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September 2012

COMPETITIVE ENTERPRISE INSTITUTE

Issue Analysis 2012 No. 7

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Executive Summary

Since biotech crops were first introduced on the market in 1994, American farmers have made them the most swiftly adopted agricultural technology in history. These high tech seeds containing patented new traits are more expensive than their conventionally bred counterparts, but farmers place great value on their ability to reduce overall costs, deliver important environmental benefits, and increase per-acre profitability. Yet, while farmers who choose biotech seeds find them worth their higher prices, many of them are eagerly awaiting the expiration of the patents on popular biotech traits over the coming few years.

The patent on Monsanto's Roundup Ready soybean trait, the most widely adopted crop biotechnology product in the world, and the patents covering another 22 biotech traits and processes are expected to expire over the next decade. Such patent expirations should make it possible for plant breeders to sell "generic" versions of these seeds, resulting in greater competition and lower prices. Unfortunately, a quirk in the way biotech crops are regulated in the United States and other countries poses several challenges that may make it difficult for breeders to develop a generic seed industry.

Both biotech and non-biotech crop varieties can be, and routinely are, patented. But, when the intellectual property rights protecting biotech plant traits expire, generic breeders need to ensure that growers and end users have legal permission to sell the seeds and to grow and sell the harvested crops. Most biotech seed products—known as "transformation events" or simply "events"—must be periodically re-approved, or "re-registered," for commercial sale by regulatory authorities in the U.S. and abroad. In key markets, this can be a lengthy, expensive, and politically unpredictable process that requires access to the proprietary testing data held by the original developers of the approved events.

The expiration of any transformation event's registration in an important export market could result in entire bulk shipments containing even relatively small percentages of that crop being rejected by an importing country's government. Such an occurrence would have tremendous negative economic effects that ripple throughout the food supply chain. Thus, as long as biotech traits must be re-registered every few years, those who sell or buy biotech seeds will have to bear the burden of meeting these on-going stewardship obligations. The heightened costs associated with doing so, however, could erase a substantial portion of the economic gains ordinarily associated with patent expirations and the subsequent development of generic products.

The re-registration requirement, however, cannot be justified scientifically, and it is needlessly complex. For 30 years, there has been broad agreement among plant scientists that using biotechnology to develop new plant varieties creates no new or unique risks compared to conventional breeding. Scientific bodies around the world, ranging from the U.S. National Academies of Science to the UN's Food and Agricultural Organization, have concluded that there is no scientific justification for regulating biotechnology, or the products of biotechnology per se, as opposed to regulating certain traits that may be associated with heightened risk. Thus, there is no justification for subjecting all biotech crop plants to special pre-market approvals or to periodic re-registration.

Adding further cost and complexity is the fact that securing re-registration requires re-submission of—or legal access to—the original safety testing data submitted

for the initial approval, along with whatever new testing and monitoring information regulatory authorities may require. Governments treat the data in approval applications as confidential business information or protected trade secrets because it often contains information about the innovator's development and production processes, quality control or management programs, and other details that would be of significant value to potential competitors.

When considering approval applications from generic producers, regulators generally may not rely on data in the innovator's application to evaluate follow-on products. However, while there are good reasons why regulators should maintain the confidentiality of an innovator's data, there is no good reason for regulatory regimes to require follow-on producers to have access to the original developer's proprietary data in the first place. After all, regulators need not evaluate a dossier submitted for re-registration of a biotech transformation event de novo. For a biotech event to have been granted market approval in the first place, regulatory scientists will have already examined submitted data and arrived at a judgment that the product is safe enough for commercial use.

The simplest solution to this problem is for governments to eliminate the unjustifiable re-registration requirement. Alternatively, regulatory agencies should, at the very least, eliminate the legal fiction that agency scientists have not already examined the original data and reached the conclusion that the product is safe for consumers and the environment. That is, there should be no need for breeders to submit or have access to original safety data when seeking a re-registration.

There appears to be little political support, in either the U.S. or abroad, for reforming biotech crop regulation, however. To fill the gap, seed breeders and the biotechnology industry have begun cooperating on a voluntary, contractual arrangement that will help to address some of these problems. Under the terms of this "Accord Agreement," participating developers will agree to maintain registrations for their transformation events for a limited time after the patents expire. Developers and generic breeders would then be able to make binding agreements to share needed regulatory data and hand off long-term regulatory stewardship obligations, thereby facilitating a seamless transition to the post-patent regulatory regime.

Any wholly private effort can at best be expected to *alleviate* the problem, not solve it entirely because the on-going regulatory hurdles must still be met. Still, this private contractual arrangement should begin to address some of the regulatory and legal challenges that stand in the way of a seamless transition to a post-patent, generic seed industry.

Introduction

Since biotech crops were first introduced on the market in the United States in 1994, American farmers have made them the most swiftly adopted agricultural technology in history.[1] Today, a handful of fruits and vegetables, and the overwhelming majority of corn, soy, canola, and cotton grown in the United States are products of biotechnology. In 2012, an estimated 88 percent of all the field corn, 93 percent of soybeans, and 94 percent of upland cotton in the U.S. were produced from seeds bioengineered to better resist insect pests or to tolerate certain herbicides.[2]

These high tech seeds containing patented new traits are more expensive than their conventionally bred counterparts, but farmers place a high value on their ability to reduce overall costs, deliver important environmental benefits, and increase per-acre profitability.[3] A recent analysis of 15 studies on the economic effects of biotech crops found that roughly two-thirds of the financial benefits accrue to farmers, consumers, and others downstream from the seed breeders.[4] Yet, while farmers who choose biotech seeds undoubtedly find them worth their higher prices, many of them are eagerly awaiting the expiration of the patents on popular traits over the coming few years.

Under normal circumstances, patent expirations should make it possible for plant breeders to begin selling "generic" versions of these seeds, resulting in greater competition and lower prices. Unfortunately, a quirk in the way biotech crops are regulated in the United States and other countries poses several challenges that may make it difficult for breeders to develop a generic seed industry. The bioengineered traits in many of these products must be periodically re-approved for commercial sale by regulatory authorities in the U.S. and abroad. In key markets, such as the European Union and China, this can be a lengthy, expensive, and politically unpredictable process that requires access to the proprietary testing data held by the original developers of the approved traits.[5]

In effect, this continuing regulatory obligation for biotech traits gives developers a government-granted monopoly long after their patents expire. In addition, the heightened costs associated with maintaining regulatory approvals could erase a substantial portion of the economic gains ordinarily associated with patent expirations and the subsequent development of generic products.

Seed breeders and the biotechnology industry have begun cooperating on a voluntary, contractual arrangement that will help to address some of these problems.[6] But any wholly private effort can only *alleviate* the problem, because the on-going regulatory hurdles must still be met. Only

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substantive reform of the regulatory framework that currently demands periodic re-approvals can eliminate the governmentally created monopolies that characterize today's biotechnology industry. Still, this private contractual arrangement should begin to address some of the regulatory and legal challenges that stand in the way of a seamless transition to a post-patent, generic seed industry.

Most discussions of this issue have focused on the expiration of the relevant patents, making the problem appear to be one associated with intellectual property protection. Therefore, it is important to note that both biotech and non-biotech crops can be, and routinely are, patented. The problem at hand is not caused by—and is only tangentially related to—intellectual property protection, as this study makes clear. To understand why, it is worth exploring the nature of biotech breeding methods, regulatory processes, and intellectual property protection for new plant varieties.

Biotech Crop Regulation

For 30 years, there has been broad agreement among plant scientists that use of recombinant DNA methods—what is commonly referred to as gene-splicing, genetic engineering, or modern biotechnology—creates no new or unique risks compared to conventional plant breeding.[7] Beginning in the early 20th century, long before the advent of genetic engineering, plant breeders routinely used conventional breeding methods to introduce the same kinds of new traits into crop plants—including insect and disease resistance and herbicide tolerance—that are now treated as unique when developed through biotechnology.[8]

What matters for human health or environmental safety, scientists have concluded, are the new traits added to a plant, not the method by which they were added. In short, there is no scientific justification for regulating biotechnology, or the products of biotechnology per se, as opposed to regulating certain traits that may be associated with heightened risk. However, in response to environmental and consumer activist demands, government authorities in the U.S. and in most other countries have developed regulatory frameworks in which all biotech crops, and only biotech crops, are subject to special scrutiny and a mandatory pre-market approval process.[9]

In the United States, every new biotech crop intended for commercial cultivation must be approved by the U.S. Department of Agriculture's Animal and Plant Health Inspection Service. Those intended for use in human food or animal feed are regulated by the Food and Drug Administration (FDA)—though the agency has no formal, mandatory pre-market approval

process for these plants. And plants bioengineered to incorporate "pest management" traits must be approved by the Environmental Protection Agency (EPA).

A non-biotech crop with a particular trait, such as insect resistance or herbicide tolerance, can be developed, tested, and sold without any government oversight or pre-approval. Biotech crops, on the other hand, are extensively regulated, even if they contain the same, or similar, insect resistance or herbicide tolerance traits as a competitor's non-biotech varieties. This regulatory oversight carefully scrutinizes the safety of each new trait for both consumers and the environment, and it examines the transformation process itself for every single bioengineered plant intended for cultivation outside a greenhouse.

Every time a breeder uses recombinant DNA techniques to insert a gene into a plant, regulators treat the modified plant as a new product—known as a "transformation event" or simply an "event." Thus, if a breeder modifies 10 corn plants by adding 10 copies of one specific gene, each of those transformed plants would be regulated as a unique product. Once transformed, though, a given plant may be bred conventionally to produce several new corn varieties, each of which will contain the regulated event. These multiple layers of biotech-specific regulation add significantly to the development costs and delay the introduction of new products onto the market by many years.[10]

Merely getting approval in the United States is only the first of many regulatory hurdles. Agriculture is a major U.S. export industry. Therefore, most American farmers are unwilling to plant crop varieties containing transformation events that are not also approved for use in food and animal feed in major export markets, such as Europe and Asia. The lack of necessary approvals could cause entire shipments of harvested commodity grains and other food products to be rejected by the many importing countries whose governments have "zero tolerance" policies forbidding even minimal traces of unapproved biotech products.[11] Conducting all the laboratory- and field-testing needed to support an application for approval in the United States can cost several million dollars. But securing approval in all of the potential export markets can cost tens of millions of dollars more for every single event.[12]

The process of developing and selling a biotech crop trait is further complicated, and the financial costs further inflated, because most countries, including the United States, require these transformation events to be periodically re-approved.[13]

In the United States, the EPA has authority to regulate biotech crops that

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express a "pesticidal"[14] trait under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA). That statute, first enacted in 1947 and substantially amended in 1972 and 1996, was drafted to regulate chemical insecticides and herbicides—products known to be safe when used in limited amounts but unsafe for consumers or the environment at very high exposure levels. FIFRA requires EPA to review the approvals, or what the statute calls "registrations," for all pesticides not less than every 15 years because farmers change their patterns of use for various pesticides over time and science's understanding of the human and environmental impacts of various chemicals continues to evolve.[15] The agency has some discretion over the timing of re-registrations, however, and in practice it typically occurs as often as every 10 years.

Mandatory re-registration gives the agency an opportunity to evaluate whether a pesticidal product has been used in accordance with any regulatory conditions or restrictions placed on it at the time of approval, whether it has had any "unreasonable adverse effects on the environment," and whether its record of safe use warrants continued registration.[16]

With biotech crops, the EPA's re-registration process focuses less on safety than on ensuring that farmers take steps to prevent pests from developing resistance to the plant's novel trait or traits. For example, when planting corn varieties with a bioengineered insect resistance trait, farmers are required to plant at least 20 percent of the crop acreage with varieties that do not include the trait, and to do so in one of four specified patterns within each field.[17] This is intended to preserve a population of insect pests that are not exposed, and which therefore remain sensitive, to the pesticidal trait. Re-registration provides the EPA with an opportunity to assess grower compliance and the effectiveness of this "refugia" approach.

However, unlike chemical pesticides, where the characteristics of the product are the subject of regulatory scrutiny, biotech crop regulation focuses on the processes used to develop the product, even though scientists agree that biotechnology processes carry no new or unique risks.[18] For example, non-biotech crops bred to better resist insect pests are subject to no EPA oversight or registration. The sole rationale for EPA's regulatory oversight is the use of recombinant DNA to introduce such a trait into the plants. Yet there is no scientific justification for subjecting all biotech plants to a mandatory pre-approval process. Therefore, there can be no scientific rationale for subjecting them to the re-approval or re-registration process developed for the management of chemical pesticides. Nevertheless, nearly all the major export markets for

U.S. commodity grains require some form of periodic re-approval for biotech transformation events.[19]

Outside the United States, most countries that permit the cultivation of biotech crops or their use in human food or animal feed have designed regulatory regimes specifically for biotech traits. There is little uniformity in the kinds of testing or formatting of the data needed for approval from country to country (perhaps because the approval process is not science-based). Yet nearly all of these biotechnology-specific regulatory frameworks have retained the re-registration component historically associated with chemical regulation.

The justification for special regulation is especially tenuous for countries that do not permit the cultivation of biotech plants, and have only approved certain transformation events for use in food or feed. By the time they are approved for cultivation and food use in the United States, the safety of those events for humans and animals has been thoroughly evaluated. Moreover, harvested crops containing those traits will have no effect at all on the importer's environment because they will not be planted in countries that permit import solely for food and feed use. Nevertheless, nearly all countries require biotech transformation events to be approved before they are first introduced, and re-approved every few years thereafter.

This is relevant because several of these countries—particularly those in the European Union, as well as China, Japan, and a handful of others—are important export markets for U.S. agricultural goods. In some of these markets, biotech traits must be re-registered as often as every three to five years.[20] While the EPA's re-registration process is indeed burdensome and unnecessary, it is the cost and complexity of foreign regulation that poses the most significant obstacle to the development of a generic biotech seed market in the United States.

Unlike generic drugs and new biotech plant transformation events, where follow-on producers must secure independent regulatory approval for their copycat products,[21] seed breeders need no special approval to place "generic" biotech seeds on the market. The rationale for special FDA approval of generic drugs is based on the fact that they are independently synthesized using the innovator's chemical formula, but may have slightly different inert or inactive ingredients than the original product. The rationale for approving similar biotech transformation events separately—even when the events result from combinations of the same gene and plant species—is that the transformation itself could give rise to subtle differences in the way the novel gene is expressed in each plant.

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innovator's approved plants and are therefore identical copies—in other words, they are the same regulated product. Thus, once the relevant patents expire, generic seed breeders theoretically face no regulatory hurdles to commercializing their products—as long as the relevant domestic and foreign registrations have not expired. But the need to keep registrations current in both the U.S. and various foreign countries poses a tremendous burden that could erase a substantial portion of the economic gains ordinarily associated with the introduction of generic competition.

Maintaining these registrations all around the world can be an expensive and time consuming process that requires a lot of scientific and political sophistication. It also requires re-submission of—or legal access to—the original safety testing data that was submitted for the initial approval, along with whatever new testing and monitoring information regulatory authorities may require.[22] It is this re-registration requirement that gives rise to concerns about the viability of a generic biotech seed market.

The way in which many foreign governments regulate combinations of two or more biotech traits in a single plant complicates matters even further. The first generation of biotech crops tended to include just a single novel trait, such as insect resistance, disease resistance, or herbicide tolerance.

More recently, breeders have begun to include "stacks" of multiple transformation events into a single seed product. Popular stacks include combinations of insect resistance and herbicide tolerance in biotech cotton varieties and combinations of two distinct insect resistance traits in corn.[23]

Generally, stacked-trait varieties have been developed by conventionally mating two previously approved biotech plants to incorporate two or more transformation events into the offspring. In the United States, these stacks are not required to be approved independently, so long as the parental events have already been approved.[24] However, in many other countries, multi-trait stacks must be approved separately, even when they result from the normal sexual mating of two or more previously approved single-trait plants. In addition, approval applications for stacks must include safety data for each single-trait parent plus newly developed testing data on the multi-trait stack. Thus, even aside from the re-registration issue, independent approval for stacked seed products will pose a challenge for generic breeders who might wish to create their own stacks by hybridizing varieties containing off-patent traits developed by more than one innovator.

For the foreseeable future, most stacks are expected to consist of combinations that *include* at least one on-patent trait. But in years to come, the possibility

that generic breeders may be able to develop stacked varieties that combine multiple off-patent traits opens up tremendous possibilities for farmers both in the U.S. and abroad.

The Role of Re-Registration

As long as the original developer of a biotech crop variety wishes to continue to sell it, the breeder has an interest in and an incentive to maintain the necessary event-specific registrations. But, where the original developer is no longer interested in selling a particular event—because, for example, it is no longer sufficiently valuable commercially or the innovator would prefer to concentrate on varieties with newer traits—the developer will be reluctant to pay the significant costs associated with maintaining the needed registrations. Indeed, the high cost of maintaining all necessary registrations in dozens of export markets may itself contribute to a developer's decision to cease selling a particular variety.

To date, developers already have allowed the registrations for several transformation events to lapse due to low adoption rates by farmers. One example is the insect resistant corn event known as Bt 176, sold under the trade names KnockOut and NatureGard. It was first approved in 1995 and discontinued in 2001, primarily due to low sales.[25] Previously, these lapsed registrations have raised little concern because the events in question were not especially popular. In any case, there was no opportunity for generic seed sales, because the patents on these events had not expired at the time they were discontinued. Yet even the registration expirations for largely unused traits could have negative impacts on global agricultural trade.

Seeds planted in a given year will produce harvested commodity grains that may not be sold and shipped domestically or internationally until the following year or later. Indeed, given the dry storage potential of harvested grains and many processed food ingredients (such as corn and soy meal), biotech plant varieties may persist in the commodity stream and food supply for many years after breeders cease selling new seeds to farmers. The StarLink biotech corn event, for example, was removed from the market in 2000, after only three years of commercial planting that never exceeded 0.5 percent of total U.S. corn acreage. Nevertheless, tiny amounts of StarLink's novel trait could be detected in the bulk commodity stream as late as 2005.[26]

Generic introductions of off-patent biotech traits would, presumably, be intended for sale over many years, and their anticipated lower prices may realistically make them popular among farmers in the U.S. and other countries. However, if the registration for one or more of these events were to expire too soon, or if they were never approved

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in an important export market in the first place, entire bulk shipments that contain even relatively small percentages of the grains could be rejected by an importing country's government.[27]

Such an incident would have tremendous negative economic effects that ripple throughout the food supply chain—from shippers to handlers and processors to farmers, all the way back to the breeder. Thus, a seed breeder may be required to maintain regulatory stewardship obligations for a particular transformation event long after it ceases selling the product, lest others in the food chain are forced to bear the costs of legal restrictions on market access.

These market access issues will become more acute over the next few years, as the patents on several very popular biotech events—including arguably the most successful crop plant ever developed—begin to expire. The patent on Monsanto's Roundup Ready soybean trait, which is incorporated into well over half of all the soybeans grown anywhere in the world, is set to expire in 2014. And the patents covering another 22 plant traits and processes are expected to expire over the course of the following decade.[28]

Naturally, many farmers see these patent expirations as a tremendous opportunity because of the possibility that seeds incorporating some or all of these traits might become available as "generics," at correspondingly lower prices. This will be possible, though, only if various long-term registration and stewardship issues can be resolved.

Patenting Crops

It is a common myth that utility patenting is only available or is in some way unique to biotech crops. In fact, any sufficiently novel plant variety can be patented, no matter what breeding method was used in its development. Non-biotech varieties can be patented just as easily as biotech ones. And many more conventional plants have been patented because many more new conventional varieties than biotech ones are developed each year, and intellectual property protection for plants became available long before the advent of recombinant DNA breeding tools.

Until the 1930s, new plant varieties and other live organisms were generally treated as "products of nature," no matter how much effort or ingenuity were required to develop them.[29] They were therefore not considered eligible subject matter under the Patent Act, and new varieties could not be granted conventional utility patents. However, the work of noted plant breeder Luther Burbank, and others who capitalized on the growing understanding of genetics developed at the dawn of the 20th century, showed the tremendous promise of conventional genetic modification and the value of novel varieties.

In an effort to incentivize innovation in the field, Congress enacted the Plant Patent Act (PPA)[30] in 1930 to give breeders patent protection for innovative new varieties of asexually propagated plant species, such as fruit and nut trees. In 1970, Congress broadened this protection with the Plant Variety Protection Act (PVPA)[31] to give patent-like rights to breeders of new varieties propagated from seeds or tubers, including corn, wheat, potatoes, and most other commercially grown vegetables and grains.

However, the rights associated with PPA and PVPA protection were not as extensive as they are for utility patents. Under these laws, competing breeders may not sell copies of protected varieties, though they may conduct research on protected varieties and use them to develop entirely new ones. And farmers may save seeds harvested from one year's crop and plant them in later years.[32]

The nature of intellectual property for plants began to change in 1980, when the U.S. Supreme Court recognized that novel variants of living organisms *were* eligible for utility patent protection. In the 1980 case, *Diamond v. Chakrabarty*,[33] the Court held that a genetically engineered bacterium designed to aid in the remediation of oil spills could be patented because "Congress plainly contemplated that the patent laws would be given wide scope" and that eligible subject matter "include[s] anything under the sun that is made by man."[34]

Five years later, the U.S. Patent and Trademark Office's (PTO) Board of Patent Appeals and Interferences extended the scope of the *Chakrabarty* decision by determining that plant varieties with sufficiently novel traits should be considered patent eligible "compositions of matter" within the meaning of the Patent Act. Since that time, the PTO has issued hundreds of utility patents for novel plant varieties, both biotech and non-biotech derived.

That move was validated by the Supreme Court in its 2001 decision in *J.E.M. Ag Supply v. Pioneer Hi-Bred International*,[35] which confirmed that innovative plant varieties may be granted utility patents. It is worth noting that the patents at issue in that case were granted for conventionally bred, non-biotech varieties. Indeed, by the time the Supreme Court decided the *J.E.M. Ag Supply* case, the Patent and Trademark Office had already issued roughly 1,800 utility patents for plants, the majority of which were non-biotech crops.[36] Today, novel varieties of both biotech and non-biotech plants are eligible for utility patent protection, as well as protection under the PPA or PVPA.

With regard to patenting, then, the only thing that distinguishes biotech seeds from conventional ones is what happens upon those patents' expiration. When

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the patents and PVPA rights on non-biotech plant germplasm expire, there are no further legal barriers preventing the introduction of "generic" versions of those crops. On the other hand, when the intellectual property rights protecting biotech transformation events expire, generic breeders need to ensure that growers and end users have legal permission, in the form of up-to-date regulatory registrations, to sell the seeds and to grow and sell the harvested crops. The question of exactly who will maintain those registrations is what has given rise to the current debate.

Data Access and Maintaining Registrations

An original developer that continues to have an interest in selling "branded" or proprietary seeds incorporating the off-patent transformation events may have sufficient financial incentive to maintain the registrations even in the face of generic competition. In many cases, however, the innovator will not want to bear the financial costs associated with maintaining the registrations for the benefit of "free riding" generic competitors. Alternatively, these firms may simply wish to focus their business on selling newer products. Whatever the reason, if the innovator ceases maintaining domestic and foreign registrations for off-patent events, the costs of doing so will have to fall to generic breeders or others in the food chain.

Further complicating matters is the question of market access for varieties containing stacks of two or more transformation events. One of the most promising aspects of biotech patent expirations is the potential for breeders to combine, or stack, multiple traits originally developed by two or more separate innovators. Thus, even if an original developer wishes to continue selling an off-patent, single-trait event, patent expirations may permit breeders to aggregate a number of biotech traits from various sources into elite cultivars that maximize the benefits for farmers. Recall, though, that most countries require entirely new approvals for stacked products.

In all of these cases, the obligation to maintain the necessary registrations (or, in the case of new stacked products, the need to secure the first registration) will fall to the post-patent users of the traits in question. For a company other than the original innovator to maintain the registrations, doing so will require either having to reproduce all of the necessary environmental and human safety data by re-conducting the tests anew, at a cost of many millions of dollars, or securing access to the innovator's testing data. Innovators, however, justifiably view this data as a valuable and protected trade secret.[37]

As discussed above, the development of the regulatory data needed to secure approval entails a lengthy, technically challenging, and extremely expensive

testing and analysis process, often costing tens of millions of dollars for each transformation event.[38] Doing so also entails high financial risks, given that many new biotech events are never approved by the necessary governments, particularly in the European Union. So, even some products that are able to secure U.S. government approval are ultimately abandoned and never marketed commercially, representing a substantial financial loss to the developers. Products that do become commercialized must therefore generate revenue sufficient for developers to cover all the costs of successful and unsuccessful events.

Given that substantial "regulatory risk," the high cost of developing and testing new biotech traits, and the reliance on safety test results for commercialization, these data (like the data for pesticides and other crop protection products) are a major asset to innovators. But beyond their basic asset value, regulatory data packages also generally contain more than simple reports of safety test results. They typically include detailed information about the manufacturing or development process, formulation details, special quality control or management programs, and other details about the innovator firm that would be of significant value to potential competitors.[39]

For both of these reasons, registration data are generally treated as proprietary trade secrets by regulatory authorities who recognize the need to keep the data confidential, at least for a specified period of time. As the U.N.'s Food and Agriculture Organization has recognized in the context of pesticide registrations:

> All data submitted by a company in support of its request for registration of its product should be treated as proprietary, and should neither be divulged nor used to evaluate the petition submitted by another applicant, unless by agreement with the owner of the data or unless a period of proprietary rights to the data has expired. … The results obtained are as much the property of the company that produced them as is the plant used to manufacture the product. Therefore, it would be unjust for registration authorities to use, for the benefit of industrial competitors, data submitted to them in good faith.
>
> Apart from the injustice of allowing competitors to benefit from the use of data to which they have no right, the consequences of such an action would be to discourage, because it is unrewarding, the research and development required for the production of new pesticides which are needed, for example, for the control of new or difficult pests or to overcome resistance.[40]

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Consequently, most OECD member countries have incorporated a "data protection" or "market exclusivity" period of from five to 15 years following the initial approval or registration of products ranging from pesticides to pharmaceuticals.[41] During this period, regulators may not lawfully divulge proprietary safety data to the public or to competitors. Nor may they approve a competitor's follow-on product during this market exclusivity period if they must rely on the innovator's proprietary data to evaluate the product's safety. In addition, a generic applicant may not ever be entitled to lawfully access necessary information without the original developer's permission, because some relevant data or other information contained in the regulatory application for a pesticide or biotech crop may be considered confidential business information or protected trade secrets.

However, while there are good reasons why regulators should maintain the confidentiality of an innovator's data in their possession, there is no good reason for regulatory regimes to require follow-on producers of biotech crops to have access to the original developer's proprietary data in the first place.

Most countries do not require generic or other re-registrants to go through the wholly superfluous process of submitting identical physical copies of the test data already in the original approval application—though some, such as China, do. And the approval of multiple-event stacks generally does entail submission of original safety testing data for each of the individual traits incorporated into the product. More commonly, governments operate under the legal fiction that regulatory authorities have not already examined the original data and reached the conclusion that the product is safe for consumers and the environment.

Consulting data in the originator's approval application may be warranted when evaluating follow-on chemicals—such as pesticides and drugs—that are independently synthesized and susceptible to minor, unintended compositional differences. In those cases, comparing new products with data on already approved products can shed the light on the safety of these subtle differences.

Generic biotech seeds, on the other hand, are produced as the offspring of an innovator's already approved product, so they are not plagued by the same problem. Consequently, when it comes to biotech event re-registration, the only thing re-submission or data access make possible is the preservation of a system that requires regulators to forget what they already know. If we hope to reap the benefits associated with the coming expiration of patents on the first generation of biotech crop traits, however, the seed industry will

have to find a way to address this re-registration data access problem.

Regulatory Solutions

There are a number of ways in which the data access issue may be resolved to ensure the development of a vibrant and reliable generic biotech seed market. Unfortunately, the most effective and scientifically justifiable approach appears to be politically impossible.

There is a broad consensus among plant scientists that the use of recombinant DNA techniques to modify plants poses no new or unique risks compared to other, more conventional, plant breeding methods. Indeed, because the molecular methods associated with modern biotechnology are more specific and precise, breeders using rDNA methods will have greater information about the traits they introduce into new varieties, and that greater precision makes it easier to test the resulting plants for human and environmental safety.[42] Dozens of scientific bodies all around the world—ranging from the U.S. National Academies of Sciences to the United Nations' World Health Organization—have concluded that there is no scientific justification for regulating biotech crop plants any differently than conventionally bred varieties.

Recall, however, that the data access problem is created by the existence of a scientifically unjustifiable regulatory regime for biotech crops. Therefore, the simplest solution to that problem would be to follow the scientific consensus regarding the regulation of novel traits and substantially loosen biotechnology oversight and approval requirements, bringing them into parity with the rules covering conventional breeding.

Regardless of the scientific consensus, though, there seems to be little political support, in either the United States or abroad, for rationalizing and streamlining biotechnology plant regulation. In the European Union, for example, six member countries refuse even to permit the cultivation of biotech crops that have already been granted full EU-wide approval in what is arguably the most stringent regulatory regime in the world.[43] Even in the United States, the Environmental Protection Agency has begun to ratchet the regulation of biotech crops upward, over the objection of scores of plant scientists.[44] The U.S. Department of Agriculture's Animal and Plant Health Inspection Service recently announced a series of minor tweaks to its regulatory regime intended to expedite the new biotech crop approval process.[45] But these changes merely serve to condense the timeline in which applications are evaluated; they do nothing to relieve the burden of duplicative and scientifically unnecessary testing procedures.

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A less substantive approach is for importing governments to end their current zero-tolerance policies and permit some limited amount of harvested grains containing unapproved biotech transformation events in bulk commodity shipments. The International Grain Trade Coalition and the International Seed Federation, along with many of their individual members, have urged countries to create or standardize policies permitting importation of commodity shipments that contain a low-level presence of unapproved events that are fully approved in their countries of origin.[46] Such policies could help prevent rejection of bulk shipments containing trace amounts of unapproved events (comprising up to, for example, 3 to 5 percent of a given shipment), but they would likely prove ineffective if varieties containing those events became broadly popular among farmers. Furthermore, even this relatively modest reform effort has garnered little support outside major grain exporting countries such as the United States and Canada.

With these more comprehensive reform proposals unlikely to gain traction politically, regulatory authorities could take the more modest step of eliminating the requirement for periodic re-registration of all biotech transformation events. Governments should instead require re-evaluation only when a legitimate, scientifically defensible concern has been raised regarding an individual event's possible health or environmental impacts.

Alternatively, regulatory agencies could, at the very least, eliminate the need for seed breeders—whether they are generic companies or the original developer—to submit or have access to original safety data when seeking a re-registration or a first registration of a new stacked-trait product. After all, regulators need not evaluate a dossier submitted for re-registration de novo. For a biotech event to have been granted market approval in the first place, regulatory scientists will have already examined submitted data and arrived at a judgment that the product is safe enough for commercial use.

Requiring ongoing data access serves no function but to preserve the legal fiction that regulators do not know what they already know. It has no purpose but to prolong the original developer's effective monopoly over intellectual property long past the expiration of a patent.

Unfortunately, even a reform as modest as this would require dozens of intransigent governments around the world taking the initiative to implement it. In the interim, it will be incumbent upon the seed and biotechnology industries to develop a process to facilitate the compensated sharing of regulatory data so that a generic biotech seed industry can become a

reality. There are many ways in which this might be accomplished, but one approach is now being developed by the American Seed Trade Association (ASTA) and the Biotechnology Industry Organization (BIO) in conjunction with a number of agricultural industry stakeholders, such as the North American Export Grain Association and American Soybean Association.[47]

The Accord Agreement

ASTA and BIO, the industry associations representing a majority of U.S. seed breeders and biotech seed developers, are currently in the process of negotiating a contractual mechanism by which biotech trait developers and generic seed breeders may make binding agreements to share needed regulatory data and hand off long-term regulatory stewardship obligations.[48] This "Accord Agreement," as the parties have dubbed it, is comprised of two elements: the Generic Event Marketability and Access Agreement and the Data Use and Compensation Agreement, each of which addresses slightly different issues associated with domestic and international registrations for biotech transformation events.[49]

In short, the combined Accord Agreement would ensure that original developers' lawfully recognized intellectual property—including patents, Plant Variety Protection rights, and trade secrets—is protected but shared in a meaningful way with follow-on producers willing to accept specified legal responsibilities. In doing so, the Accord should enable a stable and predictable process for maintaining biotech event registrations in a post-patent environment, and thereby help deliver tremendous benefits to American farmers and the food value chain.

Under the Accord, original developers will agree to maintain registrations for their transformation events for a limited time, even after the patents on those events expire. Once an original developer is relieved from the obligation of maintaining those registrations, the agreement establishes a process for handing off necessary regulatory data to generic breeders wishing to use an off-patent trait in order to facilitate a seamless transition to the post-patent regulatory regime. Where more than one generic breeder chooses to sell a particular off-patent event, both the costs of accessing the regulatory data and those associated with the ongoing regulatory and stewardship obligations would be shared proportionally among the breeders based on their respective shares of the market for that trait. Finally, generic breeders that become part of the Accord agree to assume the regulatory responsibilities and potential legal liability for covered events.[50]

The Generic Event Marketability and Access Agreement half of the Accord is expected to be finalized in 2012,

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though there appear to be a number of issues yet to be resolved before the Data Use and Compensation Agreement will be completed.[51] Although all the biotechnology and seed industry participants at the negotiating table are publicly supporting the initiative, off-the-record discussions leave no doubt that some have concerns about the ability of the Accord to resolve all necessary legal and regulatory problems. That said, participants should be commended for laying the groundwork for a smooth and efficient transition to a generic biotech seed market.

Conclusion

There is little doubt that American agriculture has benefited tremendously from the introduction of crop biotechnology. Not only has the adoption of biotech varieties reduced production costs and increased yields, but study after study has concluded that biotech crops tend to have "fewer adverse effects on the environment" than non-biotech varieties.[52] These are among the many reasons why farmers have made biotech crops the most rapidly adopted agricultural technology in history.

Still, while farmers reap significant economic benefits from patented biotech crops, many are eagerly anticipating a future in which the patents on several of today's most popular traits have expired, enabling seed breeders to offer lower-priced generic biotech seeds. Nearly two dozen biotech traits are expected to come off-patent within the next decade. That should give rise to a generic biotech seed industry capable of driving down seed prices and delivering stacked-trait varieties with new combinations of already approved biotech transformation events.

None of this will be possible, however, if various regulatory impediments are not cleared from the path forward. As long as biotech crop traits must be re-approved or re-registered every few years by regulatory authorities in the U.S. and important export markets, those who sell or buy biotech seeds will need to ensure continuity in meeting these legal obligations. The heightened costs associated with doing so, however, could erase a substantial portion of the economic gains ordinarily associated with patent expirations and the subsequent development of generic products.

The most logical and straightforward resolution to this problem would be to eliminate the re-registration or data access rules that, for no good reason, establishes the legal fiction that regulatory authorities have not already examined the safety testing data and concluded that approved biotech events are safe for consumers and the environment. However, because the regulation of biotech crops is based more on politics than science, this

kind of common sense reform seems politically impossible for the foreseeable future.

To help fill the gap, major players in the seed, biotechnology, and related industries are now developing a contractual agreement intended to facilitate the compensated sharing of regulatory data packages and ongoing regulatory and stewardship obligations. Although there are many questions regarding how well this Accord agreement will work in practice, the industries should be congratulated for making a good faith effort to resolve these issues in a way that should permit farmers and the food supply chain to continue reaping the substantial benefits of the biotech crop revolution.

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