POST-PATENT ACCESS & STEWARDSHIP

TRANSITIONING FROM PROPRIETARY TO GENERIC BIOTECH EVENTS

MOP-7 DISCUSSION

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Background

Innovation in Seed

- Innovation is the core of the seed industry
- Innovation happens through:
  - Improving germplasm by breeding – traditional & marker-assisted
  - Technology to maximize the germplasm's genetic potential
- Innovation provides:
  - Products that enable farmers to be more productive
  - Products that improve the viability and vigor of the seed

Protected Intellectual Property Rights (IPR) in a Bag of Seed

- Genetics: Plant Variety Protection (PVP), Patents and Contracts
- Breeding Technologies: Contract & Patents
- Input & Output Biotech Traits: Patents
  - Herbicide Tolerance & Insect Protection Traits
  - Quality & Yield Enhancement Traits
- Seed Treatments: Patents & Registrations
- Brands: Trademarks

Seed IPR—What is a "Generic" Seed Product?

Germplasm: Patent Protect Event: Patent Expired	Germplasm: PVP Certificate Event: Patent Expired	Germplasm: No PVP/No Patent Event: Patent Expired

Regulatory Intellectual Property Rights (IPR)

- Patents on biotech events are not the only IPR affecting the ability to sell or use seed products containing those events

- There is an entire body of "Proprietary Regulatory Property", including:
  - The data obtained from studies conducted to obtain regulatory approvals
  - The study reports developed from that data
  - The dossiers and submissions prepared to obtain regulatory approvals
  - The regulatory approvals or licenses themselves that enable placing seed products containing the biotech event on the market

Protection of Regulatory IPR

- There are substantial basic property rights in all of the original work developed and crafted by the technology developer to obtain cultivation and import approvals – the estimated regulatory cost of bringing a biotech product to market is ~ $30MM* – a substantial investment!

- The use of proprietary regulatory property is controlled by data protection and data compensation laws, property law, laws governing use of creative materials, copyright law and contract

- Test methods and the genetic information necessary to develop those methods and some materials used in testing are often subject to separate patents

* There is a range of opinion on the cost and value of a regulatory estate, but this is a consistent estimate

Context for Today's Discussions

- The first genetically engineered (GE) crop was commercialized in 1996
- Since then over 70 biotech plant products have been commercialized in the United States alone (*Citation: BioTradeStatus.com*)
- In almost every case, a biotechnology event is patented globally, and placed on the market by the developer of the event
- The first U.S. patents covering a biotech event commercialized in the U.S. are scheduled to expire in 2015
- The expiration of other U.S. patented biotech event patents will follow, and patents in other countries are expiring over time

But...What Does that REALLY Mean vis-à-vis the IPR for a Biotech Event & Seed Product?

- Even though the patents on a biotech event may expire in the cultivating country, that event may still be patented in other or importing markets
- The status of the germplasm does not change – whether PVP, patent, or contract
- Contracts & patents governing access to breeding technologies do not change
- Patents & registrations on seed treatments remain in effect
- Brands and trademarks continue to be protected
- *The Proprietary Regulatory Property related to the biotech event remains proprietary* …

The *only* change is that the biotech event itself can be accessed and inserted or bred into available, accessible germplasm

What Does that NOT Mean vis-à-vis a Generic Biotech Event?

- A generic event must still be approved in the country of cultivation
- A generic event must still be approved in the key export markets of *each* country of cultivation
- *Today*, the approval process for the generic event requires the preparation and submission of a full regulatory dossier and the completion of the full regulatory process in each of those countries
- If a generic event is stacked with another event (which is virtually ***always*** the case)… that other event is likely patented… that other event must also be approved… the stack must be approved
- A product containing a generic event must still be properly stewarded in the marketplace and through its life cycle:
  - Product integrity, purity and quality
  - Proper use to maintain utility, e.g. insect or weed resistance management
  - Prevent "matter-out-of-place"

Example:
Regulatory and Trade Context for the U.S. Discussions

U.S Regulatory Structure

- USDA *deregulates* – no "approval" or license granted
  - Deregulation not granted to petitioner & does not expire
  - Stacks not separately regulated
- EPA registers "plant-incorporated protectants" (PIPs = plant pesticides) – "license" granted to registrant
  - Registration expires – renewal
  - Registration must be maintained – conditions on registration
  - Separate registrations for each stack of pesticidal traits
  - Provides for generics with data protection & data compensation
- FDA consultation - no "approval" or license granted
  - Consultation voluntary & does not expire
  - Stacks not separately regulated

Rest of World Regulatory Considerations for U.S. Industry

- Approvals time limited in several countries
- Each new stack requires new approval in *most* countries
- Requirements for approvals always evolving or changing (e.g. South Korea, China, Kenya…)
- New approval processes come on-line (e.g. Vietnam, Indonesia, Tanzania, Mozambique…
- In all cases, maintaining approvals requires scientific, regulatory and political expertise and know-how

Regulatory + Trade Context for U.S. Industry

- Even though a biotech event is "off-patent" in the U.S., it is still highly regulated world-wide
- All major importing countries have different approaches to regulating biotechnology. This is costly and complex to navigate
- Most countries regulate stacked event seed products as new products, requiring separate approval from single event products
- Most countries do not have low-level presence (LLP) policies to manage the presence of unapproved events – creating a *de facto* "zero-tolerance" policy that delays innovation and is extremely costly to steward against
- *Unapproved events in commodity shipments will cause trade disruptions*

U.S. Stakeholder Concerns: Varied & *Vocal*

- Seed and ag biotech industry reached out to a broad & diverse group of major grain trade, processor & grower groups
- Demand for maintenance of regulatory approvals in export markets to facilitate trade
  - Exports of soybeans and soy products, corn and cotton account for over $40 billion of U.S. agricultural exports
  - One in every four rows of U.S. soybeans goes to China
- Demand for mechanism to transition to generic marketplace
  - Increased price competition
  - Availability of new combinations of generic events
  - potential for economic gains
- Expectation of high quality seed products to farmers in any marketplace (proprietary or generic)
- Expectation of continuing innovation in seed products & crop traits

Example: The Collaborative U.S. Approach

American Seed Trade Association (ASTA) & Biotechnology Industry Organization (BIO) Process

- The seed and ag biotech industries started a process in the spring of 2010 to address those stakeholder concerns… engaging those stakeholders in continuing dialogue
- After analyzing options, ASTA & BIO agreed to consider the development of a voluntary, but legally binding contractual mechanism
- ASTA and BIO principles
  - Each organization adopted a set of Board-approved principles with respect to post patent expiration access to and stewardship of biotech events
- ASTA & BIO Joint Working Group assignment:
  - Address post patent regulatory and stewardship issues
  - Set up a clearly defined framework for transition from proprietary products to seed products containing generic biotech events: the AgAccord Agreements
  - Develop the AgAccord Agreements within the parameters of the approved principles
  - The solution was not to be biased by any product specific considerations – e.g. no mention of the "elephant in the room" Roundup Ready 1 soybeans

Basic Principles Guiding ASTA/BIO Process

- Deliver benefits to value chain:
  - Maintaining and supporting export markets
- Maintain high stewardship & quality standards while allowing for business opportunities
  - Clear path for transition from proprietary to generic events
  - Immediate access to events when they become generic
  - Proper stewardship of seed products containing generic events
- Maintain support for innovation
  - Protection for all IPR (e.g. patents and regulatory intellectual property)
  - Compensation for "Proprietary Regulatory Property" (PRP)
- Promote science-based, transparent and predictable regulatory processes globally.

Key Elements of the AgAccord Agreements

- Contractually binding process
- Voluntary and open to any entity supporting biotech to become a signatory to the AgAccord Agreements – only signatories get benefits
  - Notice of patent expiration, opportunity to engage, and negotiation or arbitration of agreement for access
  - Immediate and practical access to the generic event
  - Every signatory commits to continued stewardship of the generic event
    - global approvals maintained to support trade
    - Excellence Through Stewardship or similar standards apply
  - Compensation for and access to Proprietary Regulatory Property

Resources

www.excellencethroughstewardship.org

www.agaccord.org

Looking Ahead

What Will the Future Hold for Generic Seed Products?

- With continuous advancements in technology, *will there even be a market for generic events?*
- With the stewardship need for multiple modes of action to delay development of resistance, *should there be a market for **single** generic events?*
- How can and should *regulators* transition to the generic marketplace? Who will they hold accountable and how?
  - Regulators have not begun to consider the implications of a multitude of generic seed products on the market where the original developer is no longer in the market or responsible
- Can the AgAccord Agreements provide guidance for approaches to the transition for other regions and countries?

What Will the Future Hold for the Regulation of Generic Events?

- The issues for generic biotech events are the same in every region and country: Regulatory & Stewardship
- Longer term: science-based, transparent and predictable regulatory processes must be promoted globally, to remove unnecessary barriers, complexity and costs for generic biotech events and seed products
  - By definition, a generic event has outlived its patent life, is ~20 years old, and has been on the market and in commerce for the better part of that
  - The regulatory requirements for such an event *should* be reduced or eliminated:
    - Based on familiarity
    - Based on GRAS (generally recognized as safe) for events with 20+ years of safe use
    - Through harmonization of global regulatory requirements and processes, or
    - Through regional approaches to the regulation of such products
- Regardless of the regulatory response, the products of agricultural biotechnology *must always be properly stewarded*

Thank you

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