UNDERSTANDING AND OVERCOMING AGRIBUSINESS' PERCEIVED BARRIERS TO GM TECHNOLOGY DONATIONS TO DEVELOPING COUNTRIES

Honors Thesis

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by

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i. Abstract

Plant biotechnology provides unprecedented opportunities for improvements in agricultural productivity in developing countries. Multinational agribusinesses hold intellectual property (IP) rights on much of this technology. Many developing country farmers, especially in Africa, lack the purchasing power to attract private sector innovation for their specific crops; humanitarian technology donations may provide a partial solution. This study interviewed three leading agribusinesses (Syngenta, Pioneer Hi-Bred, and Monsanto) to document firsthand the private sector's perspective on technology donations and barriers for transfers. By recognizing the barriers perceived by private sector donors, potential recipients will have a more thorough understanding of the necessary conditions and prerequisites for successful collaborations.

In most cases, corporate respondents indicated donations were justified as a moral imperative and to a lesser extent, long term new market development. While IP protection and legal liability were frequently cited valid concerns, the most pressing barriers are the lack of regulatory and stewardship infrastructure/capacity in the recipient countries, product development costs and negative international opinions towards genetically modified (GM) organisms. If a country lacks functional regulatory and biosafety systems, it would be irresponsible for a donor agribusiness to introduce transgenics. Making donations to a consortium of organizations with external funding and a wide array of expertise is the preferred method, but may not indemnify the company from legal liability or provide IP protection.

The future success of technology donations will depend on countries' regulatory and stewardship capacity, a non-hostile climate for GM crops, financial support for product development, fair GM crop import thresholds and communication between parties involved in agricultural development.

Key terms: agriculture, development, genetically modified organisms, humanitarian use technology transfers, intellectual property right, technology partnerships.

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1.0 Introduction and Objectives

The implementation and proper use of plant biotechnology provides an unprecedented opportunity for improvements in agricultural productivity in developing nations. Through advanced plant breeding techniques, hybridization, biotechnology and genetically modified organisms (GMOs), developed nations have been able to drastically increase crop yields continuously over the past decades. With the introduction of Bt (*Bacillus thuringiensis)* cotton to India, adopting farmers realized a 2.5 times increase in revenue compared to non-adopting farmers (Morse, Bennett and Ismael, 2007). However, most developing countries, especially in Africa, have largely been unable to reap these benefits. They continue to suffer from pest and weed pressures, under-adapted varieties, lack of improved seed and low yields; all leading to rampant food insecurity. While it's not the panacea for all problems facing developing countries, agricultural biotechnology offers the opportunity for greater food security and poverty reduction. However, not all smallholder farmers have access to these technologies for a variety of reasons. While public research institutions hold some technology rights, significant intellectual property (IP) is held by multinational agribusinesses.

The research indicated that with the interviewed agribusinesses it is not a lack of willingness to donate use of their intellectual knowhow or technology, but rather the excessive time and costs associated with product development, the lack of regulatory and stewardship infrastructure in the recipient countries, and international opinions that are blocking the introduction of genetically modified (GM) crops into impoverished countries. With years of R&D and then expensive regulatory and approval processes, in

many cases it is commercially not feasible to sell GM crops to small farmers in developing countries with typical business planning and for-profit motives. Poor farmers can simply not afford improved seeds that costs hundreds of millions of dollars to bring to the market. Humanitarian use technology transfers (HUTTs) offer a potential solution for getting technologies into smallholder farmer's hands, but these transfers face a variety of obstacles.

HUTTs and technology transfer donations are inherently difficult to precisely define. In this study the terms HUTTS, technology donation and technology partnerships will carry the same definition of: the sharing of proprietary technology (in-kind: constructs, GM crop lines or final products) and/or intellectual knowhow from one entity to another for previously defined use, for the benefit of poor farmers. It must be noted that since there are negligible numbers of agricultural biotechnologies patents filed in least developing countries (LDCs), an LDC could recreate the event using the original patent like a recipe. Yet, most developing countries lack the scientific capacity, facilities, and organizational capacity to successful recreate advanced GM events with usable expression levels. Product development is extremely complicated and can take years of organized experimentation to obtain the desired levels of expression. Because of the difficulties associated with creating viable GM crops, most technology donations are public-private partnerships wherein knowhow and expertise are donated along with the physical technology.

In all technology donation partnerships, it must be clearly defined what 'poor farmers' are allowed to benefit from the technology since the donor retains commercial rights to the technology for all markets and demographics except for those explicitly named in

the contact. The donor retains the right to ensure proper stewardship of the technology and has no rights to royalties or financial compensation for the technology or the products created from the technology donation partnership.

Recent studies and the available literature have reported on difficulties with HUTTs and a limited number have looked into the barriers surrounding these transfers. Most of the literature focuses on case studies on particular HUTT like Golden Rice or the transgenic papaya. The literature is incomplete in assessing the private sector's perspective on technology transfer donations since few researchers have actually contacted the agribusiness firms with the capacity to do technology transfer donations and substantially reported on the company's views. These companies and the private sector are currently under-sampled in our understanding of HUTTs; this study seeks to provide a preliminary foundation for identifying key issues affecting the transfer of technology, from the private sector's perspective. This thesis is not an exhaustive study of all companies that could potentially be involved in GM technology transfers donations, but it does interview the largest and most HUTT-active agribusinesses.

Case companies will be used to determine, via interviews, what the most important issues are to multinational agribusinesses in making technology transfer donations decisions. A particular focus will be on understanding how potential donors evaluate humanitarian donations of the use of proprietary agricultural biotechnology, in particular GM crops, and what the motivations are behind such donations. Substantial concerns over IP, legal liability, product stewardship, and regulatory process and how to overcome these obstacles will be discussed.

The goal of this study is to provide insights on identifying and overcoming barriers to transfers to the end that technology donation collaborations would be more successful in delivering valuable technology to the hands of poor farmers. By recognizing the barriers perceived by private sector donors, potential recipients will have a more thorough understanding of the necessary conditions for a successful donation and the requisite preparations. In theory, the most altruist end objective would be to use technology donations as a tool to increase agricultural productivity, resulting in increased food security and improved standard of living for farmers in developing countries.

2.0 Literature Review

"Globalization, despite its many problems, now enables the mobilization of worldwide science and technology for the betterment of humankind. However, the promise is ours only if we manage to deploy improved products to the poor and wealthy alike" (Krattiger, 2000). The ability to gain access to and deploy valuable technologies is the challenge on which this study attempts to shed light.

2.1 Studies on the Effects of GM Crops

2.1.1 Globally, primarily developed countries

In 2008, 25 countries were commercially growing GM crops, a steady increase from six in 1996 when GM crops were first introduced (James, 2008). A yearly study of commercialized biotech crops shows that of the "$44 billion in economic gains from GM crop adoption, 44% were due to yield gains and 56% due to a reduction in production costs" (James, 2008). To reach the current world yield levels without GM crops, 43 million additional hectares of crops would have had to be planted, something the world can simply not achieve (James, 2008).

A study analyzing the average performance and impact recorded in different GM crops found that in 2005 the direct farm income benefit from growing GM crops was about $5 billion (Brookes and Barfoot, 2006). Beyond income gains, GM crops in 2005 alone allowed for the "permanent carbon dioxide savings from reduced fuel equivalent to removing 430,000 cars from the road" (Brookes and Barfoot, 2006). Many of these reductions in carbon dioxide are accredited to being able to use no-till farming,

requiring less tractor use. The environmental impact of agriculture was reduced by 15.3% in the cropping area devoted to GM crops since 1996. In cotton, gains from GM adoption can be assessed at $8.44 billion, equivalent to "adding 7.3% to the value of total global cotton production." The combination of insect resistance and herbicide tolerance technology has increased incomes from maize by $3.1 billion in the last 12 years (Brookes and Barfoot, 2006).

A global computable general equilibrium analysis of the impact of the adoption or non-adoption of Bt cotton found that "annual economic welfare is estimated to have been enhanced by more than $0.7 billion from this technology's adoption since 2001"(Anderson, Valenzuela & Jackson, 2008). The study used a GTAP model of the global economy to evaluate the effects of governments allowing GM technology adoption, indicating that benefits were most accrued to the first four GM-adopting nations. This was at the cost of the non-adopting countries, which were negatively impacted by the 2.5% decrease in international cotton prices resulting of Bt cotton introduction (Anderson et al., 2008). While in general GM crops have had global benefits, there is increasing pressure to adopt to be able to compete with the increased yields and lower costs that the GM crops can generate.

2.1.2 Developing countries

According to ISAAA, the International Service for the Acquisition for Bio-tech Applications, the developing countries that as of 2009 had commercialized GM crops included Brazil, Argentina, India, China, Paraguay, South Africa, Uruguay Bolivia, the Philippines, Slovakia, Egypt, Costa Rica, Honduras, Colombia, Chile, Mexico, and

Burkina Faso. In this section of the literature review, when the term 'developing countries' is used, it refers to those listed.

From "1996 to 2005, developing country farmers have acquired 47% of the total ($27 billion) farm income benefit with both large and small farmers adopting GM crops" (Brookes and Barfoot, 2006). In 2008, the number of developing countries growing GM crops outnumbered the developed countries 15 to 10 (James, 2008). Furthermore, of the "8.5 million farmers using GM crops globally, over 90% are resource-poor farmers in developing countries" (Brookes and Barfoot, 2006). These statistics strongly support that adoption and benefits of GM crops are not restricted to developed nations, just restricted to those nations whose governments approve the introduction and growth of GM crops.

2.1.2.1 Bt Cotton

A study conducted by the University of Reading explored the impact of adopting Bt cotton on farmers in Maharashtra State, India. A questionnaire-based survey of 450 cotton producers was done in 2004, collecting data from Bt adopting and non-adopting farmers for the 2002 and 2003 growing seasons (Morse, Bennett and Ismael, 2007). The research sought to evaluate both the impact on household incomes and on inequality between 'better' and poor farmers. It was determined that adopting households had 44% higher income from cotton than non-adopting households. Based on gross margin, Bt plots had 2.5 times the gross margin of non-Bt plots of non-adopters (Morse et al., 2007). Also, there was enhanced income equality among the adopting group, something GM crop critics argued would not occur. This case clearly

illustrates the positive economic impact of a GM technology on all adopting farmers and that the technology adopting actually decreased income inequality.

2.1.2.2 Golden Rice

Golden Rice (GR) has become the post child of GM crop humanitarian use technology transfers. The project focuses on alleviating vitamin A deficiency (VAD) in developing countries by genetically engineering rice to make the vital micronutrient bio-available in the worldwide staple crop. The research is made possible by a public-private partnership, with Syngenta donating rice lines containing a proprietary transgenic event (Al-Babili and Beyer, 2005). This international consortium includes 16 public research institutions (in India, The Philippines, China, Bangladesh, Indonesia, Vietnam and South Africa) working to further develop the technology and lay the groundwork for potential release in their countries (Al-Babili and Beyer, 2005).

A study conducted by researchers from the University of Bonn quantitatively analyzed the potential impact of GR on the Philippines. Their findings supported that mitigating problems of blindness and premature deaths through the introduction of GR could have social benefits ranging between $16 million and $88 million per year and could avert 798 (optimistic scenario) child deaths per year (Zimmermann and Qaim, 2004). Since GR has not yet been commercially released, the study depended on an ex ante perspective and measured impact based on the technology efficacy (health improvement of VAD people) and coverage rate (fraction of population consuming GR). Impact was quantitatively evaluated by comparing the number of disability-adjusted life years

(DALYs) lost from VAD with and without GR, and the difference was interpreted as the technology's impact (Zimmermann and Qaim, 2004).

2.1.2.3 Transgenic Papaya

The transgenic ringspot virus resistant papaya contains the potential to revive the suffering Thai papaya crop. Papaya is high in vitamin C and pro-vitamin A carotenoids, which indirectly facilitates iron uptake. The fruit addresses two of three major micronutrient deficiencies in one product. While the transgenic papaya was first commercialized in Hawaii in 1998, progress in Thailand has been negatively influenced by an on slot of Greenpeace sponsored scare tactics. Sarah Davidson explains that despite the fact that it is "genetically engineered, the virus-resistant papaya is close to an ideal 'pro-poor' genetically engineered crop" (Davidson, 2008). The ringspot virus is currently affecting many regions in Thailand with infection rates closed to 100%, causing drastically reduced yields. With government approval and strong farmer adoption of the transgenic papaya, the negative impacts of the virus could be alleviated and high yields for a staple crop restored.

2.2 Humanitarian Use Technology Transfers (HUTT)

2.2.1 Market segmentation

India and many other developing countries are considered growth markets by multinational agribusinesses. The introduction of a publically available open pollinated variety of Bt eggplant into India is a recent example of a humanitarian use technology transfer (HUTT) that is also based in strategic business interests. A study by Deepthi

Kolady indicated "it is commercially viable for a firm to donate the [Bt] technology for poor farmers' use by restricting use to open pollinated varieties (OPVs) while selling hybrid [Bt] seeds." The case study quantitatively demonstrates that when market segmentation is possible and there are "two distinct levels of production technology" (Kolady, 2009), that HUTT is commercially viable since it allows "Mahyco [the owner of the Bt technology] to maximize revenues according to farmers' willingness to pay for higher productivity." While market segmentation was effective in this case, companies may be concerned donating technology could dilute future profitability of growing markets. Failure to properly target donations creates the situation that profits are lost if there are farmers that would have purchased the technology in the market had they not been granted preferential access via HUTT (Lybbert, 2002).

2.2.2 Barriers to HUTTs

2.2.2.1 Intellectual Property Rights

The current nature of IP rights regimes in developing nations creates a major barrier for biotechnology donations. Because of the ever-increasingly complex IP situation, there have been no instance of technology donations that included full Freedom-to-Operate (FTO); only partial licenses have been brokered to-date (Krattiger, 2000). With Golden Rice alone, there were "70 IPRs belonging to 32 different companies and universities" from which the project had to obtain free licenses for FTO (Potrykus, 2001). "Many of the countries that the ISAAA works with are not sure where to start" with developing intellectual property regulations since it is new to them. These countries therefore have little capacity to manage intellectual property issues and since having some sort of IP

framework in place is “a prerequisite to obtaining” new proprietary technologies, donations are inhibited (Kryder, 1999).

Dr. William Lesser of Cornell University took a quantitative approach to measuring the IP rights strength in terms of compliance with selected international IPR conventions, enforcement, administration and duration of protection. Strong IPR scores are positively and significantly associated with increases in both imports and foreign direct investment (Lesser, 2002). Without appropriate levels of IPR, firms will have to weigh in a greater set of risks that may come from “leakages of technology to unintended beneficiaries” which can then “erode the suppliers return on investment” (Lybbert, 2002). This can make “the cost of the donation to the supplier increase dramatically” (Lybbert, 2002), decreasing the incentive for continued HUTT and future donations. With the risk of losing control for a donated technology and it being used by untended beneficiaries, donor companies could be creating or strengthening competitors who will use their technology against them.

Some developing countries lack a historical respect for IPR. According to the literature, countries entirely lacking in biotechnological research capacity “often possess a history of technology piracy and are seen by the owners of biotechnology components as unacceptable recipients of the latest agri-biotech products” (Krattiger, 2000). Also, donors have the valid fear that their IP will become public property since they lack the legal means to enforce property rights. Poorly defined ownership with technology involving multiple stakeholders’ technologies can create problems and complexities (Lybbert, 2002).

2.2.2.2 Regulation

To ensure only technologies free from negative environmental and health impacts are introduced into any market, regulatory and biosafety systems with well-trained and informed personnel are critical in each country. With this said, relatively few developing countries have appropriate biosafety policies and procedures in place. Biosafety policies include the ability and the knowhow to first evaluate transgenic crops on various safety criteria and then be stewards of the technology after it has been released, ensuring the products are used properly and within the approved region. The lack of these policies is a growing concern for both countries under the continuous scrutiny of international non-governmental organizations (NGOs), such as Greenpeace, and for technology donors (Brenner, Sampaio, Sittenfeld, 2001). From the donor's point of view, any problems with biotechnology in one region "will adversely affect their business elsewhere" (Hautea, 1999). The absence of developed biosafety regulations effectively blocks technology donations and the field trials needed for the introduction of urgently needed improved crops.

2.2.2.3 Capacity

In order to carry out biosafety and regulatory policies effectively, technical capacity is required. This capacity is a "prerequisite for technology adaptation and long term growth" (Krattiger, 2002) and is lacking in many developing countries. The Agriculture Biotechnology Service Project (ABSP) identified the need to "improve the capacity and policy environment for the use, management and commercialization of agricultural biotechnology in developing countries and transition economies" (Brenner, et al., 2001).

One way to motivate and support biotech capacity building is "through technology donations, where countries can build their biotech capacity as they develop and deploy improved transgenic papayas to meet the needs of their small-scale farmers" (Kryder, 1999). This can create problems if those donating the use of their transgenic technologies are unwilling to transfer technologies without assurance those technologies will be handled properly. For this kind of capacity development to take place, the donation would have to occur in an active public-private partnership, wherein the donating company would be active throughout product development and testing. Capacity built through donations can make those countries more attractive for future commercial introduction of GM crops. The effort that is required to operate functional biosafety and stewardship frameworks should not be underestimated since "the efforts required to broker a biotech transfer deal pale in comparison to ensuring the proper functioning of all institutional interactions at the downstream end" (Krattiger, 2000).

2.2.2.4 Public Perceptions

Publicly visible companies can be scrutinized for every action they take. Activity in GM crop technology donations creates the risk of consumer backlash fueled by anti-GMO third parties trying to dissuade developing countries from adopting GM crops. With non-assert transfer agreements, while the donor company is not involved with the biosafety and food safety testing, they can still experience reputational damages if the recipient organization is not thorough or does not uphold the expected stewardship standards. Risks go beyond the safety of the technology since "the opposition to GMOs in Europe increases the reticence of bilateral and multilateral institutions to support projects involving GMOs" (Krattiger, 2002). Without other financial donors, the

funding levels necessary to bring a donated technology to the market can be too great to overcome. If a transgenic crop is successfully created, difficulties in distribution should be anticipated because of the situation in Europe and the value of the European market for many producers in developing countries. If the goal is actually have a transgenic product commercialized, the issue of public awareness and acceptance has to be taken into consideration from the onset of the project (Brenner, et al., 2001).

3.0 Research Methodology

3.1 Selection of Companies

Three international agribusinesses were selected to interview for the thesis, Syngenta, Pioneer Hi-Bred (Pioneer) and Monsanto. These companies were selected based on: their position as leaders in plant biotechnology and/or seed sciences; possession of patents, novel plant breeding varieties and access to germplasm; involvement in international markets; past instances of humanitarian use technology transfers (HUTT) to developing countries; and the author's personal contacts with the companies, directly or indirectly.

Due to time and money constraints, the focus of the thesis is on the largest, most relevant (holding technologies, financially able to make transfers) companies. The largest firms also have the greatest experience with HUTT and the greatest opportunity to make effective donations over the coming decade

3.2 Interview Tactics and Questions

Research was conducted primarily via interviews using direct questions and brief scenarios. In the scenarios an example of a situation, e.g. donating technology for cassava transformation in East Africa, was given and the interviewee was asked how the company would respond in that circumstance. The goal was not to learn company secrets, but to have a discussion of technology transfer donations that the interviewee felt comfortable discussing many facets of these donations. While the interview form had a set list of questions, they were used more as a guideline of topics to cover rather than a set order. Interviewees tended to talk about donations in broad terms and the

questions were used to guide the conversation towards discussion of barriers and overcoming those barriers. Handwritten notes, taken during the interview, were the only form of recording used. The notes were typed and sent to the interviewee for review to check for content accuracy and correct portrayal.

The interview questions and the way they were presented were tailored to the organization and particular person being interviewed. Interviews were conducted with a variety of different departments to gain insights from a several relevant perspectives (e.g. legal, R&D). The general questions that the research sought to answer are listed below; the full questionnaire is at the end of this section:

1. How does the technology transfer donation decision making process work?
2. What are the barriers to making donations that the company can influence?
3. What policies at the developing country level can be modified to encourage technology transfer?
4. To and with whom do agribusinesses prefer to work with and why?

3.3 Preliminary Interviews

To help ensure effective interviews and questions, preliminary interviews were conducted with faculty and staff at Cornell University who have worked with HUTTs. The interviewees were recommended by Dr. Lesser, other professors, and the interviewees themselves. A questionnaire was developed, under the oversight of Dr. Lesser, with core questions to address a range of areas on barriers to donations, decision making processes and current projects. The preliminary interviews were used to improve interview technique, tailor the wording of the questions, and identify other

areas of questioning. After each interview questions were revised and effective interview techniques discussed. Each of these interviews were conducted in person and lasted between 30 minutes and one hour.

3.4 Preliminary Interviewees and Qualifications

Dr. Richard Cahoon is the Director of Plant Variety and Germplasm Licensing at the Cornell Center for Technology Enterprise and Commercialization (CCTEC). He works on licensing Cornell's portfolio of agricultural intellectual property. He worked extensively on the transgenic papaya project in Thailand, partnering with the Thai Department of Agriculture and negotiating with third parties.

Dr. K.V. Raman is a professor in Plant Breeding and Associate Director of the Agricultural Biotechnology Service Project II (ABSPII). He has handled technology donations with Monsanto and played a key role in negotiating with the private-public sector players in the open pollinated variety donation of Bt eggplant in India.

Dr. Frank Shotkoski is the Director of Agricultural Biotechnology Service Project II (ABSPII) where he oversees crop biotechnology development projects with developing countries. He worked for Syngenta running a research program on new insecticidal proteins to engineer insect resistant crops.

Dr. Sarah Davidson is a research associate for Durable Rust Resistance in Wheat in Cornell University's International Programs. She has written extensively on the Thai transgenic papaya project and worked with Thai farmers and the government.

3.5 Agribusiness Contacts

The primary sources for this thesis were interviews conducted with employees of three agribusiness companies. The author had contacts with Monsanto from when they sponsored her summer internship at the World Vegetable Center in Taiwan. That Borlaug-Ruan International Internship was through the World Food Prize (WFP) Foundation, which has a close relationship with Pioneer. The WPF graciously put the author in initial contact with Pioneer's sustainable agriculture department. During summer 2009, the author had an internship with the Syngenta Foundation, at Syngenta. This internship at the international headquarters allowed for access to all relevant personnel within the company. This access also meant that a greater number of interviews were conducted with Syngenta than with either Monsanto or Pioneer. Also, the Syngenta employees that were interviewed all had some connection to technology transfers, but not all of them were line responsible for transfers. All those interviewed in Monsanto and Pioneer had been directly active in technology transfer donations. These differences in sampling were taken into consideration

Interviews were conducted both in person and over the phone. With Syngenta, most of the interviews were conducted over the summer in person at the company's headquarters in Basel, Switzerland. For both Monsanto and Pioneer, all interviews were conducted over the phone. Each interview lasted between 30 minutes and 1 hour, regardless of the mode of communication. There is no reason to believe the interview method affected to outcome, but the possibility that respondents replied differently in personal interviews must be recognized. In particular, during personal interviews respondents may have been less willing to disagree with the underlying thesis of the

research that humanitarian donations are beneficial and possible than they would have been over the telephone.

One person in each for the three target companies agreed to be the 'point person.' To ensure confidentially and an accurate portrayal of the company, this individual received copies of all interview notes and had review of the content of the company case study. The case study goal was to illustrate the company's positions and actions and not to reveal confidential information. This approach encouraged the employees to speak freely in interviews, knowing everything published would be reviewed. The study conclusions are those of the author alone and the companies were not invited to comment on these conclusions.

During the interviews, the contacts were asked to recommend others in their company who would be pertinent to speak for the thesis research. This method was effective in gaining contacts, especially when interviewees would serve as references within the company or even email relevant people concerning the interviews.

3.6 Interviewees and Credibility

3.6.1 Syngenta

Dr. Marco Ferroni is the Executive Director of the Syngenta Foundation for Sustainable Agriculture (SFSA) that works with farmers in developing countries. He is the chair of the technology donations and stewardship council that reviews potential technology transfers.

Dr. Michael Kock is the Head of Global IP for Seeds and Biotechnology. He handles the legality of IPR through working on company policy and with associations.

Dr. Mike Robinson is the Chief Science Adviser for SFSA wherein he supports project portfolio development and strategy. He assesses potential public-private partnerships and evaluates how Syngenta's technology can be used to address smallholder farmer's needs.

Dr. Partha DasGupta is the Regional Lead on Biotechnology Regulatory in the Asia Pacific region. He focuses on the commercialization and releasing of new biotechnology products.

Dr. Robert Berendes is the Head of Business Development and on the executive team, working on strategy and planning. He was involved with the Golden Rice humanitarian donation project and other public-private partnerships.

Dr. Vivienne Anthony is the Consultant on Regulatory Affairs and Technology Donations for SFSA. She advises on how technology transfers should work and runs a project to build biotech and stewardship capacity in developing countries.

Dr. Anders Binder is the Biotechnology Consultant for SFSA. After 25 years running the company's biotechnology department, he now advises on how Syngenta's biotechnology can be used to benefit developing countries.

Dr. David Nevill is the Head of Biotech Development. He is responsible for managing the company's stewardship and development of biotech products.

3.6.2 Pioneer Hi-Bred

Dr. Bill Niebur is the Vice President of Crop Genetics Research and Development. He is serving on the Private Sector Committee with the CGIAR centers to facilitate collaboration between the public and private sectors.

Lloyd Le Page is the Sustainable Agriculture Manager wherein he seeks out possible technology transfer collaborations and facilitates transfers donations for Pioneer.

Dr. Stephen Smith is a Research Fellow in Germplasm Security and has worked on collaborations with CGIAR centers. He facilitated Pioneer-DuPont's contribution to the Global Crop Diversity Trust endowment fund.

Dr. Peter Freymark is the Research Coordinator for Maize Product Development and works on developing and coordinating collaborations with the CGIAR and CIMMYT. He is on the advisory board for the Drought Tolerant Maize for Africa (DTMA) project.

Dr. Marc Albertsen is the Research Director and has been involved with coordinating public-private-private research collaborations for the development of basic technologies.

3.6.3 Monsanto

Dr. Ted Crosbie is the Vice President of Global Plant Breeding and is involved in coordinating the collaboration between the company, Gates Foundation and CIMMYT on Water Efficient Maize for Africa (WEMA).

Dr. Fred Perlak is the Vice President of Research and Business Operations in Hawaii and had worked in evaluating technology transfer donations and collaborations. He was one of the founders of WEMA.

Elizabeth Vancil is the Technology Sharing Manager and works on sharing for the benefit of resource poor farmers in developing countries. She has also been involved with negotiating technology license from the public sector perspective and dealing with private agribusiness.

3.7 Sample Interview Questions

General

What has been your involvement with the company?

What has been your involvement with technology transfer donations?

Why does the company do technology transfer donations?

What are current and past technology transfer projects the company has undertaken?

Are developing countries a commercial growth area in the next 3 years, 15 years?

Barriers and issues that arise with tech transfers

What are the legal liability concerns? How can they be overcome?

How could the company indemnify itself from donation-related liability?

How do stewardship capacities of the recipient country factor into the technology transfers donation decision? How can inadequate stewardship capacities be overcome?

Are the existence and enforceability of intellectual property rights important with donations? How can poor IP protection capacity be overcome?

How do regulatory and approval processes in the recipient country impact donations?

How would harmonization of approval processes by region impact donations?

Is the amount of management's time necessary for the evaluation and logistics of technology transfers taken into consideration?

Transfer Motivations, Decisions

What is the internal decision making process for technology transfer donations?

Who usually approaches the company for technology donations?

Does agribusiness have a moral obligation to share technology?

3.8 Data Analysis

The company opinions, gathered through interviews, were evaluated for patterns with respect to perceived barriers, how to overcome these barriers, what the company values in a technology transfer donation and the justification for making donations. The common barriers and the reasons for these barriers were compared to the results of the literature review. The review focused on case studies written about past technology transfer donations and reports by organizations that facilitate technology transfers. This provided a baseline of information on how academic and practical research perceived and experienced barriers to technology donations. A comparison between the literature and the direct agribusiness interviews illustrates the understanding between the private sector and others, leading to a more thorough awareness of how to work with donors for successful transfers. The companies' decision making processes were analyzed and recommendations were made on effective means for collaborating on technology transfer donations with companies.

4.0 Case Studies

The objective of the case studies is to provide in-depth examples of how agribusinesses evaluate and justify technology transfer collaborations, assess key barriers and how they are currently involved with GM crop technology transfers. The goal is to provide illustrations of the current GM technology transfer environment and to provide a basis for theorizing on what is necessary for the future of humanitarian technology transfer donations.

4.1 Case Study: Syngenta

Preface

The primary information sources for this case study were personal communications from telephone and in-person interviews conducted from June to September 2009 with employees of Syngenta. Eight people were interviewed regarding their and the company's views on GM crop technology donations and collaborations with developing countries. Each interviewee has an informed and relevant view on technology donations. This research would not have been possible without their generosity and patience.

4.1.1 Introduction

Syngenta is recognized as one of the world's leading agrochemical companies. They focus on realizing 'plant potential' by integrating genetics and biochemistry to find solutions to plant hardiness in novel ways. The Syngenta Foundation for Sustainable Agriculture (SFSA), Syngenta's independent foundation, does philanthropic work with

farmers in developing countries and would be a possible venue through which future technology transfer collaboration would occur.

With products in crop protection (chemical), field crop seed, vegetable seed, and flowers, Syngenta is active in diverse markets. The company spent roughly $1 billion in acquisitions and research in the past years to build up its seed business, now with 6,000 conventional and genetically modified varieties (Hoover.com, 2009). The seed division is a $3 billion business, which is huge growth from just several million a couple years ago. Along with this growth comes much a better understanding of the seed business and technologies. This growth would make the company a strong future collaborator on technology transfers projects.

4.1.2 Justification for donations

4.1.2.1 Future Market Development

Improvement in the livelihood of farmers from technology transfers could also create future market development opportunities. While most African markets are not immediate growth areas for the company, technology partnerships do allow for GM crop introduction and early positioning in the minds of farmers/potential customers. Cynics would view technology transfers just as investments in future markets. The company believes that it is critical to assert that these donations are purely humanitarian and would be fully transparent. While in the best case, the company could benefit from a viable market in the long term, achieving food security is the first priority, regardless of the immediate impact on the bottom line (Binder, personal communication, 2009).

4.1.2.2 Public Relations (PR)

Collaborations on technology transfers for the benefit of poor farmers could generate positive PR and reputational gains for the company. While some regard humanitarian technology transfers as the private sector living up to a moral obligation, there is the potential for backlash from anti-GMO organizations which could use these donations in their arguments against GMOs and against the companies that make them. However, the group Syngenta most cares about building a relationship with is the small farmers that receive the technology. The intended beneficiary would likely hold the company in higher regard, or just recognize their name in a positive light for potential future dealings.

4.1.3 Evaluation of Collaborations

4.1.3.1 Potential Project Evaluation

Evaluation of potential projects and collaborators is taken seriously by Syngenta. All GM crop technology donation requests are assessed on a case-by-case basis, with benefits and risks being carefully weighted. Donations to public institutions or consortia (as with Golden Rice) are the preferred mode since the recipients are professional and experienced. The projects are evaluated based on the stewardship ability, regulatory framework and process in place in the region, and the corporate and public affairs impact of the project. If an organization is lacking in one of the areas, the company would be willing to donate expertise to help with skill development within the partner organization (Berendes, personal communication, 2009). Communication between

Syngenta and a consortium as well as communication between the project and government are essential for a successful project.

4.1.3.2 Decision Making Process

To ensure a thorough evaluation, a technology donations council made up of the functional heads of regulatory, technology performance, patents, legal, public affairs, communications, licensing, and stewardship review the request. Time and high level personnel involvement are critical in identifying meaningful technology applications with acceptable levels of risk. The council makes a recommendation that balances the risks and the benefits to Syngenta if the donation is made. It is important at this step that the benefits are made clear, both to Syngenta and to the recipients of the transfer (Anthony, personal communication, 2009). The recommendation is reviewed by a corporate responsibility council, made up of top leaders in the company, and a final decision is made. The process takes into consider all the functional areas of the company to ensure due diligence and that the technology transfer is the proper use of the company's technology for the given problem and region.

4.1.4 Current Projects

4.1.4.1 Golden Rice

A technology donation partnership Syngenta is working on is the Golden Rice Project, lead by the International Rice Research Institute (IRRI). The consortium seeks to combat vitamin-A deficiency (VAD) in developing countries through biofortification of rice, the stable food crop in many regions. The potential impact of this project is

tremendous; “according to the World Health Organization, dietary VAD causes 250,000 to 500,000 children to go blind every year, more than half dying within a year” (GoldenRiceProject.com, 2009). Successful levels of expression and distribution into to the food system could drastically reduce the number of VAD individuals in a few years.

The company donated internally developed rice lines that contain genetically modified GR2 technology. GR2 reflects a change in the promoter, causing more carotenoids to be expressed and stored in the rice kernel (Anthony, personal communication, 2009). This is a purely humanitarian donation, and while the company retains the rights to Golden Rice in commercially important countries, they are donating its use and distribution to farmers in developing countries royalty-free. The donation does come with conditions regarding the stewardship to guarantee testing and regulatory affairs are done thoroughly. In order to insure proper use of the technology, the company has remained active with supplying expertise in regards to regulatory dossiers required for approval in target countries.

In the licensing agreement, IRRI has to make sure that it and its rice breeders in the countries uphold the company’s high stewardship standards. The first phase is working with the initial four target countries - Philippines, Bangladesh, Vietnam, and India. Since all have existing regulatory frameworks mentioning GMOs, Syngenta will assist in creating a thorough regulatory dossier with biosafety, environmental, toxicology, and allergenicity testing (Ferroni, personal communication, 2009). Thorough testing is critical for the deregulation of an event in a country and for the population to feel safe growing and consuming that product. The lines the company donated also contain proprietary technology that has commercial potential for the company in products

outside of the humanitarian Golden Rice. With this other commercial potential, Syngenta is interested in supporting the development of a strong regulatory system to both ensure that the donated events are tested correctly and are property regulated after being released to farmers. The public consortium may be more focused on having this single event approved, while private sector companies are looking at the longer-term potential of introducing other GM crops when the domestic markets are ready to support them.

4.1.5 Barriers

4.1.5.1 Intellectual Property

Concerns over the protection of IP rights are commonly thought to be the major barrier to technology transfers. While protecting valuable IP is a key consideration in making donations, it is not the most significant concern for Syngenta. IP is relatively well defined and respected in the developed world, but when working in developing countries the culture can differ on accountability and trust. With donations, it can become unclear who controls what technology especially when the donated GM lines are crossed into locally adapted varieties. However, these issues typically lead to liability concerns more often than IP issues. While IP is a legitimate barrier, access to proprietary information can be negotiated (Ferroni, personal communication, 2009) and in some cases IP concerns are not actually relevant.

When a technology is patented the owner must decide in which countries to file for protection. Since the least developed countries have little near-term business potential and since no other major multinational competitors are patenting their technologies in

these countries, Syngenta does not file patents either. Even if there were a filing (recognizing many countries lack the infrastructure to evaluate GM crop applications), Syngenta would not be able to control their products or stop generic reproduction in many countries.

Since no patents are filed, the least developing countries could essentially recreate the event using the original patent like a recipe. Yet, most LDCs lack the scientific capacity, facilities, and organization to successful recreate advanced genetically modified events with usable expression levels. Product development is extremely complicated and can take years of organized experimentation to obtain the desired levels of expression. Recreating a company's technology without their assistance, access to their constructs, or their biosafety/toxicology data greatly increases the time and expense of product development.

4.1.5.2 Liability

A critical concern is the potential exposure to liability Syngenta could face through donating a GM crop technology for humanitarian use. With any GM technology donation, ownership and liability will lie with the donating entity. The most common definition of a donation, in which one group simply gives to another, is not feasible with GM technology. When an organism is genetically modified, it can be easily identified as such and will have been registered with a patent publically explaining who the creator is and who has ownership. While conventionally grown lines can also be registered and identified using molecular techniques, these lines are not thought to carry with them unknown risks. Companies have been willing to donate GM crop lines and

events in many situations in the past, but the donation can only be for the use of the event since in most cases the liability still rests with the creator. Therefore while use is donated, for safety and stewardship reasons, the ownership and liability still could lie with the company that created the technology.

The main source of liability concern is with new transgenic products moving from their intended distribution area into international trade where it could enter countries that have yet to deregulate the event. If an incident like this occurred, it could be very expensive, both in monetary fines and in reputational damage (Kock, personal communication, 2009). Working with only locally consumed crops that do not have an international market would decrease the chance the product would surface internationally, but the situation would still have risk.

Ways to decrease the likelihood of liability issues include being selective regarding the organizations that the company works with on technology transfers. Dealing with professional organization lowers the likelihood of an incident since a professional organization would have more experience in their specific area and would have more internal expertise to deal with technologies appropriately. Recipient organizations would also have to guarantee long term stewardship of the technology and evaluating their financial stability could be one indicator of their ability to carry this out.

4.1.5.3 Stewardship

When the company transfers a technology it is obligated, by company tradition and standards, to ensure that the technology is used correctly and that proper stewardship ensures safe use after release to farmers. This is a substantial commitment and the

interviews indicated that Syngenta is not willing to compromise its stewardship standards when entering a developing country. The recipient country needs to have stewardship and regulatory capacity; both are almost always critically lacking and require capacity building. Stewardship is one of the most significant barriers since Syngenta requires biosafety standards to be at the company's expectation level.

To address the lack to stewardship capacity in African countries, SFSA is running Strengthening Capacity for Safe Biotechnology Management in Sub Sahara Africa (SABIMA), a project focused on capacity building for compliance and stewardship. SFSA recognizes that projects like SABIMA are helpful in laying the foundation for effectively handing of future GM technology transfers. SABIMA works with the Forum for Agricultural Research in Africa (FARA) to spread biotech knowledge by attending to the need for biosafety education. Scientists acquire knowhow on how to conduct stewardship steps, such as confined field trials. The goal of the project is to put procedures in place that would support countries when they make their own, informed decision on biotechnology and its role in their country (Anthony, personal communication, 2009).

Unique stewardship concerns arise with GM crops, especially those with insect resistance like Bt. Developed countries have refuge requirements to help ensure that insects do not become resistant to the effects of the transgene. For example, with single gene technologies the farmer can plant 80% Bt, but must also plant 20% conventional as a refuge for harmful insects. Without the refuge of non-insect toxic crops, selective pressures would be too strong and Bt resistant insects could evolve rapidly. Refuge management and other stewardship compliance can be technically

complex and difficult to establish in countries lacking the institutional capacity to teach and education farmers about them. Resistant insects would hurt both the donated crops and have hazardous impacts on crops that companies could commercialize in the region. One way to reduce the possibility of insect resistance is through more fool proof technology which utilizes a double mode of action like stacking multiple resistance genes. But to do this, technology from multiple companies would be required (logistically and legally difficult) and would then have to be bred into well adapted, high yielding varieties.

4.1.5.4 Regulatory

Regulatory systems are crucial for the deregulation of a GM product in a country and for the long-term stewardship of the product. Currently regulatory systems in developing and developed countries create serious barriers for technology transfers. While these systems need to change, developed countries hold significant power to make the necessary changes to import restrictions. More developed countries can effectively block the introduction of GM crops in developing countries by imposing ultra strict import regulations - there is currently a zero threshold level on regulated GMOs. With the fear of losing their export markets, the prohibitively low thresholds dissuade countries from growing GM crops.

Establishing a framework of mutual respect of safety regulations in Africa, as well as globally, is a step towards regulatory system harmonization. Harmonization of regulations would dictate that if a product is deemed safe in the US then it would have to undergo only region-specific regulatory testing in Europe (Neville, personal

communication, 2009). Since health issues from GM crops are considered broadly identical worldwide, a thorough health review from the US would be considered satisfactory in other harmonized nations. Environmental reviews, which assess the impact of the introduction of the GM crop on the local flora, fauna and wild relatives would need to be conducted in each country/region into which the crop would be introduced. Harmonization would alleviate some, but not all of the regulatory and approval processes. However, harmonization can be a political issue since some could argue that it is a matter of national sovereignty. Harmonization would make some deregulation costs lower (costs have been rising for years) and could make it less cost inhibitive for companies to make GM products for small markets if they did not need to conduct as extensive of regulatory testing in every country (Robinson, personal communication, 2009).

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4.2 Case Study: Pioneer Hi-Bred

Preface

The primary information sources for this case study were personal communications from telephone interviews conducted during October, 2009 with Pioneer employees. Each interviewee has an informed and relevant view on GM technology donations, all have been involved with them in the past or are currently. This research would not have been possible without their generosity and patience.

4.2.1 Introduction

Pioneer is respected as a "leading developer and supplier of advanced plant genetics to farmers worldwide" (Pioneer.com, 2009). The company was founded in 1926 and has fostered a strong partnership with the farmers they serve in over 80 countries worldwide. It is an exclusively seeds-oriented company (no involvement with chemical crop protection) and "develops hybrids of corn, sorghum, sunflower, canola, and rice, and varieties of soybean, alfalfa, wheat, and canola through 90 worldwide research facilities" (Pioneer.com, 2009).

In 1989, Pioneer became involved with plant biotechnology when it began operations on canola seed. In 1993, it entered into an arrangement wherein it purchased favorable licensing and the rights to use the Bt technology in its commercial corn lines (Charles, 2001). The company's introduction of Bt corn and herbicide-tolerant soybeans in 1997, formally entering into the GM crop business. Upon Pioneer's acquisition by DuPont in

1999, its research budget increased from $50 to $200 million (Charles, 2001), enabling the company to build a global market and research presence in plant biotechnology.

Lloyd Le Page, Technology Acceptance and Sustainable Development Manager, explained that with "80 in 80 – 80 years in business and with sales in nearly 80 countries" (Le Page, personal communication, 2009), the company has market and technological knowledge valuable in collaborations with developing countries. The experiences recently gained in working with new products and regulatory systems in developing Asian and Central American markets can be beneficial when working with Africa.

4.2.2 Justification for donations

4.2.2.1 Moral Imperative

"We have a moral imperative to drive agricultural productivity if we want to have any legitimacy. Our stakeholders and board expect us to use our technology for the prosperity, economic development, and food security for those around the world," stated Bill Niebur. This view is deeply engrained in the company. With a strong tradition of community involvement, Pioneer has taken this commitment to the next level with collaborations using their technology and talent to create improved crops for farmers in developing countries.

Stephen Smith and Peter Freymark explained that part of the rationale for making technology donations comes from the belief that any technology that is just sitting on the shelf should be used to help someone. In one case, Pioneer was pursuing a

technology for the development of a product for the US, but when it was determined there was no commercial market opportunity, the technology quickly was applied to solve an issue in the developing world for which it was well suited for – the biofortified sorghum project (Niebur, personal communication, 2009).

4.2.2.2 New Market Development

With companies always looking for new markets for their products, the long term market development incentive is taken into consideration on some project, but is not the major driving force in research collaborations. If farmers are successful with improved seeds, then their incomes and standard of living will begin to increase. They will hopefully emerge from subsistence farming to become partially commercial and then have the resources to purchase improved, commercial seed. In most cases, countries likely to be technology donation recipients are at a developmental stage where it is unlikely they would be of commercial interest to donor companies for at least 10 years. At that point though, Pioneer could benefit from the regulatory foundation that was developed through the collaboration. This foundation would make it easier for future commercialization of products, but all of Pioneer's competitors would also gain an equal advantage from the existence of the infrastructure (Smith and Freymark, personal communication, 2009).

4.2.3 Evaluation of Collaborations

In evaluating any technology donation, the first thing to consider is the "correct role of the private and public sectors with the technology" (Niebur, personal communication, 2009). Pioneer only works to apply technologies when they are welcomed and

understood by the scientists and people of the recipient country. One of the greatest challenges with collaborations is finding the right public or private institutions with which to work. Building and executing meaningful projects is dependent on having productive partnerships.

4.2.3.1 Project Evaluation

When evaluating a project proposal, Smith and Freymark emphasized that the applicant must first make it clear how the "technology can 'solve' the need." Creating the GM plant trait is far from the end of the project – there needs to be an understanding of how the seed with the trait can be 'commercialized.' This is not from a company-profit perspective, but takes into consideration the necessity of functional seed distribution networks in the region. The product must not only be able to reach the marketplace, but there must be a market for the product, or at least the potential for such a market. These criteria illustrate the need for some existing infrastructure in the countries as well as a long term commitment from the applicant and other partners. If initially the applicant partner cannot fill all these needs, it is more than acceptable to seek out other partners that can supplement weak areas.

4.2.3.2 Partners

The next key step is establishing a workable partnership with the applicant and other organizations. Partners help provide many key project execution aspects and knowhow that compliments what the company has to offer. In particular, collaborations must include partners that can supply local expertise (agriculturally, culturally, politically, and socio- economically), some on-the-ground infrastructure, relationship with funding

organizations, and similar views to Pioneer on using and regulating technologies. The project must have "a well set up, reasonable plan" (Albertsen, personal communication, 2009) which includes achievable milestones and objectives that are structured in a way that allows for accountability on the part of the partnership. Communication and meetings between members of the consortium are critical for long-term success.

Working with a consortium, as with the Bill and Melinda Gates Foundation's African Biofortified Sorghum project, is the preferred arrangement. The technology donation can be made directly to the consortium, who then owns the rights to the technology for a specific crop in a specific region. However, the company retains liability for that event. Therefore, Pioneer maintains a close link with the technology and regulatory requirement since liability could come back to it (Le Page, personal communication, 2009). Within the consortium it is critical, and a possible deal breaker, that there is measurable accountability between all partners to increase the chances the project is successful.

4.2.3.3 Review Process

The decision making within Pioneer is done at the highest level, indicative of the importance and seriousness with which the company takes GM technology donations. Pioneer's president has a small group – part of the Executive Leadership Council - that discusses the attractiveness of the donation in terms of the impact and use of the technology and also the impact on the company's brand image and the image of the partners involved (Niebur, personal communication, 2009). The project must also have a reasonable chance of success in a reasonable time frame. All partnerships have a

strong emphasis on product delivery and end-user strategies. Marc Albertsen, Research Director, explained that the company does not "do projects for the sake of doing projects," but does projects to keep up with the tradition and reputation for making a difference.

4.2.4 Current Projects

4.2.4.1 Africa Biofortified Sorghum

The main GM technology transfer project Pioneer is currently focusing on is called Africa Biofortified Sorghum (ABS). The company partnered with a Bill and Melinda Gates Foundation funded consortium of nine organizations (seven Africa-based) five years ago. The project is lead by Pioneer and Africa Harvest. Gates put out a challenge to the global community to create an improved sorghum using both breeding and biotechnology that is "as close to a super crop as possible" (Le Page, personal communication, 2009). While the inherent drought tolerant nature of sorghum makes it a staple in semi-arid Africa, it is not easily digestible and is low in iron and zinc. The consortium is working to improve vitamin A, zinc, iron, digestibility and nutrition. Phase II of the project will address the need for higher yields of improved varieties, deployment, food products, and end use.

Pioneer is active in "working at the institutional level with leadership in communications, public relations, regulatory, agronomy," (Le Page, personal communication, 2009) and the biotechnology aspects. The project utilizes many plant breeding tools from multiple angles. For the germplasm base, the consortium is using naturally selected varieties from International Crops Research Institute for the Semi-

Arid Tropics (ICRISAT). Molecular tools such as molecular markers and gene shuffling allow for more rapid selection of promising individual plants. Finally, Pioneer has donated biotech tools to the ABS consortium for genetic modifications.

But it is "not enough to donate in isolation," (Le Page, personal communication, 2009) the company is also involved in the current and long-term stewardship of the new products. The biotechnology-based research is being done in Iowa in conjunction with the training of seven African scientists at the company on advanced molecular biology and biotechnology techniques. This works to build the capacity in African scientists in the hopes they can become effective stewards of the technology in Africa as well as being able to do advanced research on home soil.

The first generation of the improved vitamin A event has been taken from Iowa to South Africa, and recently Kenya, for testing. Even with South Africa's relatively established and functional regulatory system, there were obstacles and the initial testing proposal was delayed due to the fact that sorghum is an indigenous crop. Pioneer led the effort to work with policy organizations in South Africa to provide education on GM crops in the hopes of correcting perceptions that the GM sorghum would cause gene flow to South African crops. While the program was successful and the field testing has been allowed, it is imperative that "the prevailing law of the land always take priority" (Le Page, personal communication, 2009). In this case, the laws were not clear and the consortium was able to work with the officials to clarify the intent and execution of the laws.

4.2.4.2 Hybrid Rice

Pioneer launched a new collaboration with IRRI in April, 2009 focusing on work with hybrid rice. The company will be donating the use of both conventional and GM technologies (Niebur, personal communication, 2009). This collaboration is still in its infancy and has the goal of accelerating the improvement in the productivity of rice through more extensive use of hybrids and improved varieties.

4.2.5 Barriers

4.2.5.1 Legal Liability

Legal liability is a key concern for agribusinesses when looking at donating highly regulated and sometimes controversial technologies. Bill Niebur explained that "concerns with international trade are always brought up, but the company has been in 'the game' for a long time and understands how it works." The international trade concern is that a GM event will be donated to a developing country and will be deregulated in that country, but not elsewhere. If the product somehow got into international trade and ended up in a country that had not deregulated it, the donor company would ultimately be liable and face fines and negative press. Niebur nullifies that point by stating that any "newly applied technologies in developing countries would need simultaneous import approval in the rest of the world." Such deregulations would be an expensive and time consuming process, requiring the support of a consortium. For any country the transgenic crop could end up in, commodity approval would be needed; commodity and planting are the two kinds of regulatory approval. For example, seed technology for American farmers would need planting and commodity

approval in the US and then get just commodity in Africa, EU and Japan. Planting deregulation means it can be grown in the country and commodity deregulation means that it can imported into a country, but not grown. "To date no company donation has been stopped solely because of liability concerns" (Smith and Freymark, personal communication, 2009).

4.2.5.2 Intellectual Property Rights

Concerns over the protection of Intellectual Property (IP) are of particular importance in an industry that may spend hundreds of millions identifying, developing and commercializing a transgene. The primary concern for Pioneer regarding IP is that since these countries have no tradition of respecting IP, the technologies could be 'stolen' and used against the company years later if the competition took it and commercialized somewhere else (Albertsen, personal communication, 2009). Albertsen explains that once a country develops its own IP and creates a system to protect it, they will understand that IP is good for everyone concerned. To avoid this problem, the company prefers to work in countries that have IP laws and infrastructure and where the population understands why the laws are in place. It comes down to a matter of "protecting the technology from competitors in important markets" (Smith and Freymark, personal communication, 2009).

4.2.5.3 Funding

The costs of not only developing a GM product for a developing region, but then financing the regulatory and approval process (sometimes working to create the country's system) can be cost prohibitive for a single donor company to undertake. The

problem moves from being able to obtain the technology or development expertise to identifying what organization is willing to fund and support the product through the regulatory, biosafety and distribution processes (Smith and Freymark, personal communication, 2009).

Collaborations are the most attractive option to address the cost concerns and the Bill and Melinda Gates Foundation is a preferred partner with the financial resources necessary to support a product through regulatory and approval. While one company cannot foot the whole bill, Smith and Freymark suggest that multiple agribusiness and public organizations can work together for holistic improvements that create an environment in which GM crops could be commercialized. The more public approach to funding especially the regulatory and approval process makes more sense, since the subsequent benefits are available to everyone, regardless if they carried the initial development costs.

4.2.5.4 Public Opinion

The nature of public opinion towards GM crops and the third parties that instigate negative views of GM crops, can provide barriers to successful technology transfers. While third parties may be ineffective in stopping the initial technical stages, product distribution and commercialization can be impeded when groups are actively working to prevent them (Niebur, personal communication, 2009). This barrier can only be solved through greater education and understanding on the nature of biotechnology and the scientifically based risks and rewards associated with it.

4.2.5.5 Regulatory and Stewardship

The difficulties surrounding regulatory and stewardship systems provide the greatest barrier to technology transfers. In order to abide by and respect national laws and wishes, the company will only work with recipient countries that have biosafety protocols and safeguards in place. For a collaboration to be considered, these criteria must be met in the planning phase:

1. The technology is appropriate to the problem, environment (political, social and climate) and there is not a better alternative.
2. Legal and regulatory frameworks are in place and are functional.
3. All research and development is conducted in accords with established national regulations; the partner has the expertise (supported by the company) to carry out the research.
4. Infrastructure is in place to deploy the technology, actually get the final product into the hands of farmers, and the varieties are locally adapted.
5. Protocols are in place to allow for the practice of good stewardship and monitoring of the market.
6. The ability exists to remove the product from the market through thorough tracking and control. (Niebur, personal communication, 2009).

While these criteria may appear stringent, Albertsen explains that when Pioneer "makes a GM technology donation, we have to make sure we are doing the right thing in introducing transgenes." With the donation comes with the responsibility to ensure a proper system is in place to care for the transgene properly through research being done on proteins, allergic responses, biosafety, environmental impact, etc.

When asked if a more streamlined or subsidized regulatory process would increase Pioneer's willingness to be involved further along in the development processes, Smith and Freymark responded 'yes,' but only if the countries are comfortable with the technology. GM technology cannot just be forced on countries. There is no rush to introduce the technology at the expense of having uncertainty among the population, "people need to willingly embrace the technology and they need to be comfortable eating it" (Smith and Freymark, personal communication, 2009). Albertsen echoed that sentiment with even though the regulatory framework is not cheap, that is not necessarily a bad thing since it keeps everything science-based and highly scrutinized.

4.2.5.6 Sustainability

Another concern surrounds the actual sustainability of technology transfer projects after the initial 'project' is over. It can be difficult for the donor company to ensure that the project intents and impacts are realized (Le Page, personal communication, 2009). Long term commitment, in some cases 10-15 years, on the part of both the donor company and other partners is a basic requirement when working with the lengthy process of genetic modification and plant breeding.

4.2.5.7 Communication

As discussed earlier in regards to effective partnerships, communication between the public and private sectors is critical for the creation of new projects. The long-term success of all projects rests on the fact that their products must be demanded by farmers in developing countries. Smith and Freymark expressed the idea of a two-way street with public-private partnerships wherein the private sector demonstrates what it has and

farmers, supported by the public sector/government, communicate what they need. Without this communication, Pioneer cannot understand what the problem is and if they have the technology to address it.

Pioneer works with several CGIAR centers and non-profits, including African Agriculture Technology Foundation (AATF), an intermediary organization on biotechnology projects. AATF brokers have access to agricultural biotechnology, much of which is held by private companies and it looks for a fit in existing needs that have been brought to its attention. Pioneer sees the need for "an organization to effectively navigate the land mines" (Smith and Freymark, personal communication, 2009) that surround technology donations in order to overcome inherent barriers.

4.2.5.8 Institution Building

For GM technology transfers to actually have an impact, there are extensive institutional and educational needs that must be addressed. Unfortunately, it is easy to be swayed into "just dealing with sexy biotechnology and not to focus on the mundane infrastructure, which will really make these projects work in the long term." In some respects, "science is probably the easier part – there is no impact if there is not infrastructure to reach the farmers with the new products" (Albertsen, personal communication, 2009). Seed systems need to be developed so farmers can be supplied the seed and currently there is little industry presence or new companies in the seed arena. In some situations, farmers in developing countries need help with extension, hybrids, planting times and not necessarily GM crops (Smith and Freymark, personal communication, 2009).

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4.3 Case Study: Monsanto

Preface

The primary information sources for this case study were personal communications from telephone interviews conducted during October, 2009 with Monsanto employees. Each interviewee has an informed and relevant view on GM technology donations, all have been involved with GM technology donations in the past or are currently. This research would not have been possible without their generosity and patience.

4.3.1 Introduction

Monsanto is known as a major global plant biotechnology company. The original company was founded in 1901, with a chemical focus and over 100 years the company diversified into agrochemicals, livestock treatments, seed systems and biotechnology. In 2002, Monsanto became independent and remains in that form today (Monsanto.com, 2009).

Over the past decade Monsanto has been transitioning from an agrochemical business to a seed and biotechnology company. As of 2002, 66% of their revenue came from agrochemicals; but due to the many seed company acquisitions, like the 2007 acquisition of Delta and Pine Land, Monsanto now earns a majority of its revenue from its seed business (Hoovers.com, 2009).

With the first successful transfer of material between organisms in 1973, molecular biology based genetic engineering became possible. In 1983, the Monsanto's scientists

achieved the first successful modification of a plant cell through biotechnology. Finally in 1996, the company introduced Roundup Ready™ resistant soybeans and Bollgard™ insect-resistant cotton, the first commercially released GM crop (Monsanto.com, 2009). With broad experience in plant biotechnology, Monsanto has the technology and knowhow to be a valuable partner in GM technology transfer donations.

4.3.2 Justification for donations

4.3.2.1 Sharing

"Sharing is a key part of the Monsanto Pledge. It is a deep rooted value to share technologies and talents to improve agriculture," explains Fred Perlak (Perlak, personal communication, 2009). In looking at donations, the company seeks to both do the right thing and to find mutually beneficial situations. The Pledge includes sharing data, genes and traits, but also critical expertise and knowhow for creating a safe environment of GM crops and for building the scientific foundation in developing countries. Training scientists from less developed countries creates stewards of donated technology and enables those scientists to conduct research focused on their homeland. Donations lead to improved research on improving locally important crops in lesser developed countries (LDCs) like sorghum and cassava that may not have the commercial market that would appeal to businesses enough to make large investments.

4.3.2.2 Awareness and Public Relations

Technology donations allow for increased awareness of the benefits of biotechnology. Biotechnology has been publicized as only benefitting multinational agribusinesses, but

donations provide an illustration of how biotechnology can accrue benefits directly to poor farmers and consumers in developing nations (Vancil, personal communication, 2009). While there could be public relations (PR) advantages from a successful donation, public acceptance of biotechnology in the international community is fickle, so PR cannot be the driving force (Crosbie, personal communication, 2009). The PR can be negative if third parties misrepresent Monsanto's efforts and create backlash.

4.3.2.3 Mutual Learning

Monsanto stands to benefit from understanding more about effective stewardship and specific traits through donation collaborations. In working on the WEMA (Water Efficient Maize for Africa) consortium project and supplying relevant technology, the company learned more about drought tolerance in sub-Saharan Africa through collaborations with CIMMYT.

4.3.2.4 New Market Development

With companies always looking for new markets for their products, the long term market development incentive is taken into consideration, but is not one of the driving forces. Technology donations to research institutions, for the long term benefit of resource-poor African farmers, enable these institutions to create improved crops for poor farmers that could have higher yields. While these farmers could one day be customers for Monsanto's seed business, "countries like Kenya, Uganda, etc. need so much work on their economies, infrastructure, finances that we need to think more creatively and long-term than traditional business approaches" (Crosbie, personal communication, 2009). The low level of technology management, indicated by

underdeveloped regulatory, approval, stewardship and intellectual property rights protection processes, make some countries undesirable for responsibly introduction of biotechnology.

4.3.3 Evaluation of collaborations

"We want big projects that can have a big impact – how much will it matter? how many people will it reach? what kind of benefit does it generate?" explains Dr. Ted Crosbie, VP of Global Plant Breeding (Crosbie, personal communication, 2009). In evaluating projects, the first question asked is "'why not' make the donation, not 'why' make the donation" (Perlak, personal communication, 2009).

4.3.3.1 Review Process

Requests are initially reviewed by a team of representatives from regulatory, legal, PR, product stewardship, etc. The team's recommendation is considered by the Executive Team in making the final decision (Vancil, personal communication, 2009). Monsanto sees three channels to reach smallholder farmers. These are: traditional commercial markets, humanitarian donations, and cooperative development which is a hybrid of the first two. The Executive Team uses a separate process when evaluating humanitarian gifts than it does with commercial business decision. Since commercial agriculture is meant to make money, the decision is purely business; with humanitarian projects it is completely different. Previously commercialized technology is preferred for transfers since the company has a clear patent position on it and has undertaken extremely extensive research that can be shared. Donating technologies that are early in the

developmental stages is more risky and "early stage research will look considerably different when it actually reaches the market" (Perlak, personal communication, 2009).

4.3.3.2 Potential Project Evaluation

Projects are evaluated on an individual basis and the first step is to understand who is making the request. In a meeting, the individuals are assessed on legitimacy, expertise, if the desired technology is able to solve the problem, and what exactly they would like to do (Perlak, personal communication, 2009). To ensure legitimacy, the company checks the support of other organizations for the project. The prospective partner organizations must have the credibility to ensure they understand and can maintain the product stewardship plan to keep the biotechnology secure for the farmer (Vancil, personal communication, 2009). Collaborating with organizations like foundations and governments add legitimacy to the requests and making the donation to a consortium is the preferred route.

4.3.4 Current Projects

4.3.4.1 Water Efficient Maize for Africa WEMA

Several GM technology donations and collaboration projects are underway at Monsanto. Water Efficient Maize for Africa (WEMA), launched March 2008, is a private-public partnership (PPP) with 10 organizations focused on developing and delivering drought tolerant (DT) maize for farmers in Sub-Saharan Africa (Vancil, personal communication, 2009). The project set-up is unique in that DT maize is being

developed by the company for commercial release in the US and the project will test up to 4 commercial trait genes for royalty-free use in Africa.

With the Bill and Melinda Gates and the Howard G. Buffett Foundations financing some of the research, Monsanto is working closely with the International Maize and Wheat Improvement Center (CIMMYT) and the National Agricultural Research Systems (NARS) in the African countries on product development for use exclusively in Africa. The African Agricultural Technology Foundation (AAFT) is leading WEMA. The identified trait genes will be crossed into high yielding African varieties with the help of the NARS. Monsanto has been active in WEMA from inception of the technology through the African product development. Regulatory approval is expected in the US 2012-2013 (earliest), and approval of WEMA transgenic varieties in Africa is targeted for 2017 or later depending on the transgene used (Crosbie, personal communication, 2009).

In addition to donating the use of up to four commercial trait genes, Monsanto has made significant capital and human resources investments. The company is funding one full-time position to work exclusively on the project, along with donating the time and resources of many internal experts. These experts are both doing project work and providing guidance to review the project's initiatives and progress. Dr. Fred Perlak says the resources are "justified because of the scale and scope of impact [the project] will have" (Perlak, personal communication, 2009).

4.3.4.2 Virus Resistant Cassava for Africa VIRCA

Monsanto is partnering with the nearby Danforth Plant Science Center to research and develop new resistant cassava in the Virus Resistant Cassava for Africa (VIRCA) project. The geographical focus for the project is Kenya and Uganda, with all the transformations being done in the US. The company is donating "virus resistance technology and agro-transformation, and the Monsanto Fund has donated nearly $7 million in support of the project" (Vancil, personal communication, 2009). The donated technology is just in stage 1 or 2 of 5 for cassava and it will take years to develop an end product with virus resistance.

4.3.4.3 Bt Cowpea

Monsanto also grants non-asserts to consortiums and donates the technology without being involved in the actual product development. With the Bt Cowpea project, Monsanto is donating Bt technology to a consortium which will do the transformations. A non-assert is "a license agreement that says the party can use the technology and the company will not exercise their intellectual property protection rights against that use" (Vancil, personal communication, 2009). AATF also has the right to sublicense the products. The company is not obligated to supply anything beyond the technology, but Monsanto does have a regulatory affairs manager in close contact to help support the project. Currently the product had been approved for field trials in Nigeria.

4.3.4.4 Bt Brinjal

The recently approved Bt brinjal (eggplant) in India is a commercial effort with a humanitarian component built into it. Through minority ownership in an Indian company, Monsanto is commercializing hybrid Bt brinjal and has donated the use of the

Bt technology to the Indian agricultural research service for the use of a royalty-free open pollinated variety (OPV). The target farmer for the OPV is one that cannot yet afford the hybrids, but would like to realize the benefits of reduced pesticide spraying. While Bt eggplant would have been successful without OPV, the OPV was included as a donation to benefit the farmers who need it (Vancil, personal communication, 2009)

4.3.5 Barriers

4.3.5.1 Intellectual Property

While Intellectual Property (IP) infringement is a valid concern when sending proprietary technology to countries with no IP protection framework, "it is not necessarily the biggest barrier to technology sharing (Vancil, personal communication, 2009). However, without IP protection, it is more challenging for partners to steward the products and more challenging for a company to consistently invest in a country and bring new technologies and innovations to its farmers.

4.3.5.2 Legal Liability

Potential legal liability does present a threat to GM technology donations. Dr. Fred Perlak explains that it is "always a concern and has been especially important with issues around technology for a while" (Perlak, personal communication, 2009). The first step is to make sure that all donations, especially non-asserts, are followed up on and that the regulatory systems in the country are functional. In WEMA, the company is working with the participating governments on strengthening regulatory systems to ensure technology is kept where it is supposed to be kept. The fact that the Starlink corn

brought down Aventis is not forgotten by the industry today, but lessons were learned from that case and will hopefully not inhibit technology transfers in the future. With the non-asserts "it has not yet proven if it would indemnify the company from legal liability" (Vancil, personal communication, 2009). It would work to the Monsanto's advantage that it realizes no monetary gain from the agreement.

GM products entering international trade without proper stewardship is always a concern. First, Dr. Ted Crosbie explains, "Monsanto does not put biotech genes in crops for Africa that have not been approved in the US and in Africa" (Crosbie, personal communication, 2009). With the DT gene in WEMA, if the US approves it, Monsanto would also seek approval in all countries that import US maize, about 75 countries. Therefore, if DT African grain was exported, it would face no deregulation issues internationally and there would be no liability. Furthermore, WEMA works on food security with white maize consumed in Africa; white maize is consumed and yellow corn is exported. The only liability would arise if the technology was not allowed in the African country in the first place. In VIRCA (cassava project), cassava is not an export crop for the target donation regions, so international trade is not an issue (Vancil, personal communication, 2009).

4.3.5.3 Regulatory and Stewardship

The greatest challenge beyond Monsanto's control is the lack of regulatory and stewardship systems in the developing countries. Dr. Perlak explains that "it cannot be overstressed how important a functional regulatory system is" since the majority of African countries essentially have no experience with GM crops and have no

regulations on food crops at all, developing a functional system would take expertise and resources, resources these countries lack. With a system in place, deregulation of an event can be expensive. In the US it costs about $100 million due to biosafety testing, toxicology, environmental impact, etc. Africa could cost less than that, but it is not yet clear now much less (Crosbie, personal communication, 2009).

In Burkina Faso, Monsanto took a hands-on approach to deal with the lack of regulatory system in the country through a business partnership, not a technology donation. In 2002, the Minister of Agriculture from Burkina Faso approached Robb Fraley at the World Food Prize Symposium asking the company to introduce Bt cotton into his impoverished country. But with any GM technology, it "cannot just be slipped under the door" (Perlak, personal communication, 2009). To introduce Bt cotton, Monsanto and other stakeholders worked with the Burkina Faso government to create regulatory and stewardship departments, define the process of GM crop regulatory approval, ensure functional regulations and build a long-term commitment between Burkina Faso and Monsanto. The company had employees in the country advising on regulatory, business development, and field testing. Communication was key throughout the entire process.

The government and farmers of Burkina Faso did not want a charity handout or a donation, they wanted to be business partners with Monsanto. Business makes the relationship much more equal between the two parties – they were real business partners in a real business deal. The arrangement empowered Burkina Faso farmers and enabled the government to create crucial frameworks, with experts advising, and to gain invaluable experience. While Bt cotton is commercial and not a donation, the company

"will never make enough money in Burkina Faso to cover the costs" (Perlak, personal communication, 2009). Monsanto views this arrangement as the ideal when working with GM crops in the least developed countries. A major advantage to commercialization is that the company has long-term interest in the country and therefore can be more active in the stewardship of the technology. This is a costly and labor intensive effort, so the company could only be involved in a limited number of such projects.

4.3.5.4 Product Realization

Historically, Monsanto has granted GM technology donations, but is now "increasingly realizing that a more hands-on approach is necessary in actually making sure the product gets to farmers" explains Dr. Fred Perlak who had been involved with technology donations for the company for decades. Especially with non-assert donations, the product development demands are on the public sector; unfortunately the public sector has challenges getting end products in the hands of farmers (Vancil, personal communication, 2009). Few previously donated Monsanto technologies have been made into products distributed to farmers. Part of this situation is due to the 5-10 years it takes to move from early stage technology to a commercialized product. Monsanto is now working on understanding what difficulties the public organizations are having and how these barriers can be mitigated.

4.3.5.5 Public Reward System

Difficulties in the development, approval, and distribution of GM products by the public sector could also be attributed to the fact that "the reward system for academics/public

sector is set-up differently from the private sector" (Vancil, personal communication, 2009). The private sector only profits when a technology has been commercialized in the form of an improved product that farmers are willing to purchase and repurchase. Since academia awards new papers and novel discoveries, if a "scientist wants to really follow a technology through to product development and distribution, it could take the scientist out of the competitive academic race" (Vancil, personal communication, 2009).

4.3.5.6 Other

Simply put, "free access to Monsanto's technology is not enough for the technology to actually get in the hands of resource-poor farmers" (Vancil, personal communication, 2009). There are so many pitfalls between the idea, product creation and distribution and there needs to be wide scale need education, communication, and farmer training for the technology to ever actually make an impact. The proper role of the private sector in development is still being determined and will become more clearly defined in the coming years.

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5.0 Discussion

5.1 Recommendations on Seeking Donations

Based on the private sector interviews, key elements that donor companies consider when agreeing to a technology donation are explained here.

5.1.1 Partners and Consortiums

Effective partnerships are critical for the successful introduction of modern plant technology into developing countries. Public-private partnerships (PPP) offer profit driven companies with valuable technology and expertise to work with universities, governments, and NGOs to accomplish goals that neither could achieve independently. The root problem addressed in this thesis is the lack of agricultural technology, specifically GM crops, in developing countries. While private companies might not be able to justify the massive investment necessary to enter low-income developing countries with expensive tailored GM products, PPP can be used to address this problem. Technology partnerships, wherein technology and expertise is provided by the private sector, uses the knowhow of the public sector partners to compliment what the company has to offer. This knowhow could be local expertise (agriculturally, culturally, politically, and socio- economic) built over decades of aid projects, on-the-ground personnel and offices, or relationships with funding organizations. Similar philosophies between organizations regarding how technology should be regulated and use help to make partnerships run more smoothly. Building a consortium of credible partners works

to ensure long-term commitment to the project; most importantly so a stewardship plan keeping the GM crop secure for farmers can be maintained.

Due to the emphasis put on long term commitment, consortiums were the preferred route for technology partnerships for all the companies interviewed. Collaborating with many other organizations, like foundations, governments, and other companies adds legitimacy to the technology donation requests and helps to ensure that as a whole the partners are committed and experienced. Honest and frequent communication between all partners is crucial in creating an environment of trust and accountability to guarantee milestones are reached and each partner knows their responsibilities.

5.1.2 Preliminary Project Evaluation

In all companies interviewed, GM partnership projects are rigorously assessed on a case-by-case basis. Before the actual project is evaluated, companies want to ensure that the requester has legitimacy and expertise. To verify the legitimacy, other organizations that are cited as collaborating on the project will be contacted. If this is cleared, the proposal must clearly state what technology is requested, how exactly the technology will solve the identified problem, and why the problem cannot be solved through conventional means. Since the end goal of all agricultural biotechnology projects discussed in this thesis are to have a product containing the technology in the hands of developing country farmers, the requester must have an understanding of how the seed can be deployed. The recipient country or countries must also have functional (or at least developing) legal, regulatory, and stewardship frameworks to ensure the safe handling and evaluation of GM events. Since many of these frameworks lack

satisfactory capacity in developing countries, the requester should illustrate this capacity will be built, what other partners have the expertise, and who has finances to achieve this. Finally, the project must have a reasonable chance of success in a reasonable time frame.

5.1.3 Attractive Benefits

When a potential recipient institution is approaching an agribusiness about entering into a technology partnership, it is important to recognize that these companies are looking for win-win situations. Companies assess projects based on a risk/benefit analysis; while risks should be minimized, benefits must also be clearly emphasized.

1. Since biotechnology has been cast as only benefitting multinational agribusinesses, illustrations of how GM crops can directly benefit poor farmers and consumers in developing nations are needed. Foreign companies can be part of the solution to hunger and poverty and requests should clearly define how this will be achieved.
2. Successful donations can yield positive PR on the company's brand image by illustrating how they are a responsible and generous corporate citizen.
3. The regulatory foundation that is established, tested and strengthened through collaborations could make it more feasible for the company to commercialize products in that country in the future.
4. When a technology partnership results in an improved product that is successfully distributed to farmers, it creates positive positioning for the company in the mind of future customers. This could result in an advantage if the company ever commercially entered the market.

5.2 Barrier Comparisons with Literature

The literature review illustrated potential and realized barriers to technology transfers and humanitarian product commercialization from the public sector and academia's perspectives. While it is unsurprising that many of the identified barriers were in line with what the private sector interviews revealed, there are differences in the emphasis put on the barriers. The following discussion will compare literature's assessment of individual barriers to how the private sector perceives them, as reflected by the interviews conducted for this study.

5.2.1 Intellectual Property

Literature:

From literature's perspective, IP rights are "one of the major impediments to biotechnology transfers" (Krattiger, 2000). Many developing countries have little capacity to manage intellectual property issues (Kryder, 1999) and lack a historical respect for rights to intellectual property. To a certain extent, private companies agree with and mirror these concerns, but view them as an obstacle that can be overcome since IP can always be negotiated.

Interviews:

With hundreds of millions of dollars invested in the development and commercialization of a transgenic event, handing over proprietary technology for use in a country with no IP of its own and no tradition of respecting IP, can be a risky move. Without any legal means to protect technologies, donor companies run the risk that their

transgenes will move out of the targeted donation region and into commercial markets in other countries where they could be used by competitors. Since a lack of IP protection typical goes hand in hand with inadequate stewardship capacity to monitor product movement, IP granted for humanitarian use for small farmers can easily spill over and be used by commercial/export size farmers. Each of these situation result in negative impacts on the donor company's commercial investments and sales. The most sustainable way to mitigate these problems is not only to work to developing an IP system in the recipient county, but also to support the creation of IP by scientists within that county. Having domestic IP helps to create an understanding of the benefits of protection to people that now have something to protect.

5.2.2 Regulatory and Stewardship Capacity

Literature:

Functional regulatory and stewardship processes are critical in ensuring technologies are free of negative environmental or health impacts and that the technologies can be monitored and continually assessed. The Agriculture Biotechnology Service Project (ABSP) identified the need to "improve the capacity and policy environment for the use, management and commercialization of agricultural biotechnology" (Brenner, et al., 2001). The underdevelopment and lack of capacity to support these processes in developing countries leads to intense scrutiny from both NGOs and technology donors (Brenner, et al., 2001) regarding the advisability of introducing biotechnology. Hautea explains that from the donor's point of view, any problems with biotechnology in one region "will adversely affect their business elsewhere" (Hautea, 1999).

The literature recognizes functional frameworks as key and that "the efforts required to broker a biotech transfer deal pale in comparison to ensuring the proper functioning of all institutional interactions at the downstream end" (Krattiger, 2000). In many cases, the private sector is in agreement with the literature since they view a country's ability to thoroughly evaluate and steward a transgenic product as the most important consideration to the point that it would be unethical to introduce a transgene into an underdeveloped regulatory environment.

Interviews:

Ensuring that a GM technology donation is done safely and ethically is of the utmost importance to donating agribusinesses. Companies are increasingly realizing that donations come with the inherent responsibility to ensure that both the biosafety and stewardship requirements are in place, at the company's level of expectations. Bill Niebur of Pioneer explained his companies' prerequisite donation conditions:

1. The *technology is appropriate to the problem, environment (political, social and climate*) and there is not a better alternative.
2. Legal (IP), *regulatory and biosafety frameworks are in place and are functional*.
3. *All research and development is conducted in accords with established national regulations*.
4. Infrastructure is in place to deploy the technology into the hands of farmers.
5. *Protocols in place to practice good stewardship and monitoring of the market*.
6. There is the ability to remove the product from the *market through thorough tracking and control* (Niebur, 2009).

Over half of the criteria deal with regulatory and stewardship systems. This recognizes that just because a transgenic event may be able to mitigate an agricultural obstacle, that alone does not mean it should be introduced.

The point indicated by Hautea that negative or incorrectly executed regulatory evaluations could impact a donor company's business elsewhere is an astute observation that companies take seriously. In some situations, if the donated technology contains proprietary traits that the company plans to commercialize in the donation's recipient country, or elsewhere, they could take a more active role in the creation of the regulatory dossier. If the donated trait is not approved, it could be far more difficult to have a commercial product with that event deregulated in the future.

Since effective regulatory systems require trained and knowledgeable personnel, a growing number of publicly and privately funded initiatives are being conducted to build capacity in developing countries regarding the introduction of biotechnology. The Syngenta Foundation is undertaking a project with the Forum for Agricultural Research in Africa (FARA) to spread biotechnological knowledge through education of governments and work with scientists. The goal is to educate authority figures in the countries on how to conduct procedures like confined field trials, critical in biosafety evaluations, and to scientifically understand the benefits and risks of biotechnology.

Another way to reduce the costly regulatory burden on consortiums trying to introduce transgenic crops into developing countries is through regulatory system and/or trade harmonization across regions and globally. Through harmonization, countries would respect the biosafety analysis, such as impacts on human health, of a country that has

already commercialized that trait. Each country would have to assess the impact of the introduction of the GM crop on the local flora, fauna and wild relatives since ecological situations vary by region.

5.2.3 Legal Liability

Literature:

The literature evaluated gave little attention to the most financially costly barrier to a company donating GM technology, the legal liability that will forever connect the company to any farmer growing the crop created with their technology. Significant fears regarding liability arose from the Starlink corn mishap in 2000, wherein transgenic crops ended up in human food products when approved only for animal feed use. While the preferred method of preemptively dealing with liability concerns is to have an effective regulatory system in the recipient country, the interviews indicated there are other ways to overcome this barrier.

Interviews:

Since the liability arises in large part from that absence of deregulation in importing countries, an obvious, but exceeding expensive, solution would be to deregulate the event in all countries that could potentially import the product. This approach is viable when the technology donation is for a trait in a crop that has already been deregulated worldwide because of commercial interests in other markets for the donor company. This can be achieved through parallel development of a trait in a commercial crop, for example drought tolerant corn, if it is donated for use in a target region for a particular subset of farmers. This approach allows for all the deregulation costs to be handled by

the company's commercial interest and removes liability from import to non-deregulated markets.

Different kinds of technology donation partnerships hold the potential to indemnify the donor company from some legal liability, but none have been tested in international courts. Granting non-assert licenses for technology use are believed to indemnify the donor since the company did not actually donate the technology and therefore has no obligation to steward it. However, companies are realizing that a hands-off approach to product development with their technology donations may be even more risky. Technology brokers like the African Agricultural Technology Fund (AATF) attempt to assume the liability, but the understanding in the private sector is that liability always finds the deepest pockets, in industry.

5.2.4 Public Perceptions and Reputational Damage

Literature:

With publicly visible companies potentially scrutinized for every action taken, donations create the risk of "negative public relations if the products disseminated do not meet high quality standards or regulatory procedures are not followed" (Krattiger, 2002). The literature indicates that the opposition to GM crops in Europe has had a tangible impact on the willingness of institutions to support projects involving GMOs. According to a case study, even if a donation takes place, to actually commercialize a product the issues of public awareness and acceptance have to be taken into consideration from the onset (Brenner, et al., 2001).

Interviews:

Companies are aware of the risks and risk exposure that could result from partnering with GM technology donations. Damage to a donor company's reputation can easily prove more costly than legal liability and could arise from situations where the company is arguably not at fault. This barrier can only be resolved through greater education and understanding on the nature of biotechnology and the scientifically based risks and rewards associated with it.

6.0 Conclusion: the Future of Technology Partnerships Benefiting LDCs

The study has illustrated how three major agribusinesses view GM technology partnerships to introduce transgenics into developing countries and how they evaluate barriers. In the opinion of the author, the greatest barriers facing GM crop introduction are not company specific, like IP protection or legal liability, but rather the capacity of recipient countries to thoroughly evaluate and be stewards of transgenic products. IP rights can be negotiated and crops can be deregulated in import markets, but if a country does not have functional regulatory and biosafety systems in place, it would be irresponsible for donor companies to introduce transgenics. The future success of technology introduction will depend on a number of factors:

1. Countries' abilities to support the formation and the long-term sustainability of regulatory and stewardship capacity;
2. A global climate not hostile to GM crops;
3. Continued financial support from foundations, institutions, and governments;
4. Fair GM crop thresholds for imported goods to developed countries;
5. Continued interest from agribusiness companies to enter into partnerships and share their technologies;
6. Long-term commitment and clear communication between all parties involved.

It has been demonstrated that GM crops can have a positive impact on the food security and livelihoods of farmers and consumers in developing countries. However, adopting GM crops will only be one part of the solution to agricultural and food insecurity; attention must also be paid to developing infrastructure, seed distribution systems, water

resources, and agricultural extension before food security can be realized.

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