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What's the Holdup? Addressing Constraints to the Use of Plant Biotechnology in Developing Countries

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Agricultural biotechnology offers great potential benefits to farmers in developing countries, but so far only a small handful of genetically modified (GM) crop products have been planted in only a few developing countries. This paper discusses the reasons why more GM crops have not reached farmers in more developing countries. It argues that publicly funded research efforts have largely failed, so far, in developing GM crops adapted to developing country needs, because of inadequate funding and insufficient focus on producing products. It argues that privately created GM technologies—such as Bt maize—have a better chance of reaching farmers in developing countries, but the transfer of such technologies is hampered by high biosafety regulatory costs, high seed regulatory costs, inadequate intellectual property protection, and local concerns about losing export markets. Overcoming these obstacles will require more money and product focus in public sector institutions, expanded efforts to improve regulatory environments, and the nurturing of local farmer constituencies for GM technologies.

Key words: Biosafety regulations, biotechnology, crops, developing countries, policy environment, technology transfer, transgenic, USAID.

For almost a decade, supporters of biotechnology have presented a hopeful vision of transgenic plants benefiting poor farmers in developing countries. The rate at which these technologies have spread, however, has been slower than what the optimists expected. Although there have been a few successes—soybeans in Argentina and cotton in China, South Africa, and Mexico, for example—these have been the exception rather than the rule. Farmers in developing countries, for the most part, have not yet been able to access biotechnologies to improve their productivity, incomes, and lives. What's the holdup?

This paper discusses two major categories of constraints: (a) those retarding the initial development of appropriate biotechnology products for poor farmers, and (b) those blocking poor farmers' access to biotechnology products that have already been developed, principally improved seeds. These constraints reinforce each other.

Constraints to Product Development

Before we lament the failure of biotechnologies to reach the poor, we should examine the question of whether appropriate technologies have even been developed. Have they? The answer to this question is yes, in the case of a few commercial products, and no, in the case of almost all publicly funded biotechnology projects.[1]

Commercial technologies such as insect-resistant cotton and herbicide-tolerant soybeans have been developed by companies such as Monsanto and Syngenta and marketed in North America for seven years. These commercial seed products can be made available to farmers in developing countries—they are finished products—and in a few cases, they are already being sold in these markets (e.g., Mexico, Argentina, South Africa, China, and India). To expand successfully into more tropical countries, these traits may need to be transferred by backcrossing into local, tropical crop varieties; this is not technically difficult, and in several countries (e.g., Egypt and the Philippines) the process is underway. A local corn hybrid can be made insect resistant or herbicide tolerant in less than three years. For these commercial technologies, product development is not the holdup.[2]

1. *Transgenic papaya is the only product developed by the public sector in the United States; it has not been approved for use by farmers in developing countries. China is the only developing country to produce and release its own transgenic products so far.*
2. *Traxler has labeled these technologies "temperate events" that can have "spillover" uses in tropical areas, as opposed to transgenic events designed for use exclusively in the tropics (Traxler, 2002).*

Nevertheless, for almost all of the publicly funded and noncommercial projects that we hear about—drought-resistant crops, nutritionally enhanced (biofortified) crops, disease-resistant cassava, and virus-resistant sweet potatoes—research results have indicated promise but have not yet resulted in products. To date, these projects have produced virtually no new genetically modified planting materials that are ready to be shared with or sold to farmers in developing countries. Much promise, but practically no products. Why?

Two reasons come to mind. First, the biotechnologists behind these public research projects are located mainly in universities and advanced laboratories in the United States, Europe, and other developed countries. These scientists are primarily interested in basic scientific research—making discoveries, publishing them, and in some cases patenting them. Their hearts and skills are on the research side of research and development (R&D), and they are not as experienced in, or intrigued by, the product development side of the process. In most cases, these scientists are comfortable with patenting their discoveries, then letting their host institutions license them to private companies to be integrated into products and marketed. This model is workable in advanced economies, but not when dealing with technologies designed for poor people in poor countries. Technology development companies almost never operate in these poor places. So who should do the development work?

The answer that many provide is *local partner institutions* located in developing countries, such as national agricultural research systems (NARS) and the centers of the Consultative Group for International Agricultural Research (CG Centers). These institutions can play an important role in product development; however, in virtually all cases they are inexperienced in the steps required to develop a transgenic seed product. Many believe (rightly, in my view) that training and capacity-building projects are required to familiarize more staff members at these institutions with the biotechnology R&D process, and that their scientists should be integrated as soon as possible into relevant international R&D projects to increase their understanding, sense of ownership, and commitment to moving technologies from the laboratory to the field. Local seed companies should similarly be brought on board. However, these institutions are unprepared at this point to handle effectively the process of turning technology leads into viable and approved seed products. Typically, they lack both the human and infrastructural capacity.

A second reason for nondelivery by the public sector is, of course, money. Biotechnology R&D is expensive, and in the United States, there are very few sources of funding to address the research needs of developing countries. Large research grants are obtainable from the National Science Foundation (NSF) and National Institutes of Health (NIH) for topics such as computational genomics, crystallography, and other basic plant science, and the US Department of Agriculture funds research relevant to American farmers. When one is looking for money for R&D for developing countries, however, sources are more difficult to identify. The US Agency for International Development (USAID) is probably the best hope. It initiated the Agricultural Biotechnology Support Program (ABSP) in 1991, with a core budget of about $6 million and an additional $8.6 million of support from country offices, some of which it invested in projects such as research on transgenic potatoes at Michigan State University and transgenic tomatoes at the International Laboratory for Tropical Agricultural Biotechnology (ILTAB). However, this program failed to achieve its key objective of "bringing a transgenic product to the stage of commercialization" (Brenner, Sampaio, Sittenfeld, & Thro, 2001, p. vi). The next phase—ABSP-II—is expected to invest more in such product-focused projects; however, its overall research budget is quite limited and probably adequate to fund only a handful of projects, and even those only partially. Fundraising efforts directed at companies and philanthropic foundations have succeeded in some cases, but rarely, and the resulting funds are adequate to cover only small portions of the costs associated with developing transgenic products. The Rockefeller Foundation has been the most generous, but its focus is now on establishing a new institution called the African Agricultural Transfer Foundation (AATF) and less on funding specific R&D projects. In Europe, the political controversy surrounding biotechnology has made it extremely difficult to raise funds to develop transgenic products.

Moreover, what about the financing opportunities in the NARS and CG Centers? In China, investments have exceeded $100 million annually, and the biotechnology product pipeline is healthy (Huang, Rozelle, Pray, & Wang, 2002). Virtually everywhere else, however, funding is unavailable at the levels required to develop a transgenic product. Core funding at the CG Centers has been declining in recent years, meaning that they must seek outside funding for the biotechnology projects that they undertake, and such funding, as mentioned earlier, is hard to obtain. The current biotechnology budget of all of the CG Centers combined—$25 million—will "require immense increases" to ever yield a transgenic product (Traxler, 2002).

Researchers can focus only on projects that are funded. Public institutions' chances of developing a biotechnology product for developing country agriculture will be limited as long as public and philanthropic funding for biotechnology R&D is limited. Commercial technologies, integrated into developing country varieties, are much more likely to be developed and to have a positive impact in the near term.

A third reason given for the public sector's failure to develop biotechnology products is intellectual property protection. According to this argument, public sector researchers in both the North and South are restrained by their inability to use key technologies patented by international companies. This argument loses some of its strength when one notices that these technologies are rarely patented in developing countries, and researchers tend to share them freely (especially enabling technologies such as gene promoters, transformation vectors, and plasmids). Moreover, companies have donated technologies for use in humanitarian projects such as the creation of disease-resistant cassava and nutritionally fortified Golden Rice.[3] In addition, they appear ready to donate more intellectual property through the AATF, once it becomes operational. Intellectual property rights can complicate public research efforts, but they are not nearly as constraining as the lack of funds, capacity, and the need for a product development focus.

Other Factors Blocking Poor Farmers' Access to Biotechnology Products

Earlier we stated that product development is not the holdup for commercial technologies, such as herbicide-tolerant soybeans and Bt cotton and maize. The distribution of planting materials for these technologies has been slowed by other factors, notably:

- biosafety regulatory problems,
- seed regulation and marketing problems,
- trade concerns, and
- intellectual property concerns.

Biosafety Regulatory Problems

This first challenge has proven to be the most formidable. Forty-eight of the 53 countries in Africa have not yet created official regulations governing the commercial release and distribution of transgenic seeds.[4] None of the large international seed companies that own commercial biotechnology products (Monsanto, Pioneer, Syngenta, Bayer, etc.) is willing to sell these products in countries that do not have a regulatory system in place to confirm their environmental and food safety. This is dictated by good business practice and concerns over liability. Many African countries are currently drafting regulations and legislation, but enactment has been slowed by the controversial nature of transgenic crops.

In Asia and Latin America, the situation is more promising—several countries have enacted biosafety regulations over the past decade, including the large countries of India, Brazil, and China. Other countries are working on it. The international seed companies have responded by seeking authorizations to market their transgenic products, but with success in only a few cases: Argentina (herbicide-tolerant soybeans), the Philippines (Bt maize), and China, Indonesia, and India (Bt cotton). In many more cases, applications for authorizations have become ensnarled in the bureaucratic complexities, nontransparency, and ever-increasing data demands of the biosafety systems. These systems require exhaustive, expensive, multiyear studies to demonstrate safety; without clear guidelines and with too much room for arbitrary requirements and decisions, standards tend to shift during the process. In Brazil, Monsanto has spent more than five years and presumably over a million dollars seeking authorization to sell transgenic soybean seeds, still without success at the time of this writing.[5] In Indonesia, the cost, complexity, and inefficiencies of the biosafety regulatory regime were important factors in Monsanto's 2003 decision to end its sales of Bt cotton seeds in that country, despite the good agronomic results and popularity of the technology with the Indonesian farmers who were allowed to grow them for two years (Chapman, Quemada, Kent, & Herman, 2003).

Particularly problematic is the tendency towards demanding extensive and costly biosafety assessments,

3. *Ingo Potrykus, the father of Golden Rice, wrote that "the IPR situation was easier to solve than expected" (Potrykus, 2001).*

4. *The exceptions being South Africa, which has approved transgenic crops for release, and Egypt and Kenya, which have approved field trials and have the potential to grant approvals for commercial releases, although they have not yet done so. Zimbabwe has regulations for field trials, and Malawi and Cameroon are reported to have enacted regulations very recently, although this needs to be verified.*

5. *Authorization has been held up by a court case brought by environmentalists to examine the authority of the authorizing agency.*

including food safety assessments, as a condition for approving preliminary field trials of newly developed transgenic crops. Such regulations risk stifling the emergence of locally adapted technologies by making it too expensive to take even the first step in moving them out of the lab and into field conditions. This problem affects public researchers even more seriously than companies.

With the costs of securing approvals becoming increasingly high, companies must consider whether these costs are justifiable in terms of potential revenues from sales. It may be worthwhile for important crops in large countries, but it may not be worthwhile for minor crops, experimental technologies, or in smaller country settings.

This implication is not well understood in many of the smaller countries currently drafting biosafety regulations and legislation. They are writing requirements, often with the support of the United Nations Environmental Program (UNEP), that will be complicated, time-consuming, and costly to fulfill. They may thereby be effectively pricing themselves out of the market for commercial technology transfer and stifling the development of any local biotechnology projects.

Seed Regulation and Marketing Costs

Making matters worse, seed markets in most developing countries are already difficult and expensive to serve. Reliable local partner companies with good distribution networks are rare, and small, poor, and widely dispersed farmers are expensive to reach. Governments pile on additional costs in each country through mandatory registration of new seed varieties, which is usually not granted until three to five years of testing are completed (for conventionally bred varieties), and through mandatory seed certification systems (which require companies to pay government inspectors to examine their production sites).

Trade Concerns

Trade concerns also play a role in blocking the transfer of commercial transgenic seeds. The reluctance of European and Japanese consumers and their governments to accept the import of transgenic commodities has diminished the enthusiasm of many developing country governments to approve their planting. In Egypt, for example, concerns about the possibility of a European import ban were a major factor in the government's decision to delay the approval of transgenic planting materials for potato. The situation is similar in Thailand, where the government's reluctance to approve transgenic crops reportedly has nothing to do with safety and everything to do with fear of losing export markets in Europe. In Brazil, many fear that the approval of herbicide-tolerant soybeans may hurt the privileged access that Brazilian soy finds in some markets when it is marketed as "GM free."[6]

According to Cohen and Paarlberg (2002), the slow uptake of transgenic crops in the developing world "is increasingly attributable to commercial fears, specifically a fear of lost commodity export sales to Europe and East Asia." They identify this fear as the reason behind China's informal halt on the approval of any new transgenic crops in the spring of 2001 and Argentina's decision in 1998 to hold back on the release of any new genetically modified (GM) food crops pending approvals of those crops by the European Union. These analysts argue convincingly that "a growing commercial fear of lost export sales to Europe and East Asia... and other political factors complicate biosafety approvals in developing countries."

Intellectual Property Concerns

Inadequate protection from piracy has been cited as a source of reluctance to market proprietary biotechnologies in developing countries that have weak or nonexistent legislation of intellectual property (IP) rights. Certainly the possibility of widespread piracy reduces projected revenues and therefore can tip the scale towards "no go" when a company compares the potential costs and revenues of a decision to enter a particular market. Why invest millions to move a genetic construct into local crop varieties when the resulting locally adapted product will be quickly copied and sold by someone else?

Cohen and Paarlberg (2002) point out that Monsanto exposed itself to significant local piracy of its Bt cotton seeds in China, where it knew IPR protections would be weak, as a price that had to be paid for gaining access to that nation's large commercial seed market. In the case of Bt cotton in India, Monsanto again went in without local IPR protection guarantees but hoped to protect itself by introducing a hybrid variety that farmers and competitors could not replicate locally. Therefore, IP

6. *This is despite evidence that any premium paid for GM-free crops is tiny compared to the savings in production costs made possible through herbicide resistance (Qaim & Traxler, in press), and despite the fact that up to 20% of the soybeans grown in Brazil are the product of transgenic seeds smuggled in from Argentina where they are approved.*

concerns do not necessarily stop technology transfer to large countries; however, the absence of IP protection is almost certainly a relevant factor in companies' decisions to develop or not develop transgenic seed products for smaller commercial markets.

What to Do?

The challenges outlined above are formidable but not insurmountable. Below I present some ideas to address them.

For Publicly Funded Projects

Patience is required. R&D projects are ongoing in CG Centers, NARS, universities, and advanced laboratories, and many are showing significant progress in product development, even if they have not yet delivered products. Some public institutions have conducted field trials in India, other Asian countries, and South Africa. Others, such as the Danforth Plant Science Center have promising transgenic crops in their greenhouses. Over time, a few of these projects are likely to succeed.

A product focus is required. Experience shows that products do not flow automatically from public research. Dennis Gosalves at Cornell University succeeded in developing a transgenic papaya and getting it into farmers' hands by remaining product-focused, not publication-focused. Often this involved tedious work completing regulatory requirements, but he slogged his way through these requirements because of his product focus. The final evaluation of USAID's Agricultural Biotechnology Support Project recommended abandoning upstream research and focusing instead on research for product development (Brenner et al., 2001). USAID internalized this recommendation and stressed product focus in its new project (ABSP-II). The request for proposals for ABSP-II solicited a "focus on the development and use of transgenic technologies" (US Agency for International Development [USAID], 2002a) and the implementing consortium responded by promising "product commercialization packages" instead of research (Cornell University, 2004). Currently, USAID appears much more interested in funding concrete steps towards product development (e.g., field trials) than it does in funding more basic research.

Money is required. Donors will need to increase funding for particular projects for them to succeed in product development. More money will be needed to produce more transgenic plants (independent lines) to select those worthy of converting into products. More money will be needed to pay for the extensive data collection efforts required to demonstrate food and environmental safety. This additional money should not be diverted away from the conventional breeding efforts underway at CG Centers and NARS—investments in those programs are too important and productive to be sacrificed. Instead, truly new money must be mobilized by those convinced of biotechnology's potential. Perhaps, one or two successes will motivate the mobilization of more investment. Current funding may need to be better focused to achieve these successes.

An appropriate regulatory framework is required. If developing countries want the benefits of transgenic products developed for their needs, they will need to make it possible, if not easy, to conduct field tests under local conditions. The current trend to enact highly restrictive regulations threatens to make it too expensive and difficult for public institutions to conduct field trials, thereby stifling the product development process. Similarly, regulations governing general releases will inhibit deployment by public institutions if compliance is overly expensive and time consuming. Through its new Program for Biosafety Systems, USAID will raise awareness in developing countries about the need to "link policy development and formulation of regulations more explicitly to considerations of implementation" (USAID, 2002b). This is an important and essential initiative that must become effective as soon as possible to provide an alternative to the antitechnology "precautionary principle" being disseminated widely by the United Nations Environmental Program and nongovernmental organizations throughout the developing world.

For Commercial Technologies

To encourage the transfer of commercial technologies, already developed, such as Bt maize or cotton, I offer these additional thoughts.

Improve biosafety regulations. The lack of appropriate regulations—either their complete absence or their impractical nature—is the biggest single barrier to moving commercial biotechnology products (seeds) into developing countries. Such products cannot reach farmers if their approval is impossible, denied, or endlessly delayed. To change this situation, the US government will need to encourage the development of more appropriate regulations in developing countries, through projects such as USAID's new Program for Biosafety Systems (PBS). To have an impact, this project will need to become actively involved in the development and dissemination of model regulations and legislation, as well as consulting, educational, and awareness-raising activities in targeted developing countries. The project will also need to build capacity to implement effectively the existing regulations. The US Department of Agriculture (USDA) and the office of the US Trade Representative (USTR) should sponsor similar efforts or funnel support through PBS, and local USAID missions will need to put additional funds into PBS to assist in the countries where they are based. Needless to say, the companies and their associations (such as CropLife International) also must continue their advocacy for transparent regulations, but because many people question their motivations, these efforts must be coordinated with public sector initiatives such as PBS.

Mobilize constituencies. Generally, agricultural ministries support the transfer of new agricultural technologies, whereas environmental and health ministries tend to raise concerns and demands that approvals be delayed. To succeed in achieving appropriate regulations and a welcoming regulatory climate, supporters of biotechnology need to strengthen the hand of agricultural ministries. This can be achieved by providing training to their leaders and staff in risk assessment. This training will raise their awareness about which biosafety questions are relevant and how can they best be answered. They will be more effective if they know, for example, that the kanamycin resistance gene has been extensively studied and judged safe by the US Food and Drug Administration and if they have access to these safety studies. These agricultural leaders will also be more effective if they are armed with ex ante studies estimating the potential benefits of transgenic crops for their farmers and if they become more comfortable with talking with the media about these benefits as well as biosafety. USAID, through its ABSP-II and PBS programs, is beginning to provide this training and support in some countries. Additional support from USAID and other proagriculture groups will probably be needed to have the desired impact. In India, it was only after farmers learned of the potential of Bt cotton and were mobilized to lobby for its approval that the necessary regulations were finalized and approval granted.

Address the trade impasse. Europe and Japan's reluctance to accept transgenic commodities represents a substantial challenge because of its negative effect on developing countries' abilities to benefit from these new technologies. One way around this constraint is to focus on nonfood technologies (such as Bt cotton) or crops that are not exported (such as Philippine corn). A complementary strategy is to seek clear assurances from Europe and Japan that they will not block the import of conventional crops from a particular developing country just because that country has approved the growing of transgenic crops. Their tolerance levels should also be set at reasonable levels. This could lessen the fear of lost markets. It will then be up to the developing countries to establish segregation systems, perhaps by ensuring that transgenes are inserted only into nonexport varieties. At the same time, supporters of agricultural biotechnology (from both the North and South) must continue efforts to raise awareness in Europe and Japan about the safety and benefits of transgenic crops—particularly the benefits for developing countries—in an attempt to change consumer attitudes and restrictive government policies. This will be a long battle.

Cultivate local partners. The large commercial biotechnology companies, such as Monsanto, know well that local commercial partners are important to working in foreign markets. They have created many such partnerships to market agrochemicals and conventional seeds. When it comes to biotechnology, such partnerships become even more important, as the local partners can play a key role in shepherding the product though the regulatory process—a role that requires excellent local knowledge and political skills. Local partners in some cases also provide crop varieties with agronomically desirable traits for gene insertion. For biotechnology to reach farmers in developing countries, the biotechnology companies will need to select and nurture strong local partners that have access to improved varieties and can negotiate the bureaucratic rapids.[7]

Create a welcoming policy environment. Onerous variety registration regulations, mandatory seed certification, and inadequate intellectual property protection are additional barriers, beyond biosafety, that discourage commercial technology transfer. By reducing the over-regulation of the seed business and implementing work-

7. *"[R]esearch costs and research sophistication decline in the progression towards downstream activities. Viewed in this way, it makes sense for national private sector companies to act as a conduit for technology flow from the global bioscience companies to developing country farmers (at least the commercially oriented ones)" (Pingali & Traxler, 2002).*

able intellectual property systems, developing country governments can welcome investment and trade in improved planting materials. USAID has encouraged governments to take these steps, through projects such as Egypt's Agricultural Policy Reform Project, but the responsibility is really that of national governments to recognize that improving their farmer's access to better seeds requires creating a welcoming—rather than a hostile—policy environment.

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