



FROM PROPRIETARY TO GENERIC: A PRIVATE CONTRACTUAL MECHANISM FOR BIOTECH SEED PRODUCTS

by

J. Thomas Carrato and Brandon W. Neuschafer

The first genetically engineered crop was commercialized in 1996. Since 1996, more than 50 seed products with biotechnology events have been commercialized in the United States. Several products lived their useful lives and have been replaced with better technology or, in the case of insect protection, with multiple mode of action products to delay the development of resistance and increase the longevity and effectiveness of the products.

Now, however, the agriculture industry is faced with the new and complex issue of the first commercial biotech events—still widely used—going off patent and becoming “generic” in 2015. The dilemma facing the entire value chain—particularly trait developers, the new “generic” seed product providers, and growers who hope to plant those products—is how to ensure the continued seamless management of complex global regulatory and stewardship obligations associated with the commercialization of plant products containing biotech events, especially where the trait developer may no longer wish to support the products. There is no existing public or private mechanism for the effective transfer and *continuation* of those responsibilities. The most sensitive, pressing, and complex concern is the continued maintenance of the global import approvals necessary to prevent the costly disruption of the highly valuable trade in U. S. commodity crops (e.g., one of every four rows of soybeans grown in the U.S. are exported to China, and over 95% of those soybeans contain biotech events).

In 2010, through a collaboration of the Biotechnology Industry Organization (“BIO”) and the American Seed Trade Association (“ASTA”), trait developers and seed producers began engaging stakeholders throughout the value chain (from growers to processors) in discussions on how to manage complicated post-patent obligations, including the potential transition of proprietary biotech events to generic seed production. The goal of these dialogues was to begin outlining a framework for addressing the transition of post-patent responsibility for events while assuring the continued satisfaction of regulatory and stewardship obligations and avoiding severe market disruptions. After nearly three years of identifying issues, soliciting input from stakeholders, and extensive discussion of principles, mechanism and key terms, and conditions, it is this framework that has become the Accord Agreements.

Contributing Considerations and Basic Principles of the Accord Agreements

To understand the Accord Agreements and the process that has governed their drafting, it is necessary to understand the key concerns of all stakeholders, including BIO and ASTA. Through dialogues with representatives of trait originators, growers, seed companies, food processors, and grain handlers and exporters, these stakeholders identified key issues to be addressed by the post-patent framework, including:

J. Thomas Carrato is Associate General Counsel of Monsanto Company. **Brandon W. Neuschafer** is a partner in the law firm Bryan Cave LLP.

- The scope of the solutions to facilitate a generic marketplace and protect trade in commodities would be cultivation in and export from the United States.
- Existing authorizations in export markets must be maintained and necessary new authorizations obtained to facilitate trade.
- As patents expire, growers expect to gain economic benefits that may attend transitions to generic products.
- When all patents on seed products expire, growers of some crops expect to be able to save and use seed from one season to the next.
- Stakeholder organizations expect a solution to be enforceable.
- Commodity groups and their growers expect continued development of and access to new traits and technologies.
- Those who gain value from marketing or selling a generic event should support regulatory authorizations for and stewardship of those events and seed products.
- A predictable and transparent mechanism is essential to allow public and private researchers and seed companies access to generic events and relevant data to enable generic products, including stacks, to be available after patent expiration.
- Fair compensation should be provided for any access to approvals and data necessary to support generic events.
- Intellectual property should be protected to provide incentives for continued innovation and investment.

Taking into account these guidelines, among others, the goal of the Accord drafting process established jointly by ASTA and BIO is to create a process based on binding contractual relationships which assures that regulatory authorizations and stewardship obligations will be maintained by parties who step forward to assume responsibility for marketing seed products containing generic events, assures access to the generic event, and provides for access to the proprietary regulatory property (i.e. data, dossiers and authorizations) supporting that generic event at patent expiration in return for appropriate compensation. The Accord framework and agreements will accomplish these goals through the following approaches:

Transparency and Predictability. Any entity can become a signatory to the Accord Agreements. Under the Agreements, trait developers are required to provide notice to all signatories at least three years prior to the last such expiration that all U.S. patents covering an event will expire. This gives potential generic providers the opportunity to evaluate their interest and demonstrate their capacity to satisfy regulatory and stewardship obligations, and allows generic providers and trait developers an opportunity to negotiate (or arbitrate, if necessary) obligations relating to data compensation and ongoing regulatory and stewardship costs. If no signatory expresses interest in the event, the trait developer is free to discontinue the product.

Binding Framework. As contracts, the Accord Agreements are binding upon all signatory trait developers and all signatories interested in maintaining generic events after patent expiration. They provide for negotiation and, if necessary, binding arbitration for resolution of all disputes. Bilateral agreements between signatories or between signatories and non-signatories are allowed as long those side agreements do not breach or interfere with obligations under the Accord Agreements.

Maintenance of Regulatory and Stewardship Obligations. Generic providers will need to demonstrate that they are able to satisfy the regulatory and stewardship obligations attendant to marketing generic events in order to take over responsibility for those events. For example, they will need to be a member of Excellence Through Stewardship®, or demonstrate that they have comparable stewardship programs in place. Ongoing costs will be shared by signatories that market products after patent expiration, either individually or as a task force, be they trait developers or generic providers. There is also a

mechanism for providing predictable access to, and fair compensation for the value of, existing proprietary regulatory property (e.g., global regulatory data, dossiers, and authorizations).

The Resulting Accord Agreements

The Accord actually consists of two different agreements—the Generic Event Marketability and Access Agreement (“GEMAA”) and the Data Use and Compensation Agreement (“DUCA”). Both agreements are designed to effectuate a predictable, transparent, and efficient process that begins well in advance of patent expiration. Separation of the framework into two agreements allowed for earlier completion of the GEMAA, in order to protect international trade and provide immediate post patent expiration access to the then-generic event. The DUCA is focused on the development of a data compensation mechanism for access to Proprietary Regulatory Property (“PRP”), which will facilitate and expedite the development of new proprietary combined-event or “stacked” seed products.

Several elements are common to both the GEMAA and the DUCA. Under both, events are subject to the obligations of the Accord Agreements if the event remains commercialized in the United States (the defined “last sale” has not occurred) within four years of patent expiration. Parties wishing to commercialize an event after patent expiration must demonstrate a commitment to stewardship and to the maintenance of U.S. cultivation and export authorizations, and are bound to negotiate (and if necessary arbitrate) with trait developers the terms of continued post-patent support. Commercialized events must be made available in a “usable” form at patent expiration.

The Generic Event Marketability and Access Agreement

Under the GEMAA, Proprietary Regulatory Property (“PRP”) Holders must provide access to the generic event at patent expiration. PRP Holders are required to provide Initial Notice three years prior to patent expiration, and in this notice must elect whether to: (1) independently maintain regulatory responsibility for the event; (2) seek to share regulatory responsibility; or (3) discontinue regulatory responsibility. *In all events, all Signatories must properly steward all of their commercial events.*

Independent Maintenance: The PRP Holder can choose to independently maintain covered authorizations, at its own cost, and is not required to provide access to the PRP. In order to maintain trade, a PRP Holder making this election must maintain covered authorizations at no cost to generic producers of the event for a rolling seven years, with the seven year clock starting upon the decision to discontinue the event. This provides for three years to complete the negotiation and arbitration process, and four years for the PRP Holder’s “tail” of seed products to exit the marketplace. The PRP Holder making this election must provide access to the covered event in a “usable” form at patent expiration for use in a single generic event seed product (but not for “stacks” containing that event). At any time, though, the PRP Holder may seek to share regulatory and stewardship obligations for an event or decide to discontinue its marketing of the event.

Shared Maintenance: The PRP may “seek” to share responsibility for a covered event, in which case PRP Holders and interested Signatories would begin negotiation of a joint responsibility agreement. They would have 16 months to complete negotiation of that agreement, which must provide full access to PRP (which access would allow for stacking). If any issues remain unresolved by negotiation, they would be submitted to binding arbitration, which must be completed within fifteen months. No party is required to accept the arbitration ruling, but if they do it becomes a binding joint responsibility agreement. If no entity signs the joint responsibility agreement, the PRP Holder must continue to maintain the event at its own expense for the rolling seven year period.

Discontinue Maintenance: This decision begins a seven-year transition that will result in a product-specific agreement enabling interested parties to take over responsibility for U.S. and global regulatory authorizations and stewardship, and which must provide full access to the PRP, which would allow for stacking opportunities. The resulting transition agreement will be negotiated (and arbitrated, if necessary) and executed following the same timeline and process as a joint responsibility agreement. If any verified Signatory signs the transition agreement, then the PRP Holder must execute the agreement. If no verified Signatory signs the transition agreement, then the PRP Holder and all Signatories must discontinue the event, with Last Sale within four years, while maintaining all covered authorizations for that four year period.

Under any of the three scenarios, PRP Holders and Signatories that accept responsibility for an event must give general notice of their Last Sale of the event, and must maintain authorizations for four years after such Last Sale and notice.

The GEMAA will be effective once it is executed by four entities. It will be overseen by a Committee of Signatories, which is designed to include associations of or members of the value chain stakeholder organizations. The Committee will have discretionary duties relating to administration and enforcement of the GEMAA, and will speak for the Signatories. The Committee will retain an Administrator to perform non-discretionary day-to-day duties.

BIO and ASTA executive leadership approved the final draft of the GEMAA in June, 2012, which was then subject to legal review, consultation with stakeholders, and antitrust and government review. Internal legal review and consultation with the United States government, including the Department of Justice (“DOJ”), have been completed. Consultations have also occurred with value chain stakeholders, and their comments on the GEMAA have been taken into account.

The drafters have completed the Administrative and Arbitration Provisions for the GEMAA and those provisions have been approved by the ASTA and BIO executive leadership. ASTA and BIO expect the GEMAA to have become available for execution on October 29, 2012.

The Data Use and Compensation Agreement

Under the DUCA, PRP Holders must provide access to the event and to the PRP for the covered authorizations for that event for all purposes at patent expiration. PRP Holders who have signed the GEMAA, and then sign the DUCA will no longer be responsible as PRP Holders under the GEMAA, except with respect to any joint responsibility or transition agreements previously executed under the GEMAA, or with respect to binding arbitrations that have commenced under the GEMAA.

The DUCA commits Signatories to a detailed and structured data compensation process based on negotiation and, if necessary, binding arbitration procedures. The DUCA will also be overseen by a Committee of Signatories.

Because of the complex issues related to data access and compensation, drafting of the DUCA agreement has not yet been completed, but the goal of the drafters is to present the substantive provisions of the DUCA to the BIO and ASTA governing boards in late November and early December. To that end, the drafters have held several intensive drafting sessions, and plan to hold more two day in-person drafting sessions to complete the document. If the DUCA is approved by the governing bodies, it will then be subject to internal legal review, outreach dialogue with stakeholders, and United States government review.

Conclusion

The concept of a private, contract-based mechanism to address the transition from a patent-protected to a generic marketplace is unprecedented. There is no basis in law to mandate the transition of privately created and owned technology, and even more significantly, the complex sets of health, safety and environmental studies and the dossiers compiling and explaining those studies to enable the obtaining and maintenance of multiple global authorizations for import of those products. Even if there were such basis in law, there is clearly no mechanism in U.S. law to transition the responsibility to maintain and obtain those ex-U.S. authorizations, and then to properly steward those products, assuring their product integrity, quality and proper use. The drafters believe that the Accord Agreements represent a creative concept and will establish a fair, efficient, transparent and predictable mechanism that can successfully fill those voids.