University of New Hampshire University of New Hampshire Scholars' Repository

Law Faculty Scholarship

University of New Hampshire – School of Law

6-1-2009

Crop Bioengineering: Enormous Potential for Catalyzing International Development

Peter Gregory

Stanley P. Kowalski University of New Hampshire School of Law, stanley.kowalski@law.unh.edu

Follow this and additional works at: https://scholars.unh.edu/law_facpub Part of the Food Biotechnology Commons, Growth and Development Commons, and the Plant <u>Sciences Commons</u>

Recommended Citation

Peter Gregory and Stanley P. Kowalski, "Crop Bioengineering: Enormous Potential for Catalyzing International Development," Agriculture for Development, June 2009 at 26-30, available at https://perma.cc/237A-PPPZ

This Article is brought to you for free and open access by the University of New Hampshire – School of Law at University of New Hampshire Scholars' Repository. It has been accepted for inclusion in Law Faculty Scholarship by an authorized administrator of University of New Hampshire Scholars' Repository. For more information, please contact ellen.phillips@law.unh.edu.

Peter Gregory and Stanley P. Kowalski

Peter Gregory is a Consultant on agricultural biotechnology for international development and an Adjunct **Professor in the Department of Plant Breeding and in Inter**national Programs at the College of Agriculture and Life Sciences. **Cornell University. His** primary focus is on addressing strategic issues at the interface of conventional agricultural research and modern biotechnology. **Contact:** pg46@cornell.edu

Stanley P. Kowalski is at the International **Technology Transfer** Institute (ITTI) at the **Franklin Pierce Law Center, a pioneering** global leader in legal education with specialized curricula in intellectual property and international programs in China and Ireland. ITTI's mission it to advance innovation in developing countries via education. outreach and capacity building. **Contact:** skowalski@piercelaw. edu

Crop bioengineering: enormous potential for catalyzing international development

Introduction

Bioengineering provides unique and dramatic opportunities for crop improvement. It can be used to develop crop varieties that would otherwise be unavailable and can facilitate much faster and more precise ways of developing improved varieties. It can help to increase yields and reliability and thus reduce food costs for the consumer while helping to control input costs for farmers through reduced applications of herbicides, pesticides, and fertilizer.

The extent to which this will be achieved depends on how effectively the global scientific community – including both the public and private sectors – can cooperate in harnessing the power of crop bioengineering and the allied scientific fields of genomics and bioinformatics for the poor and hungry of the world. This, in turn depends on the extent to which projects are demand-driven and holistic in approach, integrating all technical and non-technical factors relevant to the product development and commercialization/ delivery chain.

What are bioengineered crops?

Crop bioengineering is the precise transfer of desirable genes into a target crop plant without the concomitant introduction of non-desirable genes that conventional plant breeding entails (often necessitating expensive and lengthy backcrossing schemes). However, crop bioengineering is neither a panacea nor a stand-alone, but rather a biotechnological tool that complements conventional, organic or other biotechnological approaches as part of an integrated approach to crop improvement. The technology has already had considerable impact around the world - in industrialized and developing countries. Most commercialization to date has focused on internationally traded commodities such as maize, soybean, cotton and canola. The major traits that have been transferred into these crops include herbicide tolerance (to facilitate improved control of weeds and reduce tillage) and insect resistance (to reduce the need for chemical pesticide applications while improving pest control) and, to a lesser extent, delayed ripening, and virus resistance. Although the global deployment of bioengineered crops has dramatically expanded (from 10 million hectares in 1997 to 125 million hectares in 2008) the dominant countries remain the USA, Argentina, Brazil, India, Canada and China (James, 2008).

Bioengineered crops are needed for international development

The range of bioengineered crop species available to developing countries must be expanded significantly if agricultural production is to keep pace with growing populations, diminishing arable land, relentless urbanization and an ever expanding global appetite for meat consumption. Whereas multinational life sciences companies have led the research, development and commercialization of bioengineered crops, their primary focus has been, and will likely continue to be, on crops with traits having commercial value as global commodities.

Meanwhile, many crops of extreme importance to subsistence and resource-poor farmers around the world have been neglected. Such crops – often referred to as 'orphan' crops because of the relative lack of research and development applied to them – can be vitally important for nutrition and income in poor regions. These crops cover 240 million hectares in developing countries alone and

include plantain and bananas; root and tuber crops such as potato cassava, sweet potato and yam; millets such as pearl millet, finger millet and foxtail millet; legumes such as cowpeas, groundnut and Bambara groundnut; and tree crops. Moreover, indigenous crops such as tef, quinoa and many types of vegetables are critical for food security and nutrition on a regional or local basis. Whereas some of the production constraints associated with these crops are being overcome by conventional breeding and agronomic approaches, for some crop/constraint combinations bioengineering is the only answer.

The long-term technological possibilities for bioengineered crops are vast due to breakthroughs in genomics and bioinformatics¹. Ultimately plant genes encoding all agriculturally important traits will be more easily identified and isolated and, through bioengineering, transferred to target varieties. By facilitating access to, and use of, desirable genes in plant germplasm collections and naturally occurring genetic resources, the combination of genomics, bioinformatics and bioengineering will indirectly contribute to the improved conservation of biodiversity. Plant germplasm collections that are put to better practical use are less likely to be abandoned due to budgetary cuts, and ecosystems whose resources can be valorized are less likely to be destroyed or wasted.

How can the full potential of crop bioengineering be tapped for international development?

Safe and effective adoption of bioengineered crops (including orphan crops) for the developing world necessitates new project approaches involving partnerships among all relevant stakeholders. Depending on project specifics, partners might include universities, national and regional research organizations,

¹ Genomics is the study of the whole genomes of organisms. The field includes intensive efforts to determine the entire DNA sequence of organisms and fine-scale genetic mapping efforts. Bioinformatics is the application of information technology to the field of genomics and other areas of molecular biology.

the private sector, non-governmental organizations, government agencies, international agricultural research centres and other stakeholders from developing and industrialized countries who are involved in the researchdevelopment-commercialization/delivery continuum.

Projects must be demand-driven with a holistic and integrated approach that considers every technical and non-technical issue from the outset (Gregory *et al.*, 2008). It is essential in the planning and implementation of the work not to underestimate the resources needed to move a bioengineered crop from the research phase into the hands of the end-user – a point that is often overlooked by public sector organizations such as universities and national research institutes which, historically, have focused almost exclusively on the research phase.

Figure 1 outlines the actual stages of product research, development and delivery that typically need to be addressed once market assessment and feasibility studies on the candidate bioengineered crop have been conducted. Of the 14 stages in the research– development–commercialization/delivery continuum, only five relate to research. The cost of the other nine, non-research stages typically represents two-thirds of the total project. Obtaining regulatory approval for new bioengineered crops can be a particularly costly, major bottleneck.

Even though there are no known substantiated harmful effects of bioengineered crops on human health or the environment, there are theoretical environmental and health risks associated with bioengineered crop production and use. Accordingly, a regulatory package needs to be compiled to enable the commercialization of each bioengineered product. Compiling such a package can cost more than a million dollars and involve up to a decade of work. Due to these high costs it is advisable, to the extent possible, to utilize information from existing regulatory dossiers generated in other countries for the same or similar products. Depending on the focus country involved, this activity can be governed by national biosafety legislation and the authorities responsible for its implementation. Much of what is needed is codified; however, some of the work can involve negotiation and perceptions of risk. New data for the regulatory packages should be generated as much as possible within the focus country or region. An interactive relationship with regulatory authorities needs to be established - even at the outset of product development - and dialogue should be

Figure 1. Stages in the research-developmentcommercialization/ delivery continuum (Gregory et al., 2008)



- 4. Proof of concept Gene efficacy and stability (greenhouse trials, etc)
- 5. Event Selection Open field trials, molecular characterization, biosafety, IPR

Product Development

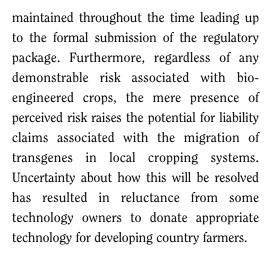
- 6. Backcrossing/Breeding Conversion of trait into advanced germplasm
- 7. Gene equivalency Establishing complete conversion
- 8. Regulatory approval Food and feed equivalency, biosafety testing, refuge, etc.
- 9. Seed multiplication Production of pure high quality seed
- 10. Market strategy-seed distribution channel, extension

Commercialization

- 11. Inventory management Seed sales, warehouse capacity, etc.
- 12. Stewardship Refuge requirements, IRM, trait durability, traceability, etc.
- 13. Advertising

Termination

14. Remove or replace product from the market



Bioengineered crops, germplasm, biodiversity and property rights

The growing importance of property rights to the development and use of bioengineered crops relates to ongoing globalization and harmonization of intellectual property rights (IPR) regimes pursuant to the World Trade Organization's Trade-Related Aspects of Intellectual Property agreement (TRIPS), the Convention of the International Union for the Protection of New Plant Varieties (UPOV) and the Patent Cooperation Treaty (PCT), and also the implementation of two international accords which affect the accessibility of crop germplasm and genetic resources, i.e., the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources for Food And Agriculture (ITPGRFA) (Kowalski, 2007).

This rather complex international web of property rights has raised concerns in both the private and public sectors. As mentioned above, most of the advances in technology development associated with bioengineered crops have been made in the private sector, which protects its inventions via IPR, that is, patent portfolios and plant variety protection (PVP) certificates. If, as we anticipate, crop technology expands to encompass a much broader range of traits and crops and new markets emerge, such IPR protection will likely increase, as is already evident when considering the trend towards overlapping IPR protection of commodity crops, i.e., layered patent, PVP, trade secret and trademark protection in maize.

Regarding germplasm, if plant resources become valuable reservoirs of genes for new bioengineered crops, it will be essential to address issues related to ownership of plant genetic resources accessed from international, regional and national germplasm collections and also from wild ecosystems. Until the establishment of the CBD, free exchange of genetic resources was the norm under the common heritage principle. However, the CBD now recognizes that countries have sovereign rights to control and use their genetic resources, and further encourages these signatory governments to formally regulate access to biodiversity. This has thus led to a decrease in global germplasm flow with regard to bioprospecting involving wild crop relatives growing in their natural habitats. The ITPGRFA, however, seeks to facilitate access to existing crop germplasm collections via its open-source type IP provisions, i.e., agreement not to seek IPR on any of the germplasm resources in the form received, thus facilitating open and continued access.

Weak IPR regimes in many developing countries, an inadequate understanding of the requirements and implications of IPR on bioengineering technology and concerns about the cost and potential liability associated with IPR, can impede the roll-out of bioengineered crops for developing countries; however, this can be ameliorated if national systems are augmented via international collaborations and partnerships coupled with concerted efforts towards capacity building in both the technological and legal frameworks requisite for advancing crop biotechnology. Indeed, depending on how it is managed, IPR can either delay or accelerate access to biotechnological innovations. IPR management capability is therefore an integral component of the holistic approach to delivering bioengineered crops to developing countries.

Conclusions

Bioengineered crops have already had substantial impact in developing, as well as industrialized, countries and they have enormous potential for providing solutions to important and previously intractable problems facing subsistence and resourcepoor farmers in the developing world. However, for this to become a reality it is essential to address, from project inception to termination, the complex technical and nontechnical issues associated with the research-development-delivery continuum for bioengineered crops. This requires a wide range and depth of expertise and facilities that extend far beyond the present or projected capacities of most individual institutions or even nations. Therefore, the full potential of bioengineered crops as tools for international development can be realized only if strong emphasis is placed on inter-institutional collaboration - including public and private sector organizations - at the national, regional and global levels, coupled with focused and sustained capacity building at both the human and institutional levels.

Perhaps most importantly, successful distribution of bioengineered crops requires a communication strategy that provides regular, accurate information on the bioengineered product(s), not only to farmers but also to local scientists, regulators, journalists, extension workers, retailers, religious groups, consumers, non-governmental organizations and others. This will facilitate product acceptance, address concerns as they arise and increase the likelihood of product acceptance and continued development of new bioengineered crops for the world's poor and hungry.

References

Kowalski, S.P. (2007). Freedom to Operate: The Preparations. In: *Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices* (Eds. A. Krattiger, R.T. Mahoney, L. Nelsen, et al.). MIHR, Oxford, U.K. and PIPRA, Davis, U.S.A. Available online at www.iphandbook.org

Gregory, P., R.H. Potter, F.A. Shotkoski, D. Hautea, K.V. Raman, V. Vijayaraghavan, W.H. Lesser, G. Norton and W.R. Coffman (2008). Bioengineered Crops as Tools for International Development: Opportunities and Strategic Considerations. *Experimental Agriculture*, 44, 277-299

James, Clive. (2008). *Global Status of Commercialized Biotech/GM Crops: 2008*. ISAAA Brief No.39. ISAAA, Ithaca, NY

Upcoming Events

2009

17 September	Marrying productivity and sustainability to achieve food security. Scottish Crops Research Institute, Invergowrie, Dundee (TAA Scotland & North of England and SCRI)
20 October	Water - our most important resource. Royal Agricultural College, Cirencester (SouthWestRuralUpdate). Details available from beverley.allen@rac.ac.uk
21 October	Ethiopia, with the theme of conservation which will include tree planting. Royal Agricultural College, Cirencester (TAA South-West)
9 December	TAA AGM and 27th Annual Ralph memorial Lecture given by Chris Garforth. Royal Over-Seas League, Park Place, St James's Street, London
2010	
8 January	Cambridge Conservation Forum Annual Symposium. Murray Edwards College (New Hall), Cambridge. Amir Kassam and Francis Shaxson will give a presentation on TAA's work in Conservation Agriculture.