LEVERAGING INTELLECTUAL PROPERTY MANAGEMENT FOR CROP BIOTECHNOLOGY INNOVATION

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AgriFood Business

Workshop on Intellectual Property Rights for Innovation in Industrial & Agricultural Sectors in Support of Economic Development

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BACKGROUND

A key development in 20th century- Roundup Ready® (RR®) soybean patented by Monsanto

The first widespread trait to come off patent

Patent rights were granted in 1994 for U.S. patent #5,352,605 → 17 years → patent expired in 2011

The patent extended to 2014 through the re-examination process in 2009 (RE39,247)

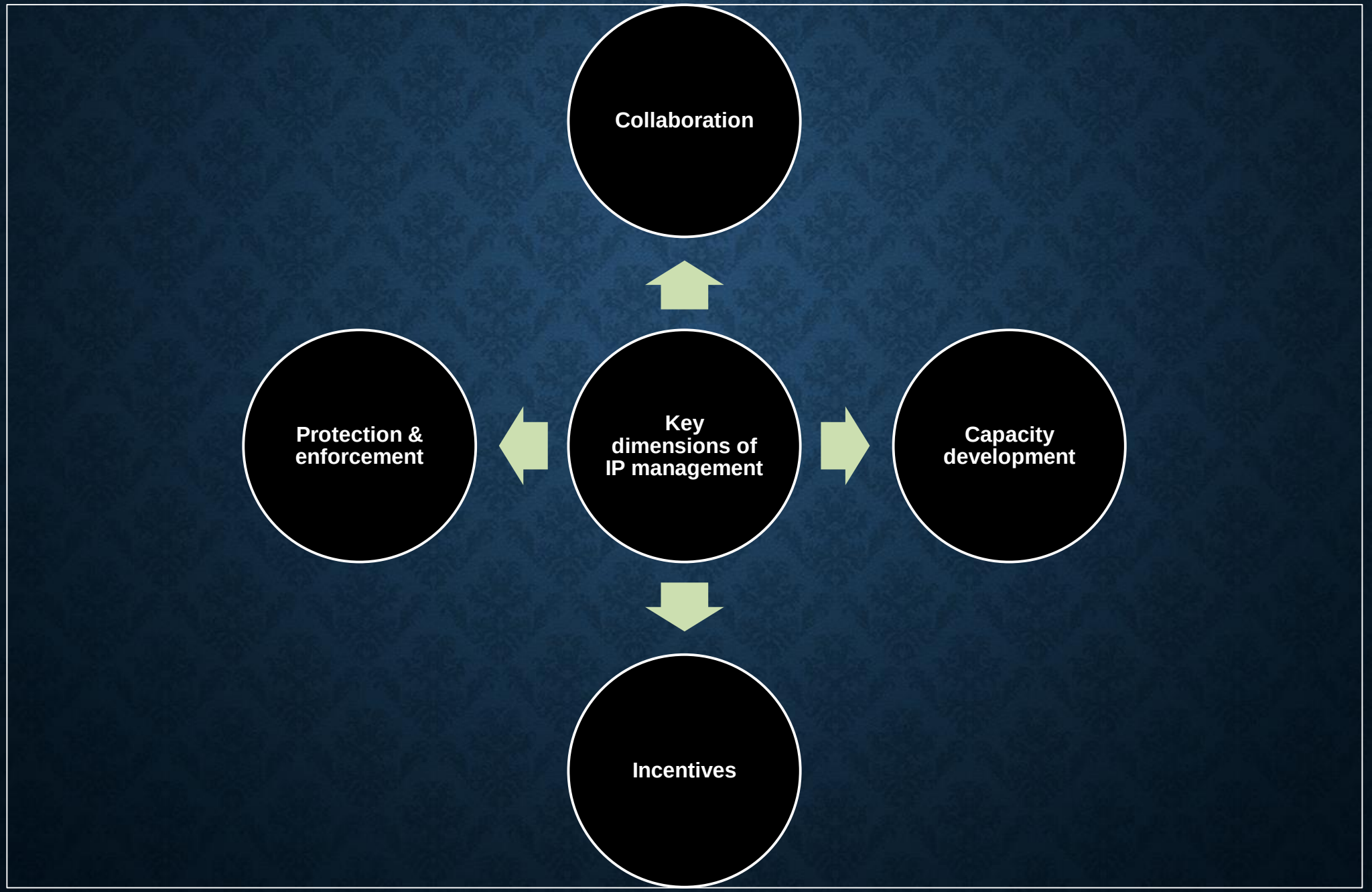
THE PROBLEM

The issue of patent expiration for RR® soybeans	Jeopardizing other licenses in a stacked seed
	Royalty payments
	Generic trait & replanted RR soybean seed saved from harvest

Objective

Identify and assess issues of IPRs and their influence on soybean biotechnology R&D

TOWARDS A CONCEPTUAL FRAMEWORK FOR IP MANAGEMENT


Collaboration
Protection & enforcement
Key dimensions of IP management
Capacity development
Incentives

INTRODUCTION & CONTEXT

- **When the patent rights on RR® soybean expire:**

➢ **The challenge and opportunities, benefits and risks**

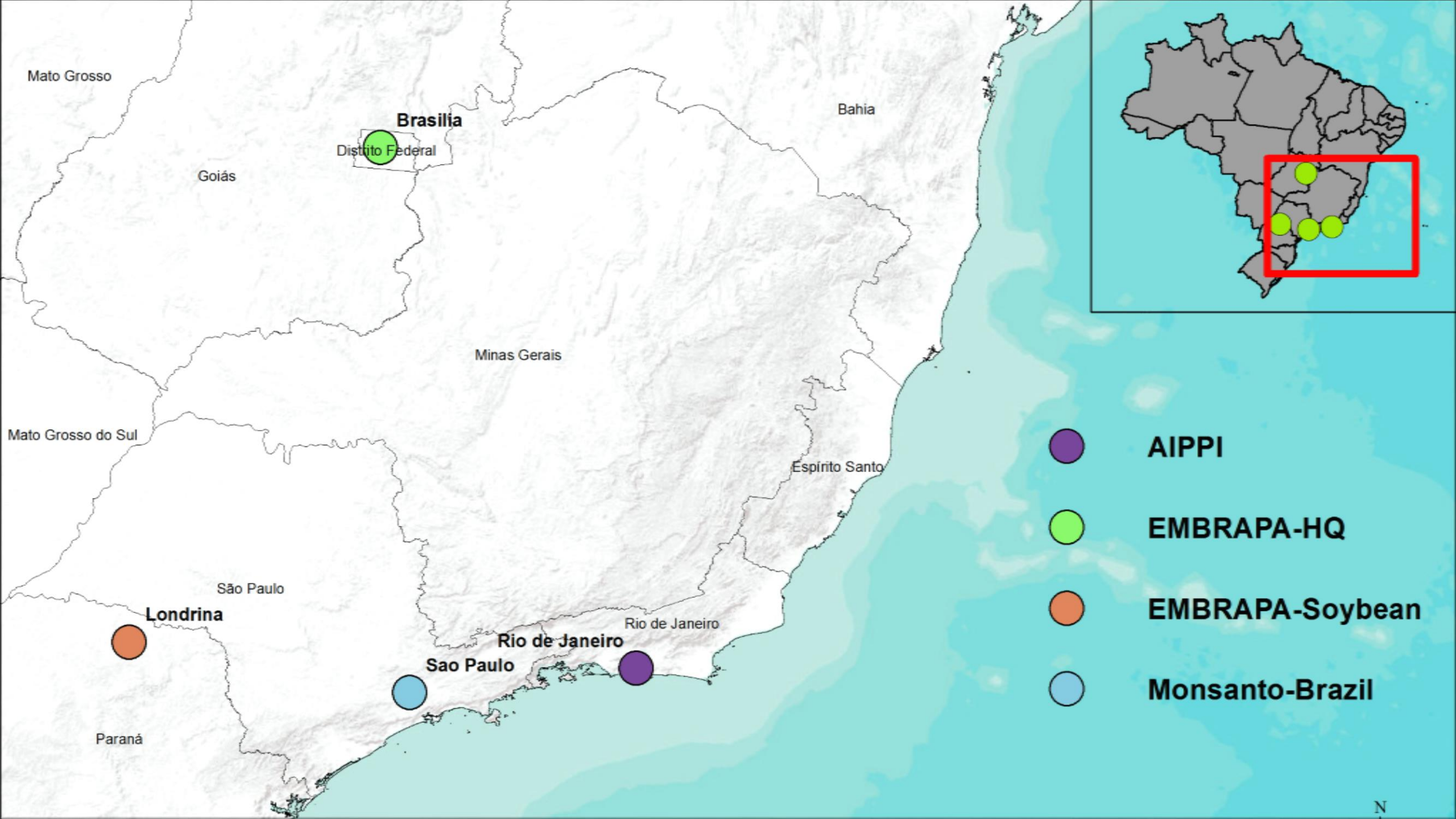
➢ **The preference by farmers to keep planting RR® first generation of soybean**

➢ **No technology fees and farmers no longer have to abide by contractual restrictions on saving and re-using the first-generation seeds**

➢ **Performance advantages with new traits and demand for enhanced seed biotechnology**

Technology timelines for the Roundup trademark and first generation glyphosate tolerant soybean

1967-1968	• Roundup trademark applied for 1967, registered 1968
1974	• Identified the herbicidal activity of Roundup® (glyphosate)
1974	• Use of glyphosate as an herbicide patent awarded
1976	• Roundup® herbicide commercialized in the U.S.
1990	• Registration of Roundup Ready® soybean in the U.S.
1996	• First generation: Roundup Ready® soybean commercialized
2000	• Patent expiration of Roundup® herbicide
2009	• Second generation: Genuity® Roundup Ready 2 Yield® launched
2014	• Patent expiration of Roundup Ready® soybean first generation, world-wide


Mato Grosso
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Rio de Janeiro
Rio de Janeiro
Sao Paulo
Paraná
AIPPI
EMBRAPA-HQ
EMBRAPA-Soybean
Monsanto-Brazil
N

EMBRAPA & PRIVATE INDUSTRIES

EMBRAPA inserted the RR® gene into an EMBRAPA cultivar to develop a new cultivar of soybean

EMBRAPA owns the new cultivar and Monsanto owns the gene (trait). BASF and Bayer Crop Science have followed the same business strategy of Monsanto

EMBRAPA is taking part of the technology fee (in the case of BASF)

Intellectual Property Office

The challenge of enforcement of IP in Brazil, and most of cases have been litigated under the PVP Act

Conventional breeding, Roundup Ready® soybean (50 cultivars), and Intacta® Roundup Ready® 2 Pro (11 cultivars)

EMBRAPA has negotiated the continued use of developing new varieties with RR® soybean first generation after the end of IP protection

Monsanto returned some funding for EMBRAPA to invest in soybean biotechnology

PATENT EXPIRATION ON HERBICIDE TOLERANT SOYBEAN

Implications from patent expiration on HTS

- **Intacta® RR® 2 Pro (HT& IR) in South America in 2013**
  Genuity® RR® 2 Yield (HT) in North America in 2009
- **Shifts in the demand of RR® 2 Pro is increasing**
- **Reduce the availability of RR® first generation soybean in the market**
  EMBRAPA has negotiated the continuity using and marketing RR® first generation soybean
- **Monsanto will maintain the regulatory approval on RR® soybean until 2021, but Monsanto will not do anything after this date**
  EMBRAPA could maintain regulatory approval beyond 2021 for China and EU if it is inexpensive and simple

THE SOYBEAN TECHNOLOGY AND ROYALTY SYSTEM

The technology fee is a major issue

- A lawsuit involved a group of farmers who claimed that Monsanto collected tech fees on its expired patent in 2011 under Brazilian laws
- Monsanto offered to reduce the price on its new Intacta® RR® 2 Pro soybeans in exchange for dropping the case

There are two set of fees

- EMBRAPA protects a new developed cultivar by PBR and collects royalty from farmers based on the UPOV system
- Monsanto collects technology fee from farmers on the patented gene at elevators or trade gates

The seed law in Brazil

- Allowed farmers to save seeds in case farmers payback royalties and technology fees on the harvested seeds

Monsanto implemented one price = soybean price and technology fee combined in one set

The biggest factor influencing the availability of RR® soybeans

- The performance advantage with new traits and breeder's choice to breed with the newest traits that provide the best chance of success for their genetics

The AgAccord (in the U.S.)

- To address IP issues post patent expiration in seed biotechnology and support a transition to the marketplace.
- The Generic Event Marketability and Access Agreement (GEMMA) & the Data Use and Compensation Agreement (DUCA)

The PVP in Canada and USA prevents farmers from saving seeds

- Public research institutions would continue to offer soybean varieties containing RR® first generation trait post patent expiration

CONCLUSIONS

- The RR® first generation soybean will remain for a period of time in the commercial supply chain. Monsanto will discontinue the regulatory responsibility after 2021

- American public research institutions were able to incorporate the RR® gene into varieties after the patent expiration. The competition with generic traits is still within public research institutions

- Brazilian farmers are benefiting from the RR® second generation which justify the quick switch-over to this technology

- Farmers do not have to pay technology fee and can save seeds to replant in the next season

- Adequate protection and incentives for GM traits development depend on seed laws, biosafety regulation and IPRs regimes

THE CONVERSATION

Academic rigour, journalistic flair

Soybean farmers in Brazil sued Monsanto for a royalty collection system that they say violates their planting rights. A soybean harvest in Mato Grosso, Brazil, March 27, 2012. AP Photo/Andre Penner, File)

Monsanto wins $7.7b lawsuit in Brazil – but farmers' fight to stop its 'amoral' royalty system will continue

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THANK YOU

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