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Nathan K. Shrewsbury

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PATENTABILITY OF LIVING MATTER RELATED TO BIOFUEL PRODUCTION IN THE U.S.

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I. Introduction

With energy prices soaring, the development of renewable biofuels in the United States is a national priority motivated by both economic and environmental concerns, including enhancement of the domestic fuel supply, and maintenance of the rural economy.[1] Biofuels are closely associated with living material, as opposed to long dead organic matter that is associated with fossil fuels.[2] Given this connection, it is not surprising that intellectual property rights in living matter play an enormous role in emerging biofuel technologies. Patents of actual living organisms are important to the U.S. biofuel industry because, as this paper will demonstrate, patents give innovators in the biofuel industry the tools required to protect the intellectual property developed through vital scientific research.

This paper will focus on the ways various forms of living matter may be patented based on the intellectual property laws of the U.S and various foreign laws that the U.S. is obligated by treaty to follow. Patentability of plant life, microorganisms, and animals will be evaluated in detail with regard to production of alcohols (ethanol), biodiesel and methane gas. Plant life will be examined from the perspective of its use as a feedstock. Microorganisms will be examined as agents of fermentation for the biofuels. It will be shown that without the ability to patent living matter, the biofuel industry would be severely hampered.

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[1] Indirect or Direct Fermentation of Biomass to Fuel Alcohol, U.S. Patent App. No. 20070275447, at Abstract (filed Nov. 29, 2007).
[2] Heath Cleveland, *Biodiesel Better Than Corn-based Cousin*, DAILY TEXAN (Univ. of Tex.), Jul 9, 2008, *available at* http://www.uwire.com/Article.aspx?id=1039960.

II. A Definition of Biofuel

A. Primary Sources

Biofuel is defined as "fuel, [such] as wood or ethanol, derived from biomass," [3] and biomass is defined as "organic matter, esp. plant matter, that can be converted to fuel and is therefore regarded as a potential energy source."[4] Ethanol is by far the most abundant biofuel in the U.S.[5] Almost all of the U.S. ethanol production is made from corn.[6] Corn is processed through standard fermentation in which the sugars and starch in corn are converted into ethanol by yeast.[7]

Biodiesel is the second most utilized biofuel in the U.S.[8] It can be created through a simple process from vegetable oil, and used in most standard diesel engines. The creator of the diesel engine, Rudolph Diesel, actually intended that his creation would run on peanut oil. Now almost 100 years later, the biofuel industry has embraced his ideal.

At this point, the production of both ethanol and biodiesel is heavily subsidized by the federal government, but new processes in the experimental stages offer the possibility of sustainable production and energy independence.[9]

B. First Generation v. Second Generation

An additional distinction used by some commentators on the modern biofuel industry that bears mentioning here, is first generation biofuel versus second generation biofuel.[10] First generation biofuel refers, among other things, to ethanol from cereal crops as well as current

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[3] Dictionary.com, Biofuel Definition, http://dictionary.reference.com/browse/biofuel (last visited Mar. 25, 2009)
[4] Dictionary.com, Biomass Definition, http://dictionary.reference.com/browse/biomass (last visited Mar. 25, 2009).
[5] Mike Ward & Tim Young, *Protecting Inventions Involving Biofuel Feedstock*, MORRISON FOERSTER INTELL. PROP. Q. NEWSL., Spring 2008, http://www.sdcma.org/docs/Biofuels%20Article%20MOFO.pdf.
[6] *Id.*
[7] Renewable Fuels Ass'n Resource Ctr., How Ethanol Is Made, http://www.ethanolrfa.org/resource/made/ (last visited Mar. 25, 2009).
[8] Ward & Young, *supra* note 5.
[9] Zfacts.com, Subsidies for Corn Ethanol, http://zfacts.com/p/63.html (last visited Mar. 25, 2009).
[10] Ward & Young, *supra* note 5.

biodiesel production. Second generation biofuels refers to lignocellulosic ethanol and other fuels generated through novel processes not yet in widespread use.[11]

III. Elements of Patentability

To obtain a patent, which amounts to a government grant of 20 years of exclusive use of the patented life form, requires a disclosure that will permit one skilled in the art to replicate the invention.[12] There are three required elements for an invention to be patentable: usefulness (utility), novelty, and non-obviousness.[13]

The courts interpret the statutory term "useful" to require disclosure of at least one available practical benefit to the public.[14] This benefit must be specific, substantial and credible.[15] Patents pertaining to biofuel should meet this requirement by playing a part in the production of usable fuel.

Novelty denotes that the invention was not known or used by others in this country or patented or described in a publication in this or a foreign country (i.e. it is not something people are already aware of).[16] Non-obviousness is the quality of an invention not being a mere combination of prior art that is obvious to a reasonable person skilled in the art to which the invention pertains.[17] The subject matter of an invention must also be legally patentable. Congress describes a piece of patentable subject matter generally as a "process, machine, manufacture, or composition of matter."[18] Living material was originally excluded from patentability, but over

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[11] *Id.*
[12] 35 U.S.C. § 101 (2006).
[13] *Id.* §§ 101, 102, 103.
[14] Brenner v. Manson, 383 U.S. 519, 533 (1966).
[15] *See, e.g., id.* ("a '*useful*' invention is one 'which may be applied to a beneficial use in society, in contradistinction to an invention injurious to the morals, health, or good order of society, or frivolous and insignificant.") (emphasis added).
[16] 35 U.S.C. § 102(a).
[17] *Id.* § 103.
[18] *Id.* § 101.

the years various avenues have been carved out for patenting living matter through legislation and judicial action.

IV. Avenues To Patentability for Living Matter

Specific acts of Congress, court rulings, and policies of the United States Patent and Trademark Office (USPTO) have created avenues for patenting living matter. Without going into a detailed history of this well documented development, it is beneficial to understand the ways various organisms may qualify for patent under current U.S. regulations.

A. Patentability of Plants

The U.S. provides three methods for obtaining patent protection of plants that act as biofuel feedstocks. "An asexually reproduced [plant] can be protected with plant patents and sexually reproduced [plant] can be protected with utility patents and/or a [Plant Variety Protection] certificate."[19] Plants are asexually reproduced by taking a cutting or graft from an existing plant and creating a new plant. Such plants are genetically identical to the original plant and are sometimes referred to as clones. Sexually reproduced refers to a plant generated from a seed.[20] A plant found in the wild will not meet the novelty requirement for patent protection, but one created by a plant breeder may.[21] "In many plant species, traditional plant breeding is limited due to the fact that the existing gene pool is narrow and prevents further development."[22] A utility patent may also be granted for plants based upon genetic modification.[23] "Issued in January 2001 after extensive public comment, the [USPTO's] guidelines clarified that companies

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[19] Ward & Young, *supra* note 5.
[20] *Id.*
[21] *Id.*
[22] Transformation System in Camelina Sativa, U.S. Patent App. No 20040031076 at Description ¶ 6 (filed Sept. 8, 2003).
[23] Diamond v. Chakrabarty, 447 U.S. 303 (1980).

could patent both whole genes as well as pieces of genes"[24] Genes provide the blueprint for all living matter and genetic modification provides the most promising avenue for achieving the modification of biofuel feedstocks.[25] Since the gene itself may be patented, a genetic modification need not be limited to a single species of plant; indeed, patents may disclose a genetic sequence and claim the modification as applied to several plants, though this is not necessary to maintain a monopoly on the use of that particular genetic modification regarding all plants.

B. Patentability of Microbes – Bergy and Chakrabarty

Microbial life forms can gain a patent in two ways, genetic modification and purification. Five justices permitted the patentability of microorganisms in the Case of Diamond v. Chakrabarty.[26] In Chakrabarty, the court granted a patent on a genetically modified microbe with the capacity to digest crude oil spilled by damaged oil tankers. This holding rejected the United States Patent and Trademark Office's (USPTO) claim "that as living things they are not patentable subject matter under 35 U.S.C. § 101."[27] In this decision, the Court also overturned the lower court's ruling on the companion case, In re Bergy, where the Federal Circuit denied patent to a purified form of naturally occurring bacteria, based on there being no law on point for patenting microbial life forms.[28] Though the Supreme Court opinion in Chakrabarty did not specifically hold that a purified version of a naturally occurring organism is patentable, the USPTO has not limited Chakrabarty to genetically modified microorganisms, and permits

[24] Am. Med. Ass'n, Gene Patenting, http://www.ama-assn.org/ama/pub/physician-resources/medical-science/genetics-molecular-medicine/related-policy-topics/gene-patenting.shtml (last visited Mar. 25, 2009).
[25] Jennie Dusheck, *The Interpretation of Genes,* NAT. HIST., Oct. 2002, *available at* http://findarticles.com/p/articles/mi_m1134/is_8_111/ai_92284523.
[26] *Chakrabarty*, 447 U.S. 303.
[27] *Id.* at 306.
[28] *Patentability of Biological Invention: Threshold Issues of Law, Science, Policy and Philosophy*, *in* 1 IVER P. COOPER, BIOTECHNOLOGY AND THE LAW § 2:5 (2008) [hereinafter COOPER, *Patentability of Biological Invention*].

purified forms of naturally occurring microorganisms to be granted patent protection.[29] In Bergy, the court considered the semantic difference between describing a pure form of bacteria as a "manufacture" or a "composition of matter" immaterial for the purposes of patentability.[30]

Purification may appear to contradict the principle of U.S. patent law regarding plants, that a plant discovered may not be patented, since purification, by definition, means that the microbe was isolated, not created or modified. The rationale for allowing a purified form of a naturally occurring microbe is that a microbe does not exist in an isolated state in nature.[31] Bergy expanded upon earlier federal court decisions regarding purified chemicals.[32] One of those cases was Parke-Davis & Co v. H K Mulford & Co, where Judge Learned Hand upheld the famous Takamine patent on the pure form of the chemical adrenaline.[33] Hand found unpersuasive arguments that the compound occurred naturally in the glands of living organisms holding that the purification made it ". . . a new thing commercially and therapeutically."[34]

V. Goals in Biofuel Industry and the Living Matter Patents That Pave the Road

The penultimate goal of the biofuel industry is to produce an amount of energy in the form of liquid fuel at less cost than the equivalent amount produced from fossil fuels. This can happen only if the cost of source material and production costs for biofuel are somehow made lower than those of fossil fuels. Currently, the price of oil-based fuels is mainly driven by demand. Agreements between oil exporters to restrict the supply result in consumer fuel prices

[29] *Id*.
[30] *Id.*
[31] *Id.*
[32] Application of Bergy, 596 F.2d 952, 975 (Cust. & Pat. App., 1979).
[33] Parke-Davis & Co v. H K Mulford & Co, 189 F. 95 (C.C.S.D.N.Y. 1911).
[34] *Id.* at 103.

that exceed fair-market costs.[35] Even with all these factors, the costs of currently utilized methods of biofuel production grossly exceed the costs of using fossil fuels. Living organisms currently awaiting U.S. patents offer the possibility for realigning the costs of biofuel production in a way that provides the U.S. with clean, affordable biofuels in meaningful quantities made from readily available sources. Living materials come with a set of limitations, but those limitations do not necessarily preclude biofuels becoming a mainstay of U.S. energy production.

A. Costs of Biofuel Production

U.S. adoption of ethanol and biodiesel as energy sources presents numerous challenges. Many of these challenges, not surprisingly, involve obtaining the feedstocks of the biofuel in necessary quantities. Both ethanol and biodiesel currently utilize food crops for the majority of their production. This puts pressures on food supplies and limits the production potential of biofuels. Some of the current obstacles to widespread production of biofuels may be overcome through the creation of new organisms and the utilization of existing organisms in creative new ways. Living matter patents play an indispensable role in both of these areas.

1. Ethanol Production

Given the high cost of ethanol productions from corn (and other cereals), which greatly exceeds the cost of gasoline and is blamed for food price issues, most analysts consider lignocellulosic biomass sources to be the feedstock for second generation ethanol.[36] Monsanto Co. intends to market a genetically modified variety of maize with higher starch content.[37] A higher starch content advances the goals of the current generation of corn based ethanol because

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[35] GovTrack.us, House Record: Oil Industry and OPEC Price Gouging, http://www.govtrack.us/congress/record.xpd?id=109-h20050524-43 (statement of Rep. Peter DeFazio (D-Or.)) ("The OPEC oil cartel conspires to restrict supply and drive up the price of oil in violation of all the so-called free trade agreements that this . . . Congress and this . . . President say should rule the world.").

[36] Ward & Young, *supra* note 5.

[37] BIOFUELWATCH ET AL., AGROFUELS: TOWARDS A REALITY CHECK IN NINE KEY AREAS (June 2007), *available at* http://www.biofuelwatch.org.uk/docs/agrofuels_reality_check.pdf.

the starch is one of the elements of corn that is fermented into ethanol by current techniques. More starch in the corn means more ethanol is produced from the corn. The utilization of lignocellulosic biomass, however, likely holds more potential for reducing the costs of ethanol production.

Lignocellulosic biomass describes all plant material that is composed of cellulose, hemicellulose, and lignin.[38] It can be divided into four main categories (1) wood residues (2) paper waste, (3) agricultural residues (including corn stover), and (4) dedicated energy crops such as switchgrass. These dedicated energy crops are the source material that researchers are working to make the main fuel source of tomorrow. An obvious strategy for useful modifications of lignocellulosic plant sources is to make them more plentiful, and more easily processed into biofuel.

One cost is the development and maintenance of more land for agricultural purposes. Plants rich in lignocellulosic biomass, like the tall switchgrass that grows on the prairie and the wood of poplar trees, are typically lower value plant matter than food crops and can often grow where food crops will not thrive.[39] This increases the potential acreage that can be utilized for energy production, without putting additional pressure on food supplies.

To make these plants more plentiful, researchers can take a number of avenues. As with food crops, plants that grow larger, more quickly, and have increased disease tolerance are desirable. The Syngenta Co. has developed another maize variety with an enzyme that rapidly breaks down starch,[40] but thee process of breaking down lignocellulosic compounds is more

[38] Ward & Young*, supra* note 5.
[39] *Id.*
[40] *Id.*

complicated than that of simple fermentation of sugars and starches, in our current process of producing ethanol.[41]

2. Biodiesel

Biodiesel production is fraught with a slightly different set of issues to those of ethanol production. Currently, most biodiesel is made from edible vegetable oils, which many experts argue places pressure upon food supplies.[42] The increased demand for biodiesel in Europe has led to fears the potential destruction of rainforests so that more acreage can be developed to raise the palm kernel.[43] This creates a potential to offset the enormous reduction in pollution from the replacing of petroleum diesel with biodiesel.[44]

The process for creating biodiesel is relatively simple, as evidenced by many Americans creating their own biodiesel from oils used in deep fat fryers with commercially-available and self-designed home kits.[45] The main hurdle for biodiesel, like that for ethanol, is finding a viable feedstock in the quantities necessary to replace its petroleum-based cousin.

B. Plant Patent Example: A Corn Plant Named Venus Express

Regarding a corn plant in first generation ethanol production, the qualities desirable in corn are identical to those sought after for corn in food production. Venus Express is not likely the fuel source of the future, but it is an example demonstrating the mechanism of a plant patent. It can additionally be observed how genetic diversity, stored within plants, is the toolbox with which our scientists work to create the second generation of plants for biofuel production.

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[41] *Id.*

[42] Esmarie Swanepoel, *Food Versus Fuel Debate Escalates*, ENGINEERING NEWS, Nov. 2, 2007, http://www.engineeringnews.co.za/article.php?a_id=119281.

[43] 'International Declaration Against the 'Greenwashing' of Palm Oil by the Roundtable on Sustainable Palm Oil (RSPO), http://www.biofuelwatch.org.uk/docs/14-10-2008-RSPO-Ingles.pdf (last visited Mar. 25, 2009).

[44] EPA, A COMPREHENSIVE ANALYSIS OF BIODIESEL IMPACTS ON EXHAUST EMISSIONS (Oct. 2002), *available at* http://www.epa.gov/otaq/models/analysis/biodsl/p02001.pdf.

[45] New Energy Watch, Biodiesel Conversion Kit, or Buy Ready-made Fuel?, http://www.newenergywatch.com/2007/11/biodiesel-conve.html (last visited Mar. 25, 2009).

1. Background of the Invention

Many patents have issued for unique corn plants. Venus Express evolved from the discovery in the 1970s of a nearly extinct relative of the corn plant called Gammagrass.[46] Scientists saw this as an opportunity to enhance the genetic diversity of the corn plant by interbreeding it with its old relative.

2. Claims of the Patent Application

This patent contains only one claim: "A new and distinct variety of corn plant . . . characterized by its profuse production of fruit, perennial habit, vigorous vegetative production of culms, . . . asexual reproduction by rhizomes, stem cuttings, and anther[*sic] culture, and its good combining ability with corn that permits movement of new genes and agronomic traits into corn using conventional plant breeding methods."[47]

3. Elements of Patentability

The Plant Patent Act states that "[w]hoever invents . . . and asexually reproduces any distinct and new variety of plant[,] . . . other than . . . a plant found in an uncultivated state, may obtain a patent therefore . . ."[48] Since Venus Express' background describes an extensive cross pollination effort culminating in the creation of the Venus Express plant itself on January 26, 2002, Venus Express was not a plant discovered in an uncultivated state, but rather a new variety of plant.[49] The background on Venus Express further states that "[t]he new plant has been propagated by rhizome divisions, cuttings, and anther culture," which meets the requirement that the plan be asexually reproduced.[50] The element of distinctness requires that a plant which

[46] Corn plant Named Venus Express, U.S. Patent No. PP17,444 at Description (filed Mar. 14, 2005 & issued Feb. 27, 2007).
[47] *Id.* at Claims.
[48] 35 U.S.C. § 161 (2006).
[49] '444 Patent, at Background.
[50] *Id*.

possesses at least one significantly different characteristic.[51] This requirement is met by the new plant providing a genetic bridge for moving genes from the newly discovered Gammagrass into corn using conventional plant breeding methods.

Venus express meets the qualifications for a plant patent in at least a prima facie sense. Since the USPTO granted it a patent, we can assume the proper disclosures were made. It is worth reemphasizing at this point that corn is not likely the primary feedstock for the future of biofuel, but the plant patent may be used in securing protection for plants with higher fuel potential. The degree of protection provided Venus Express by a plant patent is limited. The patent protection covers Venus Express (any cuttings or grafts) and its seeds, but it does not stop inventors from looking for another way to introduce the genetic material from Gammagrass into corn. A utility patent can provide a plant invention more comprehensive protection than a plant patent.

C. Utility Patent Application Example: Transformation System in Camelina Sativa –

This patent is not based on a genetically unique plant, like Venus Express, but rather upon a means of artificially introducing genetic material to particular species of plants. Variations on Camelina have been created that produce up to 20% more oil than canola plants, and can be grown in areas where food crops cannot currently be raised, eliminating potential pressure on the food supplies.[52]

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[51] Pan-Am. Plant Co. v. Matsui, 433 F. Supp. 693, 696 (N.D. Cal. 1977).
[52] Rachel Barron, *Cutting Biodiesel Costs with Camelina*, GREENTECH MEDIA, Nov. 21, 2007, http://www.greentechmedia.com/articles/cutting-biodiesel-costs-with-camelina-319.html.

1. Background of the Invention

Camelina sativa was one of the most important oil crops in Europe during the Bronze Age.[53] The search for oil sources for conversion to biodiesel created a renewed interest in this plant, commonly known as golden flax.[54] The inventors point out that "traditional plant breeding is limited due to the fact that the existing gene pool is narrow and prevents further development," and that "[g]enetic transformation of plants allows the introduction of *genes of any origin* into the target species providing novel products."[55]

2. Claims of the Patent Application

A group of Finnish scientists applied for U.S. patent on a "[t]transformation system in Camelina sativa" in September of 2003.[56] The first claim of this patent is for a "method for Agrobacterium-mediated genetic transformation . . . of Camelina sativa . . ." [57] Claims 2 through 17 characterize the method of this genetic transformation.[58] Claims 19 through 22 stake ownership of "transgenic Camelina sativa" plants, plant tissue, plant cells and cell lines, and seed "obtainable with the method of claim 1," and are the patented living organisms under consideration[59]

3. Elements of Patentability

The elements of patentability: utility, novelty, and non-obviousness; are likely met by Claims 19 through 22. These are known as product through process claims, and should give the holders rights to any plant matter produced through the claimed method.[60] This patent is for a process that creates plants and the plants created by that process. It should be noted that if

[53] Transformation System in Camelina Sativa, U.S. Patent App. No 20040031076 at Background (filed Sept. 8, 2003).
[54] *Id.* at Description ¶ 14.
[55] *Id.* at Description ¶ 2.
[56] *Id.* at Abstract.
[57] *Id.* at Claims ¶ 1.
[58] *Id.* at Claims ¶¶ 2-17.
[59] *Id.* at Claims ¶¶ 19-22.
[60] Scripps Clinic & Research Found. v. Genentech, Inc., 927 F.2d 1565, 1583-84 (Fed. Cir. 1991).

another inventor were to create a plant identical to the one created by this method, through some other method of transformation, that plant would infringe on this patent (assuming Patent 076 is granted).[61] Likewise, if the method described in Claim 1 produced a plant indistinguishable from the one already under another patent, the owner of that plant may have a valid infringement claim.[62] The treatise Patent Law Fundamentals confirms that a process cannot make patentable a product that is not patentable in its own right.[63]

In the case of J.E.M v. Pioneer Hi Bred, the Supreme Court held that plants constitute material patentable by utility patent in spite of the specific statutes passed by the U.S. Congress for the patentability of plants.[64] The subject matter of Claims 19 through 22 of Patent 076, plants, plant tissue, and seeds, is therefore patentable subject matter.

The novelty and utility elements of patentability, as defined earlier, can be met by the creation of a new plant species for the production of vegetable oils that can be converted to biofuel. Any plant produced by this method will be novel, and its utility demonstrated in that it can produce oil for biofuel.

Non-obviousness, from the perspective of the plant itself, could be achieved by creating a new plant with a uniquely-altered genetic code, through a patentable method. One definition of obvious is when an invention is a combination of two or more pieces of prior art that would be immediately apparent to a person of skill in the art.[65] The recent case of Syngenta v. Monsanto

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[61] *See id.* at 1583 ("In determining patentability we construe the product as not limited by the process stated in the claims.").
[62] *Id.*
[63] JOHN GLADSTONE MILLS III, DONALD C. REILEY III & ROBERT C. HIGHLEY, PATENT LAW FUNDAMENTALS § 7:7 (2d ed. 2008) ("Whether the claim is termed 'a product-by-process claim' or 'a product claim with process limitations,' addition of method steps in a product claim, which product is not patentably distinguishable from the prior art, cannot impart patentability to the old product. . . .").
[64] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Intern., Inc., 534 U.S. 124, 127 (2001).
[65] Graham v. John Deere, 383 U.S. 1, 11 (1966) (quoting Hotchkiss v. Greenwood, 52 U.S. (11 How.) 248 (1851)).

affects the definition of non-obviousness for transgenic plants.[66] In Syngenta, the Federal Circuit upheld a jury determination that carrying out the manifestation of a genetic modification that had been suggested in a previous patent application, but not yet implemented, fulfilled the definition of obvious.[67] The modification dealt specifically with combining genes from bacteria to manifest its disease-fighting ability in corn. The Federal Circuit found unpersuasive Syngenta's argument that the invention was non-obvious because the probability of success was unknown. The court held that "[w]hether the degree of success is unexpected . . . is a factual question."[68] It further stated that " . . . the jury had sufficient evidence, in the form of expert testimony . . ." to base its decision upon.[69] The patent in Syngenta has differences from the patent application in question, but its non-obviousness could likewise ultimately be determined by a jury considering expert testimony.

4. Pitfall of Non-obviousness: Ultimately Subjected to Jury Determination

Jurors are in an unenviable position to make a decision of this nature. Taking advice from an expert, whom one would suppose is a person of extraordinary skill as opposed to the person having ordinary skill in the art (PHOSITA) about what would supposedly be obvious to a PHOSITA could appear to have enormous error potential. It is also imaginable that when discussing whether one company or both companies can use a disease-resistant corn variety, a jury could feel apathetic. This may not be so with an energy crop having the potential to make a genuine impact that the average juror could appreciate. If twelve people have to decide between rewarding an inventor the way the founding fathers intended when they put Article I §8 cl. 8 into the U.S. Constitution, or putting the next energy crop into the public domain and into their own

[66] Syngenta Seeds, Inc. v. Monsanto Co. 231 Fed. Appx. 954 (Fed. Cir. 2007).
[67] *Id.*
[68] *Id.* at 959.
[69] *Id*.

fuel tanks possibly years earlier, that decision could hinge more on what it cost them to travel to court that day than on any U.S. intellectual property law or treaty.

Famed Psychologist Abraham Maslow taught about the "egoistic" needs of human beings within his well-known "hierarchy of needs."[70] These egoistic needs can be collectively defined as the need to feel distinguished within one's peer group.[71] These egoistic needs could tip the scales in the favor of the paid expert supporting a determination of obviousness. This expert is in effect telling the jurors "if any of you had even ordinary training in this particular art, and the tools to carry it out, you too would have created this invention." According to Maslow, everyone innately wants to believe this. This is not meant to paint every paid expert as a "hired gun" but realistically in a case like this, both sides will present expert testimony that is contradictory and a jury, with all their individual and group needs, will ultimately choose who to believe.

D. Microorganism Utility Patent Example: The Coskata Method – Indirect Fermentation of Lignocellulosic Biomass to Ethanol

The Coskata method is a revolutionary process for creating ethanol, and other alcohols that may be used for fuels, from lignocellulosic biomass and other forms of municipal waste. Patent application 20,070,275,447 claims "[a] biologically pure culture of the microorganism Clostridium carboxidivorans . . ."[72] This application discloses a microorganism capable of producing ethanol and other biofuels through two distinct processes: (1) through the direct (enzymatic) fermentation of lignocellulosic biomass to ethanol; (2) indirectly through metabolizing carbon monoxide gas made from gasifying lignocellulosic biomass or other combustible material, into ethanol and other biofuels.[73] U.S. Patent App. No. 20,070,275,447

[70] HUMAN RESOURCE AND PERSONNEL MANAGEMENT TEXT AND CASES 356 (K. Aswathappa ed., 4th ed. 2005).
[71] *Id.*
[72] Indirect or Direct Fermentation of Biomass to Fuel Alcohol, U.S. Patent App. No. 20070275447 Claims (filed Nov. 29, 2007).
[73] *Id.*

states the bacteria to be a "discovery," but the fact that it is not genetically modified should not affect its patentability.[74] This application will likely be granted by the USPTO.

1. Description of the Process

The Coskata method's indirect fermentation of lignocellulosic biomass process begins by heating the material to extreme temperatures until the materials are literally turned to a gas.[75] This gas, called syngas, is rich in carbon monoxide. The patent-pending bacteria Clostridium carboxidivorans can metabolize carbon monoxide and create ethanol.[76] While this process can utilize lignocellulosic biomass as a feedstock, it can also utilize other "industrial and urban wastes."[77] The Coskata method has been evaluated by Argonne National Laboratories as producing 7.7 times as much energy in ethanol as is required to be put into the process.[78] Coskata feels that this factor gives their process the potential to produce ethanol at a lower per gallon production cost of one dollar per gallon.[79] The Coskata method is capable of producing 100 gallons of ethanol from one ton of dry feedstock. Lowered production costs combined with lower feedstock cost yields an alternative fuel with the potential to undersell gasoline without additional subsidies from the U.S. taxpayers.

2. Analysis of Patentability

The Coskata method asserts a patentable interest in a living organism. Claim 1 of the patent application of the Coskata method, titled "Indirect or Direct Fermentation of Biomass to Fuel Alcohol," claims "[a] biologically pure culture of the microorganism Clostridium

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[74] *Id.* at Abstract.
[75] Coskata Inc., Gasification, http://www.coskata.com/ProcessGasification.asp (last visited Mar. 25, 2009).
[76] Coskata Inc., Feedstock Potential, http://www.coskata.com/EthanolFeedstockPotential.asp (last visited Mar. 25, 2009).
[77] *Id.*
[78] Coskata Inc., Advantages of the Coskata Process, http://www.coskata.com/ProcessAdvantages.asp (last visited Mar. 25, 2009).
[79] *Id.*

carboxidivorans[,] having all of the identifying characteristics of [scientific designation] [ATCC No. BAA-624]."[80] The patent application in question likely supports this claim.

The primary purpose of the patent system is to encourage inventors to disclose useful ideas instead of hiding them, hence a disclosure is required.[81] This requirement is fulfilled, regarding Claim 1, by the bacterium Clostridium Carboxidivorans, which the patent refers to as "P7" being "deposited at the American Type Culture Collection in Manassas, Va."[82]

The utility of the bacterium is proven by showing one single practical use.[83] This requirement mainly distinguishes ideas that an inventor feels will lead to a useful item, from ones that have produced an actual useful article. This element is met because the patent describes the bacteria as "capable of producing high yields of valuable organic fluids from relatively common substrates." The utility requirement of patentability is met by the ability to produce actual fuel.

The Novelty element can demonstrated by the fact that no one else has filed for a patent on the purified form of "P7." In <u>Funk Bros. Seed Co. v. Kalo Inoculant Co.</u>, the Supreme Court held that the discovery of the benefit of a combination of six bacteria to the roots of a plant was "no more than the discovery of some of the handiwork of nature and hence . . . not patentable."[84] However, in <u>Bergy</u>, discussed earlier, the court of customs and patent appeals described a non-patentable microorganism as "something preexisting and merely plucked from the earth and claimed as such, a far cry from a biologically pure culture produced by great labor in a laboratory and so claimed."[85] The application states "P7" to be "the first anaerobe described capable of both

[80] Indirect or Direct Fermentation of Biomass to Fuel Alcohol, U.S. Patent App. No. 20070275447 Abstract ¶ 1 (filed Nov. 29, 2007).
[81] 35 U.S.C § 112 (2006).
[82] '447 Patent, ¶ 19.
[83] Brenner v. Manson, 383 U.S. 519, 533 (1966).
[84] Funk Bros. Seed Co. v. Kalo Inoculant Co., 333 U.S. 127, 131 (1948).
[85] <u>Application of Bergy</u>, 596 F.2d 952, 976 (Cust. & Pat. App., 1979).

direct and indirect fermentation of lignocellulosic biomass."[86] The bacteria in this patent was isolated in a lab at great expense, rather than merely plucked from nature. It will most likely be determined novel by the PTO, since it conforms to the criteria established in Bergy.

Non-obviousness requires that an invention would not be an obvious combination of pieces of prior art to a person of skill in that art.[87] Even though the U.S. Constitution gives Congress the power to shape the patent system, the Supreme Court has stated that "[C]ongress may not authorize . . . patents [to] remove existent knowledge from the public domain, or to restrict free access to materials already available."[88] Obviousness is a question of law with four factual predicates: the scope and content of the prior art, the differences between the subject matter claimed and the prior art, the level of ordinary skill in the art, and other objective indicia of non-obviousness.[89] Regarding P7, the requirement of non-obviousness would appear to parallel that of novelty. Granting a monopoly of use on a unique, previously unknown organism, when reduced to a purified form with much labor, does not remove knowledge from the public domain. A unique organism, of course, should not be considered a combination of prior art either. P7 will surely be found non-obvious if it is first found to be novel.

D. Limitations

No resource is infinite. Biofuel offers the prospect of energy independence, but that independence will require the reallocation of certain resources and the utilization of some new ones. None of these resources are limitless, and these limitations could ultimately come into play.

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[86] '447 Patent at Description ¶ 20.
[87] 35 U.S.C. § 103 (2006).
[88] Graham v. John Deere, 383 U.S. 1, 6 (1966).
[89] *Id.* at 17-18.

One more apparent limitation to the use of living matter to produce fuel is land for plant cultivation. A specific acreage would be required for producing the fuel consumed by each member of the public, and that is certainly more land than the average consumer occupies as living space. The supply of land in the U.S. would be the ultimate limitation on biofuel production. However, a more practical concern, is that harvests vary from year to year. A heavier use of agricultural products in fuel production will put more dependence on the year to year crop production for our fuel supply. Even with increased drought tolerance being a desirable genetic modification sought by researchers, drought tolerance means that a plant will live through periods of reduced rainfall, not that it will thrive under such conditions. Switchgrass, a plant known for its drought tolerance, can have yields that vary up to 90% based upon the availability of water.[90] A stable economy cannot handle 90% variance in the availability of its fuel source.

Limitations on the degree of modification in plants have been observed as well. One of the goals scientists are trying to achieve is the reduction of lignin in lignocellulosic biomass in the plant itself. Gressel's Genetic Glass Ceilings discusses some interesting issues regarding the efforts to reduce lignin in lignocellulosic biomass. Pollution and crop quality both come into play. Switchgrass, considered by many to be an important feedstock for second generation biofuels, is a worse polluter than coal when burned.[91] The silicates produced by the combustion of switchgrass are not as easily scrubbed from the byproducts as those produced in the burning of coal.[92] This has undesirable implications for the use of switchgrass in the pyrolitic process of the Coskata methods discussed earlier. One solution to this problem is to use a genetic modification to reduce the silica content in switchgrass. The presence of silica has documented connection to the presence of lignin, so it is possible that a reduction of lignin could result in a reduction of

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[90] JONATHAN GRESSEL, GENETIC GLASS CEILINGS: TRANSGENICS FOR CROP BIODIVERSITY 182 fig. A (2008).
[91] *Id.* at 183.
[92] *Id.*

silicates.[93] Author Jonathan Gressel noted that the strategy of reducing lignin did not work well when utilized in corn.[94]

Reduction of Lignin in corn stover (stalks) had the effect of making the corn plant less sturdy and more subject to breakage (lodging).[95] Since the tough lignin molecules are responsible for making corn stalks rigid, there is a direct loss of quality in the corn plant for food purposes through the reduction of lignin due to increased lodging. It is possible that reduction of lignin in other plants, like switchgrass, rich in lignocellulosic material, could have complications affecting their usability as a fuel source. Modifications geared at reducing silicates could have a similar effect.

The two patents protecting plant life discussed in this paper both hinged on the use of genetic diversity to ferret out desirable qualities in plant life through differing methods. The available genes present the upper limit on modifications of plant life. Any transition to biofuel will require a great reallocation of resources and currently existing limitations in many areas will become more apparent.

VI. Protecting Innovations in the Biofuel Industry Would be Difficult Without the Ability to Patent Living Matter

The purpose of intellectual property protection for inventions is to ensure that those who contribute to society *vis-à-vis* innovations are compensated for their efforts and thereby encourage the search for new products and processes that improve the quality of life. Ironically, as this paper relates to biofuel, one of the first U.S. patents on living material was granted to Louis Pasteur in 1873 for “yeast free from . . . germs” for the production of ethanol for human

[93] Christopher Zygarlicke, John Pavlish, Jason Laumb & Norman Hinmanb, Suitability of Rice Straw Lignin as Boiler Fuel (Energy & Environmental Research Center, University of North Dakota, n.d.), *available at* http://www.agmrc.org/media/cms/34203_7158A78C979E9.pdf.
[94] GRESSEL, *supra* note 90, at 189-90.
[95] *Id*.

consumption (beer brewing).[96] Considering the enzymatic fermentation process claimed in the Coskata method over 100 years later (as opposed to the indirect method involving gasification), it may be hard for a layperson to understand why an invention carrying out a process thousands of years old (making alcohol), using a naturally occurring bacterial agent could meet the criteria of "novel" and "non-obvious" as described earlier. Without the ability to patent living matter, inventors would have to take more costly measures to try to protect their intellectual property. The two most likely alternate avenues inventors would take to protect their living matter inventions would be process patents and trade secrets. These methods could not replace the protections afforded by living matter patents.

A. Process Patents could not Replace Patents of Living Organisms

1. Underprotection

An inventor might try, as in the Camelina sativa patent, to capture the living organism through a process. Another early patent involving living matter, was the septic tank, that utilized bacteria to break down human waste inside the tank.[97] To be clear, in the "Septic Tank" patent, the bacteria itself was not the subject of the patent, the overall system of utilizing bacteria in the manner previously described was the subject of the patent. Utility patents on a process would fail to replace patents in living matter because improved bacteria for use in septic tanks would fail patentability due to obviousness. Breaking down human waste with a new bacteria would be an obvious combination of prior art. In this light, consider the bacteria P7 of the Coskata method.

As stated in the discussion of the Coskata method, the bacteria in question can be used as an agent of direct fermentation, like yeast. Utilizing a new bacterium in the identical way that yeast has been used for centuries could raise questions of obviousness, which is triggered by

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[96] Yeast Free from Germs, U.S. Patent No. 141,072 (filed 1872).
[97] COOPER, *Patentability of Biological Invention*, *supra* note 28, § 2:1.

combining two or more pieces of prior art in a way that a "Person having ordinary skill in the art" would find obvious. Replacing yeast with bacteria that does the same thing, could, however erroneously, be viewed as obvious to a PHOSITA by a jury charged with determining this fact.

A unique organism provides more clarity when determining non-obviousness. It replaces subjective considerations with a scientifically identifiable species. Without this clarity, an inventor would potentially forced to try emphasizing minor nuances of highly similar processes to protect the major investments of time and research devoted to preparing the organism at the heart of the process.

2. Overprotection

Consider the pyrolitic process of the Coskata method. Prior to Chakrabarty, this novel and useful invention would not have received a patent because it involved living material, but the process as a whole may have met the requirements for patent protection. If a patent similar to that of the septic tank, were issued for the Coskata method's pyrolitic process, that could stifle similar research into other bacteria with potential to make fuel through similar processes. Currently, General Motors Corporation is one of the big backers of Coskata, holding an undisclosed share in the company.[98] They have invested in other companies that utilizes a pyrolitic process and a bacteria similar to Coskata's that has shown more to be optimized for developing alcohols, like butanol, from particular feedstocks.[99] Given the need to protect these inventions, it is possible that the USPTO would issue process patents broader than the art disclosed in the invention to protect the living matter which truly forms the basis of the invention.

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[98] Detroit 2008: GM and Coskata Announce Worldwide Cellulosic Ethanol Partnership: Posting of Sebastian Blanco to Autobloggreen, http://www.autobloggreen.com/2008/01/13/gm-and-coskata-announce-worldwide-cellulosic-ethanol-partnership/ (Jan. 13, 2008, 12:01 PM).
[99] *Id.*

Given the potential for overprotection, society would benefit less without living matter patents. Given the potential for underrprotection, inventors would be more likely to resort to trade secrets for managing a proprietary organism than they are in the current regime.

B. A Trade Secret Could not Replace Patents of Living Organisms.

Trade secrets in lieu of living matter patents would be more costly and overprotective in the case of the fermentation agents, and provide almost no protection to plants utilized as energy crops in the biofuel industry.

If the owners of the Coskata method were forced to protect their bacteria as a trade secret, this could leave the owners of the Coskata method taking extreme measures to keep others from discovering their proprietary organism through reverse engineering or sifting through Coskata's industrial waste products. This could require micro-filtering of every gallon of ethanol, and jealous guarding of bacterial mediums. This could be a substantial amount of medium, considering the quantities in which fuel is consumed in the U.S..

There would likely be a reduction in availability of protections of new species of plants for biofuel with patents taken off the table. Protecting some modified crop species would still be possible but more problematic.

Justice Thomas described the common process of creating hybrids from inbred parents, in the case of J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Intern., Inc.[100] Pedegree inbred plants are produced by crossing plant with desirable qualities and inbreeding the resulting plants for several generations.[101] This inbreeding results in a homogenious plant line that is not highly productive itself, but yields extremely positive results when bred with others of its species.[102] The tendency

[100] J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Intern., Inc., 534 U.S. 124, 127-29 (2001).
[101] *Id.* at 127-28.
[102] *Id.* at 128.

of these hybrids to produce superior children is called "hybrid vigor" or "heterosis."[103] This vigor tends to wain in successive generations, thus a farmer who wants to keep getting the high yields must purchase more hybrid seed.[104]

Since the children with the desirable hybrid vigor cannot be produced without the parents, the parents can be protected by trade secret. In an unreported case in the U.S. District of Court for the Western District of Wisconsin, this strategy created problems for Pioneer Hi-bred International.[105] Some of the parent's seeds for one of Pioneer's corn varieties got mixed in with hybrid seeds. The parent plants were easily identified by their smaller size and collected by Pioneer's competitor Advanta.[106] Advanta used these inbred parents to recreate the patented hybrids as well as other lines of corn plants. The District Court declined to give Advanta a declaratory judgment stating that they had not violated Pioneer's trade secret. It held that there existed a matter of material fact as to whether Advanta had misappropriated Pioneer Hi-Bred's trade secret.[107]

In this case, Pioneer pursued patent protection under the Plant Variety Protection Act for the hybrid plant but not the inbred parents. It did this, presumably, for the purpose of holding the parent plants as a trade secret for longer than the twenty-year statutory limit on patents. A trade secret requires that the holder take reasonable precautions to protect the secret, and does not protect an invention against reverse engineering. In this case, Advanta argued that the presence of the inbred seed in the bags made them a matter of common knowledge, but Pioneer Hi-bred took the precaution of bag licenses, which require the purchasers of the seed to promise to only

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[103] Dictionary.com, Heterosis Definition, http://dictionary.reference.com/browse/heterosis (last visited Mar. 25, 2009).
[104] *Pioneer*, 534 U.S. at 128.
[105] Advanta USA, Inc. v. Pioneer Hi-Bred Int'l, Memorandum and Order 04-C-238-S (Oct. 27, 2004).
[106] *Id.*
[107] *Id.*

plant the seed.[108] Pioneer could have avoided this problem by patenting the inbred parents as well as the hybrid offspring. This solution would not require Pioneer to take measures against reverse engineering.

VII. Conclusion

Living matter patents play an integral role in the biofuel industry. Since biofuel, unlike fossil fuel, is associated with living materials, living organisms prepared by man through various means, are and will continue to be vital elements in the biofuel industry. To produce renewable biofuel in quantities that solve the energy problems experienced by the U.S., inventors must harness the power of living matter.

The law must facilitate this effort by permitting those who invest in this effort to profit from their efforts. Given the potential for jurors of laypersons to undermine an inventor's right to profit from his/her invention, appellate courts should be ready to carefully review factual findings of obviousness.

Though there are physical limitations to what can ultimately be accomplished with living organisms, for instance the problem with the corn stalks, specialized living organisms are the tools for utilizing the resources present in the U.S. to produce energy in forms we need. Living matter patents provide the emerging biofuel industry the most efficient method of protecting the intellectual property developed through painstaking research and development that results in a useful organism, be it plant, microbe, or an animal.

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[108] *Id.*