

## Mendel Biotechnology Inc.



International biotechnology promotion groups have an interest in the Monsanto vs. Schmeiser case for many reasons, including the implications the decision could have about the patentability of genetically engineered products. These companies notice that Canadian farmers seem to generally embrace herbicide-resistant crops since tens of thousands of them regularly pay license fees to use the technology. Mendel Biotechnology is a good example of this time of promotion group. According to their website ([www.mendelbio.com](http://www.mendelbio.com)):

*Mendel Biotechnology was founded in early 1997 to develop the idea that controlling gene expression would create new opportunities to improve plant growth and development. We have focused on a large class of genes called transcription factors because they control the degree to which each gene in a cell is activated. The approximately 27,000 genes in the Arabidopsis genome are controlled by approximately 1,800 different transcription factors. By systematically analyzing the function of all Arabidopsis transcription factors, Mendel scientists have discovered that single transcription factors can control complex traits such as the ability of plants to withstand freezing or drought, yield, morphology, disease resistance, nitrogen use efficiency and many other complex traits. We believe that no other company or academic institution in the world has a comparable understanding of the function of transcription factors and that Mendel is the leading company in the world in this area.*

*Knowledge of the function of plant transcription factors has enabled many novel inventions by Mendel scientists. The company has filed a large number of patents describing these inventions. We believe that the inventions described in our patent filings have placed the company in a strong position to participate in future developments in plant biotechnology, plant breeding, horticulture, and forestry. We are also using knowledge of plant gene expression to discover new ways of using chemicals to control plant growth and development.*

The following excerpts are from the “News and Events” page of Mendel Biotechnology Inc.’s website.

**April 14, 1999:**

## **Mendel Biotechnology issued patent covering method for increasing cold and drought resistance in plants**

Mendel Biotechnology, Inc. announced today that the Patent and Trademark Office has issued U.S. Patent No. 5,891,859 entitled *Method for Regulating Cold and Dehydration Regulatory Genes in a Plant*. The patent provides methods for regulating the expression of cold and dehydration regulated genes in a plant by transforming a plant with CBF1 or a homologous gene, and then expressing the gene. In addition, Mendel Biotechnology has received Notices of Allowance for a number of other related patent applications.

CBF1 is a transcription factor that binds to the upstream region of specific cold and drought regulated genes and enhances the cold and drought resistance of plants expressing CBF1. CBF1 is being commercialized under the WeatherGard™ trademark.

*Plants with the WeatherGard™ gene will be more resistant to freezing and to drought said Dr. Michael Fromm, Mendel's President and CEO. These are very important traits as the recent \$650 million of freezing damage to the California citrus crop and the \$1,600 million of drought damage to Texas crops demonstrate. Mendel is working with partners to introduce the WeatherGard™ gene into various crops to create new stress-resistant plants. Reducing the weather-related risks of farming should reduce the stress of being a farmer as well.*

The issued patent covers technology, which is being developed by Dr. Mike Thomashow at Michigan State University in association with Mendel Biotechnology and has been exclusively licensed to Mendel Biotechnology. The license grants Mendel Biotechnology the right to sublicense the technology for environmental stress resistance in different crops.

Mendel Biotechnology, Inc. is a plant functional genomics company focused on the discovery and development of technologies that will improve plant traits for agriculture, horticulture and forestry. Mendel Biotechnology has established research collaborations with Monsanto, Empresas La Moderna (ELM) and Seminis Vegetable Seeds, a subsidiary of ELM.

### **November 20, 2001:**

#### **Mendel Biotechnology Announces a New Five-Year, \$20 Million Research and Commercialization Partnership with Monsanto**

Mendel Biotechnology, Inc. ("Mendel") today announced a new five-year, \$20 million research and commercialization partnership with Monsanto Company ("Monsanto"). This new partnership expands the relationship initiated in 1997 in which Mendel successfully identified many genes that regulate high-value plant traits such as enhanced yield, drought resistance, and disease resistance. If commercialized, Mendel will receive royalties from Monsanto on products containing these genes.

"Mendel is extremely pleased that Monsanto has agreed to this expansion of our strategic partnership to discover and advance high value, plant genes," said Dave Summa, Mendel's president and chief executive officer. "Our first collaboration was about discovering gene

function. This new collaboration will continue that successful work and move into lead advancement. Monsanto is a world leader in the development and commercialization of high-value, sustainable agricultural products that bring value to growers and improve the abundance and nutritional value of food and feed crops. They are a great channel to global agricultural markets for Mendel's discoveries."

Rick Stonard, Ph.D., vice president of genomics at Monsanto added, "Mendel has delivered on time and on budget. This extension provides Monsanto with continuing access to Mendel's gene function discovery and lead advancement capabilities. We expect that Mendel will continue to play an important role in our integrated genomics network."

## **December 15, 2005:**

### **Mendel Biotechnology Awarded SBIR Phase IIB Grant for Continued Research on Disease Resistance**

Mendel Biotechnology, Inc., a privately held biotechnology company, announced today that it was granted a Phase IIB Small Business Innovation Research (SBIR) grant from the National Science Foundation. The SBIR phase IIB grant provides two years of supplemental funding for a Phase II grant awarded to Mendel Biotechnology, Inc. for development of crops with improved disease resistance, based on matching funds from a third party investor. Protection of crops against fungal pathogens is one of the most significant unmet needs in agriculture. Over \$600 million is spent each year in the United States to protect plants against fungal pathogens. Nonetheless, annual losses to fungal pathogens are approximately \$900 million in North America for soybean alone, with total crop losses of approximately \$5 billion. The grant will fund research that aims to enhance a plant's natural ability to resist pathogen infection, thereby reducing or eliminating the need for fungicides.

T. Lynne Reuber, Ph.D., Director of Research, will serve as the Principal Investigator of the grant.

Founded in 1997, Mendel Biotechnology, Inc. was a pioneer in the application of functional genomics to the study of plant genes. Mendel's initial mission, now largely complete, was to discover and characterize the function of plant transcription factor genes as the basis for creating novel products for agriculture. Mendel is now commercializing transcription factor technologies in the agricultural biotechnology and chemistry sectors. Products incorporating Mendel technologies are being developed for large acreage row crops, and for the forestry, ornamental and horticultural markets. Mendel has partnerships with leading agriculture companies, including Monsanto, the world's leader in commercializing transgenic crops.

## **Article from the New York Times by Andrew Pollack, February 14, 2006:**

### **Biotech's Sparse Harvest**

At the dawn of the era of genetically engineered crops, scientists were envisioning all sorts of healthier and tastier foods, including cancer-fighting tomatoes, rot-resistant fruits, potatoes that

would produce healthier French fries and even beans that would not cause flatulence.

But so far, most of the genetically modified crops have provided benefits mainly to farmers, by making it easier for them to control weeds and insects.

Now, millions of dollars later, the next generation of biotech crops — the first with direct benefits for consumers — is finally on the horizon. But the list does not include many of the products once envisioned.

Developing such crops has proved to be far from easy. Resistance to genetically modified foods, technical difficulties, legal and business obstacles and the ability to develop improved foods without genetic engineering have winnowed the pipeline.

"A lot of companies went into shell shock, I would say, in the past three, four years," said C. S. Prakash, director of plant biotechnology research at Tuskegee University. "Because of so much opposition, they've had to put a lot of projects on the shelf."

Developing nonallergenic products and other healthful crops has also proved to be difficult technically. "Changing the food composition is going to be far trickier than just introducing one gene to provide insect resistance," said Mr. Prakash, who has promoted agricultural biotechnology on behalf of the industry and the United States government.

In 2002, Eliot Herman and his colleagues got some attention when they engineered a soybean to make it less likely to cause an allergic reaction. But the soybean project was put aside because baby food companies, which he thought would want the soybeans for infant formula, instead are avoiding biotech crops, said Mr. Herman, a scientist with the Department of Agriculture.

In addition, he said, food companies feared lawsuits if some consumers developed allergic reactions to a product labeled as nonallergenic.

The next generation of these crops — particularly those that provide healthier or tastier food — could be important for gaining consumer acceptance of genetic engineering. The industry won a victory last week when a panel of the World Trade Organization ruled that the European Union had violated trade rules by halting approvals of new biotech crops. But the ruling is not expected to overcome the wariness of European consumers over biotech foods.

New crops are also important for the industry, which has been peddling the same two advantages — herbicide tolerance and insect resistance — for 10 years. "We haven't seen any fundamentally new traits in a while," said Michael Fernandez, executive director of the Pew Initiative on Food and Biotechnology, a nonprofit group.

Now, some new types of crops are appearing. Monsanto just won federal approval for a type of genetically engineered corn promoted as having greater nutritional value — albeit only for pigs and poultry. The corn, possessing a bacterial gene, contains increased levels of lysine, an amino acid that is often provided to farm animals as a supplement.

Coming next, industry executives say, are soybean oils intended to yield healthier baked goods and fried foods. To keep soybean oil from turning rancid, the oil typically undergoes a process called hydrogenation. The process produces trans fatty acids, which are harmful and must be disclosed in food labels under new regulations.

Both Monsanto and DuPont, which owns the Pioneer Hi-Bred seed company, have developed soybeans with altered oil composition that, in some cases, do not require hydrogenation. Kellogg said in December that it would use the products, particularly Monsanto's, to remove trans fats from some of its products.

Monsanto's product, Vistive, and DuPont's, which is called Nutrium, were developed by conventional breeding. They are genetically engineered only in the sense that they have the gene that allows them to grow even when sprayed with the widely used herbicide Roundup.

But Monsanto and DuPont say the next generation of soybean, which would be able to eliminate trans fats in more foods, would probably require genetic engineering. Those products are expected in three to six years.

Beyond that, both companies said, would be soybeans high in omega-3 fatty acids, which are good for the heart and the brain. These are now derived largely from eating fish, which in turn get them by eating algae. Putting algae genes into soybeans could allow for soy oil that is rich in the fatty acids.

"Our hope is it is easier to formulate into food without it smelling or tasting fishy," said David M. Stark, vice president for consumer traits at Monsanto.

Other second-generation crops are also on the way. DuPont is trying to develop better tasting soy for use in products like protein bars.

Some efforts are under way to develop more nutritious crops for the world's least developed countries, led by what is termed golden rice, which contains the precursor of vitamin A. Vitamin A deficiency is a leading cause of blindness in certain poor countries.

There has been progress in crops able to withstand drought. While those would mainly benefit farmers, it would also help consumers in regions like Africa, where droughts bring famine.

Mr. Stark said Monsanto had not anticipated that use of genetic engineering would discourage food companies from using the company's soybeans. "I don't get many requests for 'Is this a G.M.O. or not?' " he said, using the abbreviation for genetically modified organism. "It's more 'Does the oil work?' "

Still, opposition by consumers and food companies has clearly forced big companies like Monsanto and DuPont to choose their projects carefully. It has also made it difficult for academic scientists and small start-ups, which typically provide much of the innovation in other fields, to obtain financing.

Avtar K. Handa, a professor at Purdue, said he had stopped work on a tomato he helped develop

a few years ago that was rich in lycopene, a cancer-fighting substance. Genetically modified crops are not being brought to market and research funds have diminished, he said.

Still, opposition is not the only problem. Alan McHughen, a professor at the University of California, Riverside, said that for small companies and university researchers, the main obstacles were patent rights held by the big companies and the cost of taking a biotech crop through regulatory review. That has made it particularly difficult to apply genetic engineering to crops like fruits and vegetables, which have smaller sales than the major grain and oil crops.

Technical issues are another obstacle. While a single bacterial gene can provide herbicide resistance or insect resistance, changing the nutritional composition of crops sometimes requires several genes to alter the metabolism within a cell. That raises a greater risk of unintended effects, some experts say.

Enhanced crops must also meet the demands of farmers for high yields and of food companies for good taste and handling properties.

DuPont won approval for a soybean high in oleic acid, which could produce healthier oils, back in 1997. But instead of becoming a showcase of the consumer health benefits of genetic engineering, the crop is now used only to make industrial lubricants.

Erik Fyrwald, group vice president of DuPont's agriculture and nutrition division, said one reason the crop was not sold for use in food was that demand for healthier oils was not as great then as it is now. But other experts say there was another problem — foods made with the oil did not taste good.

"The high-oleic oils are not very well received by the consumer," said Pamela White, a professor of food science and human nutrition at Iowa State University. Further, she predicted that soy oils containing the omega-3 fatty acids would be unstable, making them hard to use in fried foods.

William Freese, a research analyst at Friends of the Earth, which opposes genetically engineered crops, said genetic engineering had been oversold. "The facts show that conventional breeding is more successful at delivering crops with 'healthy traits' than genetic manipulation, despite all the hype from Monsanto and other biotech companies," he wrote in an e-mail message.

Scientists at the International Maize and Wheat Improvement Center in Mexico have already used conventional breeding to develop corn rich in lysine, similar to the new Monsanto product, he said.

The biotech companies concede that if improvements can be made conventionally, results would come quicker because such crops do not face regulatory scrutiny. Mr. Stark of Monsanto said that if his company could develop high-oleic soybeans using breeding, the product could reach the market in three years, rather than six for the genetically engineered version.

But in some cases, scientists and executives say, it is not possible to get a trait, like the omega-3 fatty acids, without using genes from another species. "With genetic engineering you can go further," said Mr. Fyrwald of DuPont.

Mr. Fernandez of the Pew Initiative said polls have shown that consumers seem to be receptive to genetically modified products that have direct benefits for them. But whether that would be enough to win wide acceptance of genetically engineered foods remains to be seen.

One issue is whether consumers would even know what they are eating. Right now, in the United States, genetically modified and conventional crops are typically mixed together, and food made from biotech crops is not labeled.

But it is likely that crops with consumer benefits would be segregated so farmers could charge more for them. And food companies are probably going to want to label them. But the labeling is likely to proclaim that the food has healthier oil or is better for the heart, rather than mention it was the product of genetic engineering.

In Europe, food containing genetically modified ingredients has to be labeled to that effect, but it is not clear whether the health aspects would be linked to genetic engineering on the label.

Chris Somerville, chief executive of Mendel Biotechnology, a small company developing drought-resistant crops, said acceptance would depend more on big food companies than consumers. Companies, he said, would not want to risk their brands by using biotech crops if they thought there was even a slight chance of consumer rejection.

"Really, they're the gatekeepers," said Mr. Somerville, who is also head of the plant biology department at the Carnegie Institution. "The consumers aren't going to have any choice before the brand companies think it's safe to go out."

### **Article from The Saskatoon StarPhoenix by Robert Wager, April 15, 2005:**

#### **Convicted farmer makes unlikely hero for rural lifestyle**

A tremendous amount of misinformation spread by groups with an agenda makes it tough for the public to separate the wheat from the chaff when it comes to genetically engineered crops and food. The Percy Schmeiser case used by Michael Mehta in his viewpoint Biotechnology could destroy rural social fabric (SP, April 14) to illustrate the danger to privacy posed by the technology, is a prime example.

Biotechnology has engineered herbicide tolerant crops. HT crops are unaffected when sprayed with particular broad-spectrum herbicides, such as the Roundup Ready (RR) crops produced by Monsanto.

RR canola allows a farmer to spray a canola crop with Roundup and only the weeds will die. If a farmer plants these HT varieties, he can expect higher yields, plus cheaper and easier weed control. The Canadian Canola Growers Association says biotech canola seeds have reduced chemical use by 29 per cent, and increased profits by \$5.80 per acre.

Today, 70 per cent of Canadian canola farmers grow herbicide tolerant varieties -- a rapid change, given that GE canola varieties only have been available for eight years.

Biotech seeds are more expensive, and farmers who want to grow them must sign a technology use agreement promising not to save and replant the biotech seeds. More than 30,000 Canadian farmers, who know first-hand the benefits to the environment and their bottom-line from growing GE crops, have signed such agreements.

A reality of modern agriculture is that farmers rarely save seeds anymore. Most buy hybrid seed varieties, which must be repurchased annually.

In 1997, Schmeiser sprayed "a good three acres" of his canola crop with Roundup. One might ask why a farmer would purposely spray a herbicide that should destroy three acres of his crop? Once it was clear that the canola in this field was herbicide tolerant, Schmeiser decided to harvest the seed from there and save it to plant the next year. Clearly, most farmers would have realized the canola in the field was Roundup tolerant, since it survived.

The next year, he planted 1,030 acres with the saved seed, knowing that the use of such GE seed required a technology use payment. The result was 1,030 acres of 95-98 per cent Roundup-tolerant canola. When this high level (equivalent to commercial grade seed) was discovered, Monsanto asked Schmeiser to pay the fee of \$15 per acre. He refused, and the court cases began.

The Federal Court on March 29, 2001, found Schmeiser guilty of patent infringement. Said Judge Andrew MacKay: "He planted his crop for 1998 with seed that he knew, or ought to have known, was Roundup-tolerant." Schmeiser appealed.

By now, his legal war chest was growing, in part, with significant support from groups opposed to GE crops.

On Sept. 4, 2002, the Federal Court of Appeals upheld the verdict, rejecting all 17 points raised by Schmeiser's counsel. That decision was appealed to the Supreme Court, this time with a twist.

Instead of arguing that Schmeiser did not violate Monsanto's patent, his lawyer argued that the company's patent on Roundup Ready canola was invalid on grounds that no one should be able to patent a life-form.

What started as an obscure case between a farmer and a multinational corporation blossomed into a show watched closely by the entire biotechnology industry. Ramifications would be huge should the court rule against Monsanto's patent. It would mean no patent protection for biotech products in Canada, leading to their mass exodus from this country. Clearly, this was the agenda of Schmeiser's financial backers.

Fortunately, the Supreme Court found Schmeiser guilty, too. Canada is one of the world leaders in agricultural biotechnology, and the courts have determined that will continue.

People should understand this was not a David vs. Goliath case but a Goliath vs. Goliath case, with David as the front man. The real players were the biotechnology industry and the multinational, billion-dollar anti-biotechnology industry.

*Robert Wager, is a biotechnology instructor at Malaspina University College in Nanaimo, B.C.,*