the

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Plant Patent Act and the Plant Variety Protection Act do not prevent plants from being patentable subject matter under 35 U.S.C. §101); *Ex parte* Allen, 2 U.S.P.Q.2d (BNA) 1425 (B.P. A.I. 1987).

11. 1077 Off. Gaz. Pat. Office 24 (April 1987) (news release by Commissioner of Patents on PTO position on animal patents).

12. For a general discussion of the patentability issues in the context of biotechnology inventions, see Murashige, *Section 102/103 Issues in Biotechnology Patent Prosecution*, 16 A.I.P.L.A.Q.J. 294 (1989); Lentz, *Adequacy of Disclosures of Biotechnology Inventions*, 16 A.I.P.L.A.Q.J. 314 (1989).

13. For any invention to be patented, it must meet the requirements of 35 U.S.C. §§ 101, 102, 103 and 112. *See generally*, D. CHISUM, PATENTS §§ 1.01-1.06, 3.01-3.08, 4.01-4.04, 5.01-5.06, 6.01-6.04 (1986). These sections of the U.S. Code set forth the requirements that an invention be novel, non-obvious to a person of ordinary skill in the art, and that the patent application describe the invention in sufficient detail to enable others to make and use the invention.

14. *See* Diamond v. Chakrabary, 447 U.S. 303 (1980).

15. Leder & Stewart, *Transgenic Non-Human Mammals*, U.S. Pat. No. 4,736,866 (1988); Evans, Palmiter & Brinster, *Method of Obtaining Gene Product Through The Generation of Transgenic Animals*, U.S. Pat. No. 4,870,009 (1989); Meade & Lonberg, *Isolation of Exogenous Recombinant Proteins From The Milk of Transgenic Mammals*, U.S. Pat. No. 4,873,316 (1989); Wagner & Hoppe, *Genetic Transformation of Zygotes*, U.S. Pat. No. 4,873,191 (1989); Cogburn, *Endocrine Manipulation to Improve Body Composition of Poultry*, U.S. Pat. No. 4,929,600 (1990).

16. *See* Int'l. Pat. Apps. WO 88/01648 and WO 88/00239, *supra* note 6; Wall St. J., July 6, 1989, § B, at 1.

17. *See infra* notes 88-115 and accompanying text.

18. *See infra* notes 116-42 and accompanying text.

19. *See infra* notes 148-59 and accompanying text.

20. *See infra* note 145-47 and accompanying text.

21. Schneider, *Farmers to Face Patent Fees to Use Gene-Altered Animals*, N. Y. Times, Feb. 16, 1988, § A, at 16; Merges, *Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies*, 47 MD. L. REV. 1051 (1988).

amount of control that may be maintained over the transferred article under the patent law doctrines of exhaustion,[22] implied license to practice a patented process,[23] implied license to repair a patented product,[24] and field of use licenses.[25] In addition, the limits placed on these controls by antitrust law must also be determined.[26]

This Comment will set forth three separate hypothetical transgenic inventions and a specific transfer of each invention. Each hypothetical invention will be described and classified as either a product or a machine.[27] After describing and classifying these transgenic inventions, this Comment will then consider the amount of control maintained by the patentee under the patent law doctrines and antitrust law after transferring those inventions using an unconditional sale, a field of use license, a bailment, or a lease.

II. Three Classes of Transgenic Animals: Two Machine and One Product

To aid in determining the amount of control a patentee maintains after transferring each of the three hypothetical inventions addressed by this Comment, each invention will be classified as either a product or a machine. This product versus machine distinction is important because patent and antitrust law allow a different amount of post-transfer control to be maintained by the patentee depending on whether the transferred article is a product[28] or machine.[29]

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22. The patent law doctrine of exhaustion states that once the patentee has sold a patended article, the patentee cannot restrict that article's use. *See infra* notes 57-67 and accompanying text.

23. An implied license to practice a patended process arises when a patentee sells an article that can only be used in a patented process. *See infra* notes 73-78 and accompanying text.

24. A purchaser of a patented article receives an implied license to repair the patented article so as to maintain its fitness for use. *See infra* notes 79-87 and accompanying text.

25. Under a field of use license, a patentee can license the patented technology for use only to produce a certain type of product. *See infra* notes 116-31 and accompanying text.

26. A patentee can only prevent others from making, selling or using the patented article or process. The patentee cannot attempt to control related technology or products without violating antitrust laws. *See infra* notes 68-72 and accompanying text.

27. *See infra* notes 28-51 and accompanying text.

28. Munters Corp. v. Burgess Indus., Inc., 450 F. Supp. 1195, 1204 n.6 (S.D.N.Y. 1978), *aff'd*, 201 U.S.P.Q (BNA) 756, 758 (S.D.N.Y. 1978) (non-manufacturing vendor of a product cannot impose restrictions on the use of the product sold). In United States v. General Elec. Co., 272 U.S. 476, 489-90 (1926), the Court stated:

> It is well settled, as already said, that where a patentee makes the patented article, and sells it, he can exercise no future control over what the purchaser may wish to do with the article after his purchase. It has passed beyond the scope of the patentee's rights. . . . But the question is a different one which arises when we consider what a patentee who grants a license to one to make and vend the patented article may do in limiting the licensee in the exercise of the right to sell.

29. Q-Tips, Inc. v. Johnson & Johnson, 109 F. Supp. 657 (S.D.N.J. 1951), *modi-*

In general, biological inventions, such as transgenic animals, are very difficult to classify as either a product or a self-replicating machine in all potential commercial embodiments and situations. However, in specific situations and embodiments, a transgenic animal invention with a particular set of characteristics may be considered a self-replicating machine that makes copies of itself through reproduction in order to fulfill its intended use.[30] A self-replicating machine's intended use may be primarily to produce a product, such as a protein, a useful waste product, or milk.[31] Alternatively, the self-replicating machine's intended use may be to produce more self-replicating machines.[32] In addition to producing copies of itself, a self-replicating machine is not destroyed during its intended use.[33]

In other specific situations and embodiments, a transgenic animal invention with a set of particular characteristics may be considered a product that is not required to reproduce itself to fulfill its intended use.[34] A product's intended use might be as a starting material for another product such as food or glue.[35] A product is destroyed, or at least converted to a different form, during its use. A transgenic animal product would typically be slaughtered and thus destroyed as a first step in its use.

To determine whether a particular transgenic animal is a product or a self-replicating machine, its intended use under a given set of circumstances must be determined.[36] If that use requires the transgenic animal to reproduce itself in order to fulfill its intended use and that animal is not destroyed during that use, the transgenic animal would be classified as a self-replicating machine.[37] However,

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fied, 207 F.2d 509 (3rd Cir. 1953), *cert. denied*, 347 U.S. 935 (1954) (patentee of a machine can control the product produced by that machine). In this Comment, the machine classification also includes a process that produces a product.

30. This self-replicating machine can be considered a manufacturing process making the possessor of such a machine a manufacturer under the meaning set forth in *Munters Corp. v. Burgess Indus.*, 450 F. Supp. 1195, 1204 n.6 (S.D.N.Y. 1978).

31. *See infra* notes 45-48 and accompanying text. Self-replicating machines are capable of reproducing themselves and thus producing another machine.

32. *See infra* notes 49-51 and accompanying text.

33. Normally an animal is not killed during reproduction or during milking.

34. The product is entirely made and therefore the possessor of a product cannot be considered a manufacturer under Munters Corp. v. Burgess Indus., Inc., 450 F. Supp. 1195, 1204 n.6 (S.D.N.Y. 1978).

35. *See infra* notes 39-44 and accompanying text.

36. American Cotton-Tie Co. v. Simmons, 106 U.S. 89 (1882) (holding that a patentee's intent that a patented article be used only once was controlling in determining infringement questions).

37. Because there is reproduction, the possessor of the self-replicating machine is

if a particular transgenic animal is not required to reproduce itself to fulfill its intended use and is not destroyed during that use, the transgenic animal would be classified as a product.[38]

To illustrate the differences between transgenic animals that are used as a self-replicating machine or product, the following three hypothetical transgenic animal inventions will be addressed.

A. Transgenic Animals Used as a Specialized Source of Food

A transgenic animal expressing a growth modulating substance,[39] such as growth hormone,[40] has an altered growth rate and ultimately produces meat with a lower fat content than traditional animals raised for food.[41] Typically, low-fat meat transgenic animals would be produced from parental breeding stock retained by the patentee or a licensee and then transferred to a third party. This transfer would occur while the animal was young, and the third party would feed and care for the animal while it matured to a point where it would be slaughtered to fulfill its intended use as food. The use of this transgenic animal would be similar to the use of standard "feeder cattle" where the third party, usually a farmer, does not maintain breeding stock to produce animals to fatten for ultimate use as food, but rather purchases young animals from a supplier who maintains the breeding herd.

In this situation, the farmer's intended use does not depend on the reproduction of the transgenic animals, and such reproduction is actually detrimental to the final food product produced as evidenced by the sterilization of most, if not all, male animals used in this type of meat production.[42] Female animals used in this type of operation have traditionally not been sterilized and thus could be used to produce progeny if desired.[43]

The transgenic animal used in this manner appears to be accurately classified as a product rather than a machine because the transgenic animal is not required to reproduce itself and is destroyed

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considered a manufacturer. *See supra* note 30.

38. Because there is not any reproduction, the possessor of the product is not a manufacturer. *See supra* note 34.

39. Pursel, Pinkert, Miller, Bolt, Campbell, Palmiter, Brinster & Hammer, *Genetic Engineering of Livestock*, 244 SCI. 1281 (1989) [hereinafter Pursel].

40. Miller, *Growth Hormone Genes Bring Super Pigs Closer to Market*, 6 GENETIC ENG. NEWS 7 (May 1987); Moffet, *Fish Incorporate Rat Growth Hormone Genes*, 7 GENETIC ENG. NEWS 1 (Sept. 1987); Palmiter, *Metaellothionein-human GH Fusion Genes Stimulate Growth of Mice*, 222 SCI. 809 (1983).

41. Pursel, *supra* note 39, at 1285.

42. Lesser, *Applying Animal Patents in Agriculture: Lessons for Farmers and the Patent Office for Self-Reproducible Animals*, ANIMAL PATENTS: THE LEGAL, ECONOMIC AND SOCIAL ISSUES 343, 345 (1989) [hereinafter Lesser, *Applying Animal Patents*].

43. *Id.*

in fulfilling its intended use.[44]

B. Transgenic Animals Used to Produce Valuable Products or By-Products

A transgenic animal producing a valuable biological product or by-product in its milk is an economical way of producing large amounts of therapeutically useful compounds.[45] In a typical transfer, a transgenic animal secreting a product would be obtained from breeding stock maintained by the patentee and transferred to a third party manufacturer who specialized in the production and sale of the valuable biological product. This transfer to the manufacturer would occur after the patentee has verified that the transgenic animal is secreting the desired biological product. If the transgenic animal is making the biological product in its milk, the animal must be bred in order to maintain milk production.[46] This breeding or reproduction would result in the production of progeny that, depending upon the particular genetic characteristics, would also produce, or at least carry, the gene controlling the production of the biological product.[47] In addition, the transgenic animal is not destroyed while fulfilling its intended use of producing a product, such as milk. The use of this transgenic animal would be similar to the use of a standard dairy animal in that some of the progeny produced would be sold, typically all male progeny and some female progeny, and some of the female progeny would be retained and used to replace older animals in the herd.

This transgenic animal is a self-replicating machine because the transgenic animal must reproduce itself and is not destroyed in fulfilling its intended use.[48]

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44. *See supra* notes 34-38 and accompanying text.

45. Schmeck, *Gene Altered Mice Make Human Protein in Their Milk*, N.Y. Times, Oct 27, 1987, § C, at 1; Gordon, *Production of Human Tissue Plasminogen Activator in Transgenic Mouse Milk*, 5 BIOTECHNOLOGY 1183 (1987); Newark, *Protein Production in Transgenic Animals*, 5 BIOTECHNOLOGY 874 (1987).

46. S. BENT, R. SCHWAAB, D. CONLIN, & D. JEFFERY, INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY WORLDWIDE 283 (1987) [hereinafter S. BENT, INTEL. PROP. RTS.].

47. Hammer, *Production of Transgenic Rabbits, Sheep and Pigs by Microinjection*, 318 NATURE 680 (1985).

48. S. BENT, INTEL. PROP. RTS., *supra* note 46, at 281.

C. *Transgenic Animals Used to Introduce a Special Characteristic into a Herd*

A transgenic animal carrying a gene conferring on that animal a desired characteristic, such as exceptional hardiness, greater longevity, or cancer susceptibility is very useful when used as breeding stock to introduce that characteristic into an entire generation of progeny. Typically, a male or female transgenic animal carrying the desired gene would be produced by the patentee and transferred to a third party who uses the transgenic animals to produce one or more generations of progeny having the desired trait.[49] In all cases, the transfer would occur after the patentee has verified that the transgenic animals have the desired trait.

The transfer of a transgenic animal to be used to introduce a desired trait into a herd requires that the transgenic animal reproduce itself and produce progeny. This use of a transgenic animal would be similar to the use of ordinary purebred breeding stock in that the parental or grandparental transgenic animals are used to produce progeny, and some progeny are kept as breeding stock and the rest sold for slaughter. The transgenic animal would not be destroyed during its intended use of producing progeny. Some female progeny are retained as breeding stock in order to increase the herd size.[50]

This transgenic animal used to introduce a special characteristic into a herd appears to be a self-replicating machine because the transgenic animal must reproduce itself and is not destroyed in fulfilling its intended use.[51]

III. The Method of Transferring Transgenic Animals Dramatically Alters the Patentee's Post-Transfer Control

Several possible methods of transferring transgenic animals to the ultimate users include sales, licenses, leases, and bailments. The use of these transfer methods with the three classes of transgenic animals will be discussed to probe the amount of control that can be placed on transferred transgenic animals under the current patent and antitrust law.[52] In addition, the particular control advantages and disadvantages of transferring transgenic animals using each method will be determined.

The interaction of patent law and antitrust law is complex and

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49. Lesser, *Applying Animal Patents*, *supra* note 42, at 351 (the current practice in the poultry industry is for breeders to release parent or grandparent birds to hatcheries under a contract that restricts release of breeding stock).

50. Lesser, *Applying Animal Patents*, *supra* note 42, at 348.

51. S. Bent, Intel. Prop. Rts., *supra* note 46, at 281.

52. Calkins, *Patent Law: The Impact of the 1988 Patent Misuse Reform Act and Noerr-Pennington Doctrine On Misuse Defenses and Antitrust Counterclaims*, 38 Drake L. Rev. 175 (1989).

longstanding.[53] In general, patent law addresses the creation and commercial exploitation of a limited monopoly granted by the patent statute.[54] Antitrust law addresses various limits placed on any monopoly, including the monopoly granted to the patentee by the patent statute.[55]

A. Transfer Using an Unconditional Sale

An unconditional sale is a transaction where a patented article is exchanged for an agreed upon price and the article is transferred to the purchasee upon the payment of the price.[56] The unconditional sale of a patented product by an authorized seller exhausts the patentee's rights in that article with regard to that product.[57] The basic underlying principle of the patent exhaustion doctrine is that the patentee has received fair and just compensation by the first sale of the product and the limited exclusivity granted by the patent does not entitle the patent owner to more than this.[58] In *United States v. Singer Manufacturing Co.*,[59] the Supreme Court stated,

> Beyond the limited monopoly which is granted, the arrangements by which the patent is utilized are subject to general law, . . . and it is equally well settled that the possession of a valid patent or patents does not give the patentee any exemption from the provisions of the Sherman Act[60] beyond the limits of the patent monopoly.[61]

The patent exhaustion doctrine has been applied to restrictions on the use, the resale, and the resale price placed on a patented article

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53. *Id.* at 178 n.6.
54. Handgards, Inc. v. Ethicon, Inc., 601 F.2d 986 (9th Cir. 1979), *cert. denied*, 444 U.S. 1025 (1980).
55. *Id.*
56. *See, e.g.*, Henry v. A. B. Dick Co., 224 U.S. 1, 19-21 (1912), *overruled on other grounds*, Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502 (1917).
57. Adams v. Burke, 84 U.S. (17 Wall.) 453, 456-57 (1873). The court stated, "When the patentee, or the person having his rights, sells a machine or instrument whose sole value is in its use, he receives the consideration for its use and he parts with the right to restrict that use. The article . . . passes without the limit of the monopoly."
58. Comment, *The Nature Of A Patent Right*, 17 COLUM. L. REV. 663 (1917); Adams v. Burke, 84 U.S. at 456 (1873) ("[T]he patentee or his assignee having in the act of sale received all the royalty or consideration which he claims for the use of his invention in that particular machine or instrument, it is open to the use of the purchaser without further restriction on account of the monopoly of the patentees.").
59. 374 U.S. 174 (1963).
60. 26 Stat. 209, *as amended*, 15 U.S.C. § 1 (1988).
61. U.S. v. Singer, 374 U.S. at 196-97 (quoting U.S. v. Masonite Corp., 316 U.S. 265, 277 (1942)).

that is sold.[62] In *United States v. Univis Lens Co.*,[63] the court held that "the authorized sale of an article which is capable of use only in practicing the patent is a relinquishment of the patent monopoly with respect *to the article sold.*"[64] Other decisions after *Univis Lens Co.* indicate that the decision is limited to the article sold and in no way allows the purchaser[65] to "make" a new article and sell it to another without being liable for infringement of the patent.[66] Therefore, any unauthorized reproduction of a transgenic animal invention would be patent infringement.[67]

All transgenic animals, including self-replicating machines and products, are equally subject to the patent exhaustion doctrine, and thus the patent rights in the transgenic animal sold are exhausted. Once the patent monopoly in the transgenic animals is exhausted, any restrictions placed on the use of those animals is analyzed and subject to invalidation under antitrust law.

1. Antitrust Limitations on Use Restrictions Imposed After the First Sale of a Patented Article

The exhaustion of the patent monopoly after the first authorized sale of an article allows any post-first-sale restrictions placed on the use of a patented article to be subject to invalidation under antitrust law.[68] Once stripped of patent protection by exhaustion, restrictions placed on the patented article are either illegal per se[69] or subject to

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62. *See, e.g.*, 4 D. CHISUM, PATENTS § 19.04[3] n.72 (1986); Bauer & Cie v. O'Donnell, 229 U.S. 1 (1913) (attempted to set resale price of a patented article); Straus v. Victor Talking Mach. Co., 243 U.S. 490 (1917); Boston Store of Chicago v. American Gramphophone Co., 246 U.S. 8, 25 (1918) (held the patent right did not allow the patentee to violate general law regarding price restrictions).

63. 41 F. Supp. 258 (S.D.N.Y. 1941), *aff'd in part, rev'd in part*, 316 U. S. 241 (1942).

64. 316 U.S. at 249 (emphasis added).

65. *See, e.g.*, Security Materials Co. v. Mixermobile Co., 72 F. Supp. 450 (S.D. Cal. 1947) (post-sale restriction found enforceable by infringement action).

66. 35 U.S.C. § 271(a) (1991); Bauer & Cie v. O'Donnell, 229 U.S. 1 (1913); Laitram Corp. v. Deepsouth Packing Co., 443 F.2d 936 (5th Cir 1971), *rev'd in part*, 406 U.S. 518 (1972).

67. 35 U.S.C. § 271(a) (1991) (reproduction appears to be making under this statute).

68. Ethyl Gasoline Corp v. United States, 309 U.S. 436, 457-58 (1940); United States v. Ciba Geigy Corp., 508 F. Supp. 1118, 1147 (D.N.J. 1976) (non-competition agreement viewed as restraint on trade).

69. United States v. Arnold Schwinn & Co., 388 U.S. 365, 379 (1967), *overruled in* Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 58 (1977). The per se rule was overruled on the facts of *Continental T.V.*, but the Court left open the possibility of using the per se rule in other situations. Continental T.V., Inc. v. GTE Sylvania, Inc., 433 U.S. 36, 58 (1977). The per se rule, which was replaced by the rule of reason articulated in Chicago Bd. of Trade v. United States, 246 U.S 231 (1918), stated that "the true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." *Chicago Bd. of Trade*, 246 U.S. at 238.

antitrust analysis under the antitrust "rule of reason."[70]

However, an antitrust cause of action will not be found until the patented article has been *sold* and the patent exhaustion doctrine moves the article outside the patent monopoly making the article subject to antitrust law.[71] Post-sale restrictions placed on either a self-replicating machine or product are similarly subject to invalidation under antitrust law, making such restrictions useless in attempting to maintain any post-transfer control by the patentee.[72]

2. *Implied Licenses Attaching to a Purchased Product*

a. *Implied License to Use a Patented Article Purchased*

The purchaser of any patented article, including a product or self-replicating machine, "undeniably acquires the right to use the article for all purposes of the patent so long as it endures."[73] Therefore, when a patentee sells a patented article to a purchaser, the purchaser acquires an implied license to practice a patented process if the only use of the article is to practice a patented process.[74] This implied license is only as general as the parties intend[75] and is limited in scope to the use of the patented article in the condition it was purchased.[76]

When a patentee sells a self-replicating machine and at least limited reproduction is required to use the self-replicating machine, the

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This determination requires that the court consider the particular conditions present in the business to which the questionable restriction is applied both before and after the restriction is imposed and the nature of the particular restriction and its probable or actual effect. *Chicago Bd. of Trade*, 246 U.S. at 238; *Continental T.V., Inc.*, 433 U.S. at 49-50 n.15. In addition, the courts consider the intended result of the restriction and the history of the restriction. Munters Corp. v. Burgess Industries, Inc., 450 F. Supp. 1195, 1207-08 (S.D.N.Y. 1977), *aff'd*, 201 U.S.P.Q.(BNA) 756, 758 (S.D.N.Y. 1978).

70. Chicago Bd. of Trade v. United States, 246 U.S. 231, 238 (1918); White Motor Co. v. United States, 372 U.S. 253 (1963).

71. Munters Corp. v. Burgess Indus., Inc., 450 F. Supp. 1195, 1205 (S.D.N.Y. 1977), *aff'd*, 201 U.S.P.Q.(BNA) 756, 757 (S.D.N.Y. 1978).

72. *See supra* notes 68-70 and accompanying text.

73. Henry v. A. B. Dick Co., 224 U. S. 1, 19 (1912), *overruled on other grounds*, Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U. S. 502 (1917).

74. Pettibone Corp. v. Fargo Mach. & Tool Co., 447 F. Supp. 1278, 1281 (E. D. Mich. 1978); Bandag Inc., v. Lewis General Tire Inc., 207 U.S.P.Q. (BNA) 745, 754 (W.D.N.Y. 1980); United States v. Univis Lens Co., 316 U.S. 241, 250 (1942).

75. General Tire & Rubber Co. v. Firestone Tire & Rubber Co., 349 F. Supp. 345, 363 (N.D. Ohio 1972), *modified*, 351 F. Supp. 872 (N.D. Ohio 1972), *modified in part and vacated in part*, 489 F. 2d 1105 (6th Cir. 1973), *cert. denied*, 417 U.S. 932 (1974); Rubber Tire Wheel Co. v. Goodyear Tire & Rubber Co., 232 U.S. 413, 418-419 (1914); Aralac, Inc., v. Hat Corp. of America, 166 F.2d 286, 293 (3d Cir. 1948).

76. National Cash Register Co. v. Grobet, 153 F. 905, 907 (2d Cir. 1907).

purchaser is granted an implied license to make those articles required for use of the self-replicating machine.[77] However, the purchaser of a transgenic animal product would not acquire an implied license to make new transgenic animals through reproduction, because the transgenic animal product is intended to be slaughtered and not reproduced.[78]

b. Implied License to Repair the Article Purchased

In addition to the implied license to use a purchased article, the purchaser of a patented article, including a self-replicating machine or a product, acquires the right to repair that patented article when necessary to maintain its fitness for use.[79] This permissible repair includes the right to replace the individual unpatented parts of a larger patented combination or machine.[80] However, this permissible repair is limited at the point where the repair amounts to a complete reconstruction of a spent or worn out product.[81]

The Supreme Court laid down the general rule used to distinguish permissible repair from impermissible reconstruction by stating, "[R]econstruction of a patented entity, comprised of unpatented elements, is limited to such a true reconstruction of the entity as to in fact make a new article, . . . after the entity, viewed as a whole has become spent. . ."[82] This rule emphasizes determining whether there has been a "second creation" of a patented invention after the invention has become spent.[83]

In addition to determining whether an article has been recreated, at least one subsequent court has found that reconstruction has occurred when not a single element of an invention has been left untouched during a repair process[84] and has given weight to the patentee's intent in deciding whether there has been impermissible reconstruction.[85] Thus it appears that if the patented article is intended to be used only once, the implied license to repair that article

77. Illingworth v. Spaulding, 43 F. 827 (C.C.N.J. 1890); United States Indus., Inc. v. Otis Eng'g Corp., 277 F.2d. 282 (5th Cir. 1960).

78. *See* Lesser, *Applying Animal Patents*, *supra* note 42, at 345 and accompanying text.

79. Goodyear Shoe Mach. Co., v. Jackson, 112 F. 146, (1st Cir. 1901); Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336 (1961) [hereinafter Aro I].

80. Aro I, 365 U.S. 336, 345 (1961); Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476 (1964) [hereinafter Aro II].

81. Aro I, 365 U.S. 336, 346 (1961) (citing United States v. Aluminum Co. of Am., 148 F.2d 416, 425 (2d Cir. 1945)).

82. Aro I, 365 U.S. 336, 346 (1961).

83. *Id.*

84. Connecticut Tel. & Elec. Co. v. Automotive Equip. Co. 14 F.2d 957, 961 (D.C.N.J. 1926), *aff'd*, 19 F.2d 990 (3rd Cir. 1927), *cert. denied*, 275 U.S. 564 (1927).

85. *See, e.g., In re* Certain Steel Rod Treating Apparatus, 215 U.S.P.Q. (BNA) 37 (U.S. Int. Tr. Com. 1981).

does not allow its reconstruction by replacement of every element that makes up the patented article.[86]

Therefore, a transgenic animal product intended for a one time use cannot, under the doctrine of permissible repair, be reproduced because every element of that patented transgenic animal product is being replaced. In this situation, the replacement occurs simultaneously through reproduction, making this impermissible reconstruction.[87]

3. *Analysis of Sales of Three Types of Transgenic Animals*

If antitrust limitations are the doctrines of patent exhaustion, implied license and permissible repair apply to a particular transfer of a transgenic animal and will tend to severely limit the control a patentee maintains over the use of that animal by the transferee. If a particular use of a transgenic animal is found to be impermissible reconstruction, this reconstruction is not permitted and the transferee is liable for patent infringement.[88] Therefore, in each of the three types of transgenic animals, the applicability of each of these doctrines must be determined.

a. *Sales of Transgenic Animal Used as a Specialized Food Source*

The sale of a transgenic animal used as a specialized food source can be viewed as a sale of a product.[89] The patent exhaustion doctrine clearly applies to the actual transgenic animal sold. However, patent rights are not exhausted in articles that are made by the purchaser through reproduction, and thus, with respect to newly produced animals, the purchaser is liable for infringement.[90] The doctrine of implied license would not expand the purchaser's license beyond the ability to raise the animal for a sufficient time for slaughter.

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86. *See, e.g.*, Fromberg, Inc. v. Thornhill, 315 F.2d 407 (5th Cir. 1963); American Cotton-Tie v. Simmons, 106 U.S. 89 (1882).

87. *See supra* note 82 and accompanying text.

88. American Cotton-Tie Co. v. Simmons, 106 U.S. 89 (1882); *see generally*, Sease, *Patent Law: Repair-Reconstruction A Review, Analysis, and Proposal*, 20 DRAKE LAW REV 85 (1970).

89. *See supra* notes 39-44 and accompanying text.

90. "[W]hoever without authority makes, uses or sells any patented invention, within the United States during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a) (1991).

Because the patent rights on this transgenic animal are exhausted by the first sale, any restriction, express or implied, would be subject to analysis under antitrust law. It is unlikely that any restrictions on the purchaser as to the use of the purchased transgenic animal would be upheld under the *United States v. Arnold Schwinn*[91] decision.

The doctrine of permissible repair of this class of transgenic animals would certainly allow any treatment of the animal required to maintain its fitness for future use as a special food. However, the purchased transgenic animal may not be repaired to the point of recreating the transgenic animal.[92] Clearly, the producing of a new transgenic animal by reproduction would be considered reconstruction because not a single element of the invention, the entire transgenic animal, is left untouched[93] and the patentee intended that the purchased transgenic animal would only be used once and not reproduced.

Under patent law the patentee should be able to successfully bring a patent infringement action against the purchaser who reproduces a transgenic animal that was intended to be used as a specialized food source.[94] However, infringement actions are limited to cases where a purchaser is involved in large scale reproduction of the transgenic animal because of the costs and complexities of such actions.[95]

b. Sale of a Transgenic Animal Used to Produce Valuable Product

Selling a transgenic animal used to produce a valuable product can be viewed as the sale of a machine capable of producing a valuable product.[96] In addition, this type of transgenic animal will produce additional transgenic animals because of the breeding required to maintain production of the valuable product in its milk.[97]

The initial sale of a transgenic animal machine used to produce a valuable product exhausts the patent rights in that machine and also gives the purchaser the implied license to produce additional transgenic animals from that machine. However, this does not necessarily

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91. 388 U.S. 365 (1967) (holding post-sale restrictions on a patented article are illegal per se).

92. Isolation of the gene that confers the special trait upon a transgenic animal and introduction of that isolated gene into a new animal would be an example of reconstruction without sexual reproduction.

93. Goodyear Shoe Mach. Co. v. Jackson, 112 F. 146 (C.C.D. 1901).

94. *See supra* note 90.

95. It is unlikely that a purchaser who does not significantly effect the patentee's market position would be sued because of the high costs of most patent litigations.

96. *See supra* notes 45-48 and accompanying text.

97. *See* S. BENT, INTEL. PROP. RTS., *supra* note 46, at 283 and text accompanying note 46.

mean that, given a right to make these additional transgenic animals, the right to sell them is also granted.[98]

The right to make a patented product generally implies the right to use the product made because without the right to use the patented product made, the license to make the product is useless.[99] However, in this particular case, an implied license to make does not create an implied right to use the articles made. The making of the articles has value because the incidental transgenic animals were made in the process of producing milk containing a valuable product. This unique situation would seem to be an exception to the general rule that any license to make creates an implied license to use the article made.[100] The possibility that an implied license to make carries with it an implied license to use the articles made forces a consideration of whether the impermissible reconstruction doctrine will allow the patentee to exert any control over the incidentally produced transgenic animals.

The patentee's likely intent in selling the parental animal is to allow the incidentally produced transgenic animals to be made and then sold to be slaughtered as food and therefore would not dilute the patentee's market position. The incidental production of the transgenic animals results in the replacement of every element that makes up the patented article and would be considered reconstruction.[101] This reconstruction would act to terminate any implied license associated with these animals making the purchaser liable for patent infringement if the patentee brought an enforcement action.[102]

The producer of the incidental transgenic animals, armed with the knowledge that a patent infringement suit might be brought, would be unlikely to agree to the purchase of the original transgenic animal without an express license allowing the purchaser to dispose of the incidentally produced animals in some manner. This license might take the form of a field of use limitation such as the licenses discussed below.

The exact disposition of the incidentally produced transgenic animals produced incidentally to the production of milk from this particular class of transgenic animal is uncertain under current patent

98. United States v. General Elec. Co., 272 U.S. 476 (1926).
99. 6 LIPSCOMB'S WALKER ON PATENTS § 20:7 (3d ed. 1987).
100. *See, e.g.*, Poirier v. Bradford, 119 Minn. 475, 138 N.W. 687 (1912); Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp., 266 F. 71 (2d Cir. 1920).
101. *See supra* note 93 and accompanying text.
102. *See supra* note 90.

law. Therefore, the unconditional sale of such a transgenic animal should be avoided, and either a field of use license, leasing of the animal,[103] or a bailment[104] of the animal should be considered.

c. *Sale of Transgenic Animals Used to Introduce a Special Characteristic into a Herd*

Selling a transgenic animal used to introduce a special characteristic into a herd can be viewed as a biological machine that is used to produce more transgenic animals having a particular desirable trait.[105] The patent exhaustion doctrine clearly applies to the particular animal sold. Patent rights are not exhausted in the transgenic animals made by the purchaser through breeding, and without either an express or an implied license to make, use, and sell these animals, the purchaser would be liable for infringement.

The patent rights in the transgenic animal sold are exhausted and any express or implied restriction on the use of that animal would likely be considered a violation of antitrust law.[106] Any restriction on the use of progeny produced by the purchased transgenic animal would be analyzed separately under antitrust law.[107] Because the patent rights are not exhausted in the progeny of the purchased transgenic animal, antitrust law would not automatically invalidate any restriction placed upon these animals.[108]

The doctrine of permissible repair applied to this class of transgenic animals would allow treatment of the transgenic animal to maintain its fitness for use in the purchaser's breeding program.[109] Repair of the purchased transgenic animal to the point of recreating it, in this case reproducing, would be considered impermissible reconstruction and thus would not be allowed.[110] The production of new transgenic animals from the purchased transgenic animal is reconstruction, and without an express or implied license to do so, the purchaser of the transgenic animal would be liable for infringement.[111]

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103. *See infra* notes 148-59.
104. *See infra* notes 145-47 and accompanying text.
105. Desirable traits include exceptional hardiness, greater longevity, or cancer susceptibility.
106. *See supra* notes 68-72 and accompanying text.
107. *See supra* notes 69-70 and accompanying text.
108. *Id.*
109. Maintaining an animal's health would be an example of maintaining its fitness for use. *See supra* note 79 and accompanying text.
110. Production of a new animal through reproduction appears to be recreation of the patented machine. *See supra* note 92 and accompanying text.
111. Patent infringement occurs when an unauthorized person makes, sells, or uses the patented product or machine. *See supra* note 90 and accompanying text.

The sale of this class of transgenic animals would create an implied license to make new transgenic animals because this is its only use.[112] As the implied license to make new transgenic animals is of little value without an accompanying implied license to use and sell the transgenic animals produced, these licenses will be implied.[113] With this class of transgenic animals, a sale of the animal causes the purchaser to gain a license to make, use, and sell the progeny produced.[114] Thus, a more appropriate method of transfer such as a field of use license should be selected,[115] if such a transfer is absolutely required.

B. Transfer of Transgenic Animals Using Field of Use Licenses

Given the limited amount of control a patentee may maintain over a transgenic animal machine that is sold to a purchaser,[116] other methods of transferring these animals must be investigated. One alternative transfer method is to license the third party to use the transgenic animal in a specific field.

In general, the limited monopoly granted by a patent can be subdivided in various ways.[117] The patent right consists of:

> several substantive rights, and each is the subject of subdivision, so that one person may be permitted to make, but neither to sell nor use the patented thing. To another may be conveyed the right to sell, but within a limited area, or for a particular use, while to another the patentee may grant only the right to make and use, or to use only for specific purposes.[118]

Licenses granting the licensee various portions of the patent rights,

112. Because the transgenic animals intended use is to introduce a trait into a herd of animals, production of new animals is required. *See supra* note 77 and accompanying text.

113. *See supra* note 73 and accompanying text.

114. *See supra* notes 77 and 100 and accompanying text.

115. *See infra* notes 116-31 and accompanying text.

116. Poirier v. Bradford, 119 Minn. 475, 138 N.W. 687 (1912); Curtiss Aeroplane & Motor Corp. v. United Aircraft Eng'g Corp., 266 F. 71 (2d Cir. 1928); *see also supra* note 100 and accompanying text.

117. Comment, *The Nature of a Patent Right*, 17 COLUM. L. REV. 663 (1917).

118. Henry v. A. B. Dick Co., 224 U.S. 1, 46 (1912), *overruled on other grounds*, Motion Picture Patents Co. v. Universal Film Mfg. Co., 243 U.S. 502 (1917).

including territorial restricted rights[119] and rights restricted to a specific field of use,[120] have been used.

1. Licenses Restricting the Field of Use of the Patented Article

A patentee may license others to make and sell a patented article for a particular use or may accomplish substantially the same effect by limiting the particular class of customers to which the patented articles may be sold.[121] Licenses restricting the field of use of the patented article are not illegal per se as held by the Supreme Court in *General Talking Pictures v. Western Electric.*[122] The defendant that was sued for patent infringement in *General Talking Pictures* had purchased a patented amplifier with notice that its use was restricted to noncommercial fields from a licensee who could only sell to customers using the amplifiers for noncommercial purposes. The defendant had sold the amplifier for commercial use. The Court held that the defendant had infringed the patent and thus enforced the field of use restriction present in the license.[123] It is important to note that the licensee in *General Talking Pictures* was a manufacturing licensee rather than a reseller. Thus, the restrictive license was not illegal per se under antitrust law because the patented article did not pass into the stream of commerce until sold.[124] This distinction between a reseller and a manufacturing licensee is critical because:

> under a license to manufacture and sell, the patented article has not passed into the stream of commerce until it is sold by the licensee. Up to that point - when the patent has been fully practiced and the patented article is completed - the patent grants the patentee the power to place restrictions on the use or sale of the patented article. But once the patented article is sold, the patentee loses all power to control its future use of sale.[125]

Therefore, a patentee may place a restriction on the first sale of a patented article by a manufacturing licensee[126] but cannot place restrictions on the patented article after the first sale of the patented

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119. "The applicant, patentee, or his assigns or legal representatives may convey an exclusive right under his application for patents, patents to the whole or any specified part of the United States." 35 U.S.C. § 261 (1986). This section is the basis for placing territorial restrictions on a patent licensee. *But see* Adams v. Burke, 84 U.S. (17 Wall) 453 (1883) (a patentee cannot place a territorial restriction on a patented article after the first sale).

120. General Talking Pictures Corp. v. Western Elec. Co., 304 U.S. 175 (1938), *aff'd on reh'g*, 305 U.S. 124 (1938), *reh'g denied*, 305 U.S. 675 (1939).

121. *Id.*

122. *Id.*

123. *Id.*

124. *Id.*

125. Munters Corp. v. Burgess Indus., Inc., 450 F. Supp. 1195, 1203 (S.D.N.Y. 1977), *aff'd*, 201 U.S.P.Q. (BNA) 756, 758 (SD.N.Y. 1978).

126. General Talking Pictures v. Western Elec. Co., 304 U.S. 175 (1938), *aff'd on*

article.[127] The courts will allow license restrictions as long as the restrictions do "not attach a condition . . . that will enlarge [the] monopoly granted."[128] For example, restrictions limiting the use of a patented machine to produce only a certain type of product,[129] or to manufacture a product and sell it only to a certain class of customers,[130] would not violate current antitrust law.

However, any attempts by a manufacturing licensee to attach field of use restrictions to a patented product *sold* have been found a violation of antitrust law.[131] Because the patentee does not have control over patented articles once they are sold under such a license, the restrictions must be placed in the license rather than attached to the article at the time of sale.

2. *Licensee Agreements Involving Transgenic Animals*

Licenses restricting the field of use of the patented product may only be used with manufacturing licensees or such restrictions will violate antitrust laws.[132] Therefore, it is important to assure that the license granted is drafted in a way to make the licensee a manufacturing licensee.

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reh'g, 305 U.S. 124 (1938), *reh'g denied*, 305 US. 675 (1939).

127. United States v. Univis Lens Co., 41 F. Supp. 258 (S.D.N.Y. 1941), *aff'd in part, rev'd in part*, 316 U.S. 241 (1942).

128. Williams v. Hughes Tool Co., 186 F.2d 278, 284 (10th Cir. 1950).

129. Turner Glass Corp. v. Hartford-Empire Co., 173 F. 2d 49 (7th Cir. 1949), *cert. denied*, 338 U.S. 830 (1949), *reh'g. denied*, 338 U.S. 881 (1949); Q-Tips, Inc. v. Johnson & Johnson, 109 F. Supp. 657 (D.N.J. 1951), *modified*, 207 F.2d 509 (3d Cir. 1953), *cert. denied*, 347 U.S. 935 (1954) (patent owner may control the style of products produced by a patented machine).

130. General Talking Pictures v. Western Elec. Co., 304 U.S. 175 (1938), *aff'd on reh'g*, 305 U.S. 124 (1938), *reh'g denied*, 305 U.S. 675 (1939); Armstrong v. Motorola, Inc., 374 F.2d 764 (7th Cir. 1967), *cert. denied*, 389 U.S. 830 (1967), *reh'g denied*, 389 U.S. 997 (1967); Benger Laboratories, Ltd. v. R. K. Laros Co., 209 F. Supp. 639, 648 (E.D. Pa. 1962), *aff'd*, 317 F.2d 455 (3d Cir. 1963), *cert. denied*, 375 U.S. 833 (1963) (exclusive license by patentee restricted the licensee to sell only in the human field); Hull v. Brunswick Corp., 704 F.2d 1195 (10th Cir. 1983) (patentee maintains some control over the patented product produced); *see also* 4 D. CHISUM, PATENTS § 19.04[3] (1936).

131. Univis Lens Co., 41 F. Supp. 258 (S.D.N.Y. 1941), *aff'd in part, rev'd in part*, 316 U.S. 241 (1942).

132. *See supra* note 125 and accompanying text.

a. Field of Use Licenses Restricting the Use of Transgenic Animals Used as a Specialized Food Source

Licensing a transgenic animal to a licensee to be used as a specialized food source using a field of use license can be viewed as licensing a product.[133] Any attempt to use a field of use license with this particular class of transgenic animals will result in a violation of antitrust laws because the licensee would simply be a reseller rather than a manufacturer. The courts have rarely allowed any field of use restrictions to attach to a patented article once it is sold.[134]

This class of transgenic animals appears to be adequately protected when sold[135] and the patentee is afforded little extra control over the invention by using a field of use license of questionable validity.

b. Field of Use Licenses Restricting the Use of a Transgenic Animal Machine Producing a Valuable Product or Byproduct

Licensing a transgenic animal used to produce a valuable product and additional incident transgenic animals using a field of use license can be viewed as licensing a self-replicating machine with a restricted field of use.[136] The patentee could grant a field of use license that limited the licensee's use of the transgenic animals or "transgenic factories" transferred to the production of a valuable product. This would only allow the animal to be used in the production of the valuable product and would create an implied license to produce only those new transgenic animals required to produce that valuable product.[137]

This type of field of use license limiting the type of product that may be manufactured by the licensee is very common and is not an antitrust violation.[138] The patentee may also control the class of customers to whom the valuable product or the incidentally produced transgenic animals may be sold without violating the antitrust laws.[139] For example, the patentee may require that the transgenic animals be sold to the patentee,[140] to a slaughterhouse, or that all

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133. *See supra* notes 39-44 and accompanying text.

134. United States v. Consolidated Car-Heating Co., 87 U.S.P.Q.2d (BNA) 489 (S.D.N.Y. 1950); Baldwin-Lima-Hamilton Corp. v. Tatnall Measuring Sys., 169 F. Supp. 1 (E.D. Pa. 1958), *aff'd per curium*, 268 F. 2d 395 (3d Cir. 1959), *cert. denied*, 361 U.S. 894 (1959). *But see* Chemagro Corp. v. Universal Chem. Co., 244 F. Supp. 486 (E.D. Tex 1965) (purchasee who has notice of a restriction on the use of the purchased, patented article is bound by that restriction).

135. 35 U.S.C. § 271 (1991); *see also supra* note 90 and accompanying text.

136. *See supra* notes 45-48 and accompanying text.

137. *See supra* notes 75-77 and accompanying text.

138. *See supra* note 129 and accompanying text.

139. *See supra* note 130.

140. General Talking Pictures Corp. v. Western Elec. Co., 304 U.S. 175 (1938),

progeny be sterilized. The grant of a license with a restricted field of use would seem to be a good way to adequately protect the patentee's position when transferring a transgenic animal producing a valuable product in its milk.

c. Field of Use Licenses Restricting the Use of a Transgenic Animal Machine Used to Introduce a Special Characteristic into a Herd

Licensing a transgenic animal used to introduce a special characteristic into a herd with a field of use license can be viewed as licensing a biological machine for the restricted purpose of producing more transgenic animals having a particular special characteristic.[141] The patentee could grant a license to a licensee to produce new transgenic animals only for use in the licensee's own herd and not for sale to others. This license is similar to the field of use license in *General Talking Pictures* that limited the use of amplifiers produced to the noncommercial market.[142]

Because this class of transgenic animal can be viewed as a patented machine used to produce a specific product, a license limiting the use of that product to a specific field would not violate antitrust law. In addition, a license limiting the sale of the transgenic animals to a certain class of customer would be effective in controlling the transgenic progeny and would not violate antitrust law.

C. Other Methods of Transferring Transgenic Animals

Various commentators have suggested using either a lease[143] of the transgenic animal or a bailment.[144]

1. Transfer of Transgenic Animals Using a Bailment

The use of a common law bailment to transfer any of the transgenic animal inventions has the distinct advantage of maintaining ownership of that animal with the patentee.[145] However, one serious

aff'd on reh'g, 305 U.S. 124 (1938), *reh'g denied*, 305 U.S. 675 (1939).

141. *See supra* notes 49-51 and accompanying text.

142. General Talking Pictures Corp. v Western Elec. Co., 304 US. 175 (1938), *aff'd on reh'g*, 305 U.S 124 (1938), *reh'g denied*, 305 U.S. 675 (1939).

143. Schramm, *Leases of Machinery and the Antitrust Laws*, XL J. PAT. OFF. SOC'Y 110 (1958).

144. Kirn, *The Use of Common Law Bailments in Connection with the Licensing of Living Organisms*, 9 LICENSING L. BUS. REP. 1-10 (Sept. & Oct. 1986).

145. *Id.*

disadvantage in using a bailment to transfer a transgenic animal invention is that bailments have not been extensively used to transfer patented products and machines to a third party.[146] Therefore, there are relatively few cases dealing with bailments in this context and there is little experience by practitioners.[147]

2. *Transfer of Transgenic Animals Using a Lease*

Leases have been extensively used to transfer patented products and machines.[148] An implied license is overridden by express lease clauses to the contrary requiring the return of patented articles for repair and refurbishment.[149] A lease would also appear to create an implied license to use a patented process in operating a patented machine as does the sale of a patented machine that is only useful in carrying out a patented process.[150]

The use of a lease to transfer a patented product of a machine prevents the doctrine of patent exhaustion from applying. Because title to the patented article never passes to the lessee, the lessee never becomes a purchaser.[151] Despite the patentee maintaining title to the patented article, the courts have refused to enforce restrictive leases that attempt to extend the lessor's control beyond that granted by the patent.[152] Restrictions are in violation of antitrust law[153] if they attempt to control either (a) the price of an unpatented product produced by a leased, patented machine[154] or (b) the use of a competitor's supplies or other machines used with the leased patented machine.[155]

Leases of a patented article containing restrictions that do not attempt to extend the rights of the patentee beyond the rights granted by the patent have been upheld by the courts.[156] For example, a lease of a patented furnace requiring that it only be used to produce

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146. *Id.*

147. *Id.*

148. Schramm, *Leases of Machinery and the Antitrust Laws*, XL J. PAT. OFF SOC'Y 110 (1958).

149. Robertson Rock Bit Co. v. Hughes Tool Co., 176 F.2d. 783 (5th Cir. 1949), *cert. denied*, 338 U.S. 948 (1949).

150. *See supra* note 74 and accompanying text.

151. Bloomer v. McQuewan, 55 U.S. (14 How.) 539 (1852) (court held that once title had passed to purchaser, patent rights in the article sold were exhausted).

152. Turner Glass Corp. v. Hartford-Empire Co., 173 F.2d 49 (7th Cir. 1949), *cert. denied*, 338 U.S. 830 (1949), *reh'g denied*, 338 U.S. 881 (1949) (limiting the use of leased machinery is not an antitrust violation if the limiting condition is reasonably within the reward the patentee is entitled to).

153. *See supra* notes 69-70 and accompanying text.

154. *See, e.g.*, Hartford-Empire Co. v. U.S., 323 U.S. 386 (1945), *modified*, 324 U.S. 570 (1945).

155. *See, e.g.*, Chiplet, Inc. v. June Dairy Products, Inc., 89 F. Supp. 814 (D.N.J. 1950).

156. *See supra* note 152 and accompanying text.

a particular product has been declared enforceable under the antitrust laws.[157] Thus, it appears that a lease containing field of use restrictions similar to that in *General Talking Pictures*[158] is enforceable.

Leasing appears to have advantages over a sale of a patented article similar to the advantages provided by a field of use license. The application of a lease to the three types of transgenic animal invention transfers would therefore be similar, if not identical, to a field of use license.[159]

IV. OTHER SELF-REPLICATING BIOTECHNOLOGY INVENTIONS

This Comment has specifically addressed the transfer of three hypothetical transgenic animal inventions. However, the patent law and antitrust law doctrines governing the transfer of a transgenic animal invention also apply to the transfer of other self-replicating biotechnology inventions. Self-replicating biotechnology inventions include microorganisms, such as bacteria and yeast,[160] *in vitro* cell lines derived from plants[161] or animals,[162] genetically altered microorganisms,[163] genetically altered animal cells,[164] and transgenic plants.[165]

Each of these self-replicating biotechnology inventions can be classified as primarily a product or a machine that produces a product. This classification simplifies the determination of any limits placed on the production of progeny from the original self-replicating invention at the time of the transfer. For example, a yeast or bacteria

157. United States v. Consolidated Car-Heating Co., 87 U.S.P.Q.2d (BNA) 489 (S.D.N.Y. 1950).

158. General Talking Pictures Corp. v. Western Elec. Co., 304 U.S. 175 (1938), *aff'd on reh'g*, 305 U..S. 124 (1938), *reh'g denied*, 305 U.S. 675 (1939).

159. *See supra* notes 116-42 and accompanying text.

160. *See* S. BENT, INTEL. PROP. RTS., *supra* note 46.

161. Matzke & Chilton, *Site-Specific Insertion of Genes Into T-DNA of Agrobacterium Tumor Inducing Plasmid: An Approach To Genetic Engineering of Higher Plant Cells*, 1 J. MOLECULAR & APPLIED GENETICS 39 (1981).

162. *See, e.g.*, Golde & Quan, *Unique T-Lymphocyte Line and Products Derived Therefrom*, U.S. Pat. No. 4,438,032 (1984).

163. Villa-Komoraff, Effstratiadis, Broome, Lomedico, Tizard, Naber, Chick & Gilbert, *A Bacterial Clone Synthesizing Proinsulin*, 75 PROC. NAT'L. ACAD. SCI. 3727 (1978); Goeddel, Kleid, Bolivar, Heyneker, Yansur, Crea, Hirose, Kraszewski & Riggs, *Expression in Escherichia Coli of Chemically Synthesized Genes for Human Insulin*, 76 PROC. NAT'L. ACAD. SCI. 106 (1979).

164. Gething & Sambrook, *Construction of Influenza Haemagglutinin Genes That Code for Intracellular and Secreted Forms of the Protein*, 300 NATURE 598 (1982).

165. Haitt, Cafferkey & Browdish, *Production of Antibodies in Transgenic Plants*, 342 NATURE 76 (1989).

culture used in making cheese or beer[166] would be considered a product under this classification system because the culture is destroyed before its intended use is completed and the culture of microorganisms[167] is not reproduced. Thus, the culture of microorganisms is similar to a transgenic animal used as a specialized food source because they are both products and thus would be afforded a similar analysis under patent and antitrust law.[168]

Other examples of biological machines include genetically altered microorganisms, animal cells or plants, and microorganisms and cell lines that secrete a valuable product.[169] A plant or microorganism that could be used to introduce a special characteristic, such as disease resistance into a population of similar organisms, would be classified as a biological machine. This biological machine would be similar to a transgenic animal used to introduce a special characteristic into a herd and thus afforded a similar analysis under patent and antitrust law.[170]

V. CONCLUSION

The variation in the use of each of the three classes of transgenic animals leads to the patentee maintaining different amounts of control over any transgenic progeny produced. By determining whether a transgenic animal invention is intended to be used as a product or a self-replicating machine, the method of transferring the invention can be selected to maximize the patentee's post-transfer control.

Transgenic progeny produced from transgenic animal products, such as those transferred to a third party to be used as a specialized food source, can be transferred using an unconditional sale. After an unconditional sale, the limits placed on making new patented articles by the patent law doctrine of impermissible reconstruction and patent infringement statutes maintain the patentee's control over these animals.

The patentee has limited control over transgenic progeny incidentally produced from self-replicating machines, such as transgenic animals producing a valuable product or transgenic animals produced by a transgenic animal sold to a third party to introduce a specialized trait into a new transgenic progeny. Therefore, to maximize the

166. Jeffers, *Restriction of Propagation of Patented Bacteria Sold by Patentee—Can It Be Done?*, 70 J. PAT. TRADEMARK OFF. SOC'Y 75 (1988).

167. The microorganism may replicate during the production of the product, but a new culture of pure microorganisms is not made. Thus, there is not reconstruction or infringement. *See supra* note 82 and accompanying text.

168. *See supra* notes 89-95 and accompanying text.

169. *See supra* notes 161-62.

170. *See supra* notes 105-15 and accompanying text.

patentee's control, these animals should be licensed or leased with an appropriate field of use restriction placed on the transgenic progeny.

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