

## Legal Updates & News

### Legal Updates

#### Protecting Inventions Involving Biofuel Feedstock

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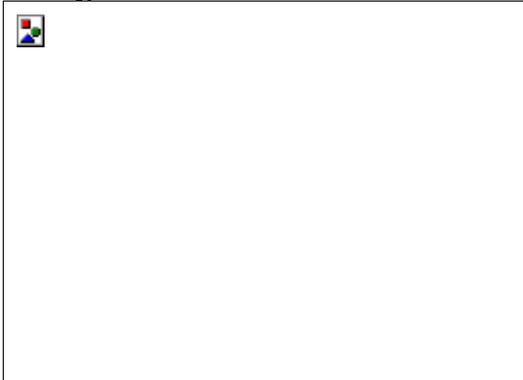
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In the near future, biofuel feedstock patents have the potential to dominate the biofuel patent landscape by covering the most cost-effective means of production. Biomass feedstock is already recognized as the most significant cost driver in biofuel production,<sup>[1]</sup> and going forward, expensive pretreatment processes will be eliminated by backing pretreatment technology upstream into feedstock plants. Analysts expect that by 2015 there may be biofuel-specific modifications to feedstock, such as enzymes or microbes that break down cellulose, directly bred into biomass sources. As more and more cost-saving technology is engineered into the already price-significant feedstock, the economics of biofuel production will crown feedstock patent portfolios as some of the most valuable throughout the biofuel patent landscape.

#### The Biofuel Generation Gap

First-generation (“1G”) biofuels refer to fuels made from sugar, starch, and/or vegetable oil using conventional technology. Corn-based ethanol is currently the leading 1G biofuel in the United States<sup>[2]</sup> and offers the opportunity to replace a small percentage of conventional gasoline in motor fuels.<sup>[3]</sup> However, corn ethanol does not offer substantial improvements in greenhouse gas emissions, overall environmental impact, or energy efficiency. Many studies suggest that corn ethanol exhibits negligible, if any, improvement over conventional gasoline in terms of its impact on the environment and carbon emissions. Moreover, corn ethanol is significantly more expensive per unit of energy than gasoline, and government-subsidized production is driving up prices for a variety of food products and agricultural commodities.

Second-generation (“2G”) biofuels use biomass-to-liquid technology, including biofuels derived from lignocellulosic material considered the most abundant renewable energy resource on the planet. Such 2G biofuels—derived from lignocellulosic feedstock like straw, grasses, and wood—will eventually succeed today’s grain ethanol. Current technologies, however, have not yet provided cost-effective production methods, creating an awkward generation gap between the environmental and energy issues of 1G fuels and economic issues of 2G fuels. (See FIG. 1<sup>[4]</sup>)



The eventual transition to 2G biofuels will reduce competition with food and feed crops, and will allow the utilization of low-value plant materials and crops, like straw and grasses. 2G biorefineries will also be able to utilize lignocellulosic crops like switchgrass and poplar, which can be grown on land unsuitable for farming.

Most forms of lignocellulosic biomass have the same major components—cellulose, hemicellulose, and lignin. Cellulose typically constitutes 40% to 50%, hemicellulose 20% to 30%, and lignin 15% to 20% of biomass.<sup>[5]</sup> The cellulose is composed of linear polymers of the six-carbon sugar glucose linked by 1,4 glycosidic bonds. Hemicellulose is a complex of primarily five carbon sugars, predominately xylose and arabinose, and lignin is a complex polymeric

heterogeneous material composed of variously substituted benzene rings.[6]

### **Pretreatment of Lignocellulosic Biomass**

The process of fermenting lignocellulosic biomass is not as straightforward as the process of fermenting simple sugars. Various pretreatment processes are necessary to deconstruct the lignocellulosic material into smaller molecules, i.e. single sugar monomers, which can be fermented. Pretreatment methods can include physical processing (milling, crushing, irradiation, steaming/steam explosion, and hydrothermolysis), chemical processing (dilute acid, alkali, organic solvent, ammonia, sulfur dioxide, carbon dioxide, and pH-controlled hydro-thermolysis), and biological processing (lignin-solubilizing microorganisms and enzymes).

The most popular pretreatment process is sulphuric acid hydrolysis. However, sulphuric acid hydrolysis is a very costly way of releasing sugar monomers. The method itself requires a lot of energy and use of sulphuric acid is extremely corrosive to equipment. Moreover, sulphuric acid hydrolysis results in large amounts of waste product in the form of calcium sulphate.[7] In addition to the high cost of traditional pretreatment, numerous compounds are generated, such as furfural, hydroxymethyl furfural, and acetic, ferulic, glucuronic, and *p*-coumaric acids, which are significant inhibitors of the fermentation process.

### **Genetically Modified Biofuel Feedstock**

New varieties of genetically modified plants are emerging that will eventually replace traditional costly and ineffective pretreatment processing. Analysts expect that by 2015 there may be biofuel-specific genetic modifications to feedstock, such as enzymes or microbes, which break down cellulose, directly bred into biomass sources.[8] The application of synthetic biology to enzyme chemistry could, for example, design an organism to include the genetic networks from a cellulose-crunching bacterium found in the gut of termites.[9] The ultimate goal is a simple single-step process in which feedstock, that contains all of the pretreatment and fermentation elements is physically broken down in a tank that outputs fuel.

Several industry leaders are currently developing and marketing biofuel-optimized feedstock. Syngenta has developed a maize variety that contains an enzyme that rapidly breaks down starch.[10] In 2008, Monsanto plans to sell a genetically modified maize variety with high starch content for ethanol production.[11] Monsanto is also developing new switchgrass varieties in a joint venture with Ceres, to produce a higher yield switchgrass.[12] DuPont has developed a high-starch maize variety that will include a micro-organism engineered to convert corn stover into ethanol.[13]

### **Protecting Biofuel Feedstock**

The biofuel patent landscape is increasingly crowded and fragmented. A recent patent study found that there are at least 850 biofuel patents and pending applications in the United States, Europe and Japan, divided among 285 companies, with only 35 companies owning more than five patents.[14] According to industry consultants, patents granted in industrial biotechnology, partially for biofuels production, increased from 6,000 in 2000 to 22,000 in 2005.[15]

In such a congested IP environment, freedom to operate issues become crucial to any entity in the space. Freedom to operate (“FTO”) is the ability to commercialize a product without infringing a third party’s intellectual property. Moreover, developing a viable patent portfolio is paramount. In addition to protecting a company’s innovations, a valuable portfolio can also be leveraged in cross licensing programs to cost-effectively pacify FTO issues.

U.S. law provides several vehicles for intellectual property protection for biofuel feedstock. While gene sequences, genetically modified organisms, and methods of modifying feedstock are examples of what may be the subject matter of utility patents, plants have a wider array of protection vehicles. Plants may be the subject of utility patents, plant patents and/or a Plant Variety Protection (P.V.P.) Act certificates. Generally, breeders who develop asexually reproducing plants seek plant patent protection for their new plants and breeders of sexually reproducing plants such as lettuce, corn, wheat, etc., seek utility patent and/or P.V.P. protection for their new lines. Moreover, a feedstock developer may obtain protection for, e.g., a new *Miscanthus* variety via a utility patent, a plant patent, and a P.V.P. Certification because it can be propagated by seed (provided the variety reproduces true to type) and by cuttings.

## Utility Patents, Plant Patents, and P.V.P. Certificates

### A. Utility Patents

35 U.S.C. §101 provides that the subject matter for utility patent protection in the United States is:

“Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.”

The United States Supreme Court has held that a living organism may fall within one of the categories listed above. In *Diamond v. Chakrabarty*, 447 U.S. 303 (1980), a genetically-altered microorganism was held patentable as either a “composition of matter” or a “manufacture.”

In 1985, *Ex parte Hibberd*, 227 U.S.P.Q. (BNA) 443 (Pat. App.) held that utility patent protection for plants under 35 U.S.C. § 101 could co-exist with the specialized plant protection statutes, i.e. Plant Variety Protection Act (P.V.P.A.). In *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred International, Inc.*, 534 U.S. 124 (2001), the Supreme Court endorsed this interpretation and conclusively established that utility patents may be granted for plants.

Pioneer has obtained U.S. Utility Patents on a number of its corn varieties. Pioneer sued J.E.M. Ag Supply Inc., (J.E.M.) for infringing several of these patents. J.E.M. countersued Pioneer asserting that the Pioneer patents were invalid because sexually reproducing plants should be exclusively protectable under the P.V.P.A. rather than patentable under the general patent statute. The lower court and Federal Circuit ruled in favor of Pioneer and J.E.M. appealed the decision to the Supreme Court.

On appeal, the Federal Circuit was not persuaded by J.E.M.’s argument and ruled that new plant varieties are both patentable as utility patents and protectable under the P.V.P.A. Among several reasons for reaching its decision, the Court stated that the only conflict between the patent statute and the P.V.P.A. is simply the rights and obligations imposed by the two statutes. The Court reasoned that it is not unusual for more than one statute to apply to a legal or property interest, and, as such, it is permissible for a new plant variety to be the subject of both a patent and a P.V.P. certificate.

The Supreme Court’s opinion endorses the dual protection position partly because of the fact that since the *Ex parte Hibberd* decision, the U.S. Patent and Trademark Office had granted several thousand utility patents on plants and Congress had not passed any legislation indicating that it disagreed with this policy. *J.E.M.*, 534 U.S. at 144-45.

The claims of a utility patent define the scope of that which is to be protected. Plant utility patents can have multiple claims of varying scope. An example of the type of claim coverage available in a utility patent directed to plants is found in U.S. Patent 4,581,847:

11. A maize plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight, wherein the seed is capable of germinating into a plant capable of producing seed having an endogenous free tryptophan content of at least about one-tenth milligram per gram dry seed weight.

This claim is not limited to a single hybrid or inbred maize line nor to the cause of the elevated tryptophan. Although the claimed plant was actually produced by selection in tissue culture, the issued claim would be literally infringed by any maize plant having elevated free tryptophan levels. An infringing plant could be created by the stable integration of a genomic element by means ranging from classical plant breeding to molecular biology that resulted in elevated tryptophan levels.

Other claims in the ’847 patent are directed to maize seeds and to tissue culture lines developed from the tryptophan overproducing plant. Method claims are also permitted in plant utility patents. Such claims can be directed to methods of creating the plant or tissue culture line and methods of using the plant. Plant genes, plant viruses and, in some cases, plant cells themselves are also patentable. The scope of plant utility patent claims can thus be quite broad.

More typically, claims to new plant varieties are directed to seeds that have been deposited with the American Type Culture Collection (A.T.C.C.). Typical claims can be crafted as follows:

1. Seed of a miscanthus line designated ABC and having ATCC Accession No. XXYZ.
2. A miscanthus plant produced by the seed of claim 1 and parts of said miscanthus plant.
3. A miscanthus plant having x phenotype, wherein at least one ancestor of said miscanthus plant is the miscanthus plant of claim 2.

An example of the type of claim coverage available in a utility patent directed explicitly to a transgenic plant is found in U.S. Pub. No. 20070250961:

133. A transgenic plant, the genome of which is augmented with: a recombinant polynucleotide encoding at least one lignocellulolytic enzyme operably linked to a promoter sequence, wherein the polynucleotide is optimized for expression in the plant, wherein the lignocellulolytic enzyme is produced at a level greater than 0.5% total soluble protein, greater than 5% total soluble protein, greater than 10% total soluble protein or greater than 20% total soluble protein.

154. The transgenic plant of claim 133, wherein the plant is selected from the group consisting of corn, switchgrass, sorghum, miscanthus, sugarcane, poplar, pine, wheat, rice, soy, cotton, barley, turf grass, tobacco, bamboo, rape, sugar beet, sunflower, willow, and eucalyptus.

Such claims can provide very effective and broad coverage of potential new varieties. For instance, Monsanto enjoyed species-wide European patent coverage on the genetic modification of almost all soybean varieties before the patent was revoked based on enablement issues.<sup>[16]</sup>

## B. Plant Patents

The subject matter of plant patents is set forth in 35 U.S.C. §161:

“Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefore, subject to the conditions and requirements of this title.”

The Patent and Trademark Office interprets the term “plant” in a general sense rather than a strict scientific one. *In re Arzberger*, 112 F.2d 834, 46 U.S.P.Q. 32 (C.C.P.A. 1940) addressed the attempt to obtain a plant patent for bacterium normally scientifically classified as a plant. The court examined the legislative history underlying the plant patent statutes and found only plants subject to asexual reproduction via budding, cutting, or layering to be encompassed by the statute.

Only plants grown in cultivated areas may be the subject of a plant patent. Plants found growing in the wild cannot be patented. The theory behind this policy is that it would be contrary to the purpose of the patent laws to grant a monopoly over discoveries that were already freely occurring in nature. See *Diamond v. Chakrabarty*.

Asexually propagated plants are those that are reproduced by means other than seeds. Asexual reproduction typically is accomplished by the rootings of cuttings, by layering, budding, grafting, etc. All asexual reproduction techniques “fragment” the original plant into several plants. The inventor must actually reproduce the plant asexually before applying for patent protection.

Only a single claim that covers the entire plant is permitted in plant patents. A plant patent claim is directed to a new variety of plant or tree and not to a distinctive fruit or flower. Unlike plant utility patents, method claims are not acceptable in plant patents since the plant itself is being patented, not the method of asexually reproducing the plant. Often, the language of plant patent claims is simply: “new and distinct variety of plant as described and illustrated.” E.g. Plant Patent 18,161 recites:

### **1. A new and distinct Miscanthus plant named ‘Super Stripe’ as illustrated and described.**

Plant patent claims can also describe the distinctive features of the plant. An example of such a claim is found in Plant Patent 4,465:

1. A new and distinct cultivar of Kentucky bluegrass plant, substantially as illustrated and described herein, which is characterized by producing turf of high quality even when grown under low to moderate nitrogen fertility levels and restricted moisture, a medium dark green color, a medium leaf texture, high tiller density, rapid greening in the spring, good fall color retention, excellent low mowing tolerance, a vigorous and spreading growth habit, rapid seed germination and vigorous establishment, sustained turf quality through entire season, high

resistance to common turf grass diseases and a sustained high yield when managed for seed production.

Such a plant patent claim is clearly very narrow and as all plant patents is only infringed by taking a cutting of a patented plant. Such a claim is relatively straightforward to prosecute because it defines the plant very narrowly. However, the scope of protection for the patentee is not nearly as broad as could possibly be obtained with multiple claims from a utility patent.

### C. Plant Variety Protection

Seven U.S.C. § 2402 of the Plant Variety Protection Act states in pertinent part: “(a) the breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefore, subject to the conditions and requirements of this subchapter . . . .”

The P.V.P.A.’s objective is “to encourage the development of novel varieties of sexually-reproduced plants and to make them available to the public, providing protection to those who develop or discover them and thereby promoting agricultural progress in the public interest.” U.S. Plant Variety Protection Act, December 24, 1970 7 U.S.C. § 2321, et seq.

Seven U.S.C. § 2402 limits protection under the P.V.P.A. to any “novel variety of sexually reproduced plant.” 7 U.S.C. § 2401 defines this term: (a) The term “novel variety” may be represented by, without limitation, seed, transplants, and plants, and is satisfied if there is: (1) Distinctness in the sense that the variety clearly differs by one or more identifiable morphological, physiological or other characteristics (which may include those evidenced by processing or product characteristics, for example milling and baking characteristics in the case of wheat) as to which genealogy may contribute evidence; (2) Uniformity in the sense that any variations are describable, predictable, and commercially acceptable; and (3) Stability in the sense that the variety, when sexually reproduced or reconstituted, will remain unchanged with regard to its essential and distinctive characteristics with a reasonable degree of reliability . . . .”

Of these, distinctiveness is the most critical. This standard is generally regarded as much easier to satisfy than that promulgated under the patent act. In *In re John Walker*, 40 Agric. Dec. 1017 (1981), one distinct, uniform and stable characteristic exhibited by the plant variety at issue was deemed sufficient to justify protection. In *Heart Seed Co. Inc. v. Seeds Inc.*, 4 U.S.P.Q.2d 1324, 1325-6 (E.D. Wash. 1987), differences in morphology as compared to seeds of recognized origin, the melanin content of seed samples, or the character of seed proteins when resolved by electrophoresis, were regarded as sufficient bases for protection under the act.

In contrast to utility and plant patents, P.V.P.A. certificates do not have a claim. Courts have limited registration under the Plant Variety Protection Act to those plants bearing seeds. First generation hybrids and genes are excluded from P.V.P.A. protection because of a perceived instability of their genetic makeup and the resulting inability to maintain these characteristics in sexually reproduced offspring. Traditional F1 hybrids can be indirectly protected by trade secrets or protecting either or both parental lines.

Unlike plant patents and utility patents, there is a breeders’ exemption for plant variety certificates. Under the exemption, competitor breeders can use a P.V.P. protected plant in breeding to develop new varieties. In contrast, competitor breeders cannot use patented varieties in breeding programs without a license.

A certificate of Plant Variety Protection is valid twenty years from the date of issuance, in contrast to utility patents, which currently have a 20-year term valid from the first filing (or priority) date. The owner has the right to exclude others from selling, offering for sale, reproducing, importing, exporting or using the protected variety in the production of a hybrid or different variety during this 20 year period.

The P.V.P. also includes protection of “essentially derived varieties.” An essentially derived variety is defined in 7 U.S.C. §2401 as:

- (i) predominantly derived from the “initial variety” or from a variety that is predominantly derived from the initial variety;
- (ii) clearly distinguishable from the initial variety; and

(iii) except for differences that result from the act of derivation, conforms to the initial variety in the expression of the *essential characteristics* that result from the genotype or combination of genotypes of the initial variety.

Thus, for example if a salt tolerant gene was added to a P.V.P. protected Miscanthus variety, the salt tolerant variety would likely infringe the P.V.P. certificate because it retains the essential characteristics of the protected variety.

## Conclusion

The race is on to create technology that allows the economic production of second generation biofuels. The core of such technology will enable the efficient utilization of lignocellulosic biomass and the economics of such technology will likely favor plant-based solutions in the form of engineered feedstock. The patent portfolios covering such feedstock will hold significant strategic and economic value and will likely overshadow the biofuels patent landscape.

An asexually reproducing feedstock can be protected with plant patents and sexually reproducing feedstock can be protected with utility patents and/or a P.V.P. certificates. A new Miscanthus variety, however, can potentially be the subject matter of all three plant protection vehicles because it can be propagated both by seed (provided the variety reproduces true to type) and cuttings. Such breadth of protection, with its diverse set of infringement and validity standards, provides the most comprehensive and robust global intellectual property protection.

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## Footnotes:

[1] Feedstock cost is often the single largest variable cost in biofuel production, sometimes constituting over 50% of total variable costs.

[2] In 2006, the U.S. produced 4.8 billion gallons of ethanol, almost entirely based on the use of corn grain.

[3] Converting 100% of current U.S. corn acreage would theoretically allow replacement of 13% of current U.S. gasoline consumption.

[4] Modified from: "Development of Cellulosic Biofuels," Chris Somerville, U.S. Dept. of Agriculture, <http://www.usda.gov/oce/forum/2007%20Speeches/PDF%20PPT/CSomerville.pdf>, (Modified from Richard Bain, NREL).

[5] "Bioconversion and Biorefineries of the Future,"

Linda L. Lasure, Pacific Northwest National Laboratory; Min Zhang, National Renewable Energy Laboratory, <http://www.pnl.gov/biobased/docs/biorefineries.pdf>.

[6] Id.

[7] "BioFuels and the Prospect of Converting Plant Fibers into Gasoline using Enzymes," Mads Hansen, The Science Creative Quarterly, Issue 3, September 2007, (<http://www.scq.ubc.ca/biofuels-and-the-prospect-of-converting-plant-fibres-into-gasoline-using-enzymes>).

[8] "Extreme Genetic Engineering: An Introduction to Synthetic Biology." The ETC Group, January 2007, <http://www.etcgroup.org>.

[9] "Patents: Taken for Granted in Plans for a Global Biofuels Market," Steve Suppan, IATP Trade and Global Governance Program, October 2007 *citing* "Extreme Genetic Engineering: An Introduction to Synthetic Biology." The ETC Group, January 2007, <http://www.etcgroup.org>.

[10] Patents: Taken for Granted in Plans for a Global Biofuels Market.

[11] "Agrofuels: Towards a reality check in nine key areas," Biofuelwatch et al. June 2007,

<http://www.biofuelwatch.org>.

[12] “Corporate control: the sequel,” Seedling GRAIN, July 2007, <http://www.grain.org>.

[13] Patents: Taken for Granted in Plans for a Global Biofuels Market.

[14] “Silicon Valley IP Lawyers Are Cleaning Up With Clean-Tech Clients” Xenia P. Kobylarz, IP Law & Business, March 22, 2007, citing ipCapital Group, Inc.

[15] Patents: Taken for Granted in Plans for a Global Biofuels Market.

[16] See EP0301749.