



RAFI COMMUNIQUE

RURAL ADVANCEMENT FOUNDATION INTERNATIONAL

July-August, 1993

CONTROL OF COTTON: The Patenting of Transgenic Cotton

ISSUE: Agracetus, Inc. a subsidiary of W.R. Grace & Co., received U.S. Patent No. 5,159,135 on October 27, 1992 which covers all genetically engineered cotton varieties. The exceptionally broad scope of coverage is unprecedented in plant biotechnology, giving the company monopoly control over all transgenic cotton plants and seeds until the year 2008. This is the first reported case where one patent covers all transgenic plants of an entire species.

Agracetus has similar patent applications pending worldwide, including patent applications in the European Patent Office, and in Brazil, China and India. Together, the United States, Brazil, China and India presently account for 60% of global cotton production.¹

IMPACT: In the United States, Agracetus now has the right to decide when and if it chooses to license its technology, and under what conditions. Cotton is a self-pollinating crop, and farmers in many parts of the world save seeds from their harvest to re-plant the following year. Under industrial patent law, however, it will be illegal for farmers to save seeds from transgenic cotton plants without payment of royalties to the patent owner. Both public and private plant breeders express dismay and concern about the broad patent granted to Agracetus, and its impact on the future of molecular biology research on cotton. Many scientists interviewed by RAFI fear that the Agracetus patent will stifle innovation on transgenic cotton, rather than encourage it.

FINANCIAL STAKES: The worldwide cotton crop is valued at (US) \$20 billion per annum. In the United States alone, the value of both cotton fibre and oil extracted from pressed seeds is (US) \$4 billion per annum. Transgenic cotton varieties are now being developed for agronomic traits such as herbicide tolerance and insect resistance; other varieties are being developed for specialty fibre markets.

PARTICIPANTS: In the USA, research & development of transgenic cotton is conducted primarily in the private sector. In addition to Agracetus, Inc. (subsidiary of W.R. Grace), Calgene and Monsanto are major players. American Cyanamid, duPont and Bayer (Germany) are also active in the development of transgenic cotton. (For more information on these companies, see page 8.)

WHEN: Calgene Inc. (California, USA) predicts that its transgenic cotton will reach the commercial market in 1994.

THE IMPORTANCE OF COTTON LINT AS A FOREIGN EXCHANGE EARNER IN DEVELOPING NATIONS COMPARED WITH OTHER AGRICULTURAL COMMODITIES

<u>#1 RANKING</u>	<u>#2 RANKING</u>	<u>#3 RANKING</u>	<u>#4 RANKING</u>
Benin	Afghanistan	Cameroon	China P.R.
Burkina Faso	Angola	Colombia	Cote d'Ivoire
Egypt	Cent. Afr. Rep.	Swaziland	El Salvador
Mozambique	Chad		Gambia
Pakistan	Iran		Guatemala
Paraguay	Israel		Madagascar
Sudan	Mali		Turkey
Syria	Nicaragua		
Togo	Peru		
	Senegal		
	Tanzania		
	Uganda		
	Zimbabwe		

Source: International Institute for Cotton, based on FAO data.



WORLD'S TOP SIX COTTON PRODUCING NATIONS 1992-93 (in metric tonnes)

<u>STATUS OF AGRACETUS' PATENT</u>	<u>RANK OF PRODUCER NATION</u>	<u>PRODUCTION</u>
PENDING	# 1 CHINA	4.5 million MT
ISSUED	# 2 UNITED STATES	3.5 million MT
PENDING	# 3 INDIA	2.3 million MT
_____	# 4 PAKISTAN	1.6 million MT
_____	# 5 UZBEKISTAN	1.3 million MT
PENDING	# 6 BRAZIL	400,000 MT

The top 6 cotton producing nations now account for 76% of worldwide cotton production. Agracetus has patents issued or pending on genetically engineered cotton in 4 of the top six.

Source: RAFI. Data on cotton production for 1992-93 comes from the International Cotton Advisory Committee, Washington, D.C.

Cotton: A Developing World Crop

Cotton is the world's most important agriculturally produced industrial raw material, and the world's leading textile fibre. It also provides a rich source of oil for human consumption and a protein-rich feedstuff for livestock.

At least 190 million people in the developing world derive all or part of their cash income from cotton growing and handling. An additional 60 million people depend upon cotton processing.²

The annual farm value of cotton is approximately \$20 billion worldwide. Developing nations account for approximately three-quarters of the total area sown to cotton (approximately 24 million hectares). Of the 77 countries where cotton is grown, 68 are in the developing world. According to FAO, in 1991 the developing countries produced approximately 13.6 million metric tonnes of cotton lint, compared to 7 million metric tonnes produced in developed countries. Since 1960, world cotton production has risen dramatically--with developing nations accounting for a gain of 110% between 1960 and 1989.

There are four main domesticated cotton types, and many strains and sub-strains, all of which originated in the developing world. *Gossypium arboreum* and *Gossypium herbaceum* are native to Africa and Asia. In contrast, *Gossypium barbadense* and *Gossypium hirsutum* evolved in the Americas. *Gossypium hirsutum*, also known as Upland cotton, contributes over 90% of the current world output and is used in the manufacture of a wide range of textile products. (The Agracetus patent covers, specifically, *Gossypium hirsutum*.)

Genetic Engineering of Cotton

Scientists at Agracetus, Inc., a subsidiary of agricultural giant W.R. Grace & Co., are widely acknowledged as early leaders in the genetic transformation of commercial cotton varieties, although their breakthroughs have drawn from the work of other researchers in both the public and private sectors. Numerous cotton researchers interviewed by RAFI readily acknowledge that practical transformation

of cotton was made possible by Dr. Norma Trollinger, a molecular biologist at Texas Tech University in Lubbock, Texas (USA) who freely shared her knowledge with Agracetus and other scientists. These researchers were shocked to learn of the Agracetus patent on genetically engineered cotton. (Dr. Trollinger is currently employed by the U.S. Department of Agriculture/Agricultural Research Service in Lubbock.)

One federally-funded cotton breeder, who spoke to RAFI on the condition of anonymity, said, "We don't know how to respond to something this broad...It might make the company rich, but it's going to make the country poor. It's so broad that it really almost restricts new ideas. I think they've [the U.S. patent office] gone too far."³

Agracetus' Cotton Patents: Cornering the Market on Genetically Engineered Products and Processes

Agracetus' patent claims on cotton are exceptionally broad and far-reaching, not only because they claim ownership of all genetically engineered cotton varieties, but two of the major techniques used to transform them as well.

In March, 1987, scientists from Agracetus first published the results of *Agrobacterium*-mediated genetic transformation of cotton varieties.⁴ This method of inserting foreign genes into cotton plants using the plant pathogen *Agrobacterium tumefaciens*, has since become routinely practiced by both commercial and academic researchers. In April, 1991, Agracetus announced receipt of a U.S. patent that "covers both the method of inserting genes into cotton using the plant pathogen *Agrobacterium tumefaciens*, as well as any plant varieties developed with this method."⁵

Agracetus also claims ownership of a complimentary transformation technique that uses the company's patented particle bombardment method for gene delivery. The so-called "gene gun" (brand name: Accell^R) uses an electrical discharge to blast minute metal particles coated with DNA directly into the cell of an elite cotton variety.⁶ The Accell^R method for gene delivery has transformed successfully some

of the most commercially important varieties in the United States, including Deltapine 50 and Deltapine 90, two cultivars that together account for over 25 percent of the U.S. market share.⁷ Agracetus claims that its new technique reduces the time needed to generate transgenic cotton by more than 50 percent. The company will not license rights to its Accell^R technology for genetic transformation of cotton.⁸

On October 27, 1992, Agracetus announced receipt of a U.S. patent on all genetically engineered cotton products. The managing editor of *AgBiotechnology News* asked: "If most important cotton varieties in the future are genetically engineered, then does this mean that Agracetus will have, more or less, 'patented cotton,' just like Polaroid has patented its instant processing cameras?"⁹

Agracetus' vice-president of finance, Russell Smestad, responds to this question unequivocally: "All transgenic cotton products, regardless of which engineering technique is used, will have to be commercially licensed through us before they can enter the marketplace."¹⁰

It is important to note that Agracetus will retain exclusive use of its patent on transgenic cotton for fiber modification. According to Agracetus, this will preserve the company's position as "the sole provider of specialty natural fibres." Through genetic engineering, the company is developing customized cotton fibres with new traits such as improved dye binding, thermal characteristics, and absorbency. Agracetus claims that its specialty fibres will "make possible entirely new product concepts in woven and non-woven markets, in addition to improving process economics."¹¹

The Goals of Transgenic Cotton Research-- What's In the Pipeline?

Two U.S.-based plant biotechnology companies, Monsanto and Calgene, are major players in the development of transgenic cotton varieties. Agracetus has licensed its broad patent on transgenic cotton to both companies, but only for the purpose of modifying agronomic traits of

cotton. Terms of the licensing agreements were not made public.

The involvement of Calgene and Monsanto in transgenic cotton R & D is particularly noteworthy. Together, these two companies own, or have significant interests, in the two largest cotton seed companies, accounting for approximately 61% of the U.S. cotton seed market.¹²

In 1986, Calgene Inc. acquired Stoneville Pedigreed Seed Company, the second largest cotton seed company in the United States. Calgene has a joint development agreement with Rhone-Poulenc (France) to develop cotton varieties resistant to its proprietary herbicide bromoxynil, which will be marketed by Stoneville Pedigreed. The so-called BXN^R cottons will be grown commercially on 3-6,000 acres in 1994. Calgene's target, according to company spokesperson John Callahan, is to reduce the use of agrichemicals on cotton to just one-fifth the current level through the introduction of herbicide tolerant and insect resistant cultivars over the next 15 years.¹³

In June, 1993, Monsanto purchased 500,000 shares of Delta & Pineland, which was previously the largest independently-owned cotton seed company in the United States. Delta & Pineland varieties accounted for 53.6% of all cotton acreage planted in the U.S. in 1992.¹⁴

Out of 50 applications submitted to the U.S. Department of Agriculture for field testing of genetically engineered cotton varieties between 1988-1993, 22 applications were submitted by Calgene, and 20 by Monsanto.¹⁵ Both companies are working on two traits: herbicide tolerance and insect resistance. Other companies active in R&D on transgenic cotton include Dupont, American Cyanamid, and Miles, Inc. (a subsidiary of Bayer pharmaceutical of Germany).

What Impact on the Future of Cotton R&D?

One of the primary concerns voiced by scientists interviewed by RAFI is the potential impact of Agracetus's patent on the future of molecular biology research on cotton.

Professor Neil D. Hamilton, Director of Drake University's Agricultural Law Center (Iowa, USA) writes, "*A claim to a whole crop species is perhaps the ultimate trump card in a serial stacking of competing patent claims. If such a broad based patent is in fact possible it would have a direct effect on the ability of other researchers, both public and private to continue their efforts to improve cotton.*"¹⁶

Research exemptions allow the use of protected intellectual property for true research purposes, without infringement of patent rights. Utility or industrial patent law (the type of patent granted to Agracetus) makes no provision for a research exemption, although judicial decisions (in U.S. courts) appear to provide an exemption for non-commercial research. But ambiguities arise in determining what constitutes "non-commercial" research. In recent years, for example, some public sector researchers have received "intimidating" letters from corporations warning that the researchers' work might infringe intellectual property rights.¹⁷

Traditionally, the work of public sector plant breeders in U.S. universities and agricultural research stations was to release varieties to the public--a public service performed by tax-supported public servants. But all of that is changing rapidly. Increasingly, the work of public sector breeders is germplasm enhancement.

With sharp cutbacks in state and federal funding, taxpayer-supported agricultural researchers in the United States are under intense pressure to seek research funds from private industry. Private companies generally expect preferential (increasingly exclusive) access to intellectual property that might be developed with their support. Not surprisingly, many scientists believe that intellectual property rights increasingly restrict the exchange of germplasm and information. As one scientist put it: "We used to cooperate with private industry very openly--but it's a new day in research. Now it has gotten to the point where you need a lawyer to discuss things with their lawyer."

Dr. Jerry Quisenberry, Director of USDA's Cotton Systems Research Laboratory in

Lubbock, Texas oversees a federally-funded program on molecular biology of cotton. In reaction to the Agracetus patent, he states: "*It's very unfortunate, and it has set a precedent...what's to say the same thing won't happen for other commodities? It sets up a potential road block. Agracetus, after all, can decide to license their product or not. Public research on cotton, at least at the molecular level, will have to come to a screeching halt.*"¹⁸

Ultimately, it is the farmer who will pay the highest price. Quisenberry explains: "*What we will be forced to do in our research is to go to a large company and enter into an agreement with them for releasing our genetically engineered cotton variety--we won't be able to do varietal release directly to farmers anymore. We can't afford to.*"

If a public university develops a genetically engineered variety and they want to release it, how much royalty will they be obliged to pay to Agracetus? According to Russell Smestad, Vice-President of Finance for Agracetus, "*We have not established a standard fee structure. We're dealing with this on a case-by-case basis.*"¹⁹

In regard to the issue of a research exemption, Smestad states, "*Whether the concept of a research exemption is codified or not, Agracetus is interested in fostering cotton R&D, and we would solicit any suggestions on how that could be accomplished. After all, we're plowing new ground here.*"²⁰

What Impact on Farmers?

Both public and private cotton researchers interviewed by RAFI believe that cotton is a crop that could benefit enormously from the application of genetic engineering. Cotton is one of the largest consumers of agrichemicals. According to the Pesticide Action Network, an estimated (US) \$2-3 billion is spent globally each year on pesticides to produce cotton. Of more than 300 million kilograms of pesticides used annually in the Third World, half is for cotton.²¹

If genetic engineers succeed in developing cotton varieties with built-in resistance to major insects, farmers could potentially benefit from lower input costs, and

inestimable benefits to human health and the environment.

But given Agracetus' portfolio of patents on cotton, will farmers ultimately realize added value in genetically engineered cotton varieties? Professor Neil Hamilton of Drake University's Agricultural Law Center observes: *"...the ability of a company, or perhaps a series of companies licensing the technology, to claim the patented crop would create a mechanism for them to capture most or all of the "higher value" engineered into the product, with farmers paying more for the improved genetics but perhaps the only "improvement" being found in the profits of the companies marketing the seed."*²²

Industrial (utility) patents make no provision for cotton farmers to save seed from their harvest to be re-planted the following year. In the United States, the practice of saving cotton seed is practiced primarily in the high plains of Texas. It is a common practice in other areas of the world, however. Some observers note the difficulty of enforcing violations of farmer-saved seed, not to mention the impracticality of bringing legal claims against farmers--the seed company's customer. It is important to note, however, that several U.S. seed companies (primarily Asgrow Seed Co., a subsidiary of Upjohn Pharmaceutical) have initiated between 30 to 40 law suits against U.S. farmers for the practice of "brown-bagging" seed (re-selling harvested seed that is protected by breeders' rights).²³ What was once viewed as the farmer's inalienable right--the 10,000 year-old ritual of saving seed--is clearly jeopardized by recent developments in plant intellectual property rights.

What Impact on the Developing World?

Despite the potential benefits of genetic engineering for a major Third World crop, the Agracetus patents illustrate how intellectual property rights may ultimately restrict, rather than promote innovation in agricultural biotechnology in the Third World. If Agracetus receives broad patent protection in India, Brazil and China, for example, these patents could provide a tremendous disincentive for molecular biology research and genetic improvement

in cotton in some of the world's most important cotton producing nations. For public researchers, in particular, the cost of royalties could become prohibitive, thus stifling innovation and improvement of this multi-billion dollar Third World crop.

Robert Jondle, a patent attorney in Omaha, Nebraska (USA) describes the complex chain of licensing agreements that could present serious financial obstacles for researchers from around the world who are developing transgenic products: *"If you don't have any patents, techniques, constructs or products to exchange licenses with, then you will need to negotiate a royalty with every licensor of each component of the final product you wish to market...The tricky thing is not to pay so much in royalty fees that you can't make a profit."*²⁴

Trade Impacts

It is important to note that the U.S. International Trade Commission has already placed Brazil, India and China on its watch list of major "offenders" of U.S. intellectual property rights. These countries are under enormous pressure at the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) to adopt more stringent intellectual property laws. Ironically, Third World nations at the GATT negotiations are being offered concessions of import liberalization for raw cotton into the United States market (the U.S. has strong quotas regulating imports of raw cotton).

But if Third World nations decide to reject the Agracetus patent claim, they could be prohibited from importing transgenic raw cotton into the United States and any other country that accepts the claim. It is also possible that textiles or finished goods produced from transgenic cotton could be barred from entry into countries accepting the claim. In effect, this would mean that developing countries would only be able to use transgenic cotton for domestic consumption. In the future, if developing nations wish to export transgenic cotton and its products, they would be obliged to accept the Agracetus patent claim.

Will Agracetus' Patents Jeopardize Exchange of Cotton Germplasm?

The Agracetus patent will likely jeopardize future exchange of germplasm and information from Third World centres of cotton diversity. As news of the Agracetus patent spreads, scientists, farmers and government officials from these countries may become increasingly reluctant to share/exchange important germplasm which ultimately becomes the subject of monopoly control, not only in the North, but in the South. If Third World cotton farmers find themselves paying royalties on genetically engineered varieties developed with germplasm that originated in the Third World, industrial breeders/genetic engineers in the North may soon find that access to cotton germplasm is severely restricted. This scenario has serious implications for the future of the cotton industry worldwide.

Will Agracetus's Cotton Patent be Challenged?

RAFI finds that public and private cotton researchers in the United States are just beginning to comprehend the potential impact of the Agracetus "species patent." Industry and government officials are cautious in what they will say publicly. Groups like the National Cotton Council and USDA/ARS are now examining the potential impacts, but have not taken a formal position on the issue. Given that the U.S. government invests \$56 million per annum on cotton research, the patenting of transgenic cotton should prompt considerable concern.

Patent attorneys who work for competing agricultural biotechnology companies are also guarded, stressing that, once issued by the U.S. government, the Agracetus patent on genetically engineered cotton "enjoys the presumption of validity."

Although some researchers believe the Agracetus patent will be challenged in the United States, much depends on the terms of negotiated licensing agreements. According to John Callahan of Calgene Inc., one of the first companies to obtain a license from Agracetus for transgenic cotton, "We were offered a license under very

*favorable terms, so we took it. If they [Agracetus] get too unreasonable, it will probably be challenged in the future."*²⁵

What may be "reasonable" terms for Monsanto or Calgene, however, may be entirely out-of-reach for researchers in the developing world. More importantly, while it is not surprising that Agracetus would choose to keep the license fee at a "reasonable" level with this first-ever "species" patent in the hopes of avoiding challenges and confirming a vital precedent, it is likely that future species claims will come with higher fees and additional market conditions.

Conclusion

The Agracetus patent claim on all genetically engineered cotton sets a dangerous and disturbing precedent in all biotechnology-related intellectual property rights worldwide. The potential impacts on cotton farmers and both public and private research on transgenic cotton are far-reaching, especially in the developing world. Furthermore, is this just the beginning of "species patents" for other food and fibre crops?

RAFI concludes that the Agracetus patents on cotton will stifle rather than stimulate innovation on genetically engineered cotton outside of the 3 to 4 major corporations and plant biotechnology companies that dominate transgenic cotton R & D.

Industrial patents are "legal monopolies," granted by a government in exchange for benefits to society as a whole. RAFI concludes that the negative social and economic impacts of the Agracetus patent far outweigh any positive social benefits. Unfortunately, RAFI believes that the problem will not be "fixed" simply by challenging the Agracetus patent. The issue demands broad societal review of intellectual property laws affecting biological products and processes.

* * * *

1. International Cotton Advisory Committee, Washington, D.C., for 1992-1993. Information provided by Terry Townsend.

2. Information on cotton in the developing world comes from: The International Institute for Cotton, "The Importance of Cotton to Developing Countries," Brussels, Belgium, July 1989.

3. Telephone interview with RAFI, July, 1993.
4. Umbeck, P., Johnson, G., Barton, K. and Swain, W. 1987. Genetically Transformed Cotton (*Gossypium hirsutum* L.) Plants. Bio/Technology 5: 263-266.
5. Agracetus News Release, "Cotton Transformation Patent Awarded to Agracetus," April 2, 1991.
6. McCabe, Dennis E., and Brian J. Martinell, 1993. "Transformation of Elite Cotton Cultivars via Particle Bombardment of Meristems," Bio/Technology, Vol. 11, May, p.596
7. Agracetus Press Release, "Agracetus Develops Method to Genetically Engineer Elite Cotton Varieties." May 16, 1991.
8. Telephone conversation with Russell R. Smestad, Vice-President for Finance, Agracetus, Inc., July 30, 1993.
9. Smestad was quoted in article by Karol Wrage, "Agracetus Claims Patent on "All" Genetically Engineered Cotton." AgBiotechnology News, December, 1992, p.1.
10. Ibid.
11. Agracetus, Inc., Brochure entitled, "Specialty Cotton Fiber from Agracetus, Inc.: The Innovator in Natural Fibers," undated.
12. USDA, AMS, Cotton Division, Market News Branch, Memphis, Tennessee.
13. Telephone interview with John Callahan, Vice-President for Cotton Program, Calgene, Inc., August 2, 1993.
14. USDA, AMS, Cotton Division, Market News Branch, Memphis, Tennessee.
15. Information on U.S. field tests provided by Dr. Jane Rissler, National Wildlife Federation, Washington, D.C.
16. Hamilton, Neil D., 1993, "Who Owns Dinner: Evolving Legal Mechanisms for Ownership of Plant Genetic Resources or Will Recognizing Intellectual Property Rights in Plants Re-shape International Agriculture?, published by Drake University Agricultural Law Center, Des Moines, Iowa, March, 1993, p.43.
17. Telephone interview with Dr. Tallent, USDA-ARS, Office of Technology Transfer.
18. Telephone interview with Dr. Jerry Quisenberry, July, 1993.
19. Telephone conversation with Russell Smestad of Agracetus, July 30, 1993.
20. Ibid.
21. Dinham, Barbara, "Cotton, Pesticides and the Global Economy," Pesticide Campaigner, May, 1992, p.1.
22. Hamilton, Neil D., "Who Owns Dinner...?," op.cit.
23. Upjohn has sued farmers for "brown bagging", the practice of farmers re-selling proprietary, open-pollinated seed from their own harvest in plain paper bags. The seed industry claims that "brown bagging" infringes on their proprietary rights and unfairly deprives them of the profits from their research and investment.
24. Quoted in: Anonymous, "The Licensing Game: Without Patents You Don't Get to Play," AgBiotechnology News, December, 1992.
25. Telephone conversation with Dr. John Callahan, Calgene, Inc., August 2, 1993.

This issue of the *RAFI Communique* was written by Hope Shand. *RAFI Communique* is a publication of the Rural Advancement Foundation International. RAFI is dependent on contributions and grants to support our research. We ask that credit is given to RAFI whenever our work is used or re-printed. Thank you!

Coming soon...more on cotton! The September issue of the *RAFI Communique* takes a look at native colored cottons. We invite our readers to send us updates on "Control of Cotton" for the next issue of *RAFI Communique*.



MAJOR CORPORATIONS AND AG BIOTECH COMPANIES INVOLVED IN GENETIC ENGINEERING OF COTTON (ranked by 1992 annual sales by *Fortune Magazine's "The World's Largest Industrial Corporations,"* July 26, 1993.)

<u>1992</u>		<u>Sales (US\$ millions)</u>
26	E.I. Du Pont de Nemours (USA)	37,386.0
43	Bayer (Germany)	26,625.3
171	Monsanto (USA). Major interest in Delta & Pineland, largest cotton seed company in USA	8,485.0
237	W.R. Grace (USA). Parent company of Agracetus, Inc.	6,329.6
285	American Cyanamid (USA)	5,242.7

Calgene (USA)-not ranked-owns Stoneville Pedigreed, the second largest seed company in the USA. In 1992, Calgene's R & D budget for all plant biotechnology was approximately US\$15 million.