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The Muddled Law of Biotechnology: Frustrating Agricultural and Biomedical Progress

by

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COMMENTS

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INTRODUCTION

Sometime around 9500 B.C., in various regions of the Fertile Crescent in the Near East, man began cultivating and harvesting cereal grains, and not long after, probably somewhere near what is now northern Iraq, he began herding wild beasts instead of hunting them.[1] These momentous strides were man's greatest in all of prehistory, startling him out of a slow rhythmic march into a headlong dash toward civilization.[2]

Agriculture—this domestication of animals and plants—was born of man's ancient ambition to control and utilize his environment, an ambition which would engender countless miraculous discoveries and inventions. In the early 1970's, almost eleven millennia after the revolutionizing debut of agriculture, several scientists discovered a technique which would form the basis of man's second great transformation of his organismal environment.[3] The resulting field of biotechnology has influenced agriculture and health care in enormous ways: it has allowed us to improve our crops and our livestock, treat elusive genetic diseases, supply pharmaceuticals more inexpensively, and strive to extinguish

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[1] J.M. ROBERTS, HISTORY OF THE WORLD 21-26 (1976).

[2] *Id.*

[3] In 1972, Paul Berg worked to determine ways of cutting and joining pieces of DNA. The next year, Stanley Cohen and Annie Chang showed that a recombinant DNA molecule can be maintained and copied within *E. coli* bacteria. Then Cohen and Herb Boyer joined DNA pieces from different species. DAVID A. MICKLOS & GREG A. FREYER, DNA SCIENCE 42-43 (1990).

world hunger.

Unfortunately, these vital developments in biotechnology which promise to enhance the quality and longevity of life are threatened by an unpredictable patent system.[4] Biotechnology has been tormented by a fickle and inadequate structure of protection in which the only certainty is enormous litigation expense.[5] From its inception in the 1970's, the technology's rampant progress immediately outgrew the existing patent system, which has struggled awkwardly with the sophisticated science. The issues of patenting life, protecting "obvious" processes in the production of recombinant products, and controlling international piracy are driving the industry's call for reform. Recent cases demonstrate the frustrating and inconsistent guidelines available to companies that must invest five to ten years and millions of dollars in the research and development of a single product or process, all the while wondering how the capricious law will view the patentability of their result. And even if the product or process is given patent protection, international pirates are likely to utilize it outside of the United States (and the bounds of its protection) and import the finished product back into the United States to compete with the inventor.[6] Private researchers who are denied patent protection for their innovations may be forced to turn to trade secret law for protection,[7] and the ensuing throttle on the disclosure of critical discoveries could devastate the progress of biotechnology and, in turn, its benefit to society.[8] Clearly, the biotechnology patent system must be modified soon or the incentive to invent will ultimately fade with the diminishing reward and burgeoning expense.

Part I of this comment provides a brief overview of the field of biotechnology—its most outstanding accomplishments, and the basic concepts and techniques underlying it. Part II discusses the origins and

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[4] *E.g.*, James Boyle, *A Theory of Law and Information: Copyright, Spleens, Blackmail, and Insider Trading*, 80 CAL. L. REV. 1413, 1416 ("[I]f we look at the legal treatment of genetic information . . . we find a morass of formalism, circular arguments, and incoherent theories of property."); Michael S. Greenfield, *Recombinant DNA Technology: A Science Struggling with the Patent Law*, 44 STAN. L. REV. 1051, 1054-55 (1992) ("[T]he very laws the Framers of the Constitution and legislators in Congress intended to foster their inventions inhibited them. Such a result is inconsistent with the purposes underlying the patent system.").

[5] Jeanette L. Murphy & Martha M. Rumore, *U.S. Legislation to Protect Biotechnology Intellectual Property*, BIOPHARM, Nov.-Dec. 1992, at 36-37.

[6] *Proposal to Protect Patents is Examined at House Hearing*, Patent, Trademark & Copyright Law Daily (BNA) (June 10, 1993).

[7] James R. Chiapetta, *Of Mice and Machine: A Paradigmatic Challenge to Interpretation of the Patent Statute*, 20 WM. MITCHELL L. REV. 155, 160 (1994).

[8] *Id.*

purposes of patent law and some of the theories supporting it. Part III reviews basic patent law and the requisites for obtaining a patent. Part IV looks back to the earliest intersection of patent law with biotechnology and then through the slow historical development of protection. Part V examines patent law as it is currently applied to biotechnology, and the ways in which the union may become more harmonious.

I. BIOTECHNOLOGY

A. Major Achievements

Biotechnology, the manipulation of genetic material, has revolutionized biology, medicine, and agriculture. Only within the last 25 years have we had the ability to examine the genetic content of an organism and manipulate a desired element of that information with specificity in order to derive from it a desired trait or biological product.[9] As an industry, United States biotechnology sales totaled $3.7 billion in 1992; human biotherapeutics and diagnostics accounted for about $3.5 billion, and agricultural products accounted for $70 million.[10] Predicted growth of the young industry for 1993 was 16%, to total approximately $4.3 billion.[11] Other sources project that in the year 2000, biotechnology sales will approach $40 billion in the United States and surpass $100 billion worldwide.[12]

Agricultural genetic manipulation, the search for genetically improved plants and animals, has an ancient origin and a long history, but selective breeding for a desired trait, the forced mating of parents chosen for their exceptional qualities, has always been complicated by the unpredictable plethora of other traits (generally undesirable) inherited from the cross between two plants or animals.[13] The inception of biotechnology, however, allowed the genetic transfer of a single specific

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[9] The inception of recombinant DNA technology might be traced back to 1953, when Watson and Crick uncovered the structure of DNA based on x-ray results of Franklin and Wilkins. In 1972 and 1973, DNA cloning was achieved in the laboratories of Boyer, Cohen, and Berg at Stanford University and the University of California at San Francisco. BRUCE ALBERTS ET AL., MOLECULAR BIOLOGY OF THE CELL 293 (1994).

[10] *Biotechnology Starts to Gain Momentum*, CHEMICAL WEEK, Jan. 6, 1993, at 32.

[11] *Id.*

[12] Greenfield, *supra* note 4; *see also* 141 CONG. REC. E129 (daily ed. Jan. 19, 1995) (statement of Rep. Moorhead).

[13] Traditional breeding of plants and animals results in an unpredictable distribution of the parental genetic material and, in turn, the parental traits.

trait without changing the others.[14] This ability has dramatically affected agriculture, providing improvements in crops, bacterial pesticides and fertilizers, and livestock. For example, many traits have been transferred into plants by genetic engineering: higher nutritional content,[15] improved hardiness, and altered fruit ripening.[16]

The nutritional content of plants can be improved through the transfer of important genes. Pea plants, for example, have been genetically transformed to express favorable traits,[17] and other plants have been engineered to over-produce lysine, an important amino acid in the diets of humans and other animals.[18] Corn and rape seeds are being modified to produce higher levels of oils for use as more nutritious animal feed.[19] Cereals, which are the major food source for most of earth's population, are considered incomplete protein sources because they lack at least one of the amino acids required by the human body.[20] So biotechnologists have been searching for methods of introducing the gene coding for those missing amino acids into grains such as corn.[21] This agricultural accomplishment, more than any other, will have a phenomenal effect on worldwide nutrition;[22] indeed, biotechnology's ability to produce pest-resistant, high-yield, and high-nutrition crops has been hailed as "the opportunity to banish hunger from even the poorest nations of the Third World."[23]

Hardiness can be conferred on plants as insect and disease resistance and herbicide tolerance. Bacterial insecticides, usually variations of the bacterium *Bacillus thuringiensis* which naturally produces an insecticidal toxin, have been developed to safely control many different crop

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[14] Recombinant DNA technology allows the physical movement of a single gene into another animal. In this way a single trait can be conferred.

[15] BERNARD R. GLICK AND JACK J. PASTERNAK, MOLECULAR BIOTECHNOLOGY 329 (1994).

[16] Calgene has produced the FLAVR SAVR tomato which has received approval by the Food and Drug Administration. The tomato can be vine-ripened without rotting before it reaches the market. Keith D. Parr, *Developments in Agricultural Biotechnology*, 19 WM. MITCHELL L. REV. 457, 460.

[17] U.S. Patent 5,286,635.

[18] U.S. Patent 5,258,300.

[19] David Rotman, *Agchem Producers Sow Plans for a Rich Harvest*, CHEMICAL WEEK, Aug. 18, 1993, at 33.

[20] DAVID A. MICKLOS & GREG A. FREYER, DNA SCIENCE 175 (1990).

[21] *Id.*

[22] *Id.*

[23] Graeme Browning, *Genes in the Bottle*, NATIONAL JOURNAL, Jan. 1, 1994, at 16; *see also* James E. Ellis, *Can Biotech Put Bread on Third World Tables?* BUSINESS WEEK, Dec. 14, 1992, at 100.

pests. For example, particular *B. thuringiensis* strains which kill ants, moths, and caterpillars have recently been patented.[24] And plants, themselves, have been fortified to resist insect pests;[25] the same *B. thuringiensis* genes that code for insecticidal toxins have been removed from the bacteria and transferred into plants in an attempt to confer insect resistance.[26] The toxin is harmless to humans and other mammals who might eat the plant, and it does not persist in the environment.[27] Researchers have created cotton and potato plants that safely kill the larvae and beetles that have persistently devoured much of the United States' crops.[28] Conventional attempts to control cotton pests alone account for 40% of the insecticide used in the country.[29] And the rampant and extremely expensive use of chemicals has poisoned land, groundwater, and wildlife.[30] Other plants have been "vaccinated"[31] to resist viral diseases.[32] In addition, bacteria are now being developed to act as fertilizer on the roots of plants to fix nitrogen from the environment, making it available for use by the plants.[33]

Herbicidal tolerance has been created in plants that have been engineered to tolerate chemical herbicides such as glyphosate (e.g., Roundup),[34] phosphinothricin,[35] bromoxynil,[36] and sulfonylureas.[37] Herbicides usually attack a critical enzyme in a metabolic pathway found only in plants, such as photosynthesis or the synthesis of certain

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[24] *E.g.*, U.S. Patents 5,268,297 and 5,268,172.

[25] *E.g.*, European Patent Application No. 142,924.

[26] GLICK & PASTERNAK, *supra* note 15, at 340.

[27] GLICK & PASTERNAK, *supra* note 15, at 341.

[28] Mark Fischetti, *The Blossoming of Biotechnology: Harvesting Miracle Drugs, Better Plants, and Lots of Confusion*, OMNI, Nov. 1992, at 68.

[29] *Id.*

[30] *Id.*

[31] GLICK & PASTERNAK, *supra* note 15, at 345.

[32] *E.g.*, P.P. Abel et al., *Delay of Disease Development in Transgenic Plants that Express the Tobacco Mosaic Virus Coat Protein Gene*, 232 SCIENCE 738 (1986).

[33] Marvin Scher, *Biotechnology's Evolution Spurs Food Revolution, Foods of Tomorrow*, FOOD PROCESSING, Jan. 1993, at 36.

[34] H.J. Klee et al., *Cloning of an Arabidopsis thaliana gene encoding 5-Enolpyruvylshikimate-3-Phosphate Synthase: Sequence Analysis and Manipulation to Obtain Glyphosate-Tolerant Plants*, 210 MOL. GEN. GENET. 437 (1987).

[35] W. Wohllenben et al., *Nucleotide Sequence of the Phosphinothricin N-Acetyltransferase Gene from Streptomyces viridochromogenes Tu494 and its Expression in Nicotiana tabacum*, 70 GENE 25 (1988).

[36] International Patent Application No. PCT/US87/00044.

[37] J. Hattori et al., *Multiple Resistance to Sulfonylureas and Imidazolinones Conferred by an Acetohydroxythase Gene with Separate Mutations for Selective Resistance*, 232 MOL. GEN. GENET. 167 (1992).

required amino acids.[38] Therefore, because herbicides are as lethal to crops as they are to weeds, farmers could benefit from crops that are immune to their effects.

Farmers will also profit from livestock with improved disease resistance, growth, reproduction, and nutritional content of milk. Some animals have even been engineered to develop leaner, more nutritious meat.[39] Researchers hope to improve the health of farm animals by introducing into them genes that confer resistance to common bacterial, viral, and parasitic infections, the prevention of which currently costs farmers up to 20% of the total production value.[40] Disease resistance might also be conferred by a boosted immune system resulting from the transfer of genes coding for certain immunological molecules.[41] The milk of dairy cattle could be made to contain more protein for higher nutritional content in milk and cheese, or to contain no lactose for those who are lactose intolerant.[42] Another goal of transgenic research is to utilize the mammary glands of domestic animals as biological factories for valuable therapeutics for humans.[43] The gene products secreted in the animals' milk are harmless to the animals and can be purified from the large quantities of milk. In chickens, the goal is lower fat and cholesterol in eggs, higher meat quality, and disease resistance.[44]

Overall, the influence and benefits that biotechnology has upon agriculture are profound and will continue to transform the farming industry. However, because these effects on agriculture are not as widely publicized as the biotechnological advances in medicine, the current focus of the industry (and the public) is on pharmaceuticals.[45] Here, the public sees the greatest and most immediate benefit to humankind—and so here lies biotechnology's greatest commercial attraction and, therefore, its greatest litigation enticement. In the field of biotherapeutics, for example, human genes, such as the gene encoding the insulin protein, are often placed within bacteria which then synthesize great amounts of human protein, such as insulin.[46] Prior to the commercial production of recombinant human insulin, millions of diabetics

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[38] DAVID A. MICKLOS & GREG A. FREYER, DNA SCIENCE 174 (1990).

[39] U.S. Patent 5,075,229.

[40] GLICK & PASTERNAK, *supra* note 15, at 373.

[41] GLICK & PASTERNAK, *supra* note 15, at 373.

[42] GLICK & PASTERNAK, *supra* note 15, at 373.

[43] GLICK & PASTERNAK, *supra* note 15, at 374.

[44] GLICK & PASTERNAK, *supra* note 15, at 375-77.

[45] *See supra* note 10.

[46] S. Raptis & G. Dimitriadis, *Human Insulin*, 3 CLIN. PHYSIOL. BIOCHEM. 29 (1985).

were relegated to lifelong dependence on insulin extracted from the pancreases of dead mammals. The old preparation was expensive and problematic due to its non-human nature, and the new preparation is cheap and highly effective.

Although insulin was the industry's first major commercial and medical success,[47] several others followed shortly thereafter: various types of interferon for the treatment of leukemia and cancers,[48] human growth hormone for the treatment of pituitary deficiencies (e.g., dwarfism),[49] tissue plasminogen activators for the treatment of blood clots,[50] a hepatitis B vaccine,[51] Factor VIII:C (a blood clotting component) for the treatment of hemophilia,[52] and erythropoietin (EPO; a stimulator of red blood cell production) for the treatment of anemia.[53] Hundreds of other biotherapeutics are in production—a protracted and extremely costly enterprise.[54]

B. Background

The reproducibility of life and the continuity of heredity depend on the information preserved in DNA (deoxyribonucleic acid), an enormous fragile molecule carrying a linear sequence of four different subunits.[55] In the cells of higher organisms, DNA is held sacrosanct

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[47] Recombinant human insulin, cloned by Genentech, is one of the most widely distributed genetically engineered biotherapeutics. Fischetti, *supra* note 28.

[48] Graeme Browning, *Genes in the Bottle*, NATIONAL JOURNAL, Jan. 1, 1994, at 16.

[49] Recombinant human growth hormone was produced first by Genentech. Fischetti, *supra* note 28.

[50] R.S. Crespi, *Claims on Tissue Plasminogen Activator*, 337 NATURE 317 (1989).

[51] Browning, *supra* note 48.

[52] Genentech was the first to produce recombinant Factor VIII:C. Worldwide, over 30,000 hemophiliacs were estimated to use naturally isolated Factor VIII:C at a cost of $500 million. *Two Top Factor VIII Firms Settle Lawsuit Out of Court*, 9 BIOTECH NEWSWATCH, Apr. 3, 1989, at 1. Only small amounts of the Factor occur naturally in blood plasma so great amounts of donated plasma are required to obtain therapeutic amounts.

[53] Amgen was the first to produce recombinant EPO, which has broad and lifesaving therapeutic value for millions of patients who suffer anemia related to diseases such as AIDS, cancer, and renal disease. Vast amounts of urine must be utilized to obtain therapeutic amounts of the naturally occurring protein. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200, 1203 (Fed. Cir. 1991).

[54] Bringing a new biopharmaceutical to market typically takes ten years and costs between $100 and $200 million. Diane Gershon, *Protecting U.S. Biotech Firms*, 352 SCIENCE 4 (1993).

[55] DNA consists of four nucleotides arranged in various arrangements, spelling out different linear messages. Each complete, functional message is designated as a gene.

within the nucleus, so its information must reach the rest of the cell indirectly. Segments of the instructions written in the DNA are copied into small mobile molecules, messenger RNA (mRNA), which carry the information from the nucleus to machinery within the cytoplasm where, according to the mRNA's instructions, proteins are made.[56] These resulting proteins may be hormones or growth factors which will be shipped out of the cell into the bloodstream, structural components of the cell itself used for maintenance and repair, or enzymes used to catalyze the cell's biochemical reactions.[57]

In the field of recombinant DNA, the specific stretches of DNA (the genes) which carry the code for these valuable proteins are of great interest. If the particular gene can be identified, it can be cut out of the human DNA molecule (a chromosome) and be placed into yeast, mammalian, or bacterial machinery which will produce its protein in abundance.[58] The protein—a human protein coded by human DNA and synthesized by universal biochemical components employed by all living organisms—can be collected from the cellular factories, purified, and used to treat or vaccinate against human diseases, or to replace necessary hormones. Similarly, genes from other animals may be utilized to create proteins to treat animals.

The actual excision of a gene from a long DNA molecule is performed by cutting enzymes that are sequence-specific endonucleases (restriction endonucleases).[59] They identify a particular short sequence (4-8 bases, usually) within the DNA and cut only at sites with that sequence.[60] Since the 1970's, more and more cutting enzymes have been discovered and have provided a method for cutting DNA at precise locations and reducing the huge DNA molecule into manageable and identifiable pieces. When the correct piece of DNA (the one with the gene coding for the desired protein) is found, it can be "cloned" or inserted into a plasmid (a small ring of DNA) that is capable of repli-

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GLICK & PASTERNAK, *supra* note 15, at 19-23.

[56] Once in the cytoplasm, the copied message is "read" off the mRNA by ribosomes, structures which orchestrate the production of protein with the help of transfer RNA's which deliver individual amino acids to the growing protein chain. ALBERTS ET AL., *supra* note 9, at 201-02.

[57] ALBERT L. LEHNINGER ET AL., PRINCIPLES OF BIOCHEMISTRY 984-94 (1993).

[58] *Id.*

[59] Restriction endonucleases are derived from various bacteria where they serve to chop up and destroy foreign DNA which enters the cell. The bacteria's own DNA is protected from this mechanism. ALBERTS ET AL., *supra* note 9, at 293.

[60] ALBERTS ET AL., *supra* note 9, at 293.

cating itself and the inserted gene of interest.[61] When that plasmid carrying the inserted gene is placed within a bacterium, it creates copies of itself so that when the bacterium divides, each cell receives a copy of the bacterial chromosome and at least one copy of the plasmid. In this way, the dividing bacteria, which double their population approximately every 30 minutes, create millions of copies of the plasmid with its inserted gene. Additionally, each bacterium is a fully-equipped protein-synthesizing factory that utilizes its own parts and tools to "express" that gene, to produce the desired protein just as if it were one of its own.[62]

Recombinant technology has also allowed the introduction of desirable genes into plants. These genes bring to plants highly beneficial traits such as increased nutrient production, resistance to herbicides, insects, and viruses, resulting in greater yield and reduced use of environmentally damaging chemicals. The method of introducing genes into plants utilizes naturally occurring plasmids of the soil bacterium *Agrobacterium tumefaciens*, which invades plant tissue at the site of wounds and transfers a part of its plasmid DNA into the plant cell where it is actually incorporated into the cell's DNA.[63] If, first, the desired gene is inserted (by cutting and splicing) into the *Agrobacterium*'s plasmid, that desired gene can be passed into the plant tissue.[64] There it is replicated and expressed into protein along with the plant cell's own chromosomal DNA. The infected plant cells carrying the introduced gene are transferred to a special medium that encourages growth of an entire, new recombinant plant that can then reproduce naturally and pass on the new gene.[65]

The direct introduction of a desired gene into an organism (as op-

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[61] In addition to plasmids, viruses can be used as vectors to introduce foreign DNA into bacterial cells. LEHNINGER ET AL., *supra* note 57, at 992.

[62] The use of cultured mammalian or yeast cells offers some advantages over bacterial cells. Although bacteria can produce a human protein according to the mRNA's instructions, they cannot always "finish off" the product in the same way. This finishing includes "post-translational" processing, such as glycosylation, that adds important details to the protein. Whereas bacteria are prokaryotes (lacking a nucleus) and are fundamentally different from mammalian cells, yeast are single-celled eukaryotes (containing a nucleus) and, because of their more advanced nature, are capable of some "post-translational" processing. Cultured mammalian or human cells can produce proteins in exactly the same form as that produced by intact cells. Unfortunately, the culture of yeast and mammalian cells is more expensive and considerably slower due to the cells' less frequent divisions. GLICK & PASTERNAK, *supra* note 15, at 113-31.

[63] LEHNINGER ET AL., *supra* note 57, at 1002-04.

[64] LEHNINGER ET AL., *supra* note 57, at 1002-04.

[65] LEHNINGER ET AL., *supra* note 57, at 1002-04.

posed to the administration of a protein, the *result* of gene cloning) as in the plant example above, is actually a form of gene therapy. A gene is introduced to provide a supplemental trait that would be highly beneficial (as in the plant example) or a normal trait that is lacking due to a genetic deficiency. A transgenic animal carries a gene that was introduced into the animal, or an ancestor, at an embryonic stage (usually the one-cell stage).[66] This early introduction ensures that all cells of the animal will contain the gene and that it will be passed on to future generations.[67] Some of these animals, which provide the basis for a new industry called "pharming," are engineered so that they secrete into their milk or blood huge amounts of cheap pharmaceuticals.[68]

Human gene therapy generally attempts to deliver needed genes via the patient's own altered cells or via altered viruses. This medical field is a new, extremely exciting frontier with great promise for correcting or even curing genetic diseases and some cancers. Thus far, gene therapy has been used to successfully treat cystic fibrosis.[69]

II. Origins and Purposes of a Patent System

A. Venetian Origin

Although there is evidence that a patent structure existed in ancient Greek civilization,[70] the modern patent system is generally believed to have had its origins in the profitable silk commerce of fifteenth-century Venice.[71] There the first patent statute, created by the Council of Venice in 1474, granted an exclusive ten-year privilege to inventors of any machine or process that facilitated or improved silk making,[72] and was, from its beginning, motivated strictly by commerce.[73] In the United States, Congress implemented the first patent system in 1790.[74]

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[66] Lehninger et al., *supra* note 57, at 1006-07.

[67] Lehninger et al., *supra* note 57, at 1006-07.

[68] Fischetti, *supra* note 28.

[69] Fischetti, *supra* note 28.

[70] Arthur R. Miller & Michael H. Davis, Intellectual Property 4 (2d ed. 1990).

[71] David G. Scalise & Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 Fordham Int'l L.J. 990, 996 (1993).

[72] *Id.*

[73] *Id.*

[74] Act of Apr. 10, 1790, ch. 7, 1 Stat. 109 (promoting the progress of useful arts) (repealed by Act of Feb. 21, 1793, ch. 11, 1 Stat. 318) (current version at 35 U.S.C. §§ 101-112 (1994)).

B. Purposes for Patents

Although patent protection grants a kind of monopoly, explicitly anathema to the tenets of modern enterprise, it is justified by the need to encourage innovation and progress.[75] Analysis of that justification is usually founded on four theories. Two, the incentive to invent theory[76] and the disclosure of discovery theory,[77] are economic analyses; the other two, the law of nature theory[78] and the reward by monopoly theory,[79] are equitable.

The incentive theory states that the prospect of patent protection will motivate the inventor to invest the great amount of time and money required for the research and development of a new invention. If, after his invention, others were free to create and market his invention, he would be unable to profit or even recover his costs due to the competition and resulting lower price.[80] The disclosure theory stands on the proposition that only with protection would an inventor reveal her invention, thereby contributing to the storehouse of public knowledge. Without protection, the inventor would likely conceal her invention as a trade secret, depriving society of its benefit.[81] The law of nature theory is based on the premise that every person's ideas are his own property and that society is morally obligated to protect that property.[82] Under the reward by monopoly theory, an inventor is entitled to a reward of protection which is commensurate with the benefits which her invention imparts on society. Only if her contribution is useful will she be given exclusive rights to it.[83]

Regardless of the justification for granting a patent's exclusive rights, "[t]he authority of Congress is exercised [in the patent laws] in the hope that 'the productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of in-

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[75] "The Patent Clause itself reflects a balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'" Bonito Boats, Inc. v. ThunderCraft Boats, Inc., 489 U.S. 141, 146 (1989).

[76] Greenfield, *supra* note 4, at 1058.

[77] Greenfield, *supra* note 4, at 1059.

[78] Greenfield, *supra* note 4, at 1060.

[79] Greenfield, *supra* note 4, at 1060.

[80] Greenfield, *supra* note 4, at 1058; *see also* Yusing Ko, *An Economic Analysis of Biotechnology Patent Protection*, 102 YALE L.J. 777, 791 (1992).

[81] Greenfield, *supra* note 4, at 1059; *see also* Ko, *supra* note 80, at 795.

[82] Greenfield, *supra* note 4, at 1060.

[83] Greenfield, *supra* note 76, at 1060.

creased employment and better lives for our citizens.'"[84]

III. Basic Patent Law

A. Constitutional Empowerment

The Constitution empowers Congress to grant patents to inventors "[t]o promote the Progress of Science and useful Arts . . . ."[85] Although the Framers of the Constitution disdained monopolies, they understood the necessity for a "balance between the need to encourage innovation and the avoidance of monopolies which stifle competition without any concomitant advance in the 'Progress of Science and useful Arts.'"[86] Thomas Jefferson, an early patent commissioner, inventor, and author of the 1793 Patent Act, admitted that there are "things which are worth to the public the embarrassment of an exclusive patent."[87]

B. Statutory Implementation

With the implementation of the Patent Act,[88] Congress sought to achieve this balance between the incentive for innovation and the restriction of competition.[89]

1. Requirements

The Patent Act provides 17-year patent protection for "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof."[90] More explicitly, three elements are required for patentability: utility, novelty, and nonobviousness. To fulfill the utility element of § 101, the invention must present a "substantial or practical utility."[91] The law refuses to protect trivial accomplishments and seeks to promote innovation of those inventions that can most benefit society with their usefulness.

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[84] Diamond v. Chakrabarty, 447 U.S. 303, 307 (1979) (quoting Kewanee Oil Co. v. Bicron Corp., 416 U.S. 470, 480 (1974)).

[85] U.S. Const. art. I, § 8, cl. 8.

[86] Bonito Boats, Inc. v. ThunderCraft Boats, Inc., 489 U.S. 141, 146 (1989).

[87] Graham v. John Deere Co., 383 U.S. 1, 10-12 (1966).

[88] Act of Apr. 10, 1790, ch. 7, 1 Stat. 109 (promoting the progress of useful arts) (repealed by Act of Feb. 21, 1793, ch. 11, 1 Stat. 318) (current version at 35 U.S.C. §§ 101-112 (1994)).

[89] Bonito Boats, Inc. v. ThunderCraft Boats, Inc., 489 U.S. at 146.

[90] 35 U.S.C. § 101 (1994).

[91] Cross v. Lizuka, 753 F.2d 1040, 1044 (Fed. Cir. 1985).

The novelty element of § 102 requires that the invention must not have been previously described, made, or patented.[92] Prior art which discloses every element of the invention, which is said to "anticipate" the invention, precludes its patentability. Under the § 103 definition of obviousness, if the invention would have been obvious to a person with ordinary skill in the art at the time the invention was made, it is not patentable.[93] Since it fails to add "a measure of worthwhile knowledge to the public storehouse," it will not be protected.[94] The Supreme Court believes that "[t]aken together, the novelty and nonobviousness requirements express a congressional determination that the purposes behind the [Patent Law] are best served by free competition and exploitation of that which is either already available to the public, or that which may be readily discerned from publicly available material."[95]

In addition to the three basic requirements, § 112 requires that the patent applicant provide a full and clear disclosure of the invention and the process by which it is made so that a person skilled in the art could repeat the invention.[96] The applicant must also describe the best mode she knows for carrying it out.[97]

2. Scope of Subject Matter

Beyond the explicit terms of the statute, judicial doctrine has expounded upon the scope of subject matter that is not patentable. This non-patentable subject matter includes scientific truths, mathematical formulas, abstract principles, laws of nature, physical phenomena, and products of nature.[98] When applied to biotechnology, the product of nature doctrine[99] has caused considerable controversy, generally due to the misconception that human-altered organisms are products of nature rather than products of man.

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[92] 35 U.S.C. § 102.

[93] *Id.* § 103.

[94] *See, e.g.*, *In re* Argoudelis, 434 F.2d 1390, 1394 (C.C.P.A. 1970) (Baldwin, J., concurring).

[95] Bonito Boats, Inc. v. ThunderCraft Boats, Inc., 489 U.S. 141, 150 (1989).

[96] 35 U.S.C. § 112.

[97] *Id.*

[98] Parker v. Flook, 437 U.S. 584 (1978); Gottschalk v. Benson, 409 U.S. 63, 67-68 (1972); Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 130 (1948); General Electric Co. v. DeForest Radio Co., 28 F.2d 641, 642-47 (3d Cir. 1928), *cert. denied*, 278 U.S. 656 (1929); Le Roy v. Tatham, 14 How. 156, 175 (1853).

[99] Scalise & Nugent, *supra* note 71, at 999-1001.

IV. Historical Development of Biotech Patent Law

A. Early Biotech Law: A Paucity of Protection

1. Product-of-Nature Doctrine

The product-of-nature doctrine[100] states the obvious fact that if a thing exists in nature, it is not new and cannot meet the novelty requirement. That requirement demands an inventive step on the part of the inventor; the mere discovery of a previously existing element in nature is inadequate for patent protection, and though the doctrine appears to represent a simple truth, its difficult application lies in determining what constitutes an inventive step.[101] Indeed, the U. S. Patent and Trademark Office (PTO) wielded the product-of-nature doctrine against nearly every patent application for protection of living matter, resulting in over three decades of frustration, denial of protection, and most tragically, stifling of scientific research and innovation.[102]

Funk Brothers Seed Co. v. Kalo Inoculant Co.[103] is a classic example of the doctrine's early application—and probably its high-water mark. Kalo originally claimed that Funk infringed its patent for combining six bacterial strains as an inoculant for increasing the nitrogen fixing capacity of leguminous plants.[104] The United States Supreme Court rejected Kalo's patent by stating that the combination inoculant was "no more than the discovery of some of the handiwork of nature and hence [was] not patentable."[105] The Court's application of the product-of-nature doctrine led it to determine that Kalo had failed to take an inventive step when it mixed bacteria to produce an improved fertilizer: "The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metal, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none."[106]

Even then, however, the doctrine was questioned by some. Justice Felix Frankfurter, who was concerned about the ambiguous and expansive interpretation of the doctrine, proposed a different reading that

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[100] Scalise & Nugent, *supra* note 71, at 999-1001.

[101] Scalise & Nugent, *supra* note 71, at 999-1001.

[102] Scalise & Nugent, *supra* note 71, at 1001.

[103] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948).

[104] Leguminous plants, such as peas, have the physiological ability to draw nitrogen from the atmosphere and utilize or "fix" it to produce organic compounds (including nutritious proteins) in their tissues. *Id.* at 128.

[105] *Id.* at 131.

[106] *Id.* at 130.

would allow a natural product with a new and useful result to satisfy the novelty requirement: "For these are vague and malleable terms infected with too much ambiguity and equivocation. Everything that happens may be deemed 'the work of nature,' and any patentable composite exemplifies in its properties 'the laws of nature.' Arguments drawn from such terms for ascertaining patentability could fairly be employed to challenge almost every patent."[107]

2. Minimal Protection for Plants

In attempts to improve the status of the law and promote the progress of agriculture, Congress twice enacted plant patent acts. The Plant Protection Act of 1930 (PPA)[108] provides protection for inventors of new and distinct varieties of asexually reproducing plants (that is, plants which are not grown by seed, but are, for example, propagated by grafting). Whoever "invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings . . . may obtain a patent therefor . . . ."[109]

The Plant Variety Protection Act (PVPA)[110] protects new varieties of sexually reproducing plants (those grown by seed), with the exception of fungi and bacteria: "The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety . . . shall be entitled to plant variety protection therefor . . . ."[111] This Act provides an 18-year exclusive right to encourage research, development, and marketing of novel plant varieties. But until very recently, its protection was weakened by a major exemption. Section 2543, the farmers' crop exemption, allowed farmers to save some of their protected crop as seed for replanting in their fields, and to use seed crops for non-reproductive uses, such as animal feed.[112] And most damagingly, it permitted farmers who chose not to use the reserved seed to sell it to other farmers, providing that the farmers were not in the seed business.[113] Commonly,

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[107] *Id.* at 135 (Frankfurter, J., concurring).

[108] Act of May 23, 1930, ch. 312, 46 Stat. 376 (current version at 35 U.S.C. §§ 161-164 (1994)).

[109] *Id.* § 161.

[110] Act of Dec. 24, 1970, Pub. L. No. 91-577, 1970 U.S.C.C.A.N. (84 Stat.) 1793 (current version at 7 U.S.C. §§ 2321-2582 (1994)).

[111] 7 U.S.C. § 2402 (1994).

[112] *Id.* § 2543.

[113] *Id.*

farmers have sold seed they harvested from protected plant varieties in transactions known as "brown-bag sales."[114] This is the practice in which farmers buy seed from a seed company that developed the seed variety, they plant, harvest, and clean the seed, then place it in brown bags for sale to other farmers. Brown-bagging can have a dramatic commercial effect, as it did on Pioneer Hi-Bred International, Inc.[115] In 1989, 92% of the acres planted with Pioneer's winter wheat variety 2157 were sold by brown-baggers rather than Pioneer, leaving Pioneer to benefit from only eight percent. The financial losses were so great that Pioneer chose to stop breeding the variety in Kansas.[116]

In a recent case, *Asgrow Seed Co. v. Winterboer*,[117] the Federal Circuit court upheld such a broad reading of the PVPA's crop exemption that it has been called "a travesty of statutory interpretation."[118] Winterboer, an Iowa farmer, planted 265 acres of protected soybean varieties, then sold his entire crop as seed: 10,529 bushels capable of planting 10,000 acres in the following year.[119] The farmer did not dispute that he grew the crop primarily for sale as seed, but he claimed that he was protected by the PVPA.[120] The court agreed that the farmers' crop exemption permits brown-bag selling, but not "marketing," which it defined in the context of the PVPA to mean "extensive or coordinated selling activities, such as advertising, using an intervening sales representative, or similar extended merchandising or retail activities."[121]

In a scathing dissent of the denial for rehearing, Judge Newman declared the panel's reading of the exemption as "contrary to the statute and its purpose."[122] He questioned the "curious construction" of the term "marketing" and suggested that there was "no basis for departing from the ordinary, contemporary, common meaning of 'market-

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[114] The Asgrow Seed Co. v. Winterboer, 982 F.2d 486, 488 (Fed. Cir. 1992) [hereinafter *Asgrow II*].

[115] Neil D. Hamilton, *Why Own the Farm If You Can Own the Farmer (and the Crop)? Contract Production and Intellectual Property Protection of Grain Crops*, 73 NEB. L. REV. 48, 95 (1994).

[116] *Id.*

[117] Asgrow Seed Co. v. Winterboer, 989 F.2d 478 (Fed. Cir. 1993) [hereinafter *Asgrow III*], *cert. granted*, 114 S. Ct. 1535 (1994), *rev'd*, 115 S. Ct. 788 (1995) [hereinafter *Asgrow IV*].

[118] *Asgrow III*, 989 F.2d. at 480 (Newman, J., dissenting).

[119] *Id.* at 481-82 (Newman, J., dissenting).

[120] Asgrow Seed Co. v. Winterboer, 795 F. Supp. 915, 917 (N.D. Iowa 1991) [hereinafter *Asgrow I*].

[121] *Asgrow II*, 982 F.2d 486, 492 (Fed. Cir. 1992).

[122] *Id.* at 479.

ing' as 'selling'."[123] Newman noted that although farmers such as Winterboer "who have opportunistically entered the seed business for certified varieties" may be uninterested, the widespread massive brown-bag sales have resulted in the termination of research projects and the abandonment of new varieties, and an "eviscerated incentive to innovate in plant varieties."[124]

Reversing the Federal Circuit decision, the Supreme Court agreed with the dissent's interpretation of the word "marketing," suggesting that it requires only the "act of holding forth property for sale, together with the activities preparatory thereto," and does not require that "the promotional or merchandising activities connected with the selling be extensive."[125] The Court held, therefore, that brown-bag sales constitute marketing and are not permitted by the farmers' exemption of § 2543.[126]

In the time between the Federal Circuit and the Supreme Court decisions, however, Congress amended the PVPA[127] in an attempt to make it consistent with the International Convention for the Protection of New Varieties of Plants. One result of the amendments is the elimination of the exemption for farmers who sell protected seed to other farmers for reproductive purposes; in other words, brown-bag sales are now statutorily barred. But, "[t]he amendment does not diminish the right of a farmer to save seed for replanting and to use the resulting crop or to sell the seed for other than reproductive purposes."[128] Additionally, when a farmer cannot use his saved seed due to serious illness, financial distress, or other unanticipated events, he may sell his seed to another farmer for reproductive purposes provided that he receives permission from the owner of the protected seed, and even then, the farmer may only sell the amount of seed that he had saved for planting that year's crop on his own land.[129]

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[123] *Id.* at 481.

[124] *Id.* at 483.

[125] *Asgrow IV*, 115 S. Ct. 788, 793 (1995).

[126] 7 U.S.C. § 2543 (1988).

[127] Plant Variety Protection Act Amendments of 1994, Pub. L. No. 103-349, 1994 U.S.C.C.A.N. (108 Stat.) 3136 (codified in scattered sections of 7 U.S.C.). This amendment did not, however, affect certificates issued before April 4, 1995, which is why the Supreme Court decided *Asgrow IV*. *Asgrow IV*, 115 S. Ct. at 792 n.2.

[128] 140 CONG. REC. S7826 (daily ed. June 28, 1994).

[129] *Id.* at S7826-27.

3. Continued Resistance to Patenting Living Matter

Unfortunately, neither the PPA nor the PVPA extends protection to microorganisms or animals,[130] and exemptions weaken the protection they do offer.[131] Thus, as a result of the judicially dispensed product of nature doctrine and the failed efforts of Congress to protect living matter, early biotechnologists lacked not only protection, but incentive, to disclose their progressive work.[132] In fact, until 1980, both the PTO and the federal courts seemed determined to prevent the patenting of living matter, most effectively by using the product of nature doctrine, and when that failed, the PTO or plaintiffs would demonstrate Congressional intent to afford protection to plants only, as evidenced by the creation of the PPA and PVPA.[133]

B. Patent Protection for Living Matter

1. *Chakrabarty*

But in 1980, the United States Supreme Court finally championed biotechnology when it decided the landmark case of *Diamond v. Chakrabarty*.[134] Chakrabarty was a microbiologist whose patent application for a genetically engineered bacterium capable of breaking down crude oil components had been denied by the PTO. Chakrabarty had inserted certain plasmids (independently replicating rings of DNA) into a *Pseudomonas* strain, which, due to the presence of the plasmids, gained the ability to metabolize the oil components. The resulting bacterium offered significant utility for treating oil spills.

The PTO had denied Chakrabarty's patent on two grounds: a bacterium is both a product of nature and a living thing.[135] On appeal, the Patent Office Board of Appeals rejected the PTO's product of nature argument, recognizing that the bacterium had been altered and was not naturally occurring.[136] Nevertheless, the Board agreed that, as living matter, the bacterium was not included in the subject matter of § 101,

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[130] *See* 7 U.S.C. § 2402 (protection is limited to plants "other than fungi, bacteria, or first generation hybrids").

[131] Scalise & Nugent, *supra* note 71, at 1002. Fortunately, in 1995 Congress amended the PVPA to remove the farmer's crop exemption, probably the most detrimental of all exemptions. Plant Variety Protection Act Amendments of 1994, Pub. L. No. 103-349, 1994 U.S.C.C.A.N. (108 Stat.) 3136, 3142.

[132] Scalise & Nugent, *supra* note 71, at 1003.

[133] Scalise & Nugent, *supra* note 71, at 1003.

[134] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

[135] *Id.* at 306.

[136] *Id.*

and that Congress had clearly not included microorganisms in its Plant Acts, and therefore did not intend to patent them.[137] The Court of Customs and Patent Appeals reversed, based on *In re Bergy*[138] which held that "the fact that the microorganisms . . . are alive . . . [is] without legal significance" in patent law.[139]

The Supreme Court granted review to determine whether Chakrabarty's altered bacterium constituted "a 'manufacture' or 'composition of matter' within the meaning of 35 U.S.C. 101."[140] The Court began its statutory construction noting that, in examining the language of a statute, "unless otherwise defined, words will be interpreted as taking their ordinary, contemporary, common meaning,"[141] and that courts "should not read into the patent laws limitations and conditions which the legislature has not expressed."[142] Adhering to these tenets, the Court defined the § 101 term "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,"[143] and "composition of matter" as "all compositions of two or more substances and . . . all composite articles, whether they be the result of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."[144] Based on the wording of the statute, the Court held that Congress clearly intended it to have an expansive construction, but that the statute did not protect the traditional judicial exceptions such as laws of nature.[145] The Court held that Chakrabarty had "produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patenta-

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[137] *Id.*

[138] *In re* Bergy, 563 F.2d 1031 (C.C.P.A. 1977), *vacated sub nom.*, Parker v. Bergy, 438 U.S. 902 (1978), *judgment reinstated on remand*, *In re* Bergy, 596 F.2d 952, *cert. granted sub nom.*, Parker v. Bergy, 444 U.S. 924 (1979), *vacated as moot sub nom.*, Diamond v. Chakrabarty, 444 U.S. 1028 (1980).

[139] *In re* Bergy, 563 F.2d. at 1038.

[140] *Chakrabarty*, 447 U.S. at 307.

[141] *Id.* at 308 (quoting Perrin v. United States, 444 U.S. 37, 42 (1979)).

[142] *Id.* (quoting United States v. Dubilier Condenser Corp., 289 U.S. 178, 199 (1933)).

[143] *Id.* (quoting American Fruit Growers, Inc. v. Brogdex Co., 283 U.S. 1, 11 (1931)).

[144] *Id.* (quoting Shell Development Co. v. Watson, 149 F. Supp. 279, 280 (D.C. Cir. 1957)).

[145] *Id.*

ble subject matter under § 101."[146] In its famous holding, the Court stated that § 101 allows protection of "anything under the sun that is made by man."[147]

2. *Ex parte Allen*

Even after the plain "anything-under-the-sun" decree by the Supreme Court, the PTO continued to incorrectly interpret patent law according to the product of nature doctrine. For example, seven years after *Chakrabarty*, in *Ex parte Allen*,[148] the Patent Office Board of Appeals examined a denied patent for a process which induced polyploidy (the state of bearing more than one set of chromosomes) and sterility in oysters. The sterility allowed the oysters to develop greater meat content. The PTO had denied Allen's patent under both the product of nature doctrine and obviousness.[149] The Board of Appeals agreed that prior art which disclosed methods of inducing polyploidy rendered the claim obvious, and so denied the patent.[150] But the Board, citing *Chakrabarty*, took the opportunity to state clearly that, as non-naturally occurring matter, the polyploid oysters "are within the confines of patentable subject matter under 35 U.S.C. 101."[151] Thus the *Allen* court not only reiterated the position of *Chakrabarty*, but was the first to explicitly extend patent protection to complex living organisms.

3. PTO Notice

Only days after the *Allen* opinion, the PTO finally reacted with a notice of its major change in policy toward patenting living matter.[152] The PTO, apparently chagrined by *Allen*'s criticism that the Supreme Court, not the PTO, is responsible for interpreting law, responded to the rebuke by promising full compliance with *Chakrabarty*.

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[146] *Id.* at 310.

[147] *Id.* at 309 (quoting S. REP. NO. 1979, 82d Cong., 2d Sess. 5 (1952); H.R. REP. NO. 1923, 82d Cong., 2d Sess. 6 (1952)).

[148] *Ex parte* Allen, 2 U.S.P.Q.2d 1425 (Bd. App. & Int. Apr. 13, 1987), *aff'd*, 846 F.2d 77 (Fed. Cir. 1988).

[149] *Id.*

[150] *Id.* at 1427.

[151] *Id.* at 1426.

[152] 1077 OFF. GAZ. PAT. OFFICE 24, Apr. 21, 1987.

C. Patent Protection for Mammals

1. The Harvard Mouse Patent

In April 1988, the PTO issued the first patent[153] for a complex living organism. Scientists at Harvard University had genetically engineered a transgenic mouse that carried an activated oncogene causing the animal to be extremely susceptible to cancer. Because it developed cancer rapidly and predictably, the mouse strain was ideal for research into the causes and treatment of cancer.[154]

2. Opposition

The overdue, but unequivocal, endorsement of transgenic animal patents pronounced in the PTO's notice[155] and the subsequent Harvard Mouse patent[156] fueled the fears of some farmers and animal rights activists and ignited attempts to slow the accelerating momentum of biotechnology.

Small farmers feared that they would be out-competed by corporate farmers who could afford to buy the genetically improved animals.[157] Their concerns compelled the proposition of the Transgenic Patent Reform Act of 1988[158] which provided an exemption for farmers to use the patented genetically engineered animals on the farm, but not for transfer or sale of ova, sperm, or embryos from the animals. The Act, however, was defeated, as was a similar bill[159] in 1989, but agriculture has continued to push for a farmers' exemption or royalty-free compulsory license on animal patents used by small-scale breeders.[160]

Most probably, farmers would not ultimately benefit from such an exemption anyway. If companies lack patent protection for the progeny of their patented organisms, they likely will decide to control and consolidate the production of their animals to the exclusion of the small

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[153] U.S. Patent 4,736,866.

[154] *Id.*

[155] 1077 OFF. GAZ. PAT. OFFICE 24, Apr. 21, 1987.

[156] U.S. Patent 4,736,866.

[157] Elizabeth J. Hecht, *Beyond* Animal Legal Defense Fund v. Quigg: *The Controversy Over Transgenic Animal Patents Continues*, 41 AM. U. L. REV. 1023, 1042 (1992).

[158] H.R. 4970, 100th Cong., 2d Sess. (1988).

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

[160] This pressure, however, has let up somewhat since Rep. Kastenmeier of Wisconsin, a farming proponent, left Congress. *Disclosure Duty and Cost Concerns Dominate "PTO Day" Discussions*, Pat., Trademark & Copyright J. (BNA) No. 1062, at 184 (Jan. 2, 1995).

farmer. Otherwise the expensive development of transgenic animals that can replicate themselves for their new owners would not be financially feasible and would be curtailed. Alternatively, the price for the original patented animal would be significantly higher to account for the losses due to the unprotected progeny.

The history of the recently amended PVPA's farmers' exemption,[161] as discussed earlier, presents a valuable lesson. When the exemption allowed farmers to save and sell protected plant seed varieties, seed companies were losing so much money that it was clear that the PVPA was not offering adequate protection to encourage the continued research into new plant varieties. In fact, many companies resorted to protecting their plants under the utility patent statute[162] instead of under the PVPA as an effort to control the rampant use of unprotected progeny.

In an attempt to gain a forum to debate the morality and ethics of patenting animals, a coalition of animal rights advocates and farmers brought suit to dispute the PTO's authority. In *Animal Legal Defense Fund v. Quigg*,[163] the plaintiffs alleged that the PTO, in issuing its notice without first allowing for public comment, had violated the Administrative Procedure Act (APA).[164] In addition, it alleged that the notice had exceeded the PTO's statutory authority.[165] The court, however, held that the notice had interpreted previous PTO and court decisions and was "thereby exempt from the public notice and comments requirement of the APA."[166] The Court of Appeals for the Federal Circuit affirmed, again relying on the interpretive, rather than substantive, nature of the notice.[167]

3. Three More Mouse Patents

On December 29, 1992, for the first time since the Harvard mouse patent, the PTO issued patents for three more genetically engineered

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[161] Plant Variety Protection Act Amendments of 1994, Pub. L. No. 103-349, 1994 U.S.C.C.A.N. (108 Stat.) 3136 (amended the Plant Variety Protection Act, Pub. L. No. 91-577, 1970 U.S.C.C.A.N. (84 Stat.) 1793.

[162] The regular patent statute, 35 U.S.C. §§ 101-112 (1994).

[163] Animal Legal Defense Fund v. Quigg, 932 F.2d 920 (Fed. Cir. 1991) [hereinafter *ALDF*].

[164] Act of June 11, 1946, ch. 324, 60 Stat. 237 (codified as amended in scattered sections of 5 U.S.C.); *ALDF*, 932 F.2d at 931 (alleged violation of 5 U.S.C. § 553(b)-(c)).

[165] *ALDF*, 932 F.2d at 924.

[166] *Id.* at 931.

[167] *Id.*

mice. One patent covers a mouse strain whose males develop enlarged prostate glands,[168] another which develops an incomplete immune system,[169] and a third which is virus-resistant.[170] Although debate has been raging in certain sectors since the Harvard mouse patent, Congress has yet to outlaw the patenting of transgenic animals, and this bold gesture by the PTO has been followed by a constant stream of pending patents—and so far it appears that Congress is not going to change its mind.

4. Proposed Moratorium

Legislation prohibiting the patenting of transgenic animals has been proposed in every session of Congress since 1987.[171] In 1993, Senator Mark Hatfield (R-Ore.) again introduced a bill[172] that would impose a 2-year moratorium (he previously proposed a 5-year period) on the patenting of transgenic animals and also certain human tissues and organs to provide Congress with an opportunity to pause and examine the ethical implications of animal patents and to organize a regulatory mechanism. These bills are supported mainly by animal rights groups and religious groups who oppose animal patenting on moral grounds.

Those who support patenting of transgenic animals claim that the moratorium would squelch vital research and have a devastating effect on the progress of health care and the search for cures to agonizing diseases such as cancer. Additionally, the ban would dramatically reduce the capital investment in biotechnology and attenuate our leading position in the global biotechnology market. Fortunately, as in the preceding years, enactment of such a bill appears to be extremely unlikely in the 104th Congress.[173]

V. Patent Law Applied to Biotechnology

Despite the unique nature of biotechnological innovations, the PTO continues to either deny protection or grant overbroad patents and the courts continue to awkwardly grapple with traditional doctrine in infringement suits, resulting in tremendous confusion and uncertainty

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[168] U.S. Patent 5,175,383.

[169] U.S. Patent 5,175,384.

[170] U.S. Patent 5,175,385.

[171] Senator Hatfield has introduced moratorium bills in each session of Congress since 1987. 140 Cong. Rec. S14,739 (daily ed. Oct. 7, 1994) (statement of Sen. Hatfield).

[172] S. 387, 103d Cong., 1st Sess. (1993).

[173] Scalise & Nugent, *supra* note 71, at 1009.

among researchers as to the protection and financial compensation they may or may not receive for their time-consuming labor.

Section 101 of the Patent Act[174] provides for two types of patents: product (machine, manufacture, or composition of matter) and process. Although product and process patents are by far the most common, a third type of patent, product-by-process, was judicially created for those products which could be described only by the method of their making.[175]

A. Product Patents

1. Product Patents Granted for Naturally Occurring Products

Ironically, the product of nature doctrine,[176] which courts for decades administered harshly against biotechnologists by deeming altered living matter non-patentable products of nature, has now been inexplicably abandoned in the application to purified natural isolates, again to the detriment of biotechnology. Product patents have been freely granted to applicants who have isolated and purified a naturally occurring product without altering the actual product in any way.[177] This application of product patents to purified products of nature represents the mistaken conception that the product itself has been modified by man or has resulted from an even vaguely inventive step. The product existed before its discovery or its purification. Isolating and purifying a product of nature can be considered analogous to cleverly vacuuming the coins out from the deep crevasses of dozens of sofas, sifting them out from the lint bag, washing them in the dishwasher, and collecting them all together in a hat—then claiming the invention of small change.

The protection granted to applicants who discover a method of collecting a thing of nature should be commensurate with their beneficial contribution to society. Awarding them a monopoly over that thing of nature is disproportionate and illogical; they should, rather, be granted a monopoly over their new and useful process. The incentive then remains for others to discover even better means to the same important end, and progress is thereby promoted.

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[174] 35 U.S.C. § 101 (1994).

[175] DONALD S. CHISUM & MICHAEL A. JACOBS, UNDERSTANDING INTELLECTUAL PROPERTY LAW 2-167 (1991).

[176] Scalise & Nugent, *supra* note 71, at 999-1001.

[177] *E.g.*, U.S. Reissue Patent RE 32,011; U.S. Patent 4,677,195.

2. Natural Isolates Versus Recombinant DNA Products

By their intended essence, a naturally occurring product and a recombinant product are usually as identical as possible; only in that way will the recombinant product function exactly like its natural analogue. In this context, that is the entire purpose for the pursuit of recombinant proteins.[178] Obviously, a product patent cannot logically apply to a product which exactly duplicates an already existing product, yet patents are granted, then usually held to infringe the natural isolate.[179] Lower courts have upheld the granting of patents for purified naturally occurring chemicals[180] and pure cultures of naturally occurring bacteria.[181] The granting of overbroad product patents, where process patents would be more suitable, inevitably leads to infringement litigation.

For example, the PTO granted Scripps a product patent[182] for the naturally occurring purified Factor VIII:C, a protein necessary for normal blood clotting. This product was known prior to its purification, which represented the only novel or innovative step by the applicant. Subsequently, Genentech sequenced the protein, cloned the gene into a plasmid, and induced host cells to produce the recombinant protein (rFactor VIII:C). Genentech's recombinant protein was later held to infringe Scripps' natural isolate patent due to the similarity between the molecules.[183]

In another case similar to *Scripps*, scientists who had discovered a superior method for purifying erythropoietin (EPO), a glycoprotein which induces red blood cell production in the bone marrow, received a

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[178] Unlike the pharmaceutical industry, the goal of the biotechnology industry is often to recreate as perfectly as possible vital proteins within the human body——and to do it efficiently and cheaply so that protein can be used therapeutically by society. It is arguably absurd to penalize an inventor who has succeeded in the extremely difficult task of copying nature's process of producing a human protein.

[179] *E.g.*, Scripps Clinic & Research Found. v. Genentech, Inc., 666 F. Supp. 1379 (N.D. Cal. 1987) [hereinafter *Scripps I*]; 707 F. Supp. 1547 (N.D. Cal. 1989) [hereinafter *Scripps II*]; 927 F.2d 1565 (Fed. Cir. 1991) [hereinafter *Scripps III*]; Amgen, Inc. v. Chugai Pharmaceutical Co., 706 F. Supp. 94 (D. Mass. 1989) [hereinafter *Amgen I*].

[180] *E.g.*, *In re* Bergstrom, 427 F.2d 1394 (C.C.P.A. 1970) (pure prostaglandins isolated from natural source patentable as new products).

[181] *In re* Bergy, 563 F.2d 1031, 1038 (Fed. Cir. 1977).

[182] U.S. Reissue Patent RE 32,011.

[183] *Scripps I*, 666 F. Supp. 1379. In a full hearing on the merits, Scripps' patent was held invalid for failing to disclose the best mode and for inequitable conduct. But again, the legal conclusion stood unchanged. *Scripps II*, 707 F. Supp. 1547. On appeal, the circuit court reversed the holding that the patent was unenforceable due to inequitable conduct. *Scripps III*, 927 F.2d 1565.

product patent[184] for EPO itself, a naturally occurring molecule which the scientists had not invented. When Amgen later received a product patent[185] for certain DNA sequences, vectors, and host cells which it used to prepare recombinant EPO (rEPO), the court held that rEPO infringed the purified product.[186]

Unfortunately, infringement of a patented product is more easily discovered than infringement of a process; therefore, most applicants prefer to obtain product patents. Nevertheless, it seems fair that an inventor should be granted protection for the product only when it is isolated in the particular manner that he utilized. In that way, other scientists will not be discouraged from finding more efficient and cost-effective ways of producing the product, and will continue to improve the quality of life through technological advances.

B. Product-by-Process Patents

The product-by-process patent is not described by statute, but originated as a way "to enable an applicant to claim an otherwise patentable product that resists definition by other than the process by which it was made."[187] It provides an avenue for claiming a product whose structure, because it is too complex to describe, can only be identified by a description of the way it was created. Unfortunately, the law of product-by-process patents is an intimidating quagmire of contradictions. The Federal Circuit judges are in plain dispute as to whether a product-by-process patent covers a product regardless of how it is produced, or only the process itself.[188] Their decisions have been unpredictable and contradictory, and have resulted in fierce internal debate and great confusion for scientists and patent attorneys. As a Federal Circuit judge cautioned, "a new product of biotechnology, if incapable of independent structural definition, may or may not have useful product patent protection, depending on which Federal Circuit panel is

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[184] U.S. Patent 4,677,195.

[185] U.S. Patent 4,703,008.

[186] The court held that rEPO infringes purified naturally occurring (in urine) EPO (uEPO). *Amgen I,* 706 F. Supp. 94 (D. Mass. 1989). In a full hearing on the merits, the infringement ruling was upheld. Amgen, Inc. v. Chugai Pharmaceutical Co., 13 U.S.P.Q.2d (BNA) 1737 (D. Mass. 1989) [hereinafter *Amgen II*]. On appeal, the Federal Circuit reversed, but on other grounds, and so remains the law that a recombinant protein infringes its naturally occurring analogue. Amgen, Inc. v. Chugai Pharmaceutical Co., 927 F.2d 1200 (Fed. Cir. 1991) [hereinafter *Amgen III*], *cert. denied,* 112 S. Ct. 169 (1991).

[187] *In re* Thorpe, 777 F.2d 695, 697 (Fed. Cir. 1985).

[188] Tropix, Inc. v. Lumigen, Inc., 825 F. Supp. 7 (D.C. Mass. 1993).

drawn."[189]

In early cases, the Supreme Court approved the idea that a product-by-process claim was limited by the process, and did not cover the product when made by a different process.[190] Later, however, the PTO began issuing product-by-process patents when the product could have been otherwise described, but the applicant chose to define it in terms of the process by which it was made.[191] These cases held that the patents covered the product, regardless of the method of its making. *In re Thorpe*[192] exemplifies this line of cases: "Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself."[193] In other words, product-by-process claims should be evaluated differently for infringement determinations by the courts than they are for patentability determinations by the PTO. Again six years later, the same Federal Circuit judge announced in *Scripps III*[194] that "[i]n determining patentability we construe the product as not limited by the process stated in the claims."[195] Thus, product-by-process claims were deemed "true" product claims which are infringed by similar products manufactured by a different process.[196] But this decision marked a departure from the *Thorpe* precedent by stating that claims are evaluated in the same manner for both infringement and patentability determinations. "Since claims must be construed the same way for validity and for infringement, the correct reading of product-by-process claims is that they are not limited to product prepared by the process set forth in the claims."[197] But another year later, in *Atlantic Thermoplastics Co. v. Faytex Corp*,[198] a different panel of the Federal Circuit held that a product-by-process patent covers only products made by that process, but not similar products made by other processes, and that claims should be given a different, narrower evaluation when determining in-

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[189] Atlantic Thermoplastics Co. v. Faytex Corp., 974 F.2d 1279, 1283 (Fed. Cir. 1992) (Newman, J., dissenting) [hereinafter *Atlantic II*].

[190] *E.g.*, Smith v. Goodyear Dental Vulcanite Co., 93 U.S. 486, 499 (1877); Merrill v. Yeomans, 94 U.S. 568, 571 (1877); Cochrane v. Badische Anilin & Soda Fabrik, 111 U.S. 293, 306 (1884).

[191] *In re* Thorpe, 777 F.2d at 695.

[192] *Id.*

[193] *Id.* at 697.

[194] *Scripps III*, 927 F.2d 1565 (Fed. Cir. 1991).

[195] *Id.* at 1583.

[196] *Id.*

[197] *Id.*

[198] Atlantic Thermoplastics Co. v. Faytex Corp., 970 F.2d 834 (Fed. Cir. 1992) [hereinafter *Atlantic I*].

fringement than when determining patentability.[199] The court chose not to follow its *Scripps* decision because "a decision that fails to consider Supreme Court precedent does not control if the court determines that the prior panel would have reached a different conclusion if it had considered controlling precedent."[200] An uproar followed the *Atlantic* decision, crying mutiny, heresy, and illegality in the panel's refusal to follow the *Scripps* precedent:[201]

> [T]hese overtly conflicting decisions will repose in the official reporters, I suppose some day to be resolved, but meanwhile to place this law in disarray. This does not serve the public, or litigants, or trial judges, who are entitled to know how the Federal Circuit will interpret a certain class of product-by-process claims, without depending on the luck of the draw of the appellate panel.[202]

Nevertheless, in 1993, the *Tropix, Inc. v. Lumigen, Inc.*[203] court followed the *Atlantic* precedent, but with admitted hesitation:

> [t]he resolution of this dispute should turn upon a prediction of the precedential effect which the Federal Circuit would give to [*Scripps* and *Atlantic*]. Unfortunately, the judges of the Federal Circuit Court are in open disagreement on the point, making such a prediction hazardous.[204]

C. Process Patents

Process patents cover only the process by which the product was made, but not the resulting product.[205] A process can be a method of making something or a method of using something. This is the most important type of patent for biotechnologists because much of what they do utilizes techniques, or processes, to create products which are badly needed, but are already known to exist.

1. Obvious Processes Before 1988

In 1985, a Federal Circuit decision, *In re Durden*,[206] determined that an obvious process is not patentable even if the starting material

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[199] *Id.*

[200] *Id.* at 838 n.2.

[201] *Atlantic II*, 974 F.2d 1279, 1281 (Fed. Cir. 1992) (Newman, J., dissenting); *CAFC Judges Write Stinging Dissents on Prior Panel Rule and En Banc Review*, Pat., Trademark & Copyright Law Daily (BNA) (Sept. 1, 1992).

[202] *Atlantic II*, 974 F.2d. at 1282 (Newman, J., dissenting).

[203] Tropix, Inc. v. Lumigen, Inc., 825 F. Supp. 7 (D.C. Mass. 1993).

[204] *Id.* at 8.

[205] 35 U.S.C. § 101 (1994).

[206] *In re* Durden, 763 F.2d 1406 (Fed. Cir. 1985).

and/or resulting product are novel and nonobvious (i.e. patentable). Application of *Durden* to biotechnology cases renders most inventions non-patentable since many processes, such as cloning or expressing a gene, are well known in the field. Although new techniques are constantly discovered, most valuable contributions are utilizations of known techniques to locate important genes, clone genes into bacteria, and produce critical proteins. For years, scientists and patent attorneys have claimed that the misapplication of *Durden* has suppressed research and resulted in the unfair exclusion of valuable inventions from patent protection.[207]

2. International Patent Piracy

Until 1988, United States biotechnology companies were plagued by international patent piracy; it was legal to use a patented process outside of the United States to produce a product and then import it into the United States for sale.[208] Actually, process patents obtained during this period contributed to, rather than discouraged, rampant international patent piracy because a United States patent application requires that the inventor describe how to make and use the invention and the best mode for carrying it out.[209] In essence, our process patents, which prohibit American competitors from using the patented process, were teaching foreign competitors how to produce our inventions, which were then returned to the United States market.

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[207] "[T]he bill overrules a widely criticized Federal circuit court decision that has been routinely misapplied by the U.S. Patent and Trademark Office. Under the legislation, and inventor will now be able to obtain a patent on the method of making or using a product if either the starting material or the end product itself can be patented." 139 CONG. REC. S8816 (daily ed. July 15, 1993) (statement of Sen. Lautenberg). "[T]he . . . Act would overturn, *In re* Durden, a troublesome Federal circuit case that is being used as a basis for rejecting biotechnology process patent claims . . . . The application of Durden in the biotechnology area has denied protection to innovation that can only be protected through process patents." *Id.* (statement of Sen. DeConcini).

[208] *See* United States v. Studiengesellschaft Kohle, m.b.H., 670 F.2d 1122, 1127-28 (D.C. Cir. 1981) ("A sale of a product made by a patented process does not itself infringe the patent; it is the unauthorized use of the process [in the United States] that infringes the patent.").

[209] 35 U.S.C. § 112 (1994).

3. The Omnibus Trade and Competitiveness Act of 1988 and the Process Patent Amendments Act of 1988

In response to the estimated $40 billion losses per year to international patent piracy,[210] Congress enacted the Omnibus Trade and Competitiveness Act of 1988,[211] which dramatically amended the Tariff Act of 1930.[212] The Process Patent Amendments Act of 1988 (PPAA)[213] prohibits the importation of a product that would have constituted patent infringement had it been made in the United States.[214] In other words, foreign manufacturers are free to use patented processes, but not to import products made from those processes.

4. *Amgen*: The Gap Left Unclosed

Although the 1988 PPAA was enacted with biotechnology in mind, its literal interpretation has produced a profound gap in its protection. In *Amgen*,[215] a highly publicized case, Amgen alleged that Chugai violated the PPAA by importing and selling recombinant EPO made with the genetically engineered DNA and host cells covered by Amgen's patent. The Federal Circuit court held that the 1988 Act did not apply to Amgen since its patented genetically engineered machinery for the production of rEPO did not qualify as a process, but was instead a product.[216] The court's narrow, literal reading of the PPAA returned American researchers to the same disadvantageous position with foreign competitors.

5. Proposed Legislation

The anxiety and bewilderment over product and process patents pushed several companies, such as Genentech, to appeal directly to Congress,[217] and in March 1991, Congress introduced its attempt to

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[210] 134 CONG. REC. S10,713 (daily ed. Aug. 3, 1988) (statement of Sen. Lautenberg).

[211] Pub. L. No. 100-418, 1988 U.S.C.C.A.N. (102 Stat.) 1107 (codified in scattered sections of 35 U.S.C.).

[212] Act of June 17, 1930, ch. 497, 46 Stat. 590 (1930) (codified as amended in scattered sections of 19 U.S.C.).

[213] Omnibus Trade and Competitiveness Act of 1988, Pub. L. No. 100-418, tit. IX, 1988 U.S.C.A.A.N. (102 Stat.) 1563.

[214] 35 U.S.C. § 271(g) (1994).

[215] *Amgen III*, 927 F.2d 1200 (Fed. Cir. 1991), *cert. denied*, 112 S. Ct. 169 (1991).

[216] *Id.*

[217] *E.g.*, 136 CONG. REC. E213 (daily ed. Feb. 7, 1990) (statement of Rep. Boucher).

close the loophole found in the 1988 Act and left open by the courts—the Biotechnology Patent Protection Act.[218] Introduced by Representative Rick Boucher (D-Va.), the bill was followed by a companion bill[219] in the Senate.

The bill was intended to strengthen biotechnology patents in two ways. First, the bill overruled *Durden*, the "widely criticized Federal Circuit court decision that has been routinely misapplied by the U.S. Patent and Trademark Office."[220] Thus it would have removed the obstacle to biotech process patents by allowing a patent for an obvious process if the product or starting material is patentable. This would have a monumental effect on the industry since many biotech inventions can be protected only by process patents.

Second, the bill closed the gap that, despite the 1988 legislation, so flagrantly damaged Amgen, powerless to prevent Chugai from exploiting its patented host cell overseas then importing the product back into the United States to compete with Amgen's product.[221] By amending the infringement section of the Patent Act,[222] the bill deemed the importation of products made using a patented biotech material (e.g. cell, DNA, etc.) to be not only piracy, but infringement. In other words, the patented molecular machinery would be considered a patented process.

Proponents of the bill suggested that it would resolve the confusion that has led to inconsistent decisions and extremely expensive patent litigation that drains most biotech firms and ruins many,[223] and that it would finally end the rote application of *Durden*.[224] It would reward and protect this productive industry which "vitally depends on patents to protect the vast research and development costs necessary for technological breakthroughs and commercial development."[225] The long-term effect of the failure to overturn *Durden* would be a "dampening of venture capital investments," the continued draining of biotech compa-

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[218] H.R. 1417, 102d Cong., 1st Sess. (1991) (unenacted).

[219] S. 654, 102d Cong., 1st Sess. (1991) (unenacted).

[220] 139 CONG. REC. S8816 (daily ed. July 15, 1993) (statement of Sen. Lautenberg).

[221] *Id.*; *Proposal to Protect Patents is Examined at House Hearing*, Pat., Trademark & Copyright Law Daily (BNA) (June 10, 1993).

[222] 35 U.S.C. § 271 (1994).

[223] "While the Japanese are spending money on research, we're paying the damn lawyers. We're bleeding the system of money that could be spent on research. It's nauseating." Sandra Sugawara, *Drug Patent Race Heads to the Bench; Biotech Firms Spend Time, Resources on Legal Fights as Courts Grapple With Thorny Issues*, WASH. POST, Sept. 15, 1991, at H1 (quoting Roger Salquist, Chairman, Calgene, Inc.).

[224] Murphy & Rumore, *supra* note 5, at 36-37.

[225] 139 CONG. REC. S8816 (daily ed. July 15, 1993) (statement of Sen. DeConcini).

nies' resources by litigation (which increased 52% between 1980 and 1990), and the inability to pursue promising new therapies.[226] Further, proponents claimed that foreign competitors are not subject to doctrines similar to *Durden*, and that its elimination would make United States biotech companies' patent protection comparable to that available abroad and would bring United States laws more into "harmony" with the rest of the world's—a goal of all who work in the global marketplace.[227] Finally, proponents asserted that the Act would "prevent blatant foreign exploitation of patented biotechnological material"[228] in a "research-intensive industry" where "[p]iracy is simple and easy when breakthroughs are published and disseminated in scientific journals."[229]

Opponents, however, claimed that rote application of *Durden* is not necessary; instead of legislation, the PTO should educate itself so that it could examine process patent claims in a more enlightened manner.[230] They argued that process patents would be granted too freely, absent the usual "obviousness" examination, and that the resulting uncertainty concerning the validity and scope of the protection would itself result in expensive litigation.[231]

The bill passed the Senate unanimously on September 18, 1992, but due to pressure from the opposition, the House failed to vote even at the subcommittee level. Then, on July 15, 1993, the Senate passed another similar bill,[232] the application of which was limited to biotechnological processes. The House's more generic counterpart, the Process Patent Protection Act of 1994,[233] which passed on September 20, 1994, dropped the biotechnology limitation and the important international piracy amendment to the infringement section of the Patent Act.[234] On October 6, 1994, the Senate passed an amended version of the bill,[235] which again limited the statute to biotechnological processes.[236] This

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[226] Murphy & Rumore, *supra* note 5, at 37. "The current patent law also leads to inconsistent decisions, and time-consuming patent litigation that drains companies' research resources." 140 CONG. REC. S14,434 (daily ed. Oct. 6, 1994) (statement of Sen. Kennedy).

[227] Murphy & Rumore, *supra* note 5, at 37.

[228] 139 CONG. REC. S8816 (daily ed. July 15, 1993) (statement of Sen. DeConcini).

[229] *Id.* at S8817 (statement of Sen. Kennedy).

[230] Murphy & Rumore, *supra* note 5, at 36-37.

[231] *Id.*

[232] S. 298, 103d Cong., 1st Sess. (1993) (unenacted).

[233] H.R. 4307, 103d Cong., 2d Sess. (1994) (unenacted).

[234] 35 U.S.C. § 271 (1994).

[235] H.R. 4307, 103d Cong., 2d Sess. (1994) (unenacted) (passed the Senate, after amendment, by voice vote Oct. 6, 1994). 140 CONG. REC. S14,434 (1994).

[236] *Id.* The revised bill defines a "biotechnological process" as "a process of geneti-

limitation is a result of concerns voiced by the chemical industry and the PTO, which fear that the bill would otherwise create overreaching process claims that would result in overbroad patents.[237]

Although there was a prospect for reconciliation between the House and Senate versions of the Process Patent Protection Act of 1994, it failed to occur before the 103d Congress adjourned. As a fourth attempt, the Biotech Process Patent Protection Act of 1995[238] was proposed on January 19, 1995. Because the bill is nearly identical to the measure passed by the Senate in 1994,[239] it may have a better chance of enactment than it has ever had before.

CONCLUSION

Recombinant DNA technology has already delivered on its promise to dramatically affect health care and agriculture, but the industry's progress is frustrated by the unpredictable patent laws. It is these laws, when untangled, which will promote innovation in this enormously powerful field, and which will permit the necessary and expensive research by encouraging investment.

The muddled law left in the wake of *Scripps* and *Amgen* remains, and has seriously dampened scientific progress. Product patents granted for purified naturally occurring biochemicals, which inevitably discourage research into cheaper, more widely available recombinant forms of those biochemicals, should be replaced with process patents which grant an inventor exclusivity only over what he invented.

Clear change in patent law needs to come directly from Congress.[240] The often-proposed biotech patent bills attempt to rectify the shortcomings in the Omnibus Trade and Competitiveness Act of 1988 which permit devastating international piracy and troublesome and inappropriate application of *Durden*, but fail to address the ongoing patenting of naturally occurring products. Action by Congress will result in re-

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cally altering or otherwise inducing a cell or a living organism to express an exogenous nucleotide sequence or to express specific physiological characteristics."

[237] 140 CONG. REC. S14,434 (daily ed. Oct. 6, 1994) (statement of Sen. DeConcini); *Reality Check*, BUSINESS WEEK, Sept. 5, 1994, at 6.

[238] H.R. 587, 104th Cong., 1st Sess. (1995) (unenacted).

[239] H.R. 4307, *supra* note 235. The new bill differs mainly in its more detailed definition of "biotechnological process." ***Biotech Process Patent Legislation is Reintroduced***, 49 Pat., Trademark & Copyright J. (BNA) 302 (Jan. 26, 1995).

[240] "Because so many of the biotech inventions are protected by patents, the future of that industry depends greatly on what Congress does to protect U.S. patents from unfair foreign competition." 140 CONG. REC. H9284 (daily ed. Sept. 20, 1994) (statement of Rep. Moorhead); *see also* 141 CONG. REC. E129 (daily ed. Jan. 19, 1995).

newed investment in biotechnology and tremendous benefits to health and agriculture.

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