EXHAUSTION DOCTRINE IN BIOTECHNOLOGY

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Biotechnology is a multi-billion dollar industry in the United States, with the capacity to become a key sector of the economy. [n.1] One of the most intriguing issues in biotechnology is how to adapt patent law to "machines" that automatically make copies of themselves. [n.2]

The holder of a patent enjoys a virtual monopoly on the claimed subject matter of the patent because of the holder's right to "exclude others from making, using, or selling the invention throughout the United States." [n.3] The First Sale Doctrine or Doctrine of Exhaustion of Patent Rights (the *290 Exhaustion Doctrine), is a case law imposed limitation on these rights. [n.4] Under this doctrine, an individual purchasing a patented item from the patentee or his licensee "exhausts" the patent right and is subsequently free to use and resell the item free of the patent monopoly. [n.5] Thus, the purchaser of the patented item buys not only the product, but also an implied license to use and resell that product. This implied license will have an effect on the emerging field of biotechnology, where the use of the product could include either duplication of itself or the production of a closely related product.

Although the courts have never ruled directly on an implied license to make a patented biotechnology product, case law surrounding the Exhaustion Doctrine -- developed early in the history of patent law -- provides solutions to many of the problems that may arise in this novel realm. [n.6] In addition, where discoveries in biotechnology lend themselves to obvious variations and uses, the scope of patent rights over these variations and uses may also be constrained by the Exhaustion Doctrine. While the grant of a patent is often described as the right to exclude all others from making, using, and selling the invention, [n.7] the Exhaustion Doctrine could significantly affect the breadth of this right in biotechnology.

In Diamond v. Chakrabarty, [n.8] the Court indicated neither constitutional nor statutory bars foreclosed the patentability of living organisms. The scope and repercussions of patenting living organisms remain confusing because many of the qualities of a living organism, such as the capacity to make copies of itself and the multiple uses of the components of the organism, have not been considered by the courts.

Special interest groups have attempted to railroad the biotechnology industry into a morass of legal requirements and activities by petitioning the courts for extensive environmental impact statements and challenging the *291 legitimacy of patenting

inventions encompassing living organisms. [n.9] The 101st Congress witnessed a reintroduction of the Transgenic Animal Patent Reform Act. [n.10] The Act would have permitted farmers the unrestricted use of any purchased transgenic animals; [n.11] however, the Act would have statutorily emasculated the fledgling industry by removing many of the patent rights and economic incentives conferred by patents. [n.12] The legislation would have *292 permitted farmers owning transgenic animals to allow the animals to reproduce, [n.13] to utilize the animals in any farming operation, [n.14] and to sell the transgenic farm animals or any of their offspring. [n.15] Part of the impetus for the Act was a fear that individuals might not be able to fully utilize their property [n.16] (i.e., the animal) or might completely lose their property. [n.17] This fear has not abated and is in part responsible for current legislation that includes statutes designed to completely prohibit the patenting of multicellular organisms. [n.18]

As transgenic organisms become commonplace, [n.19] the possibility increases that a patented organism will accidentally become either the "building block" of a patentably distinct [n.20] transgenic organism or a component of an industry's breeding program. The resulting risk of infringement thereby expands. Furthermore, while legal principles exist for determination of ownership of feroe naturoe, [n.21] it is not clear that an "escaped" transgenic organism would fall into this category. Even if the actual organism were considered feroe naturoe, would patent property rights cover the organism's *293 offspring? These may seem minor concerns regarding transgenic laboratory animals such as mice; however, the majority of the world's grain crops are wind pollinated. [n.22] It is impossible to constrain the wind, and any offspring of the claimed organism usually fall within the claimed subject area of the patent. [n.23] These prospects raise public concern and anxiety regarding the introduction of biotechnology into the marketplace.

In addition to the concern felt by potential buyers of biotechnological products, concern should be manifest in patent owners, assignees, and licensees. In many cases, patented products of biotechnology companies are marketed to the public [n.24] with no supplemental protection through contract law. [n.25] While the holders of such biotechnology patents may believe that they alone have the right to decide who will make, use, and sell their product, these rights appear to be a poorly developed area of the law. Furthermore, providing unrestricted gifts of an invention, e.g., vectors or libraries, [n.26] to colleagues and friends in the field of molecular biology may present long-term problems for the donor patent owner in subsequent attempts to restrict the making, using, and selling of the invention.

Some of the questions and potential problems in this arena of property rights in living organisms are peculiar to molecular biology, and the problems arise from recent advances in this science. Other questions already have established answers in case law that has developed around the Exhaustion Doctrine.

This article argues that the distinctive qualities of biotechnology will establish the Exhaustion Doctrine as a license implied in fact [n.27] and weaken *294 the implication in law. [n.28] Further extensions of the Exhaustion Doctrine could provide additional protections for the biotechnology industry. Section I of this Note outlines the general

basis for the grant of intellectual property rights in original inventions as well as an overview of the rights and remedies available to the patent owner. Section II provides an overview of the disposition of patent rights granted by the government and the historical basis of the Exhaustion Doctrine. This section also sets forth the distinctions between a license implied in law, such as the Exhaustion Doctrine, and a license implied in fact, such as contractual terminology. Section III sets forth several very general considerations regarding the nature of biotechnology and obtaining patent protection in the field. The third section also discusses recent attempts to negate patent protection in the field. The specific application of the Exhaustion Doctrine to biotechnology is discussed in Section IV. The premise that the distinctive qualities of biotechnology will establish the Exhaustion Doctrine as an issue implied in fact and weaken the implication in law is also considered in this section. Further extensions of the Exhaustion Doctrine could provide additional protections for the biotechnology industry and advance important policy considerations. The principles for such a broad interpretation are set forth in Section V.

I. BACKGROUND

The patent system of the United States has been exceedingly successful in protecting new ideas and inventions. The concept of government protection for a limited period of time was considered of sufficient import by the Founding Fathers to explicitly set forth the right in the Constitution. [n.29] The government provides this protection to the patent holder in exchange for a public disclosure of her invention. A by-product of the transaction is the creation of a data base of technology in the form of public, indexed, and therefore accessible, issued patents. [n.30] This section sets forth both the constitutional basis of the grant and the nature of the grant. The present congressional implementation and requirements are also considered, as well as the rights conferred upon the grant of a patent and remedies for violation or infringement of those rights.

*295 A. Constitutional Authority

Authority to grant exclusive rights to inventors is specifically set forth in the Constitution. Article I, section 8, clause 8 of the United States Constitution provides Congress with the authority "to promote the Progress of . . . useful Arts, by securing for limited Times to . . . Inventors the exclusive Right to their . . . Discoveries." This right is one of only two property rights set forth in the originally proposed Constitution. [n.31] The explicit presence of the right in the text of the Constitution signifies the great importance that the Founding Fathers placed upon its protection. [n.32]

The text of this section of the Constitution indicates that this right is qualified. [n.33] The grant of the right is to promote progress, that is, the general good, not the individual good of the inventor. Any grant or right to the inventor is tempered by whether the grant provides sufficient overall benefit to the People [n.34] to justify a monopoly right. Therefore, the right is a privilege conditioned by a public purpose. [n.35]

The exclusionary grant can ultimately benefit the public by a variety of direct and indirect mechanisms. These mechanisms include: (1) providing the prospect of obtaining exclusive rights, thereby giving an incentive to invest in the initial research; [n.36] (2) providing an incentive to develop and market an invention in which the inventor holds possession of an exclusive *296 right; [n.37] and (3) promoting disclosure of new inventions and, thereby, enlarging the public storehouse of knowledge. [n.38] Moreover, the creation of a data base of technology in the form of indexed and available issued patents provides the public with accessible data in a wide variety of fields. [n.39]

B. Congressional Implementation and Requirements

Statutory implementation of the constitutional authority to confer patents has varied throughout the history of United States. [n.40] The present embodiment for utility patents is found in the 1952 Patent Act. [n.41] As set forth in section 101: "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent . . . . " [n.42] Thus, the subject matter of the statute requires the invention be any one of: a process, which is defined as a method, art, or process and includes any new use of any known machine, process, material, composition of matter, or manufacture; [n.43] a machine, which is meant to embrace any type of mechanism, device, or apparatus; [n.44] an article of manufacture or simply manufacture; [n.45] or a composition of matter. [n.46] While these categories may appear to be all *297 encompassing, they are actually limited, and of limited scope; principles, [n.47] laws of nature, [n.48] physical phenomena, [n.49] abstract ideas, [n.50]. and, especially, products of nature are not patentable. [n.51]

An invention must also be useful and possess some human intervention to be patentable. [n.52] This human intervention can be as straightforward as purification and isolation of a product of nature. [n.53]

In addition to delineation in an established statutory category, possession of utility, and creation by human intervention, an invention must also be unanticipated, i.e., new to the public. [n.54] While there is an absolute requirement for novelty at the actual time of invention, there is no such requirement for the date of filing the application for the patent. However, a statutorily mandated bar requires filing for a patent within one year of disclosure of the invention by the inventor or anyone else. [n.55]

Even if the invention satisfies the requirements of Sections 101 and 102 of Title 35, a patent is still not guaranteed unless the invention is nonobvious. [n.56] Thus, each invention must be unique and nonobvious - but *298 nonobvious to whom, and nonobvious with respect to what? Such potentially subjective questions in the determination of nonobviousness were clarified in Graham v. John Deere Co. [n.57] The Court set forth the primary inquiries for the determination of obviousness as a three prong test: (1) determining the scope and contents of the prior art or knowledge in the area; (2) ascertaining the differences between the prior art and the claimed invention; and (3) resolving the level of ordinary skill in the pertinent field of the invention. [n.58] The

factual inquiry attempts to bring objectivity to the subjective qualities of nonobviousness through a "reasonable man" standard [n.59] within fields of varying expertise by creating a reasonable man of ordinary skill in each of these fields. Secondary considerations, such as "commercial success, long felt but unsolved needs, failure of others, etc." are also set forth as relevant indicia of obviousness or nonobviousness. [n.60] The Court's ruling in John Deere thereby clarified the statutory concept of nonobviousness, a requirement in addition to utility and novelty.

C. Rights Conferred Upon Grant of Patent

Statutory authority gives the owner or holder of a patent the "right to exclude others from making, using, or selling the invention throughout the United States" for a term of seventeen years. [n.61] The grant of a patent is the grant of the right to invoke the power of the State to exclude others from utilizing the patentee's discovery without his consent. [n.62] The exclusive right of the patent holder is an exclusionary right only; the patentee himself has no actual affirmative right to make his invention and must follow all laws, including other exclusionary property rights granted in other patents that might be required to practice his invention. [n.63] Thus, a patent property right is a very limited one. [n.64]

*299 D. Infringement

Infringement of the patent holder's right can be of three types: direct, [n.65] active inducement, [n.66] or contributory. [n.67] Knowledge is not an element of violation of 35 U.S.C. § 271(a); [n.68] therefore, one can be guilty of direct infringement even with a lack of any intent. [n.69] Case law has implied a *300 requirement of intent for violations of 35 U.S.C. § 271(b) [n.70] and intent is an element of 35 U.S.C. § 271(c). [n.71] Even repair, if extensive, can be considered to be an infringing act, although the courts consider it permissible to make a repair that is not a complete reconstruction. [n.72]

The remedies for infringement include court orders to enjoin the manufacture, use and sale of the infringing product [n.73] as well as damages for lost profits. [n.74] For circumstances in which there is clear intent to infringe, up to three times actual damages and legal fees can be granted. [n.75] The court can also demand the outright destruction of the infringing article. [n.76] Title 35 U.S.C. § 283 expressly permits the courts to "grant injunctions in accordance with the principles of equity to prevent violation of any right secured by patent, on such terms as the court deems reasonable." [n.77] These remedies are discretionary, governed by the rules of equitable relief and, thus, *301 grants and denials of injunctions are reviewed solely for clear error or abuse of discretion. [n.78]

II. DISPOSITION OF PATENT RIGHTS AND THE DEVELOPMENT OF THE EXHAUSTION DOCTRINE

The property rights bestowed by the government upon the grant of a patent can be used or transferred by the patent grantee. An invention, such as a composition of matter, can be separated into the actual physical object of the invention per se and the intellectual property rights that permit the patentee to exclude all others from making, using, or selling the object of the invention. The rights to the physical object that has been patented can be transferred by any contractual method. The patent rights, or intellectual property rights, are distinct from the physical object that has been patented; the patent rights exist only to the extent permitted by the laws of the government. In addition to explicit contractual agreements for the transfer of these rights, courts will imply the transfer of certain rights via the Exhaustion Doctrine, by the mere sale of an object of an invention. [n.79] The interest acquired by the purchaser of patented articles that are sold without any condition or limitation entitles the purchaser to the absolute right to the use and disposition of the articles. Where notice of some limitation on the transferred rights is given, however, the formation of the contract for sale implicitly accounts for the limitation in right. The interest purchased is thus limited, and violation of that limitation is an infringement of the patent right.

A. Disposition of Patent Rights

The owner of a patent acquires the entire bundle of property rights that constitute the patent and has the right to exclude others from making, using, or selling the invention. [n.80] The rights can be transferred on an exclusive or non-exclusive basis. [n.81] In addition, the owner can transfer rights to specific *302 embodiments of the invention delimited as individual "claims." [n.82] The Patent Act makes no express statement about the divisibility of the patent right other than that the right may be territorially assigned. [n.83] Nevertheless, patent rights are typically transferred in a number of different quanta including assignment, grant, and license. [n.84] Transfer of the res, or the object per se that is the subject of a patent, is simply considered a "sale"; the physical object that is the subject of a patent is distinct from the intellectual property rights that are granted by the government to the patent owner. [n.85]

The assignment of a patent is the transfer of the patent rights to another entity. [n.86] While individual claims may be assigned to the exclusion of other claims, an assignment is the transfer of all or an undivided interest of the rights of the claims at issue. [n.87] This undivided interest refers to an interest in the claimed invention without limitation as to field of use. An assignment limited to specific geographical territory is a grant as provided for in 35 U.S.C. § 261. [n.88]

If any of the rights of the assignment is withheld, the transfer is a license. A license is either a permission to make, use, or sell articles embodying the invention, or a transfer, "which does not affect the monopoly of the patent other than by estopping the licensor from exercising prohibitory powers in derogation of privileges conferred on the licensee." [n.89] A license can take different forms with different rights retained by the patent owner. An individual can possess the right to make and use an invention but lack the

ability to sell or make certain types of sales of the invention. [n.90] A license *303 may be either express and conferred by a written instrument or implied by circumstances operating to estop the patent owner from denying rights to the apparent licensee. [n.91]

A sale of the res is simply the purchase of the object that is protected by the patent without explicit sale of any of the patent rights. When the invention is a process, the sale is of an intellectual object because there is no physical object accompanying a process patent.

If the Patent Act was the only guiding force, the patent owner, who has a right to exclude others from using the invention, might appear able to exert control over a purchaser's use long after the sale of the invention. Under this strict statutory interpretation, the purchaser of the actual physical object or res could be enjoined from using the object purchased. The object would become little more than technological art after the sale.

The courts, however, have not permitted the patent right to be construed so expansively. Instead, the courts assumed an exhaustion of some of the rights granted by the State at the time of sale and created the "Exhaustion Doctrine." [n.92] If the patent owner, or a valid licensee, sells the object that is the subject of a patent, the courts will imply a limited license to use the object. [n.93] Thus, the transfer of the res from the patent owner or licensee is also a transfer of some of the intellectual property rights granted by the state.

B. Development of the Exhaustion Doctrine

Early patent statutes permitted a renewal of the patent term, thereby extending the patent monopoly. [n.94] In Bloomer v. McQuewan, [n.95] the plaintiff attempted to reclaim control of the patented articles sold under the first term by using the renewed patent. The theory behind this action was that the buyer had purchased only for the first term. The Court did not permit this broadening, indicating that the first sale implied a right to practice or use the *304 item for any patent term of the invention. [n.96] This decision had the effect of exhausting the patent holder's right to control the item after the first sale. [n.97]

This implied right was broadened in Adams v. Burke, [n.98] where the patentee assigned the right to manufacture, sell, and use the invention within a limited geographical area, i.e., a grant. The defendant in Adams, an undertaker, had purchased coffins incorporating a patented coffin lid from the grantee in another geographical area, but utilized the coffins for burial within the geographical area granted to another assignee. [n.99] The Court held that a purchaser of the patented object acquires the right to use it anywhere, without reference to other assignments of territorial rights by the same patentee. [n.100] The Court stated that "in the essential nature of things, when the patentee, or the person having his rights, sells a machine or instrument whose sole value is in its use, he receivesthe consideration for its use and he parts with the right to restrict that use." [n.101] Apparently, the right to use the purchased object stands on a different

ground from the right to make and sell the object, and is inherent in the nature of a contract of purchase that carries no implied limitation of the right to use within a given locality.

This case law restriction of the statutory right has become known as the Exhaustion Doctrine, and is an implied license to practice the invention "freed from any claim of the patentee." [n.102] The implied license includes both a license for resale of the object as well as for repair of the object. [n.103] The *305 exhaustion of the patent owner's rights upon sale is also an intimate part of the right to repair because use of an invention could cause a need for repair. [n.104] Since the right to practice the invention has already been purchased, the right need not be repurchased when the patented article is repaired. [n.105] While the courts have willingly implied a license to use and a license to sell, they have not implied a license to make. In fact, the implied license to repair is qualified to only those repairs that do not constitute "making" the object of the invention. [n.106]

The limited license was further qualified in General Talking Pictures Corp. v. Western Electric Co., [n.107] to permit a field of use restriction. At issue was whether the patentee could restrict the use of a device manufactured under the patent after that device had passed into the hands of a purchaser and consideration had been paid for it. The manufacturer in the case had knowingly sold patented amplifiers for use in a field reserved for others by exclusive licenses and the manufacturer's license was expressly confined to sales outside of that field of use. [n.108] The Court found that the manufacturer had infringed since it did not own the patents or any interest in them and was a mere licensee under a non-exclusive license. [n.109] The license amounted to no more than a waiver of the right to sue as long as the manufacturer operated within the narrow ambit circumscribed by the license. [n.110] The defendant, who had purchased from that manufacturer, had actual knowledge of the original license restrictions at the time of purchase as a result of both communications with the licensee and notice printed on the purchased containers. [n.111] Accordingly, the defendant was found to have infringed the patent. Thus, in the case of an individual who purchased items with *306 knowledge of the limitation of use from a manufacturer with a limited license, the Supreme Court was willing to hold the purchaser to the limitation and find infringement when the limitation was violated. [n.112]

In both the original opinion and on motion for rehearing, the Court refused to decide the question of whether such a restriction should be enforced against a purchaser of goods manufactured under the patent and taken without notice. [n.113] The Court did not consider lack of intent to be a factor in the case since the goods were illegally manufactured and sold, and were purchased with actual knowledge of the license restrictions. [n.114] Thus, the Court never reached the issue of sale by a limited licensee to a purchaser without notice of the status of the patented article. [n.115] The limitation of the *307 Exhaustion Doctrine via contractual obligations was recently reaffirmed by the Federal Circuit in Mallinckrodt Inc. v. Medipart Inc. [n.116] The plaintiff had sold a patented device bearing the inscription "Single Use Only". [n.117] In addition, the package insert provided with each device indicated that it should be used for a single patient only and set forth instructions for proper disposal. [n.118] The district court held

that such a restriction could not be imposed under patent law. In support of its ruling, the district court invoked the Exhaustion Doctrine and cited a group of cases in which the Supreme Court had considered and affirmed the basic principle "that unconditional sale of a patented device exhausts the patentee's right to control the purchaser's use of the device . . . . " [n.119] In reversing the district court, the Federal Circuit stated that: "[t]he principle of exhaustion of the patent right did not turn a conditional sale into an unconditional one." [n.120] The court further indicated that the "right to exclude may be waived in whole or in part. The conditions of such waiver are subject to patent, contract, antitrust, and any other applicable law, as well as equitable considerations. . . . As in other areas of commerce, private parties may contract as they choose, provided that no law is violated." [n.121] On remand, the district court was requested to determine whether Mallinckrodt's restriction was reasonable within the patent grant or whether "the patentee [had] ventured beyond the patent grant and into behavior having an anticompetitive effect not justified under the rule of reason," [n.122] and if the sale was actually conditioned on the license notice. [n.123] Thus, the Federal Circuit recognized both the vitality of the Exhaustion Doctrine and the ability to limit the Doctrine's breadth.

An equitable rationale underlies the underpinnings of the Exhaustion Doctrine. Selling a patented article to an individual, but precluding the use of the article, would be inequitable unless the sale took place with notice of the restriction. In United States v. Univis Lens Co., [n.124] the Court stated *308 "[a]n incident to the purchase of any article, whether patented or unpatented, is the right to use and sell it . . . . "

From these cases two general rules can be ascertained. First, if only a limited interest is purchased, as in General Talking Pictures, [n.125] exceeding the limitation produces infringement. On the other hand, where the interest transferred is not expressly limited, as in Adams, [n.126] no limitation will be implied. Express restrictions on purchased goods are, therefore, enforceable under patent law so long as it is clear to the buyer what she has purchased. [n.127] Where the court refused to apply the Exhaustion Doctrine to all of the claimed embodiments of the patent, the buyer had purchased with notice that the sale was for a limited use. [n.128]

During the 1952 revision of the United States patent laws, no legislative qualifications of the Doctrine occurred. This survival of the Doctrine suggests an implicit recognition of the Exhaustion Doctrine by the Congress since it was not statutorily prohibited or qualified. [n.129]

Normally, the exercise of the patent rights is cut-off after the first sale of the patented item, since the sale provides adequate financial reward to stimulate invention. [n.130] If this cut-off did not occur, the patent owner could independently exert absolute control over the goods for the life of the patent, even in the absence of notifying the purchaser of this intent, due to the *309 patent owner's right to exclude all others from using and selling. [n.131] The Exhaustion Doctrine protects a purchaser from interference in the use of the purchased patented item and in its disposition or sale. [n.132] A license is implied in law through the fiction of a quasi-license to use the purchased item. [n.133] The court will not delve into the factual elements of the case to determine implications of

fact when no express limitations or conditions have been set forth. Instead, the license is imposed by the State regardless of any actual intent by the parties to be legally bound. Thus the license is implied in law; [n.134] it is an obligation imposed by law on the parties' agreement and is not subject to their unexpressed subjective intent. [n.135]

The law governs the parties' agreement but does not write the entire agreement. [n.136] The scope of the contractual obligation comprises two components: the actual written agreement and the rules of law a court imposes to fill in gaps in the written agreement. [n.137] Thus, where the agreement is silent regarding a component of the contract, such as the sale of coffin lids in Adams, the court will imply in law a license to use in any manner the purchaser wishes. When the contract is not silent in an area, but instead exhibits specific, well-defined obligations, such as in General *310 Talking Pictures, the court will not imply a license contradictory to the specific well-defined obligations of the contract. [n.138]

The value of the Exhaustion Doctrine is evidenced by both the spread of the concept to other domains of intellectual property, and the international adoption of the concept. Thus, similar licenses implied in law are found in other areas of intellectual property such as trademarks and copyrights, although different names are occasionally used for the implied license. [n.139] The Exhaustion Doctrine has also been adopted internationally in common law and code jurisdictions. [n.140] The Exhaustion Doctrine is therefore a firmly established element of intellectual property law, in general, and patent law, in particular.

*311 By permitting an implied license to use, the Doctrine facilitates simplified sales of patented articles. For a simple case in which only a single possible use exists, the purchaser also implicitly buys a license for that use and a license for disposition of the property in any desired manner. [n.141] If a sale takes place with clear notice of reasonable restrictions, those restrictions can be enforced against the purchaser. [n.142] Thus, for a sale with clear notice, the law will imply a loss of the patent owner's "right to exclude others from . . . using and selling the invention throughout the United States." [n.143]

Along with the right to exclude selling and using the invention, an additional exclusionary right is found in the statute. This right allows exclusion of all others from making the invention, [n.144] and is perhaps the most basic of the three rights conferred by the grant of a patent. Courts have never been asked to determine whether an implied license for this exclusionary right might exist under certain circumstances. Without an implied license to make the invention, the original purchaser cannot compete with the patent owner for sale of the res. Furthermore, the owner can indirectly maintain her exclusionary rights regarding using and selling simply by regulating distribution of the patented object of the invention. [n.145] The patent owner can obtain sufficient financial reward in the initial sale of the item, as well as provide express limitations at the sale. Thus, the patent owner can incrementally recoup developmental costs via individual sales to a large number of individuals because the patent owner is the sole source of the patented object. Anyone else making the object is an infringer, in direct competition with

the patent owner for the market, and responsible for destroying the patent monopoly and the benefits that accrue to the patent owner from that monopoly. [n.146]

Until recently, any question of an implied license to make copies of an invention would not have arisen, because manufacturing the res and its subsequent sale is at the heart of the mercantile value of an idea or invention. Furthermore, "making" was never a necessary element of using the invention. An implicit license to make the patented article, simply because of the sale of the article, would destroy the patent monopoly; this destruction would restrict the inventor's benefit. The question of whether the implied license extends to making the patented article could never emerge because, until recently, making the article required specific intent, *312 and using the article did not require making the article. Recent advances in biotechnology, where the patented article can, and sometimes must, make copies of itself, bring this question to the forefront of the scope of any implied licenses which transfer at the time of sale. These recent advances may necessitate tinkering with the Exhaustion Doctrine to make the license one implied in fact and not one implied in law.

III. BIOTECHNOLOGY AND PATENTS

Biotechnology is "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals or to develop microorganisms for specific uses." [n.147] Biotechnology is at least as old as bread or wine-making via the activity of yeast, but it is now becoming more important due to improvements in the methods of characterizing the activities of the living organism as well as improvements in the manipulation of those activities. [n.148] Because of the great cost, in terms of both time and money needed to discover and develop biotechnology products, inventors frequently attempt to obtain patent protection for their discoveries. [n.149] This section will briefly consider the scientific underpinnings upon which biotechnology is built, the property rights granted when this technology is patented, and current proposals to restrict those property rights.

A. Science Behind Technology

Deoxyribonucleic acid (DNA) is a large polymeric molecule that directly and indirectly controls the production and reproduction of the cell, organ, and animal. [n.150] DNA is made up of four simple subunits, the ordering of these *313 subunits results in genes that are the basic unit of heredity. [n.151] The sequence of DNA's subunits, called nucleotides, determines the exact biochemical characteristics of an organism. [n.152] Although the number of uniquely different nucleotide sequences along the DNA molecule is enormous and results in the great diversity of living systems, the similarity of components is so great that the cellular machinery of vastly different organisms can frequently use the same genes and gene products. [n.153] These genes are linked together in a linear array to produce a chromosome. [n.154] A structure capable of

incorporating DNA and delivering it to the inside of the cell is a vector and will frequently comprise a chromosome or part of a chromosome. [n.155]

Usually, the DNA directs the manufacture of ribonucleic acid (RNA) which, in turn, directs the production of proteins. [n.156] The proteins are frequently of use per se or can be modified or even used to manufacture antibodies. [n.157] Normally, the DNA as a chromosome is packaged with the necessary protein machinery to carry out its function -- replication -- within structures known as cells or bacteria. [n.158]

Cells serve as the basic building block for organs and multicellular organisms. Genetic manipulation of the genes in a multicellular animal or plant through the introduction of extraneous genetic material gives rise to transgenic animals and plants. [n.159] These transgenic organisms can arise from incorporation of a functionally active gene or by destroying a normal gene via insertional mutagenesis or homologous recombination. [n.160] The most common scientific technique for producing a transgenic animal is microinjection, which is accomplished by injecting purified copies of a gene into a fertilized animal egg. [n.161]

In the biotechnology of multicellular organisms, the initial organism is the most difficult and costly to engineer or create. [n.162] Once the first *314 organism is produced, conventional breeding methods can be used to make other transgenics. [n.163] To prove origin, these subsequent transgenic organisms can be related to their founder organism using such technological advances as DNA fingerprinting. [n.164]

B. Historical and Present Role of Patenting in Biotechnology

The component parts of living organisms are treated as any other chemical compound by the United States Patent and Trademark Office. DNA and RNA are classified as carbohydrates because of the presence of the deoxyribose or ribose sugars, respectively. [n.165] Proteins are simply a part of the carbon-containing class of compounds. [n.166]

Although patents to life forms existed at least as early as 1873 when a patent was granted to Louis Pasteur for isolated yeast, [n.167] patent protection for biological materials was restricted for many years because of the long-standing belief that living organisms and cells were unpatentable products of nature. [n.168]

Case law provided a basis for this belief. Since naturally occurring organisms were not new, the grant of a patent would remove from the *315 public domain something "which nature has produced and which nature has intended to be equally for the use of all men." [n.169] Thus, although microorganism-related inventions were patentable, [n.170] the microorganisms per se were held unpatentable. [n.171]

Patenting biotechnological inventions, such as living organisms, presents unique administrative obstacles because biotechnology is the only known art where the enablement [n.172] and notice requirements of 35 U.S.C. § 112 cannot always be met by

words or diagrams alone. These problems have led to the deposit of microorganisms and plants for patent purposes. [n.173] To simplify compliance with deposit rules, the United States agreed to the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure in 1979. [n.174] The Treaty provided methods and procedures to be followed in depositing microorganisms to comply with the disclosure requirements of the signatories' patent laws. [n.175]

The following year, the Supreme Court considered the question of whether a man-made microorganism was patentable subject matter under 35 U.S.C. § 101 in Diamond v. Chakrabarty. [n.176] The Court found that an engineered bacterium, which was capable of degrading crude oil, was patentable under the statute reasoning that "Congress plainly contemplated that the patent laws would be given wide scope" [n.177] and intended patentable subject matter to "include anything under the sun that is made by man." [n.178] Thus, the relevant distinction was "not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions." [n.179] *316 The Supreme Court thus assumed the microorganism to be a patentable manufacture or a patentable composition of matter. [n.180]

Following the broad language of the Supreme Court in Chakrabarty, the Board of Patent Appeals and Interferences, in Ex parte Allen, [n.181] held that multicellular organisms were patentable subject matter. Four days after the Allen decision was handed down, the Patent Office announced it would accept applications for patents on "naturally occurring nonhuman multicellular living organisms, including animals." [n.182] The announcement indicated that, for a patent to be granted, an animal must be "given a new form, quality, properties or combination not present in the original article existing in nature." [n.183]

Minor modifications in the rules promulgated by the Patent and Trademark Office may be necessary to permit reproducibility, and therefore fulfill the statutory requirements of the Patent Act. [n.184] There is, however, no fundamental difference between the patenting of multicellular organisms and *317 the patenting of any other animate or inanimate object. Most of the public concern surrounding the patenting of multicellular animals is actually grounded in a vague notion of the moral implications of altering the genetic component of a living organism. [n.185] The concern is not so much whether these inventions should receive patent protection as it is whether this type of research should be permitted at all.

Congressional reaction to the announcement by the Patent and Trademark Office sanctioning animal patents included the introduction of several bills to impose a moratorium on such patents. [n.186] To permit time for legislative action, the Patent Office instituted a self-imposed eight month moratorium, [n.187] after which it granted the first animal patent -- a mouse used as an experimental model. [n.188] The patent prompted a backlash from animal-rights groups that appeared to generate a second self-imposed moratorium. [n.189] The second moratorium recently ended with the granting of three patents to animals, and more than 180 applications for animal patents are awaiting action by the Patent Office. [n.190]

*318 This issue of patenting multicellular organisms has also been considered internationally. While Japan took a pragmatic approach to animal patents, Europe was initially hesitant to permit the patenting of animals. [n.191] Recent court decisions indicate that patentability of multicellular organisms is permitted under the PCT. [n.192]

C. Farmers' Exemption

While Diamond v. Chakrabarty [n.193] indicated that neither constitutional nor statutory bars on the patentability of living organisms exist, the scope and effect of patents on living organisms has yet to be determined. Attempts have been made to institute unnecessarily restrictive legal requirements regarding biotechnological inventions associated with agricultural production. [n.194] Some farmers believe that by purchasing transgenic animals they will become little more than hired hands, following the dictates of the patent owner, who may appear to have the legal right to exclude them from making, using, and selling animals that they bought and raised. [n.195] Thus, farmers and a few of their congressional allies have attempted to legislate away what is perceived as a threat to the farmers' way of life. [n.196]

Congressional action to impose a long-term moratorium on animal patenting has found insufficient support to become law. The 101st Congress saw a reintroduction of the Transgenic Animal Patent Reform Act, [n.197] which would have permitted farmers unrestricted use of purchased transgenic animals. According to the Act, the owner of a farm would have the legal right to breed (i.e., make) any purchased transgenic animals, use the animals and their offspring, and sell the animals and their offspring. [n.198]

Ironically, this type of legislation could actually damage the economic position of the small farmer, the very individual the legislation was intended to benefit, and the legislation could also damage the fledgling industry by removing economic justification for inventing transgenic animals. The damage could result from severely restricting the patent monopoly granted to the inventor and removing much of the economic benefit of engineering the *319 "founder" organism. Every purchaser of the transgenic organism would become a competitor of the inventor in the marketplace. Without some method to control the invention after the sale, selling a genetically engineered cow would amount to handing over the keys to the factory. The inventor would be forced to sell to only those large enterprises that could afford the total cost of development; therefore, the inventor could not incrementally recoup his investment through sales to a large number of small enterprises because any of the enterprises could immediately go into direct competition with him. Thus, the small farmer would be unable to obtain these improved varieties and would have to compete from a technologically inferior position, i.e., using "low tech" animals. [n.199]

IV. EXHAUSTION DOCTRINE IN BIOTECHNOLOGY

The Exhaustion Doctrine permits a lawful purchaser of a patented item to use that item in spite of the exclusionary rights set forth in the Patent Act. [n.200] The underlying equitable rationale for the Exhaustion Doctrine remains the same whether using a patented invention such as a coffin lid, as in Adams, or a microorganism engineered to make insulin. A principled way of making a distinction between applying the Exhaustion Doctrine to an inanimate invention and an animate one is not apparent.

How extensively this Doctrine will be applied in biotechnology is unclear. Some applications of the Doctrine to biotechnology present a case of first impression, since existing case law has developed around compositions and machines with a single use, while in biotechnology, compositions and machines may have many commercial uses. Furthermore, the case law was developed for compositions and machines that were not able to replicate, while in biotechnology the compositions or "machines" can make copies of themselves. The Exhaustion Doctrine permits an implied license for "use" of an invention and an implied license to dispose of or sell the purchased item.

*320 Holding that there is also an implied right to use the invention in any obvious method of use [n.201] or in any non-statutory use, [n.202] however, might work an injustice on the patent holder. For an obvious [n.203] or a non-statutory use such as breeding, the inventor could not obtain separate method of use patents. [n.204] The sole protection would be the exclusionary rights granted by the Patent Act for the initial invention. By implying a license to use the invention for replication or breeding, the Exhaustion Doctrine would be creating a future competitor at each sale. The buyer could breed the animals or grow the cell lines at a cost similar to that of the inventor. The purchaser would, however, forego the great development cost of the original parent or founder organism. Any offspring or descendants could then be sold or used by the purchaser. [n.205] The creation of competitors at each sale would destroy the monopoly patent right, and greatly decrease the benefit bestowed by the grant of a patent.

The great development costs accrued during the production of the founding organism could not be incrementally recouped in many small sales but would have to be generated by one or by a few large sales, thereby greatly reducing the potential market and alienability. The inventor would have a greatly restricted market for his invention and would risk the patent monopoly at the first and each subsequent sale. Such a scenario would hardly entice individuals to invest the large amounts of time and money necessary to create founder organisms and pursue research and development in biotechnology. By failing to provide sufficient protection and rewards to those willing to risk the time and efforts, the law would fail in its stated purpose of promoting "the Progress of . . . useful Arts." Therefore, reading the Exhaustion Doctrine in the broadest sense possible, and implying a legal *321 right to use the replicating organism in any manner the purchaser wishes, could harm the economic incentives of the patent system.

Alternatively, by not invoking the Exhaustion Doctrine and not implying a license to use the invention, the courts could work an injustice on the purchaser. In many situations in biotechnology, the replication, or "making", of the organism or composition is an actual

requirement for effective use, e.g., cloning or screening. [n.206] The ability to use must be implied for the sale to be a rational exchange between two parties. As an example, purchase of a transcription vector construct specifically designed to provide high levels of transcription would make little sense if the purchaser could not grow the transcription vector in a recipient organism in a quantity sufficient for effective transcription. Similarly, sale of an animal capable of improved litter size or increased reproductive abilities would be of little use to a buyer not permitted to fully utilize such attributes.

A. Proposal for the Exhaustion Doctrine in Biotechnology

To avoid injustice, the courts should apply the Exhaustion Doctrine such that it becomes a doctrine implied in fact instead of a doctrine implied in law. Different factual contexts, as well as different understandings by the parties involved in the purchase and sale, will affect the outcome of the imposition of the Doctrine and increase the importance of creating a clear paper trail for the transaction. When the parties involved in the sale of a biotechnological invention have bargained for specific rights, the court will have to protect the benefit of the bargain. Even when the protection of this benefit requires the court to imply an additional right, i.e., one not explicitly set forth, such as the right to make the invention, the court will have to imply such a right.

A factual inquiry regarding the consideration paid by the purchaser will often lead to a determination of what was actually intended in the transaction; it would stretch the imagination to imply a license to make *322 large amounts of the invention if only a minor consideration were provided at the initial sale. Evidence of the consideration provided, coupled with any indication of the mental or subjective intent of the parties involved, should strongly influence the outcome. Although innocent infringement is no defense to a suit of infringement, infringement by reason of unclarified contract terms, i.e., whether the buyer was permitted a limited license to make the organism, should be construed to the detriment of the patent holder because General Talking Pictures has provided him with the ability to limit the implied license by express notice of limitations. If the patent owner requires a detailed contract, with demands for extensive record keeping and royalties for all of the offspring, he might have to contend with potential buyers unwilling to purchase an animal that comes with a lifetime of paperwork.

The court should analyze the issue of implied license on a case-by-case basis, looking into the facts surrounding each sale. Any suit for injunction for patent infringement brought by the patent owner against the purchaser of a biotechnological product will be presented in a court that has been granted wide discretion to fashion remedies. [n.207] The equitable nature of the resultant proceedings suggests that fairness can be of paramount importance. In situations where efficient use requires "making" the invention, e.g., cell lines and genes, the court would totally destroy the value of the purchaser's bargain by enforcing restrictions. If multiple uses of the invention are possible, the intent of the contracting parties should be of primary importance in fashioning a remedy. Thus, discerning the intent of the purchaser at the time of sale will be paramount to the court's decision. The Exhaustion Doctrine would, thereby, be transformed from a principle

implied in law to one implied in fact. This transformation would transfer the decision-making from a judge to a jury, perhaps an unpleasant alternative for a large agribusiness concern attempting to enjoin a small farmer in his own community. [n.208] By considering the likely intent of the parties and applying an overriding concern for fairness, a court should be *323 able to reach a conclusion in several broad areas in which the Exhaustion Doctrine might be applicable.

Several typical scenarios typical in biotechnology may be illustrative of the nature of the inquiry and the problem facing the court. Unrestricted gifts to a colleague represent a particular problem in the area of biotechnology, a discipline that has been marked by cooperation and sharing. If a gift sequence or microorganism is used in the construction of a subsequent invention, the gift recipient would not be able to use or, in some cases, even maintain this subsequent invention without the extension of the Exhaustion Doctrine to permit "making" [n.209] the invention. Because of this eventuality, a court of equity might be easily persuaded to grant this permission. Unrestricted gifts, if no case can be made for the gifts' use in experimental development, could allow the recipient to use the gift for any intended purpose so long as this gift was originally obtained from the patent owner or his agent. [n.210]

In the case of the purchase of a regulatory sequence, or promoter, [n.211] where the primary use of the sequence is to form a self-replicating construct, the court would have to permit the purchaser to use the sequence as a promoter so that the purchaser can receive the benefit of the bargain. The only conceivable utility for the promoter would be its use in conjunction with a self-replicating system since an individual microorganism produces only de minimus amounts of material.

In the sale of an oligonucleotide of a gene sequence, which can be used as a nucleic acid probe [n.212] for that sequence, the probe might be only a small part of the claimed invention (e.g., claims to a probe for a gene, claims to a gene, claims to a protein, and claims to an antibody to the protein [n.213]). The gene sequence per se may or may not have utility or usefulness other than to *324 make the protein. [n.214] If the gene has no recognized utility, except for the production of the protein, the court should imply a license to make the protein, otherwise there would be no economically rational incentive for the purchase of the gene. Similarly, the primary use of the protein may be to make antibodies. If the only utility of the invention were to be found in the antibody, the sale of the gene would seem to provide an implicit license to replicate the gene, to make host cells carrying the gene, to make the protein, and, subsequently, to make antibodies to the protein.

Methods of use can be individually pursued as distinct inventions. [n.215] Selling one patented invention, such as a gene, while the protein is the subject of another patent, would still permit the patent owner to control the use of the protein. [n.216] However, when the gene is lumped together with its product, antibodies to its product, host cells, and other methods of use in the same patent, the rights being transferred in the simple sale or unrestricted gift of a gene or probe are not apparent. Without a clear indication in

the transaction regarding intention, the court is left to decide the scope of the sale and which licenses were implied in the sale.

As a further illustration, in buying a cell line, the purchaser is faced with a dilemma: either feed the line or let it die. If the new owner feeds the cells they will multiply, and, if not for an implied license to make, the owner would be infringing. The sale or unrestricted gift of a cell line would, thus, seem to imply a license to keep the cell line alive and permit it to multiply.

In the case of transgenic multicellular organisms, a purchaser without the protection afforded by the Exhaustion Doctrine might infringe under 35 U.S.C. § 271 (a) or (b) any time male and female transgenic organisms were together. Simply keeping the genders together might be considered a form of inducement. Whether the infringement were innocent or with intent would affect only violation under § 271(b) and the extent of damages. If the facts of the case implied a license to breed the animals, no suit would lie.

*325 B. Policy Reasons for Broad Interpretation of the Exhaustion Doctrine

Transforming the Exhaustion Doctrine from a principle implied in law to one implied in fact would obviate many of the potential problems that will occur when the doctrine is applied to inventions that make copies of themselves. In addition, the courts could further refine the Exhaustion Doctrine to permit its use for only certain types of sales. For example, an implied license to "make," where the object made will be used only by the original purchaser, might be permitted by the court; however, the court may not grant an implied license to "make" by subsequent purchasers. Enforcement of such a holding would be simplified because, under § 271(c), sale of the item by the original purchaser for use in "making" the invention might be an act of contributory infringement. [n.217] The equitable and legal rationale previously detailed favors implementation of the Exhaustion Doctrine in Biotechnology as a license implied in fact. The following section considers policy reasons for interpreting the Doctrine broadly.

1. Promotion of Alienability and Certainty

At present, a purchaser of an object that is the subject of a biotechnology patent does not know exactly what rights she is buying. This situation leads to confusion in the market and generally lower value for the products. One of the costs of not maintaining control of the self-reproducing invention -- thereby injecting a measure of uncertainty into the commercial arena of biotechnology -- should be loss of some of the ability to exclude. Maintenance of all of the patent rights requires only a clear delineation of the actual intent of the parties, i.e., formation of a license. If the sale is in violation of a license, then the buyer is taking illegal goods and the license holder and seller would be guilty of infringement under § 271(a). [n.218]

The actual formation of the licensing contract is beneficial due to the clarification inherent in reducing the rights to the concrete form of a contract. The required formality of a written contract "promotes deliberation, seriousness, . . . and shows the act was a genuine act of *326 volition." [n.219] The buyer can bargain for whatever rights are desired; this opportunity to bargain should promote greater efficiency in the market as needless rights are not purchased. Greater alienability of patent rights would occur since an earlier purchase of the product would not operate under different rules after assignment of the patent. In the absence of an express limitation, any use of the product not treated as a separate invention would be permitted. Laches defenses would be less common and, therefore, the value of a patent would be increased, provided the owner was diligent in regard to protecting her rights.

2. Living Systems Should Receive Similar Protection

Similar objects should receive similar protection to promote uniformity and clarity. Improved plants, another invention capable of self- production, already receive some modified protection. [n.220] Plant patents permit the owner to preclude asexual reproduction of the plant. [n.221] This limitation encompasses a determined set of statutory methods that do not include simple binary fission. [n.222] A broad interpretation of the Exhaustion Doctrine would permit genetically engineered organism patents to follow plant patents that permit sexual reproduction.

Although the Plant Variety Protection Act (PVPA) [n.223] gives some protection for the inventor of sexually-reproduced plants, this protection is very limited if the organism is used in a development/breeding program. The legislative history of this Act indicates that use of a protected variety in a development or breeding program does not constitute infringement. [n.224] In addition, the Union for the Protection of New Varieties of Plants (UPOV) *327 treaty, [n.225] to which the United States is a signatory, requires that the production of a novel variety does not constitute infringement. [n.226]

3. Promote the Production and Development of Useful Varieties

Broad interpretation of the Doctrine would greatly promote crossbreeding of different transgenic organisms since such a use would be unlikely to create liability. This crossbreeding would create greater diversity of life forms or stock and would increase the potential for improved, useful varieties, thus advancing the ultimate aim of the Patent Act. The ability to crossbreed would also permit purchasers to make their own observations and analyses: essentially to perform their own experiments since they could benefit from any improvement. This profit motive would add "the fuel of interest to the fire of genius in discovery and production of new and useful things." [n.227]

Furthermore, the Exhaustion Doctrine should be interpreted broadly to restrict monopoly rights and promote competition. By limiting the market control exerted by a patent owner after the sale of the invention, competition would be heightened.

4. Avoidance of Inequities

At a minimum, the court should impose the Exhaustion Doctrine where the purchaser was without notice and unaware of the existence of any patent rights. Thus, when a patented animal or cell line, without notice, becomes the building block of farmers' or corporations' breeding programs, the doctrine should be invoked. Imposition of a broadened Exhaustion Doctrine is particularly critical because contamination or misidentification of biological materials is a frequent occurrence in some areas of molecular biology. [n.228] Without imposition of a broadened Exhaustion Doctrine, innocent intent would still form a clear case of infringement since intent is of noimportance in determining infringement. [n.229] Thus, a patent owner who had not maintained effective control of his invention could bring a *328 corporation or farmer to a halt by injunction and thereby potentially benefit because of his negligent practices. Without some broadening of the present Exhaustion Doctrine, no harm could befall such a patent owner, while a definite benefit might accrue. Although in a court of equity some flexibility is possible, the result of litigation is not guaranteed. [n.230]

Because of the great cost of engineering certain cells or organisms, in the absence of an expansion of the Exhaustion Doctrine, animals with unknown parentage could never be used as the basis of a breeding program because of the potential risk that a property right in the animal might be held by an unknown party. Thus, no matter what valuable attributes the organisms lacking pedigree displayed, they could not be utilized. If these organisms were mistakenly utilized, their offspring could be considered a "constructive trust" for the patent owner, as is found for infringement of the Plant Patent Act. Such "orphan" animals could never be used as the founder organism for transgenic manipulation because of the great risk of losing the entirety of the investment due to infringement of an unknown patent claiming the founder organism. Thus, not only would one of the great benefits of the patent system -- disclosure of inventions so that others can make improvements -- be lost, but biotechnology without the Exhaustion Doctrine would require extensive safeguards to ensure the animals used were not patented, because patented ancestry could preclude use and maintenance of the animals.

For organisms acquired from the wild, the court will have to balance the rights of the patentee with those of the "finder". The ability of the patentee to show that she took any necessary and reasonable precautions to avoid excessive loss of the organism to the environment would be of great importance in determining the outcome of the case. In addition, the court may need to determine how much knowledge the "finder" had regarding any unexpected properties of the material in his possession.

V. MAINTENANCE OF PATENT RIGHTS

The extent to which courts will apply the Exhaustion Doctrine in biotechnology is not clear. Courts are, however, perfectly willing to *329 impose a strict limit on the doctrine

where notice is involved. [n.231] The limitation of the Exhaustion Doctrine in General Talking Pictures [n.232] demonstrates the great value of licensing agreements. Such agreements could be as simple as the shrink-wrap agreements found for computer software. [n.233] A licensing agreement could require the farmer to sterilize (e.g., geld) any marketed animal or its offspring. Merely providing notice that the invention was not sold for commercial use could provide some protection against purchasers becoming competitors. [n.234] Naturally, any licensing agreement that acted as an adhesion contract still comes under the vitiating powers of contract law. [n.235]

Any dangers from the Exhaustion Doctrine can be completely obviated by avoiding a sale altogether. One method to forego the sale of the item is by bailment, which provides protection without the requirements of a patent. [n.236] Strong protection via bailment is especially true for location- specific genetic material since proof of the material's initial origin would be greatly simplified via DNA fingerprinting techniques. [n.237] Thus, the delivery of goods to an individual without any actual transfer of title (i.e. in trust), with a contract to perform the trust, [n.238] and redeliver or dispose of the goods as contracted, would protect the monopoly right. [n.239] The unique nature of *330 biotechnological inventions would make identification of the founder organism relatively straightforward through DNA fingerprinting techniques.

VI. CONCLUSION

The sale of a patented article exhausts many of the exclusionary rights held by the patent owner and creates an implied license to use the patented article. The scope of this license is not clear when one of the uses of the invention is to make copies of itself or to make some other object that is also claimed by the same patent. Sale of such a self-replicating article by the patentee could exhaust the patent monopoly and permit the purchaser to make the patented invention. For the court to invoke the Exhaustion Doctrine, a determination of the presence or absence of an implied license to make the invention will, by necessity, be factually based in biotechnology. Societal benefits would accrue from an expansion of the Exhaustion Doctrine in biotechnology. These benefits include greater alienability of the patented object, uniformity of interpretation of intellectual property law, and promotion of greater and more diversified varieties of plants and animals. Licensing agreements provide an alternative for individual patent owners to maintain their right to exclude others from making their self-replicating article.

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[n.1]. Former NIH Director Bernadine P. Healy has stated "I don't think there is any doubt that the biotech industry is going to be as important to this country as the car industry was." A16 Washington Post Feb. 13, 1992; "Biotechnology is likely to be the principle scientific driving force for the discovery of new drugs and therapeutic chemical entities as the industry enters the 21st century," Office of Technological Assessment, U.S. Congress OTA-BA- 494, Biotechnology in a Global Economy 7 (1991) [hereinafter OTA Global Biotech]; the President's Council on Competitiveness, Report on National Biotechnology Policy has indicated that the $2 billion domestic industry is expected to increase to $50 billion by the year 2000. Id. at 27. Nelson Sneider, analyst for E. F. Hutton, has stated: "[w]hen you add up all the industries that could be impacted by biotechnology, you're dealing with up to 70 percent of the gross national product [by the year 2010]." Sharon McAuliffe and Kathleen McAuliffe, Life for Sale 26 (1981).

[n.2]. Self replicating organisms such as viruses, bacteria, cells, plants and animals fall within this broad definition of machines.

[n.3]. 35 U.S.C. § 154 (1988). The right is frequently referred to as the patent monopoly. Because of the pejorative connotations of the term "monopoly" in United States courts, it has been argued that other terminology should be used to avoid prejudice and confusion. See Nickola v. Peterson, 580 F.2d 898, 902 n.25 (6th Cir. 1978) (stating: "[t]he patent right, solely that of excluding others, is the fundamental element of all human rights called 'property.' The statutory, and therefor proper, characterization is not 'patent monopoly,' but 'patent property'").

[n.4]. See generally, 3 Peter D. Rosenberg, Patent Law Fundamentals § 16.04 (2nd ed. 1994).

[n.5]. 4 Donald S. Chisum, Patents § 20.03[7][b][i] (1994).

[n.6]. See infra Section II B: "Development of the Exhaustion Doctrine."

[n.7]. 35 U.S.C. § 154 (1988).

[n.8]. 447 U.S. 303 (1980). The case was brought by the Commissioner of Patents and Trademarks and presented two arguments for denying patentability: (1) The passage of the 1930 Plant Patent Act and the 1970 Plant Variety Protection Act evidenced a congressional belief that "manufacture" and "compositions of matter" excluded living

things; and (2) Living things "cannot qualify as patentable subject matter until Congress expressly authorizes such protection." Id. at 198-99. The Court found neither argument convincing in light of the clear meaning of the statutory language, legislative history, and the broad Constitutional grant of power to Congress to promote the progress of science and the useful arts. Id. at 198-200.

[n.9]. E.g. Foundation on Economic Trends v. Lyng, 817 F.2d 882 (D.C. Cir. 1987) (seeking injunctive relief against the Department of Agriculture for failing to prepare an environmental impact statement regarding all aspects of animal productivity research; no injunction issued); Foundation on Economic Trends v. Bowen, 722 F. Supp. 787 (D.D.C. 1989) (seeking to enjoin the National Institutes of Health from supporting recombinant research for failing to prepare environmental impact statements on each advance in the methods used in biotechnology; no injunction issued); Foundation on Economic Trends v. Thomas, 637 F. Supp. 25 (D.D.C. 1986) (seeking injunction to bar field testing of bacteria strains altered by recombinant DNA technology; no injunction issued); Animal Legal Defense Fund v. Quigg, No. C88 2938 WHO (N.D. Cal. 1988) (Complaint for declaratory and injunctive relief to enjoin patenting of animals; no injunction issued); Jehremy Rifkin, Algeny 255 (1984) (questioning whether humans have the right to utilize the sequence information found within any organism's genome). See generally, Office of Technological Assessment, U.S. Congress OTA-BA-370, 5 New Developments in Biotechnology 102 [hereinafter OTA Patenting Life]. Several pieces of legislation to restrict the patenting of life forms were introduced in the 100th session of Congress, but never adopted. This legislation includes: an amendment to a supplemental appropriations bill (Senate Amendment 245 to H.R. 1827, 100th Cong., 2d Sess. (1988)) to prohibit the use of appropriated funds for the patenting of genetically altered or modified animals; H.R. 3119, 100th Cong., 1st Sess. (1987) to establish a 2- year moratorium on the patenting of animals and to revoke previously granted patents; S. 2111, 100th Cong., 1st Sess. (1987) to prohibit animal patents and revoke previously granted patents; and H.R. 4970, 100th Cong., 2d Sess. (1988), the Transgenic Animal Patent Reform Act, which provides exemptions from infringement for 1) making or using a patented animal solely for research or experimentation without any commercial intent, or 2) for a person whose occupation isfarming, to reproduce through breeding, to use or to sell a patented transgenic farm animal under most circumstances.

[n.10]. H.R. 1556, 101st Cong., 1st Sess. (1989).

[n.11]. Initially, transgenic or transgeneic animals were animals that had been engineered to incorporate genetic material or nucleic acid from a different species. John W. Gordon and Frank H. Ruddle, 101 Methods in Enzymology, Recombinant DNA, Part C 411 (1983). The term "transgenic" has come to mean an animal into which any extraneous genetic material has been added or deleted and which can pass this material to its offspring. See generally, Hogan et al., Manipulating the Mouse Embryo (1986). If genetic

material is not passed on to the offspring, the animal is likely to be simply a chimeric or mosaic animal. Id. at 87.

[n.12]. H.R. 1556 was later incorporated into H.R. 5598, 101st Cong., 1st Sess. (1989) a bill addressing several patent related issues. Other restrictive legislation of the 101st session concerning patenting life forms includes H.R. 3247, 101st Cong., 1st Sess. (1989) to impose a 2-year moratorium on the granting of patents on genetically altered animals, except for animals whose commercialization is subject to a Federal regulatory process that imposes environmental, health and safety and biomedical ethical standards, and S. 2169, 101st Cong., 1st Sess. (1989), similar to H.R. 3247.

[n.13]. "[M]aking," 35 U.S.C. § 154 (1988).

[n.14]. "[U]sing," 35 U.S.C. § 154 (1988).

[n.15]. "[S]elling," 35 U.S.C. § 154 (1988).

[n.16]. Reagen Anne Kulseth, Biotechnology and Animal Patents: When Someone Builds a Better Mouse, 32 Ariz. L. Rev 691, 704 (1990) (indicating the motivations of different special interests groups backing the legislation).

[n.17]. Breeders might inadvertently introduce a transgenic animal into their herd and lose control of the disposition of the herd to the patent owner who could then enjoin the owner from breeding and selling the offspring under 35 U.S.C. § 283. The statute grants federal courts the right to enjoin violation of any right secured by a patent such as the right to exclude others from making or selling.

[n.18]. S. 1291, 102d Cong., 1st Sess. (1991) and H.R. 4989, 102d Cong., 2nd Sess. (1992) would both impose a moratorium of five years on the patenting of genetically engineered animals. S. 387 was introduced in the 103d Cong. 1st Sess. (1993) to impose a moratorium on the patenting of animals, human tissues and organs, and human germ cells.

[n.19]. The first transgenic mammals were mice and appeared in the early 1980's. By 1987, transgenic rabbits, pigs, sheep, and cattle had been produced. R.B. Church, Embryo Manipulation and Gene Transfer in Domestic Animals, 5 Trends in Biotechnology 13 (1987); see also Ian Wilmut et al., A Revolution in Animal Breeding, New Scientist, July 1988 at 56 (indicating that selective breeding for more than 10,000 years had resulted in

the variations presently found in domesticated animals but that transgenic methods promised more rapid genetic changes).

[n.20]. Patentably distinct within the meaning of 35 U.S.C. § § 102-03 and thereby qualified subject matter for a patent. See Section I B infra.

[n.21]. Pierson v. Post, 3 Cai. R. 175 (N.Y. Sup. Ct. 1805) (holding that once a person has gained possession of such an animal, he has rights in that animal superior to those of the rest of the world).

[n.22]. Carl L. Wilson et al., Botany 307 (5th ed. 1971).

[n.23]. Patent claims drawn to a transgenic organism with a specific gene sequence would cover any offspring of the founder organism which contains the gene sequence. For an organism with two copies of the gene sequence, this would usually mean all offspring in the first generation and at least 50% of the second generation.

[n.24]. See, e.g., Bethesda Research Laboratories, Catalogue & Reference Guide 97 (1988) (offering for sale lambda GT11 nucleic acid and cloning system. While no user licensing requirements are made by Bethesda Research Laboratories, this nucleic acid and cloning system is the claimed subject matter of United States Pat. No. 4,788,135, "System for efficient isolation of genes").

[n.25]. Contract law protection would occur via licensing agreements explicitly setting forth the terms of the sale and the duties of the parties.

[n.26]. Vectors are molecules or supramolecular constructs (e.g., virus) used for the introduction and maintenance of genetic material in the host or recipient organism; in their most basic sense, vectors are just little pieces of nucleic acid to which other nucleic acid can be appended. See generally, James Darnell et al., Molecular Cell Biology 248-55 (1986). Vectors include virus and phage, plasmids, cosmids, and minichromosomes. Id. Libraries are large collections of gene fragments inserted into vectors, preferably one gene fragment molecule per vector molecule. Id. at 255.

[n.27]. See infra notes 134-37 and accompanying text.

[n.28]. Id.

[n.29]. See U. S. Const. art. I, § 8, cl. 8.

[n.30]. Statutory authority for setting up libraries and disseminating copies of patents to centralized locations is provided in 35 U.S.C. § § 8- 13 (1988).

[n.31]. The other right is that preserved for authors and is also found in Article I, section 8, clause 8 of the United States Constitution.

[n.32]. Apparently, these rights were uncontroversial as there is no record of any debate of this matter. See Robert A. Choate and William H. Francis, Patent Law 74 (1981). Indeed, James Madison indicated: "[t]he utility of this clause will scarcely be questioned. The copyright of authors has been solemnly adjudged in Great Britain to be a right at Common Law. The right to useful inventions seems with equal reason to belong to the inventors. The public good fully coincides in both cases with the claims of individuals. The States cannot separately make effectual provision for either of the cases, and most of them have anticipated the decision of this point by laws passed at the instance of Congress." The Federalist No. 43.

[n.33]. The right has been provided to inventors to promote progress, and it is limited to specific durations.

[n.34]. Preamble of the United States Constitution.

[n.35]. See Vitamin Technologists, Inc. v. Wisconsin Alumni Research Found., 146 F.2d 941 (1944) (denying injunctive right to patent owner when its enforcement would be against the public good). See generally, W. Bowman, Patent and Antitrust Law, 2-3 (1973).

[n.36]. See generally, Rebecca Eisenberg, Patents and the Progress of Science: Exclusive Rights and Experimental Use, 56 U. Chi. L. Rev. 1017, 1024- 28 (1989) (pointing out that too few inventions will be made in the absence of patent protection because an invention requires a capital investment for research and development before it provides a return; once the invention is made it is easily appropriated by competitors who do not labor under this initial cost).

[n.37]. Id. at 1036-38 (offering the additional argument that even after an invention is made, considerable further investment may be needed before commercialization: without patent protection the commercial embodiment may never be developed because any final product could be expropriated by competitors).

[n.38]. Universal Oil Prods. Co. v. Globe Oil & Ref. Co., 322 U.S. 471, 484 (1944) (stating "[a]s a reward for inventions and to encourage their disclosure, the United States offers a seventeen-year monopoly to an inventor who refrains from keeping his invention a trade secret").

[n.39]. See supra note 30.

[n.40]. The Patent Act of April 10, 1790 (1 Stat. 109) was the first federal law directed to patents.

Other major organizational developments are found in the Patent Act of July 4, 1836 (5 Stat. 117), which required an examination and designated the official in charge as Commissioner of Patents.

[n.41]. 35 U.S.C. § § 1-376 (1988).

[n.42]. 35 U.S.C. § 101 (1988).

[n.43]. See E. Lipscomb III, Lipscomb's Walker on Patents § 2:7 at 134-35 (2d ed. 1984).

[n.44]. Id.

[n.45]. The Court has defined manufacture as "'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.'" Diamond v. Chakrabarty, 447 U.S. at 308 (quoting American Fruit Growers, Inc. v. Brogdex Corp., 283 U.S. 1, 11 (1931)).

[n.46]. This category includes "all compositions of two or more substances and . . . all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gasses, fluids, powders, or solids." Id. at 308 (quoting Shell Development Co. v. Watson, 149 F. Supp. 279, 280 (D.C. Cir. 1957)).

[n.47]. E.g., Le Roy v. Tatham, 55 U.S. (14 How.) 156, 175 (1983) (holding that a principle in the abstract is a fundamental truth that cannot be patented).

[n.48]. O'Reilly v. Morse, 56 U.S.(15 How.) 62 (1854), (holding that the use of electromagnetism for printing intelligible signs, characters, or letters at a distance is not patentable; however, a specific apparatus using such a law of nature is patentable).

[n.49]. See Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948) (stating that a phenomenon is not patentable even by the first to discover it, but one can obtain a patent on a process of applying that phenomenon to a new and useful end).

[n.50]. Gottschalk v. Benson, 409 U.S. 63, 67 (1972) (holding that a mathematical algorithm is a method of calculation analogous to a mental process and thus not patentable); see also Parker v. Flook, 437 U.S. 584, 593 (1978) (stating abstract ideas are not patentable); Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980) (emphasizing the Congress did not intend section 101 to cover every discovery and that "laws of nature, physical phenomena, and abstract ideas" are not patentable).

[n.51]. See B. Chaucer, Life, the Patent Office and Everything: Patentability of Lifeforms Created Through Bioengineering Techniques, 9 Bridgeport L. Rev. 413, 420 (1988).

[n.52]. See Diamond v. Chakrabarty, 447 U.S. 303, 309 (1980).

[n.53]. E.g., United States Patent No. 4,361,509 (claiming purified Factor VIII:C, a naturally occurring blood clotting protein). The patent withstood an attack on its validity, was found to be enforceable, and was found to be infringed in Scripps Clinic and Research Foundation v. Genentech Inc., 927 F.2d 1565 (Fed. Cir. 1991).

[n.54]. 35 U.S.C. § 102 (1988).

[n.55]. Id. at (b).

[n.56]. 35 U.S.C. § 103 (1988) (withholding a patent "though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject

matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains").

[n.57]. 383 U.S. 1 (1966).

[n.58]. Id. at 467.

[n.59]. Cf. Vaughan v. Menlove, 132 Eng. Rep. 490 (1837) (measuring conduct with a regard to caution such as a person of ordinary prudence would observe); Delair v. McAdoo, 324 Pa. 392 (1936) (holding that an ordinary person has a duty to know general knowledge); Heath v. Swift Wings, Inc., 252 S.E.2d 526 (N.C. 1979) (holding that a greater standard of care than that of the ordinary person may apply for persons shown to possess special skills); Boyce v. Brown, 51 Ariz. 416 (1938) (holding that one licensed to practice medicine is presumed to possess the degree of skill and learning that is possessed by the average member of the medical profession in good standing in the community).

[n.60]. Graham v. John Deere Co., 383 U.S. 1, 7 (1966).

[n.61]. 35 U.S.C. § 154 (1988).

[n.62]. Zenith Radio Corp. v. Hazeltine Research, 395 U.S. 100, 135 (1969).

[n.63]. See, e.g., Ex parte Murphy, 200 U.S.P.Q. 801, 803 (Bd. App. 1977) (upholding claims directed to "one arm bandit" gambling machines and overturning an attack based upon unpatentability of the invention as an illegal device); see also, OTA Patenting Life, supra note 3 at 5 ("Although a patent excludes others from making, using, or selling the invention, it does not give the patent owner any affirmative rights to do likewise. As with other forms of property, the right to make, use, or sell a patented invention may be regulated by Federal, State, or local law.").

[n.64]. Cochrane v. Deener, 94 U.S. 780 (1877) (finding that a patented improvement invention was nevertheless within the scope of the patentee's right to exclude others from making, using, and selling); Hughes Aircraft Co. v. United States, 717 F.2d 1351 (Fed. Cir. 1983) (holding that even improvements unforeseen at the time of a basic patent application was filed was nevertheless still covered by that patent); cf. Tanabe and Wegner, Japanese Patent Law, § 060:41-42 (1979) (noting that in Japan a patentable improvement of a senior patent may be outside of the scope of the patent right of that basic invention as well as requirements for mandatory licensing).

[n.65]. 35 U.S.C. § 271(a) (1988) ("Whoever without authority makes, uses or sells any patented invention, within the United States"). See, e.g., Eibel Process Co. v. Minnesota & Ontario Paper Co., 261 U.S. 45, 50 (1923) (finding infringement of the plaintiff's patent and pointing out "[i]f defendant or others can do what Eibel accomplished in another way, and by means he did not include in his specifications and claims, . . . they are at liberty to do so and avoid infringement").

[n.66]. 35 U.S.C. § 271(b) (1988) (stating "[w]hoever actively induces infringement of a patent shall be liable as an infringer"). See e.g., Water Technologies Corp. v. Calco, Ltd., 850 F.2d 660, 665 (Fed. Cir. 1988) (upholding a finding of induced infringement based upon a defendant having given the formulas to an infringer, helping the infringer make the infringingresins, and preparing consumer use instructions for the infringer); see also American Technical Machinery Corp. v. Masterpiece Enterprises, Inc., 235 F. Supp. 917 (M.D. Penn. 1964) (holding that when the president of a corporation deliberately acts as the moving, active or conscious force behind an infringement, he may be held personally liable under 35 U.S.C. § 271(b)).

[n.67]. 35 U.S.C. § 271(c) (1988) (stating "[w]hoever sells a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement . . . shall be liable as a contributory infringer"). See, e.g., Preemption Devices, Inc. v. Minnesota Mining & Manufacturing Co., 803 F.2d 1170 (Fed. Cir. 1986) (finding that there was no available market for the component other than its use in the infringing system and that Preemption Devices, Inc., had the requisite knowledge to support a case under 271(c)).

[n.68]. 35 U.S.C. § 271(a) (1988) (stating "[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" (1988).

[n.69]. Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 481 n. 8 (1964) (stating "[t]he suggestion that a person cannot be liable even for direct infringement when he has no knowledge of the patent or the infringement is clearly refuted by the words of § 271(a), which provides that 'whoever without authority makes, uses or sells any patented invention . . . infringes the patent,' with no mention of any knowledge requirement. And the case law codified by § 271 has long recognized the fundamental proposition that '[t]o constitute an infringement of a patent, it is not necessary that the infringer should have known of the existence of the patent at the time he infringed it or, knowing of its existence, it is not necessary that he should have known his doings to constitute an infringement.'" quoting 3 Walker on Patents § 453 (Deller ed. 1937)).

[n.70]. Water Technologies Corporation v. Calco LTD., 850 F.2d 660, 665 (Fed. Cir. 1988) (stating "[a]lthough section 271(b) does not use the word 'knowing,' the case law and legislative history uniformly assert such a requirement.").

[n.71]. Supra, note 67.

[n.72]. See Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336 (1961) and Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476 (1964) (holding that where the patentee has explicitly authorized the purchasers to use the product, imposing limitations on where unpatented replacement parts could be purchased was not permitted). See also Dana Corp. v. American Precision Co., 827 F.2d 755, 758 (Fed. Cir. 1987) (stating that the question of what constitutes repair and what constitutes "reconstruction is primarily one of law").

[n.73]. 35 U.S.C. § 283 (1988) (courts "may grant injunctions in accordance with the principles of equity to prevent violation of any right secured by patent, on such terms as the court deems reasonable.").

[n.74]. 35 U.S.C. § 284 (1988) (awarding damages adequate to compensate for the infringement).

[n.75]. Id.

[n.76]. See, e.g., Kennedy v. Lasko Co., 414 F.2d 1249 (3d 1969) (requesting treble damages as well as surrender for destruction the machines which infringed the plaintiff's patent).

[n.77]. 35 U.S.C. § 283 (1988); See Roche v. Bolar Pharmaceutical Co., 733 F.2d 858, 861 (Fed. Cir. 1984) (noting that "[i]f Congress wants the federal courts to issue injunctions without regard to the historic principles of equity, it is going to have to say so in explicit . . . language"). Several specific examples of extreme hardship resulting from the grant of an injunction are found in Bradford J. Duft, Patent Infringement and Biotechnology, 16 AIPLA Q. J. 339, 385 (1989).

[n.78]. Hybritech Inc. v. Abbott Laboratories, 849 F.2d 1446 (Fed. Cir. 1988) (stating "[o]ur review of a district court's grant of a preliminary injunction pursuant to 35 U.S.C.

§ 283 is limited to determining whether, in granting the preliminary injunction, the district court abused its discretion, committed an error of law, or seriously misjudged the evidence).

[n.79]. See infra, Section II B.

[n.80]. 35 U.S.C. § 154 (1988).

[n.81]. 5 Irving Kayton, Patent Practice § 19-2, (4th ed. 1989).

[n.82]. Id., In disclosing the invention in an application for a patent, the specification of the invention "shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." See 35 U.S.C. § 112.

[n.83]. See Harold Marquis, Limitations on Patent License Restrictions: Some Observations, 58 Iowa L. Rev. 41, 56 n.40 (1972). The purpose of the explicit consideration of territorial assignment in the Act would appear to be simply to provide that a territorial assignee may sue for patent infringement and to resolve questions of priority among assignees. Id. Title 35 U.S.C. § 261 (1988) provides that the "applicant, patentee, or his assigns or legal representatives may in a like manner grant and convey an exclusive right under his application for patent, or patents, to the whole or any specified part of the United States."

[n.84]. 5 Irving Kayton, Patent Practice § 19-6 (4th ed. 1989).

[n.85]. The bundle of rights, or grant, might also be considered a res. To avoid confusion, however, this Article refers to the res as the actual machine, useful process, article of manufacture, or composition of matter that is the subject of the patent grant.

[n.86]. See 3 Peter D. Rosenberg, Patent Law Fundamentals § 16.01[1] (2nd ed. 1994).

[n.87]. 5 Irving Kayton, Patent Practice § 19-6 (4th ed. 1989).

[n.88]. Id.

[n.89]. De Forest Radio Telephone & Telegraph Co. v. Radio Corp. of Am., 9 F.2d 150, 151 (D. Del. 1925) (holding that a license is merely a promise not to sue for infringement).

[n.90]. See 5 Irving Kayton, Patent Practice § 19-6(B) (4th ed. 1989).

[n.91]. De Forest Radio Telephone & Telegraph Co. v. Radio Corp. of Am., 9 F.2d 150, 151 (D. Del. 1925).

[n.92]. Adams v. Burke, 84 U.S. 453 (1873). A similar principle holds for authorized sale of items adapted for use in a patented process, i.e., the purchaser has an implied license to use the items to perform the patented process. See, e.g., Met-Coil Sys. Corp. v. Korners Unlimited, Inc., 803 F.2d 684 (Fed. Cir. 1986).

[n.93]. Adams v. Burke, 84 U.S. 453, 457 (1873).

[n.94]. Patent Act of July 4, 1836 (5 Stat. 117). This act permitted renewal of patent rights. Limited forms of extension are presently permitted if the patented product has been subject to a regulatory review period before its commercial marketing. See 35 U.S.C. § § 155-56 (1988).

[n.95]. 55 U.S. (14 How.) 539 (1852).

[n.96]. Id. But see Mitchell v. Hawley, 83 U.S. (16 Wall.) 544 (1873) (holding that if the sale was made with an express time limitation, that time limitation could be enforced).

[n.97]. Bloomer v. McQuewan, 55 U.S. (14 How.) 539, 541 (1852).

[n.98]. 84 U.S. 453 (1873).

[n.99]. Id. at 454-55.

[n.100]. Id. at 457.

[n.101]. Id. at 456.

[n.102]. Id. at 457; cf. Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476, 478 (1964) (stating "it is fundamental that the sale of a patented article by the patentee or under his authority carries with it an implied license to use").

[n.103]. See,e.g., Unidisco, Inc. v. Schattner, 824 F.2d 965, 668 (Fed. Cir. 1987) (holding an authorized sale of the patented invention by a licensee to a third party puts any resale by the third party out of the reach of the infringement statute by reason of the third parties "authority to resell the product" derived by the original sale by the licensee); see also, Lisle Corp. v. Edwards, 777 F.2d 963, 965 (Fed. Cir. 1985) (stating that resale subsequent to an authorized sale does not create a sublicense). But see Chemagro Corp. v. Universal Chemical Co., 244 F. Supp. 486 (E.D. Tex. 1965) (holding that where the defendant purchased for resale, resale of the diluted product was prohibited because original sale was with notice of specific limitations on resale). An example of the license to repair is described in Sanofi v. Med-Tech Veterinarian Products, Inc., 565 F. Supp. 931, 938 (D. N. J. 1983) (holding that when the patent "owner sells an article without any reservation respecting its use, or the title which is to pass, the purchaser acquires the whole right of the vendor in the thing sold: the right to use it, to repair it, and to sell it to others; and second purchasers acquire the rights of the seller, and may do with the article whatever the first purchaser could have lawfully done if he had not parted with it").

[n.104]. Wilbur-Ellis Co. v. Kuther, 377 U.S. 422, 423-24 (1963) (finding "the question in terms of patent law precedents [was] whether what was done to the[ ] machines, the original manufacture and sale of which had been licensed by the patentee, amounted to 'repair,' in which there was no infringement, or 'reconstruction,' in which event there was. The idea of 'reconstruction' in this context has the special connotation of those acts which would impinge on the patentee's right 'to exclude others from making,' 35 U.S.C. § 154, the article").

[n.105]. Id.

[n.106]. Wilbur-Ellis Co. v. Kuther, 377 U.S. 422, 423-24 (1963).

[n.107]. 304 U.S. 175, reargued 305 U.S. 124 (1938). The defendant manufacturer had purchased the right to make amplifier components for private home use but was forbidden by the license contract from making the identical components for commercial or public use, e.g., use in theaters. Id.

[n.108]. Id. at 179-80.

[n.109]. Id. at 181.

[n.110]. Id.

[n.111]. Id. at 180, 182.

[n.112]. Id., One court has suggested that the qualification found in General Talking Pictures is solely for restriction of a manufacturing licensee and that the purchaser of amplifiers in General Talking Pictures simply infringed by purchasing an article which was not made under the granted field-of-use-license. Munters Corp. v. Burgess Indus. Inc., 450 F. Supp. 1195, 1200-02 (S.D.N.Y. 1977) (holding that contractual restrictions on the use of patented corrugated packing material were unenforceable). Thus, General Talking Pictures would not stand for the proposition that express restrictions are per se valid and bind purchasers, but only that express restrictions bind those who make the articles. This interpretation argues that the Court's emphasis on the knowledge of the purchaser in General Talking Pictures was mere dicta. Such an interpretation would appear to run counter to that of Mitchell v. Hawley, 83 U.S. (16 Wall.) 544 (1873) (holding that if the sale was made with an express time limitation for use of the object, that time limitation could be enforced). Neither interpretation affects the analysis presented in this Article because "making" a biotechnological product would bring the purchaser within the ambit of "manufacturer." See also, Chemagro Corp. v. Universal Chemical Co., 244 F. Supp 486 (E.D. Tex. 1965) (holding that where the defendant purchased for resale, resale of the diluted product was prohibited because original sale was with notice of specific limitations on resale). In addition, the vitality of interpreting the Supreme Court's statements as mere dicta was vitiated by the Federal Circuit's Mallinckrodt decision, described infra in notes 116-23 and accompanying text. Cf. Bement & Sons v. National Harrow Co., 186 U.S. 70, 91 (1902) (holding that "the rule is, with few exceptions, that any conditions which are not in their very nature illegal with regard to this kind of property, imposed by the patentee and agreed to by the licensee for the right to manufacture or use or sell the [patented] article, will be upheld by the courts").

[n.113]. General Talking Pictures Corp. v. Western Electric Co., 304 U.S. 175, 182 (1938); General Talking Pictures Corp. v. Western Electric Co., 305 U.S. 124, 125 (1938).

[n.114]. Id.; cf. Mitchell v. Hawley, 83 U.S. (16 Wall.) 544 (1873) (holding that if the sale of the patented item was made with an express time limitation on its use, that time limitation could be enforced by an action for infringement).

[n.115]. The reasoning of the Court followed the theory that since a patentee can restrict the use of patented goods by a manufacturing licensee and the amplifiers were knowingly manufactured and sold to a purchaser for an unauthorized use, the sale to the defendant was an infringing sale. Because the defendant knew that the sale was infringing and yet purchased and used the invention anyway, the defendant was also guilty of infringement. 304 U.S. at 182.

[n.116]. 24 U.S.P.Q.2d 1173 (Fed. Cir. 1992).

[n.117]. Id. at 1174.

[n.118]. Id.

[n.119]. Id. at 1178.

[n.120]. Id.

[n.121]. Id. at 1176.

[n.122]. Id. at 1179.

[n.123]. Id. at 1180. In accordance with the Uniform Commercial Code a license notice may become a term of sale, even if not part of the original transaction, if not objected to within a reasonable time. U.C.C. § 2- 207(2)(c) (1977).

[n.124]. 316 U.S. 241, 249 (1942); cf. General Electric Co. v. United States, 572 F.2d 745 (Ct. Cl. 1978) (stating "[i]t can be properly assumed that as part of the bargain the seller of a device incorporating a patented combination authorizes the buyer to continue to use the device . . . ").

[n.125]. 304 U.S. 175, reargued 305 U.S. 124 (1938).

[n.126]. Adams v. Burke, 84 U.S. 453 (1873).

[n.127]. The enforceability is, however, limited to contractual restrictions that are not found to be for restraint of trade and thus free of antitrust violations. See, e.g., Continental TV, Inc. v. GTE-Sylvania, Inc., 433 U.S. 36 (1977), overruling United States v. Arnold Schwinn & Co., 388 U.S. 365 (1967) (holding that contractual restraints for patented articles can be in violation of antitrust laws but noting that such a conclusion should not be a per se rule as required by Schwinn). See also International Salt Co. v. United States, 332 U.S. 392 (1947) (holding that a contractual obligation to purchase a nonpatented product from the patent holder as an incident to leasing patented machines violated § 1 of the Sherman Act and § 3 of the Clayton Act).

[n.128]. See United Nickel Co. v. California Electrical Works, 25 F. 475 (C.C. Cal. 1885) (finding alternate uses and notice of use limitation in sales contract); Popsicle Corp. v. Weiss, 40 F.2d 301 (S.D.N.Y. 1929) (finding alternative uses of the purchased item: purchaser was notified of the existence of the patents and the necessity of a license if he intended to practice the process); General Electric Co. v. Continental Lamp Works, Inc., 280 F. 846 (2d Cir. 1922) (finding alternative uses and notice of use limitation in sales contract).

[n.129]. See generally, Goodyear Atomic Corp. v. Miller, 486 U.S. 174, 184-85 (1988) (holding that as a general rule of statutory construction it can be presumed that Congress is knowledgeable about existing law pertinent to legislation it enacts and considers such law in its enactments). But see Alaska Airlines, Inc. v. Brock, 480 U.S. 678, 686 (1987) (stating that ordinarily, "Congress' silence is just that - silence").

[n.130]. Adams v. Burke, 84 U.S. 453, 456 (1873).

[n.131]. 35 U.S.C. § 154 (1988); cf. General Talking Pictures Corp. v. Western Electric Co., 304 U.S. 175, reargued 305 U.S. 124 (1938) (Black, J., dissenting) (disagreeing with the Court's holding regarding purchase with notice case since "[t]he exclusive right to vend does not - any more than the exclusive right to use - empower a patentee to extend his monopoly into the country's channels of trade after manufacture and sale which passes title.").

[n.132]. Adams v. Burke, 84 U.S. 453, 456 (1873).

[n.133]. United States v. Univis Lens Co., 316 U.S. 241, 249 (1942) (holding that the sale of a lens blank by the patentee is "in itself both a complete transfer of ownership of the blank, which is within the protection of the patent law, and a license to practice the final stage of the patent procedure," even though there was no express licensing contract covering the case at issue).

[n.134]. In clarifying the distinguishing characteristics of agreements implied in law and agreements implied in fact, the court in Bloomgarden v. Coyer, 479 F.2d 201 (1973), indicated that a contract implied in law "is not a contract at all, but a duty thrust under certain conditions upon one party" in fairness. Id. at 208. In contrast, a contract implied in fact "is a true contract, containing all necessary elements of a binding agreement; it differs from other contracts only in that it has not been committed to writing or stated orally in express terms, but rather is inferred from the conduct of the parties in the milieu in which they dealt." Id.

[n.135]. Restatement (Second) of Contracts § 4 cmt. b (1981) indicates that contracts implied in law "are not based on the apparent intention of the parties to undertake the performances in question, nor are they promises. They are obligations created by law for reasons of justice."

[n.136]. Helen Hadjiyannakis, The Parole Evidence Rule and Implied Terms: the Sounds of Silence, 54 Fordham L. Rev. 35, 37-38 n.34 (1985).

[n.137]. Id. at 38.

[n.138]. That is, a court is capable of finding infringement in spite of the Exhaustion Doctrine. See Chemagro Corp. v. Universal Chemical Co., 244 F. Supp. 486 (E.D. Tex. 1965), supra note 112. Contractual restrictions which are intended to restrain trade are outside the scope of the court's protection of licensing agreements. See supra.note 127

[n.139]. In trademarks the selling or importation of goods will not be barred if the United States registered goods and the foreign registered goods possess trademarks owned by the same or related entities, i.e. the mark and the goods are genuine. To be genuine, the manufacturer must have had a legal right to apply the mark to the goods in the place and under the circumstances that it did. See K Mart Corp. v. Cartier, Inc., 486 U.S. 281 (1988). Thus, the original sale exhausts the trademark owner's right to control the mark on the purchased items. Copyrights can be subdivided into a right to make copies and a right to distribute those copies, each of which can be individually infringed. In the absence of contract notice to the contrary, once the copyright owner consents to a transfer of title of the copyrighted work to a third party, the third party is entitled to sell or

otherwise dispose of that copy without obtaining the copyright owner's consent. Thus the copyright owner has the right to control the initial sale but thereafter copyright law gives the copyright owner no right to control the original purchaser's resale or other transfer of title. See Section 109 of the 1976 Copyright Act.

[n.140]. Smith Kline & French Laboratories Ltd. v. Salim (Malaysia) Sdn Bhd, Case No. C 1181 (High Court (Kuala Lumpur) 1989), as reported in 21 Int'l Rev. of Indus. Prop. and Copyright L. 720 (1990) (concerning the Tagamet pharmaceutical in Malaysia and holding that where a drug manufacturer sells his product on the open market in one of the European Community countries without notice of restrictions in respect of resale, the importation and sale of such product into Malaysia could only be prohibited if the importer had acted with knowledge of the restrictions). The international importance of the exhaustion doctrine should increase for the same reason it was important in the Adams case: territorial licenses. In the developing Common Market, individual countries may attempt to control patented goods that are manufactured under a valid patent outside of the country and imported for sale into the country. See Leo Schmid, Gebietsbeschrankungen in Patenlizenze- und Know-How-Vertragen im Wettbewerbsrecht der USA und der EG 33-41 (1988) (describing the origins of the exhaustion doctrine in the United States and contrasting it with that of the exhaustion principle of the EC that arose from the rule that free movement of goods within the European Communities should not be impeded by national industrial property rights).

[n.141]. Adams v. Burke, 84 U.S. 453 (1873).

[n.142]. General Talking Pictures Corp. v. Western Electric Co., 304 U.S. 175, reargued 305 U.S. 124 (1938).

[n.143]. 35 U.S.C. § 154 (1988).

[n.144]. Id.

[n.145]. Id.

[n.146]. See supra note 3 and accompanying text.

[n.147]. OTA Patenting Life, supra note 9 at 3.

[n.148]. See generally, OTA Global Biotech, supra note 1 at 39-41, describing biotechnology and competitiveness.

[n.149]. The General Accounting Office has indicated that the backlog for biotechnology applications is about twice that for regular patent applications and has recently swelled despite the hiring of more examiners at the Patent and Trademark Office. See Edmund L. Andrews, Long Delay Seen in Patents for Genetic Engineering, N. Y. Times, July 19, 1990 at D1.

[n.150]. James D. Watson and Francis H. C. Crick, A Structure for Deoxyribose Nucleic Acids, 171 Nature 737 (1953); see also O. T. Avery et al., Studies on the Chemical Nature of the Substance Inducing Transformation of Pneumococcal Types. Induction of Transformation by a Desoxyribonucleic Acid Fraction Isolated from Pneummococcus Type III, 79 J. Experimental Med. 137 (1944).

[n.151]. See generally, James D. Watson, Molecular Biology of the Gene 70- 75 (1976).

[n.152]. Ursula Goodenough and Robert P. Levine, Genetics 291 (1974).

[n.153]. 2 Joseph Sambrook et al., Molecular Cloning 12.1-12.7 (2d ed. 1989).

[n.154]. P. G. N. Jeppesen et al., Gene Order in the Bacteriophage R17 RNA, 226 Nature 230 (1970).

[n.155]. R.W. Old and S.B. Primrose, Principles of Gene Manipulation 5, (3d ed. 1985).

[n.156]. James D. Watson, Molecular Biology of the Gene 281-82 (1976).

[n.157]. 2 Joseph Sambrook et al., Molecular Cloning 18.3-1810 (2d ed. 1989).

[n.158]. See generally, 2 Benjamin Lewin, Gene Expression, (2d ed. 1980).

[n.159]. Ian Wilmut et al., A Revolution in Animal Breeding, New Scientist, July 1988 at 56.

[n.160]. See generally, Hogan et al., Manipulating the Mouse Embryo (1986).

[n.161]. OTA Patenting Life, supra note 9 at 13.

[n.162]. See Ian Wilmut et al., A Revolution in Animal Breeding, New Scientist, July 1988 at 56-57 (indicating that even when enabling methods are known, a low proportion of experimentally manipulated eggs actually become transgenic animals. This proportion is about 1% in farm animals but in most cases the transgene will be passed on to offspring in the same way as the animal's own genes.).

[n.163]. Id. at 56.

[n.164]. Leigh C. Lawson, DNA Fingerprinting and Its Impact Upon Criminal Law, 41 Mercer L. Rev. 1453 (1990).

[n.165]. Patent and Trademark Office, Manual of Classification 536-1 (1990). "Class 536 is an integral part of Class 260 and follows the schedule hierarchy, retaining all pertinent definitions and class lines of class 260." Id. Class 260 encompasses "Chemistry, Carbon Compounds." Id. at 260-1. Class 536 provides for carbohydrates or derivatives thereof. Specifically, nucleic acids are "Phosphorus containing Adenosine or derivative with plural nitrogen containing hetero rings attached by an N-Glycoside linkage." Id. at 536-1.

[n.166]. "Class 530 is an integral part of Class 260." Id. at 530-1. Specifically, proteins of more than 100 amino acid residues would be found in Class 530, subclasses 350-426.

[n.167]. United States Patent No. 141,072 (claiming pure yeast culture).

[n.168]. See In re Mancy, 499 F.2d 1289, 1291 (C.C.P.A. 1974) (stating that "we presume (without deciding) [that these applicants would] be unable to obtain such a claim [for the organism per se] because the strain, while new in the sense that it is not shown by any art of record, is, as we understand it, a 'product of nature.'"); accord Ex parte Bergy, 197 U.S.P.Q. 78, 79 (Bd. App. 1976) (stating "[i]t is our view that 35 U.S.C. § 101 must be strictly construed and, when so interpreted, precludes the patenting of a living organism). This case was reversed by Judge Rich, who previously authored In re Mancy. Rich stated that the sole question on review was "whether the uncontroverted fact that the biologically pure culture, as claimed, is alive removes it from the categories of inventions

enumerated in § 101. Our conclusion is that it does not." (emphasis in original). In re Bergy, 195 U.S.P.Q. 344, 348 (C.C.P.A. 1977).

[n.169]. Ex parte Latimer, 1889 Dec. Comm'r Pat. 123, 125 (1889) (refusing a patent for an application claiming fibers which occurred naturally in the needles of Pinus Australis).

[n.170]. E.g. In re Mancy, 499 F.2d 1289 (C.C.P.A. 1974) (finding claims to a process for preparing antibiotic by cultivating a new microorganism strain to be patentable).

[n.171]. Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948) (refusing a patent for a mixture of microorganisms which existed naturally in nature).

[n.172]. OTA Patenting Life, supra, note 9 at 18.

[n.173]. Id. Requirements for deposit of biological material are found in Biotechnology Invention Disclosures, 37 C.F.R. § § 1.801-09 (1989).

[n.174]. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, 1979, 32 U.S.T. 1241 (becoming effective on August 19, 1980, T.I.A.S. 9768); See Reid G. Adler, Can Patents Coexist with Breeders' Rights? Developments in U.S. and International Biotechnology Law, 17 Int'l Rev. of Indus. Prop. and Copyright L. 195, 200 (1986).

[n.175]. Id.

[n.176]. 447 U.S. 303 (1980).

[n.177]. Id. at 308.

[n.178]. Id. at 309 (quoting S. Rep No. 1979, 82d Congress, 2d Session 5; H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952)).

[n.179]. Id. at 313.

[n.180]. The invention ultimately became United States Patent No. 4,259,444. The claimed invention could arguably also be considered a machine if it were used to make an item, i.e. if it were a micro factory. Considering the organism to be a machine would permit use of "means" language as sanctioned by 35 U.S.C. § 112, sixth paragraph and might broaden the scope of the claimed invention without violating the requirements of 35 U.S.C. § 112.

[n.181]. 2 U.S.P.Q.2d 1425 (Bd. App. 1985).

[n.182]. 69 J. Pat. & Trademark Off. Soc'y 328 (1987).

[n.183]. Id.

[n.184]. See supra notes 172-75 and accompanying text. Because of the greater complexities of animals, vis-a-vis cells, slightly different enablement concerns are raised. While a depository as set forth in 37 C.F.R. § § 1.801- 09 is not available for adult animals, the American Type Culture Collection will permit the deposit of frozen embryos that would satisfy enablement concerns. See International Patent Culture Depository, American Type Culture Collection, Guide to Making Patent Deposits 2 (1990). For enablement of plants, another type of multicellular organism under the Plant Variety Protection Act (7 U.S.C. § 2321 (1988)), the Department of Agriculture has requested a deposit of at least 2,500 seeds. See 7 C.F.R. s 180.6 (d) (1988) (requiring "the applicant . . . submit with the application at least 2,500 seeds of the viable basic seed required to reproduce the variety"). Such a deposit could be extended to animal patents. Alternatively, the deposit could be accomplished by embryonic stem cell techniques, i.e. production of an entire animal grown from a specialized tissue culture line via a chimeric animal intermediate. The importance and type of deposit requirement depends on the type of protection desired. In the case of location-non-specific transgenic organisms, where the transferred gene is capable of integrating into a large variety of different locations with similar results, a simple description of the inserted genetic material should suffice. When the transferred genetic material must be inserted in a precise location to express or destroy a specific function, enablement for reconstruction of the invention is more problematic and the value is in the actual animal; the specific genetic location is impossible or highly unlikely to be duplicated. The deposit of a minimum number of embryos would be necessary to satisfy the statutory reproducibility requirements found in 35 U.S.C. 112, first paragraph.

[n.185]. Robert P. Merges, Intellectual Property in Higher Life Forms: The Patent System and Controversial Technologies, 47 Md. L. Rev. 1051, 1061 (1988) (pointing out that animal rights proponents oppose patenting live organisms because of a belief that animals have a consciousness that is similar to humans and that animals possess minimum

inherent rights which must be respected); Reagen Anne Kulseth, Biotechnology and Animal Patents: When Someone Builds a Better Mouse, 32 Ariz. L. Rev. 691, 706-07 (1990) (reviewing opposition to patenting animals and considering the morality of "reducing animals to commercial commodities"); Jehremy Rifkin, Algeny 255 (1984) (questioning whether humans have the right to utilize the sequence information found within any organism's genome); Animal Legal Defense Fund v. Quigg, No. C88 2938 WHO (N.D. Cal. 1988) (challenging the use of any recombinant technology without filing environmental impact statements and challenging the environmental impact statements filed).

[n.186]. See supra notes 9 and 12.

[n.187]. 34 Pat. Trademark & Copyright J. 277 (1987). The Patent and Trademark Office assured the Congressional conference committee that no patents on bio-engineered animals would be issued for the balance of fiscal year 1987. Id.

[n.188]. United States Patent No. 4,736,866, granted to Philip Leder et al. for a transgenic mouse engineered to develop cancers more rapidly than normal mice. In fact, the Patent and Trademark Office issued several patents for multicellular animals before and after the mouse patent (e.g. 4,615,883; 4,765,275; 4,701,326; and 4,753,799); however, these multicellular animals are not sufficiently photogenic to generate public concern, i.e. they are small worms called nematodes.

[n.189]. Edmund L. Andrews, U.S. Resumes Granting Patents On Genetically Altered Animals, N.Y. Times, Feb. 3, 1993, at Al.

[n.190]. Id. at A1, D5. These three patents all claimed transgenic mice and were issued on Dec. 29, 1992. See United States Patent Nos. 5,175,383; 5,175,384; and 5,175,385. Six months prior to the issuance of these patents; however, a transgenic chicken resistant to viral infection was registered by the Patent Office under the Statutory Invention Registration Program as registration number H1065. See 35 U.S.C. § 157 (1988). Although initially filed as an application for a patent, the Statutory Invention Registration does not grant the exclusionary rights obtained by a patent. Id. A fourth animal patent, for a transgenic rabbit, was granted on Feb. 2, 1993. See United States Patent No. 5,183,949.

[n.191]. Towards the Patenting of Animals, 336 Nature 293 (1988).

[n.192]. Supra note 1, OTA Globel Biotech at 217.

[n.193]. 447 U.S. 303 (1980).

[n.194]. Supra note 9.

[n.195]. Marsha L. Montgomery, Building a Better Mouse - and Patenting It: Altering the Patent Law to Accommodate Multicellular Organisms, 41 Case W. Res. L. Rev. 231, 250 (1991).

[n.196]. Id.

[n.197]. H.R. 1556, 101st Cong., 1st Sess. (1989).

[n.198]. Id.

[n.199]. This argument to avoid a small farmer exemption is not meant to imply that, sans legislation, small farmers have nothing to fear from biotechnology in the agricultural marketplace. Advances that make the farm industry more productive will decrease the demand for farmers per se. However, workers in many industries are displaced by gains in productivity, which is a required cost of maintaining competitiveness in an industry. The continual decline in the number of individuals employed in the agricultural sector may represent a loss to the nation's cultural landscape, but such a loss is not a sufficient justification to stifle biotechnology.

[n.200]. Supra Section II B.

[n.201]. The act of breeding would generally not support an individual method of use patent due to the method's obviousness. See In re Durden, 763 F.2d 1406 (Fed. Cir. 1985) (holding that even when one or more starting materials is novel, the application of an old process to such materials to produce the expected result would still be obvious within the meaning of 35 U.S.C. § 103).

[n.202]. The act of breeding would generally not support an individual method of use patent due to the method's non-statutory character. See In re Merat, 519 F.2d 1390 (Fed. Cir. 1975) (holding that "a method of breeding animals is not a 'process' within the meaning of Section 101").

[n.203]. An invention that is obvious within the meaning of 35 U.S.C. § 103 and therefore unpatentable.

[n.204]. See In re Durden, 763 F.2d 1406 (Fed. Cir. 1985) (holding that even when one or more starting materials is novel, the application of an old process to such materials to produce the expected result would still be obvious within the meaning of 35 U.S.C. § 103 and therefore unpatentable. It appears to the author that mating two animals is a relatively old process.

[n.205]. Permitting such unlimited use by the purchaser is essentially the Farmers' Exemption described supra Section III C.

[n.206]. 1 Joseph Sambrook et al., Molecular Cloning 1.53-73, 2.82-07, 3.27- 55 (2d ed. 1989) (requiring replication for clonal selection); see also United States Patent No. 4,788,135 wherein claim 2 is: "A method for screening a genomic cDNA (sic) library which comprises: inserting foreign cDNA sequences into lambda GT11 phage vectors at a unique site in the <<BETA>>-galactosidase gene of said lambda GT11 wherein expression results in production of fused polypeptides; transforming a high-frequency lysogenic bacterial host with said vectors containing said cDNA sequence; growing said host to high density and inducing said phage to high copy number with concomitant expression of said fused polypeptides; and isolating a fused expression product of said <<BETA>>- galactosidase gene and cDNA." Both "growing" and "inducing said phage to high copy number" would effectively "make" the subject matter of claim 1, i.e. lambda GT11.

[n.207]. Federal courts maintain exclusive jurisdiction in patent and plant variety protection cases under 28 U.S.C. § 1338 (1988). See also 35 U.S.C. § 283 (1988) (stating that courts "may grant injunctions in accordance with the principles of equity to prevent violation of any right secured by patent, on such terms as the court deems reasonable").

[n.208]. See generally, J. Ric Gass et al., Handling Sympathy in Jury Trials, in Third Annual Litigation Management Supercourse 1992, at 45, 47-50 (PLI Litig. & Admin. Practice Course Handbook Series No. 432, 1992) (pointing out the difficulty of counteracting sympathy as well as a natural juror bias to castigate and punish "that depersonalized segment of society identified variously as 'big business,' 'soulless corporation,' or 'industrial complex'").

[n.209]. 35 U.S.C. § 154 (1988).

[n.210]. If the facts of the case indicated that the parties involved had meant the article to be tested for potential uses, perhaps with a request for communication of any positive results, the inventor could maintain control over the use of the invention because the inventor arguably never intended to permit unrestricted use and was simply a bailor. See infra, note 236-39.

[n.211]. A regulatory sequence, or promoter, is a precise nucleic acid sequence which participates in the control of gene function. See generally, Mark Ptashne, A Genetic Switch 44-45 (1987). An example of such a sequence is found in United States Patent Number 4,518,690 (claiming the DNA promoter sequence of Avian tumor virus and use of the promoter for enhanced gene expression in E. coli).

[n.212]. A probe is any nucleic acid used to identify another nucleic acid by sequence complementarity.

[n.213]. See, e.g., United States Patent No. 4,885,236 (claiming cDNA fragments to matrix proteins, isolated matrix proteins, antibodies to matrix proteins, methods of detecting such proteins, and determining cellular abnormalities associated with such proteins).

[n.214]. See generally, Brenner v. Manson, 383 U.S. 519 (1966) (holding that "the basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility . . . in currently available form.") Id. at 513.

[n.215]. 35 U.S.C. § 101 (1988).

[n.216]. Patent prosecution by the examiners of the Patent and Trademark Office in the biotechnology area has tended to subdivide - known as restriction practice - many of the patent applications, thereby creating independently patentable inventions. See Edmund L. Andrews, Long Delay Seen in Patents for Genetic Engineering, N. Y. Times, July 19, 1990 at D1. See also 35 U.S.C. § 121 (providing that such a subdivided application gives rise to a separate and independent patent). Thus, the Patent and Trademark Office's present restriction practice is effectively clarifying the scope of future sales because an implied license to use one patent is not likely to be construed as an implied license to use an entire portfolio of separate patents.

[n.217]. This scenario assumes sale of less than the entire stock, i.e., an individual in direct competition with the patent owner, assignee, or holder of an explicit license.

[n.218]. See supra, notes 107-11 and accompanying text. If the purchaser knowingly permitted the invention to make copies of itself, the license holder and seller might also violate § 271(b) as "inducing" infringement. See supra note 66.

[n.219]. S. Rabel, The Statute of Frauds and Comparative Legal History, 63 L. Q. Rev. 174, 178 (1947).

[n.220]. 35 U.S.C. § § 161-64 (1988) (indicating a description and basis for plant patents).

[n.221]. 35 U.S.C. § 163 (1988); "In the case of a plant patent the grant shall be of the right to exclude others from asexually reproducing the plant or selling or using the plant so reproduced." Id.

[n.222]. In re Arzberger, 112 F.2d 836 (C.C.P.A. 1940).

[n.223]. 7 U.S.C. § 2321 (1988).

[n.224]. See H.R. Rep. No. 1605, 91st Congress, 2nd Sess. at 11 (1970). Although not explicitly stated in the statute, the Committee report explicitly states that the production of a new variety for the market from a variety protected under the PVPA does not constitute infringement. Id. See also S. Rep. No. 1138, 91st Cong., 2nd Sess. (1970).

[n.225]. Union for the Protection of New Varieties of Plants and the adoption of the International Convention for the Protection of New Varieties.

[n.226]. See Adler, supra note 174 at 208-09, 213.

[n.227]. A. Lincoln quote directed to patents in general, Lecture on 'Discoveries, Inventions and Improvements' 1860.

[n.228]. Stephen J. O'Brien et al., A Molecular Approach to the Identification and Individualization of Human and Animal Cells in Culture: Isoenzyme and Alloenzyme Genetic Signatures, 16 In Vitro 119 (1980) (discussing Hela cell contamination and characterization).

[n.229]. See supra notes 64 and 69.

[n.230]. E.g. Vitamin Technologists, Inc. v Wisconsin Alumni Research Foundation, 146 F.2d 941 (1944) (denying injunction for patent owner when its enforcement would be against the public good); Hybritech Incorporated v. Abbott Laboratories, 849 F.2d 1446 (Fed. Cir. 1988) (denying preliminary injunction on specific embodiments when it was against the public interest but granting the injunction on other infringing embodiments); Abend v. MCA, Inc., 863 F.2d 1465 (9th Cir. 1988) (refusing injunction although finding clear infringement).

[n.231]. See supra note 128 and accompanying text.

[n.232]. General Talking Pictures Corp. v. Western Electric Co., 304 U.S. 175, reargued 305 U.S. 124 (1938).

[n.233]. See Richard H. Stern, Shrink-wrap licenses of Mass Marketed Software: Enforceable Contracts or Whistling in the Dark?, 11 Rutgers Computer & Tech. L.J. 51 (1985) (finding that many limitations in the licenses are enforceable).

[n.234]. See supra, note 123 and accompanying text.

[n.235]. See Wheeler v. St. Joseph Hospital, 63 Cal. App.3d 345 (1977) (holding contract unenforceable); Standard Oil Co. of Calif. v. Perkins, 347 F.2d 379, 383 (9th Cir. 1965) (holding contract unconscionable and unenforceable). But see Lechmere Tire and Sales Co. v. Burwick, 277 N.E.2d 503 (Mass. 1972) (holding that contract at issue was an adhesion contract but was not unconscionable).

[n.236]. See, e.g., Simpkins v. Ritter, 204 N.W.2d 383, 385 (Neb. 1973) (delivery of personality for some particular use upon a contract, express or implied, that after the purpose has been fulfilled it will be redelivered to the person who delivered it, or otherwise dealt with according to directions, or until the owner reclaims it).

[n.237]. See generally, Leigh C. Lawson, DNA Fingerprinting and Its Impact Upon Criminal Law, 41 Mercer L. Rev. 1453 (1990) (describing the ability to distinguish individuals using the pattern formed by their DNA).

[n.238]. See e.g., Wentworth v. Riggs, 143 N.Y.S. 955 (N.Y. App. Div. 1913) (bailment arising where the person having possession of a chattel holds it under such circumstances that the law imposes upon him an obligation to deliver it to another).

[n.239]. Because the owner still has control over the item, the individual possessing the patented item is no more than an agent of the owner. See e.g., Smith v. State, 148 P.2d 206, 208 (Okla. Crim. App. 1944) (indicating that the bailee is a species of agent to whom something movable is committed in trust for another, the owner).