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American Seed Trade Association
<http://www.amseed.org/>



<http://www.bio.org/>

FACTSHEET

The AgAccord[®] is now completed as the Data Use and Compensation is Open for Signature

Background

The first of the commercial biotechnology events in the United States will be going "off-patent" and becoming "generic" in 2014. To prepare for this transition, the Biotechnology Industry Organization (BIO) and the American Seed Trade Association (ASTA), together with its members worked with the agricultural value chain to create a voluntary, industry led mechanism, the AgAccord[®].

The AgAccord is now complete and will support a seamless transition to a marketplace that includes both proprietary and off-patent biotechnology events. Creation of the AgAccord is a substantial milestone for the agricultural biotechnology industry and it is in place well in advance of the need. The number of events coming off-patent in the near future is small and won't increase significantly until after 2020.

The AgAccord was established to ease the transition to the post patent marketplace by creating a contractual framework to support business opportunities for those seeking to use off-patent events in the United States, while ensuring important global regulatory authorizations are maintained so that U.S. exports to important markets are not disrupted. The AgAccord is intended to provide a predictable and transparent contract based system to address patent expiration for agricultural biotechnology events.

The AgAccord includes two separate agreements that cover the full spectrum of issues related to patent expiration – the Generic Event Marketability and Access Agreement (GEMAA) and the Data Use and Compensation Agreement (DUCA). The GEMAA entered into effect in November 2012 and currently has 10 signatories. The DUCA opened for signature in December 2013.

The AgAccord agreements promote continued innovation in the U.S. seed and biotechnology industry and choice in the seed marketplace by supporting access to off-patent events and preserving intellectual property rights. Further, these agreements complement industry's already extensive use of licensing agreements. Pre-patent expiration licensing and cross-licensing in the biotechnology and seed industry is responsible for the wide-spread use of patented biotechnology

events in the United States and has contributed to continued growth in the combined -event (stacks) seed product market. Currently, it is estimated that over 50 percent of the combined-event seed products on the market today are the result of pre-patent licensing agreements.

The AgAccord agreements simply establish contractual mechanisms to make off-patent events and the proprietary regulatory information that support these events available to interested parties that might not otherwise have access prior to patent expiration.

The AgAccord provides agricultural stakeholders:

- confidence that trade will be maintained, by providing a contractual framework for signatories to commit to maintenance of regulatory authorizations post patent expiration;
- access to off-patent events;
- continued stewardship of off-patent events
- alternative processes for negotiating and arbitrating access to proprietary regulatory information, such as data and studies, thereby enabling the ability to create new proprietary combined event seed products that include off-patent events.

The AgAccord: A Unique Private Sector Solution

The AgAccord sets out rights and obligations for signatories involved in commercializing biotechnology seed products containing off-patent biotechnology events to ensure international regulatory and stewardship responsibilities are maintained. The AgAccord comprises two agreements: The Generic Event Marketability and Access Agreement (GEMAA) and the Data Use and Compensation Agreement (DUCA). While both of these agreements are voluntary, they are binding contracts among their respective signatories. They promote continued innovation in the seed industry, preserve strong protection for intellectual property rights and provide for new business opportunities.

The GEMAA entered into force and became operational in November 2012. The DUCA is now open for signature.

Scope of the AgAccord

The AgAccord agreements cover signatories' biotechnology events are commercially cultivated in the United States and are within 4 years of patent expiration in the United States. The agreements will support U.S. cultivation and regulatory authorizations needed to facilitated U.S. exports of grains and oilseeds.

Driver of the AgAccord: Maintaining U.S. Agricultural Export Markets

Biotechnology events are highly regulated world-wide. Regardless of the status of patents on events, biotechnology events must be authorized for import into our major trading partner countries. Often, these authorizations are time-limited and must be monitored and maintained by companies that developed and are marketing seed containing these events. Following the expiration of U.S. patents covering a biotechnology event, companies that are already selling that event may continue to sell seed containing the event in the U.S. market, but it is also probable that other seed companies will market seed containing the off-patent event. As companies invest in innovation, they could also use these off-patent events in the development of new proprietary seed products.

It is, therefore imperative the U.S. agricultural biotechnology value chain have access to a transparent and predictable mechanism that maintains regulatory authorizations after patent expiration and obtains any necessary, new authorizations in order to keep U.S. agricultural export markets open. To this end, the AgAccord creates a process in the United States that:

- Is based on binding contractual relationships
- Provides for equitable sharing of ongoing regulatory and stewardship costs
- Maintains obligations for product stewardship practices

Driver of the AgAccord: Promotion of Innovation and Business Opportunities

A basic principle underlying the AgAccord is the promotion of continued innovation and business opportunities, while still maintaining the seed industry's high product quality standards.

Fundamental components to this principle are:

- Transparency and predictability in the mechanisms of the AgAccord
- Access to generic events at patent expiration
- Fair compensation for access to proprietary regulatory data and authorizations
- The protection of all intellectual property rights to maintain incentives for continued investments in innovation

The AgAccord: The Basic Elements of Both the GEMAA and DUCA

The GEMAA and the DUCA both provide the following basic elements:

- An opportunity for members of the U.S. agricultural value chain to participate in the process and steer the future direction of the agreements
- Notice three years in advance of patent expiration that an event's patent will expire
- An obligation to provide access to the biotechnology event, in a "usable" form at the time of patent expiration
- Mechanisms for sharing or transitioning of regulatory costs and responsibilities through negotiation with binding arbitration, if necessary
- A predictable process for signatories, or groups of signatories, to become "verified" to ensure that they are able to share or take over regulatory responsibilities
- Stewardship requirements for signatories
- A clear path for a signatory exiting the market for an event to 1) transition the responsibility to other signatories interested in maintaining authorizations for an off-patent event; or 2) if there are no signatories interested in taking over an event, an orderly process for discontinuing that event

The Data Use and Compensation Agreement (DUCA)

The DUCA was developed to address the marketability issues covered by the GEMAA, and has many shared principles and commitments with the GEMAA. The DUCA provides for an alternate mechanism for data compensation in return for access to proprietary regulatory property (PRP) at patent expiration.

Access to PRP is important for companies interested in using off-patent events as a single event product once the original developer exits the market; or if companies wish to create new seed products that combine an off-

Proprietary Regulatory Property
Apart from intellectual property within the seed, such as patents on an event or seed germplasm, companies that have developed and marketed biotechnology events have generated data and research studies in order to gain regulatory authorizations in the U.S. and its export markets. This data is proprietary regulatory property (PRP) that companies own and is separately protected apart and distinct from United States patent law.

patent event with other proprietary events. Under either circumstance, companies would need access to the original PRP or may otherwise create their own, which can both costly and time consuming. Under the DUCA, access to PRP and data compensation is mandatory.

KEY ELEMENTS OF THE DUCA

- **Communication:** Both AgAccord agreements encourage communication among signatories and with the value chain. The GEMAA and DUCA were designed with the intention of enabling broad participation, including biotechnology companies, seed companies, universities and national farmer organizations, so that key members of the value chain are kept informed of developments related to patent expiration.
- **Transparency:** Facilitation of information among stakeholders is a core component of the AgAccord. Much like the GEMAA, the DUCA creates obligations around providing a series of “notices”, including initial notice, which requires signatories to inform the public no later than three years before expiration, that the last patent covering a commercial event will expire.
- **Predictable Timelines:** The DUCA outlines a series of important deadlines to ensure that milestones within the DUCA process are met. This provides necessary predictability throughout the DUCA process. For example, the DUCA specifies the timeframe for negotiations and arbitration of an event-specific comprehensive agreement so that signatories have confidence that negotiations for access to an event and its PRP will conclude in a timely manner.
- **Pre-patent access:** Both AgAccord agreements include a requirement for Signatories with events coming off-patent, upon the request of another signatory, to enter into good faith negotiations for access to the event and PRP prior to patent expiration. However, it is not required that an agreement for pre-patent access be executed if the parties do not reach agreement on terms.
- **Access to Off-Patent Events in a Suitable Form:** Like the GEMAA, the DUCA also requires that signatories will provide access to the event in a suitable form (meaning without associated intellectual property restrictions) to other DUCA signatories that execute an event-specific comprehensive agreement.
- **Objective Verification:** The DUCA requires each signatory to be “verified” in order to join negotiation of an event-specific comprehensive agreement. Signatories interested in becoming verified must establish their ability to steward events (individually), and together with other signatories seeking to become verified must identify a single party (operator) to provide regulatory services for an event; and establish a verification fund that will constitute the negotiating parties’ financial wherewithal to share in or take over global regulatory responsibility for an event.
- **Negotiation and Arbitration:** The DUCA is structured to enable all verified signatories to enter into negotiation of a comprehensive agreement on an event-by-event basis. Each event-specific comprehensive agreement will detail the level of data compensation for access to PRP as well as establish the regulatory and stewardship responsibilities that must be maintained when marketing an off-patent event. Parties negotiating an event-specific comprehensive agreement have the flexibility to determine the terms and conditions of each comprehensive agreement. However, if parties negotiating a comprehensive agreement cannot reach agreement within two years of initial notice, all unresolved issues will go to

binding arbitration. The signatory that is the PRP Holder is required to execute the resulting event-specific comprehensive agreement, unless no other negotiating party executes that comprehensive agreement.

- **Compensation:** Each signatory that gains access to an event through a comprehensive agreement is required to pay a share of basic regulatory costs (BRC) and continuing maintenance costs (CMC). BRC compensates the PRP Holder for the current replacement costs of the relevant PRP submitted to regulatory authorities through patent expiration. BRC will be depreciated for those signatories accessing PRP for use only as a single event. CMC are the actual costs of maintaining and obtaining new authorizations and paying the Operator for regulatory services under an event-specific comprehensive agreement. The PRP Holder is also responsible for a share of BRC and CMC if still commercializing seeds containing the event.
- **Combined Event Seed Products (Stacks):** The DUCA establishes a standard set of rights and obligations for signatories interested in creating proprietary combined event seed products containing an off-patent event covered under the DUCA. Signatories that create combined event seed products that contain only generic events will pay compensation based only on the single events accessed through the DUCA, unless that combined event seed product becomes patented.

For more information on the AgAccord, including copies of the GEMAA and DUCA and frequently asked questions, please visit www.agaccord.org.