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ASSESSING THE PROSPECTS FOR THE TRANSFER OF GENETICALLY MODIFIED CROP VARIETIES TO DEVELOPING COUNTRIES

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Although genetically modified varieties (GMVs) have been commercially successful in the United States(U.S.), their future in developing countries (DCs) with smaller markets is uncertain. How likely is it that relatively small countries will gain access to GMV technology? Will the dominance of biotechnology by multinational firms make GMV technology too expensive for small DCs? In this paper we attempt to draw lessons from the U.S. experience to speculate on the prospects for developing countries to gain access to GMV technology. We conclude that small countries could be attractive markets for life science and seed companies if biosafety and intellectual property systems become institutionalized.

Key words: genetically modified varities (GMVs); developing countries (DCs); intellectual property rights; technology transfer.

Genetically modified crop varieties (GMVs) have been rapidly adopted by U.S. farmers in three major field crops. In 1998, just the third year after the first GMVs were introduced, GMVs occupied 28% of the area planted to maize, soybeans and cotton and more than 500 different GMVs were available. The U.S. accounts for nearly three-quarters of GMV area worldwide (James, 1998). Argentina and Canada each planted more than a million ha to GMVs in 1998, and six additional countries planted areas of less than 100,000 ha each (James, 1998). Among developing countries only Argentina, Mexico, South Africa and China are using transgenic technology.

A handful of vertically coordinated "life science" firms including AgrEvo, Novartis, DuPont and Monsanto have been the key players in ushering in the biotechnology revolution in the United States and are major suppliers of GMVs in other countries. These firms have been successful in linking useful genetic events with high quality germplasm to create GMVs with the ability to gain rapid market penetration and to capture value. In the U.S. the life science giants have used mergers, acquisitions and licensing agreements to ally their financial, scientific, and organizational strengths with the genetic resources of traditional seed companies such as Delta and Pine Land (D&PL), Asgrow, Pioneer, DeKalb and dozens of smaller seed companies. In all three major biotechnology markets the life science firms have simultaneously marketed their genes through owned subsidiaries and licensing partners, in effect creating competition for their subsidiaries.

In this paper we review the 1996-98 experience of the United States and other countries with the introduction of GMVs. We examine United States data on the origin of transgenic events and their

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movement into commercial crop varieties. We attempt to draw lessons from the experience and to speculate on the prospects for developing countries to gain access to GMV technology.

The Scientific And Regulatory Process For Generating Genetically Modified Crop Varieties

The creation of a commercially viable GMV is the result of combining the products of two distinct scientific undertakings – a biotechnology step and a plant breeding step. The biotechnology step produces a genetic event or gene transformation that is useful in solving an economically important agricultural problem. The gene must then be combined with an adapted crop variety to create a viable commercial GMV. The two steps are separate scientific enterprises and need not occur in the same institution, or even in the same country. For example, Monsanto has introduced the most commercially successful genes to date, yet it has only recently acquired capacity in traditional plant breeding, and has maintained its conventional breeding capacity in separate subsidiaries. All Monsanto GMVs use germplasm from subsidiary or licensee seed firms. On the other hand, the world's leading marketer of GMVs, Delta and Pine Land Seed Company, has never had significant biotechnology research capacity[1]. D&PL is a modest size seed company with eight U.S. based cotton breeders and three breeders in other countries.

The large life science firms have received 84% of the United States Department of Agriculture's (USDA's) Animal and Plant Health Inspection Service (APHIS) permissions to conduct GMV field trials in the United States. A total of 135 institutions received one or more permissions to conduct trials of GMVs in field crops, including 29 public institutions, 28 large private firms and 39 smaller firms. The ten most active firms received 75% of all field trial permits, and just three companies, Monsanto, Pioneer, and AgrEvo, have conducted 51% of field trials. The USDA Agricultural Research Service (ARS) has 96 permits, more than three times as many as the next most active public institution.

The Animal Plant and Health Inspection Service has approved 51 genetically modified (GM) articles for commercialization. Sixteen private companies have received at least one APHIS approval, but the large life science firms dominate approvals. Only Monsanto, AgrEvo and Calgene have received more that two approvals, and these three companies account for nearly two-thirds all approvals. Just five approvals have been received by smaller firms (DNA Plant Technology, Bejo, Plant Genetic Systems and Agritope) and just two approvals have been received by public sector institutions. Overall, the APHIS data suggests that smaller institutions are finding themselves capable of the scientific effort required to discover genetic events, but that the larger firms possess some advantage either in carrying through the final steps of the approval process, or in other aspects of the pre-commercialization process. In any case, it appears that the large private firms are likely to dominate the commercialization of GMVs for the foreseeable future, and the public sector will need to focus on complementing private sector commercial and discovery activities. This could be even more true in developing countries, so the question becomes one of identifying the conditions under which firms might be willing to produce GMVs for developing countries.

GM Crop Varieties In The United States

The first commercial *Bacillus thuringiensis* (Bt) cotton varieties were developed through a strategic alliance between Monsanto and the dominant U.S. seed cotton firm, D&PL. Two Bt cotton varieties were introduced in 1996, NuCOTN 33^B and NuCOTN 35^B. These varieties have subsequently been marketed in several countries. In 1996, the first year of commercial availability, Bt cotton was planted on 729,000 ha or 14% of the cotton area in the United States. This area has increased to

slightly more than 1 million ha in 1998. Bromoxynil (BXN) resistant cotton varieties were also introduced in 1996, with Rounup Ready® (RR) resistant and stacked Bt+RR varieties appearing in 1997. A total of nearly 2.5 million ha were planted to all GM cotton varieties in 1998. The number of cotton GMVs has increased from just four in 1996 to 42 in 1998. The median area per GMV is relatively low, less than 30,000 ha for all products except BXN cotton. The average and median areas for conventional cotton varieties in 1998 were 22,317 ha and 3,240 ha (USDA, 1999).

The only soybean GMVs commercialized to date are Roundup Ready® varieties. The gene was developed and patented by Monsanto. More than 10 million ha were planted to RR soybeans in 1998. The RR gene was licensed for use in some 300 soybean varieties, with Monsanto expecting more than 1,000 RR soybean varieties to be available in 1999 (Monsanto 1998 Annual Report). The 300 varieties available in 1998 indicates an average area per variety of approximately 33,000 ha. Licensed varieties are being produced by all types of institutions, including public institutions and all sizes of private seed companies.

Five Bt genes for lepidopteran resistance have been developed for use in maize in the United States. Since the first appearance in 1996, hundreds of Bt resistant maize varieties[2] are being marketed in the U.S. by all sizes of seed companies, including small firms that may have only a few hundred clients[3]. In 1998, approximately 4 million ha were sown to Bt corn varieties and approximately 2 million ha were planted in herbicide tolerant varieties of corn.

GMO Crop Varieties In The Other Countries

GMVs of cotton, soybeans and maize were marketed in seven other countries in 1998. The GMVs that have been commercialized are Bt cotton in five countries, RR soybeans in Argentina[4], Bt maize in Canada and Argentina, and herbicide tolerant maize in Canada. With a total of 4.3 million ha, and approximately 62 percent of the soybean area, RR soybeans in Argentina have attained by far the largest GMV area in any country other than the United States. No other gene has achieved an area of more than 100,000 ha in any single country (James, 1998).

The primary international technology supplier is Monsanto. Monsanto has used different approaches to obtain the germplasm necessary to produce marketable GMVs for cotton and soybeans. Because cotton is agroclimatically adaptable, U.S. GMVs have been introduced directly in Mexico, China, Australia, Argentina, and South Africa. Delta and Pine Land's variety NuCOTN 33^B, one of the two varieties that successfully launched Bt cotton in the U.S. in 1996, was the first GMV sold in all five countries. Because of Mexico's proximity to the U.S., D&PL will be able to rely exclusively on U.S. varieties in Mexico. South Africa will also be able to rely on U.S. varieties because of its small market size. Adaptation of D&PL varieties by joint venture partners is underway in the countries with larger market potential - Australia, Argentina and China. The partner is a cooperative in Australia, a private seed company in Argentina, and a provincial company in China. Australia is the only one of the five countries with a D&PL breeder in country.

A Model Of The Transfer Of GMVs To Developing Countries

Under what conditions does a small country represent an attractive market opportunity for a multinational biotechnology or seed firm? A short list of conditions that a company might look for would include the following: 1) proprietary control over a gene that adds market value, 2) access to adapted germplasm, either through a subsidiary or a local seed company willing to negotiate a license, 3) a centralized transparent, science based regulatory process, 4) the ability to protect intellectual property, and 5) acceptance of GMVs by farmers, regulators, processors and legislators. If all of

these conditions can be met, the holder of the genetic event will likely be willing to enter into countries with quite small markets, as evidenced by D&PL's entry into South Africa, which has just 90,000 ha of cotton.

The minimum market size needed for a firm to enter is smaller for GMVs than it is for conventional varieties. Launching a conventional breeding program implies substantial fixed costs associated with establishing a research facility, assembling a germplasm collection and hiring personnel. Depending on the quality of the initial breeding germplasm, it may take 5-10 years to get a product to market, and success is quite uncertain when challenging for a share of the conventional seed market. The limited experience to date with the launch of GMVs in new markets has been one of relatively rapid capture of market share. Genetically modfied variety development costs are low compared to conventional varieties, since the gene is just being backcrossed into a successful existing variety whose agronomic properties have already gained market acceptance. Fixed costs are very low for the biotechnology firm if they are able to partner with a national seed company. Finally, entering a new market with the direct introduction of U.S. GMV, such as NuCOTN 33^B requires virtually no fixed costs since no breeding is done. It requires only that seed be reproduced and marketed. Not only are research and development (R&D) costs lower, but GMVs generally sell at a premium of $15 to $85 per ha. Because of the price premium on GMV seed, it is conceivable that multinationals might choose to enter markets in countries even if it means investing in setting up a conventional breeding program. Development costs are no higher for a GMV than a conventional variety once the genetic event has occurred.

Why then do so few countries currently have access to GMV technology? The primary obstacle at this point in time is regulatory. For example, in 1999 the United States is the only country to have fully approved the planting of Bt cotton, and only the U.S. and Argentina allow unrestricted planting of RR soybeans. All other countries have restrictions on total area planted.

In summary, small market size would appear to be a relatively minor obstacle to developing country access to GMVs, given the low costs of the plant breeding research required to adapt an available genetic event once the transformation has been achieved. Furthermore, the high value added by GMVs effectively increases seed market size by 50% or more in many cases. This will make small countries relatively attractive targets for life science and seed companies once biosafety and intellectual property systems become institutionalized.

Endnotes

[1] D&PL's first investment in biotechnology research occurred in 1998. By 1999 one scientist was operating a small lab focussing on identifying useful markers.

[2] It is not clear whether the counts of maize and soybean "varieties" are all truly distinct lines, or whether some of the "varieties" being counted are the same cultivars being marketed under different names by several companies.

[3] For example Doebler's Pennsylvania Hybrids, a family owned regional company, sells 12 GMV hybrids under their name. These hybrids contain four different genes, with technology licensed from Monsanto, AgrEvo and American Cyanamid (http://www.doeblers.com/).

[4] RR soybeans were introduced on a limited basis in Mexico.

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