INDEPENDENT PROFESSIONAL SEED ASSOCIATION

+1 (870) 336-0777 office | +1 (901) 831-1057 mobile | todd@ipseed.org

June 15th, 2022

The Honorable Tom Vilsack
Secretary
U.S. Department of Agriculture
Jamie L. Whitten Building
1400 Independence Avenue, S.W.
Washington, DC 20250

Re: Docket No. AMS-AMS-22-0025
Response to Notice of Request for Information and Public Comment Regarding Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs in Federal Register Vol 87, No. 52

Submitted Electronically via Federal eRulemaking Portal (http://www.regulations.gov)

Dear Secretary Vilsack:

Thank you for the opportunity to submit this comment.

The Independent Professional Seed Association (IPSA) was formed in 1989 to represent the unique needs of Independent Seed Companies, or "Independents." After more than 30 years and an ever-changing market, IPSA represents 124 seed companies from more than 25 states, Canada, and Mexico who produce corn, soybeans, small grain, and forage seeds. The Independent Seed Company Segment holds roughly a 22% market share across corn and soybeans sold in the United States. In addition, the Association has over 110 associate and affiliate members, representing many facets of the seed industry.

We recognize we are a minority voice. While we share members with larger associations across commodity groups, our focus is singular. Our members are small businesses. They are the definition of small and medium-sized enterprises (SMEs). Many of them are family-owned and multi-generational businesses that have their roots in the very innovation that brought the hybridization of corn to the United States Farmers in the early 20th century. Independent Seed Companies are not just selling seeds – we are community catalysts. We have payrolls in rural towns, participate in local events, and contribute to the ag economy by supporting farmers. We are American made, American built, and part of the backbone of the American economy and vibrancy of rural America.

American Agriculture has enjoyed a century of innovation. Innovative plant breeding brought forth corn hybridization. We have seen additional productive measures brought forth in synthetic fertilizers, pest control systems and mechanization.

But there has been no parallel to the consolidation of the agriculture industry since the biotechnology revolution during the 1990s. In 1992, there were 12 major multi-national companies involved in crop protection inputs for row crops, including seed. Today, that number is 4. Gone are the historic names of Ciba, Monsanto, American Cyanimide, and others. In that same period, the market has lost 100 Independent Seed Companies in the United States.

Not only did the corn and soybean seed market consolidate, but ownership also moved outside of the United States. With consolidation in the agriculture industry, our businesses remain under constant threat, as does American competitiveness.

Comments from IPSA in this RFI will focus on the specific issues from President Biden's Executive Order 14036, "Promoting Competition in the American Economy" (E.O. 14036). We will cover two key facets we experience in the corn and soybean seed marketplace: (I.) impacts of consolidation, business practices, and competition matters and (II.) reduced competition beyond reasonably contemplated in patent and environmental regulations. These two factors drive Independents out of business and higher prices for farmers who will have fewer technology options because of lack of competition.

We note this information is coming from IPSA because our member companies fear retaliatory actions in the marketplace should they choose to comment individually. We have included anonymous company comments at the end of our document.

Consolidation, business practices and competition matters

(1) Please describe challenges, concerns, and any other views (including relating to any benefits) with market concentration and market power in the agricultural input industries, including, as applicable, effects on farmers, competitors, and related markets; pricing; availability; transportation and delivery; quality; research and innovation; economic growth, labor markets, and inequality issues; supply chain resiliency; and any other factors.

A world with fewer American Independent Seed Companies means less competition, less choice (increased monoculture), and higher seed prices for farmers. It means less community activity in rural America and more control from foreign-owned corporations. It means fewer small businesses across rural America available to provide valuable agricultural services for seeds, particularly in two ways: generating competition and providing an individualized buying experience.

Competition: Independent Seed Companies sometimes sell seeds with similar genetics and similar traits. Beyond that, they are fiercely independent. Farmers demand choice, and Independent Seed Companies provide just that. Looking into seed quality, specializing in specific seed treatment and enhancement, offering numerous options, and finding the exact genetic on the exact acre are just a few of the options that Independent Seed Companies offer with their product line up. Independent Seed Companies can provide more options across brands than any one company can offer with its own brands. By looking at specific and local genetic performance, Independent Seed Companies bring products that are specialized in their geographies. That is value creation on a local level that translates to the best seed products on farm.

Buying Experience: We succeed, even with consolidation in the seed industry, because of our farmers' experience with us. Many farmers prefer the local approach to doing business with someone they know and trust. Nothing is better than being able to talk to the person with their name on the bag when something goes wrong in the field. With us, a farmer doesn't call an 800 number to a phone tree or call center; that farmer can call the president of the seed company. Like local and independent businesspeople everywhere, our members know how to serve and care for customers. Farmers need a trusted advisor, and Independent Seed Companies fill that role by maintaining personal contact with farmers to garner a clear understanding of the farmer's needs and to provide vital feedback season to season. Never forget, we are farmers too. We take the time to

understand what the farmer faces and provide the best recommendations built on years of knowledge and experience working locally with farmers.

The Business Cycle of Independent Seed Companies: Understanding the flow of the business cycle for Independent Seed Companies is critical to understanding the difficult situation of the current market and the reason this RFI is important to our members.

Many people don't understand how the seed industry works — they see all the seed brands and think there must be competition, but all those brands pay royalties back to the large companies that own the genetics and traits and, therefore, control the industry.

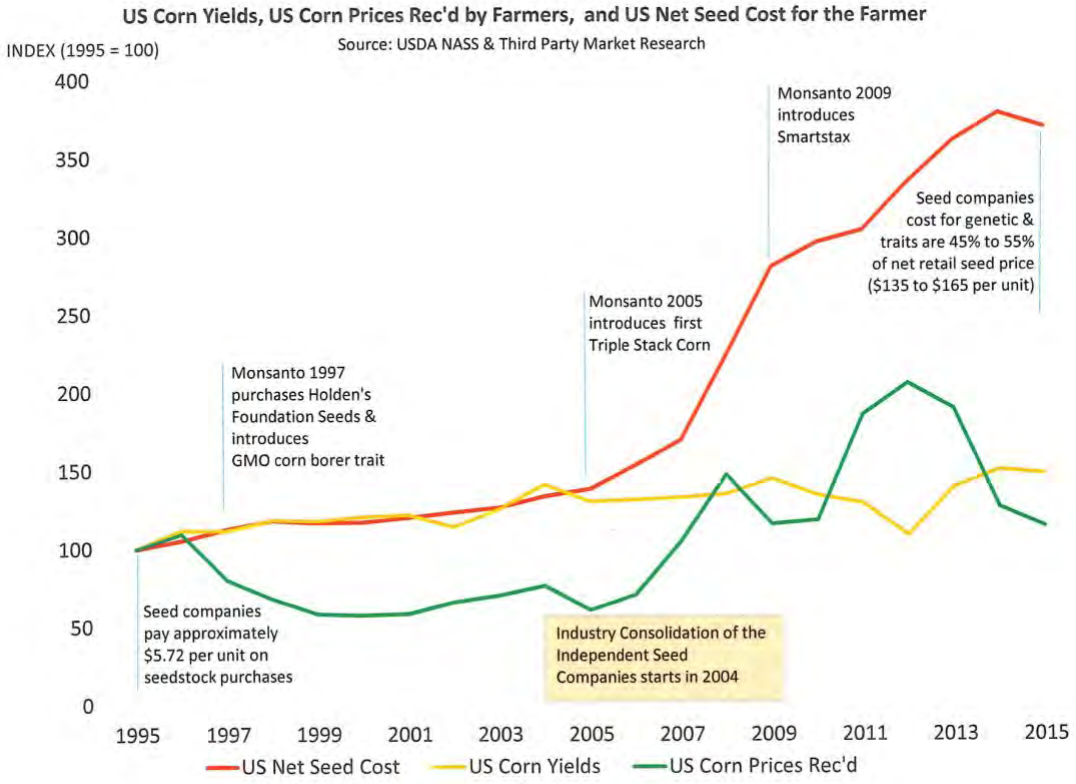
Independent Seed Companies run a 22-month cycle on seed. This cycle encompasses planning for the crop and buying parent seed in January of year one all the way through farmers harvest in the fall of year two. During this cycle, our Seed Companies, make a production plan, purchase parent seed, plant the inbred production seed, maintain, and harvest that hybrid seed (in the case of corn), condition, treat and bag the seed, and then they enter the sales year. Now, they sell and service the seed to farmers, store the seed, deliver the seed. During this time, they are required to pay the Intellectual Property bill or the licensing fee for this seed, both for genetics and biotechnology traits.

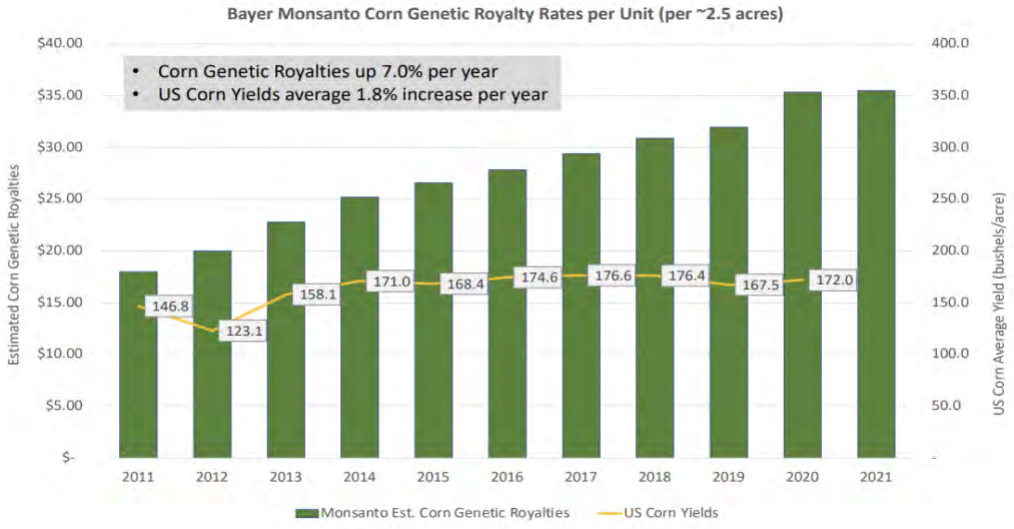
Independent Seed Companies hold the credit risk of the farmers that buy their seed. They own the inventory risk of the seed they produce. Like farmers, they also own the production risk. Make no mistake about it, Independent Seed Companies ARE Small Businesspeople (SMEs) AND Independent Seed Companies ARE Farmers.

IPSA and Independent Seed Companies have been actively involved identifying the concerns to government agencies during the recent multi-national consolidation. Concerns of the dangers of consolidation were so severe that beginning in late 2016, IPSA and member companies met directly with attorneys from the Anti-Trust Division of the Department of Justice. These meetings continued through 2017. Additionally, IPSA met with the National Economic Council at the White House, Federal Trade Commission and numerous Senators and Members of Congress. In each of these meetings, issues concerning the concentration of crop genetics and biotechnology traits were discussed.

In October 2019, meeting in a Des Moines, Iowa hotel, a group of IPSA members met to discuss the market going forward and challenges facing Independent Seed Companies. Two major factors were identified as the largest concerns by the companies; (1) shrinking margins and (2) continued access to genetics.

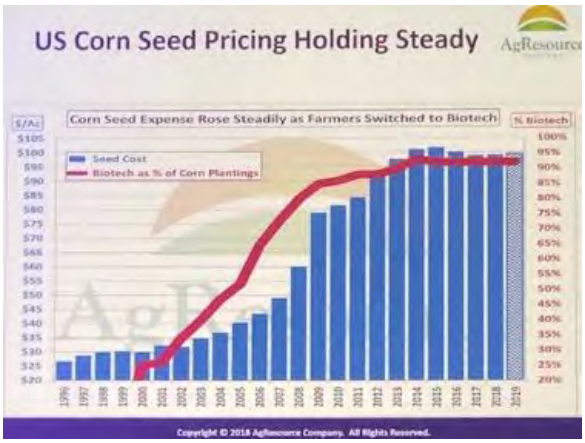
As E.O. 14036 identifies, four companies account for 85% and 76% of corn and soybean seed markets.[i] Furthermore, genetically modified (GM) seed prices rose more than 700% between 2000 and 2015.[ii] We put together the following two charts showing a dramatic increase in U.S. net seed costs as well as increases in genetic royalty rates.





It is worth noting from the chart above, that despite claims of continued genetic improvement resulting in greater yields, the current rate of genetic gain, as paced by the U.S. average corn yields are very low at 1.8% per year.

Even more concentrated is the ownership of corn elite germplasm: About 90% of the commercial varieties are owned — directly or indirectly through licensing — by two companies. Bayer CropScience recently declared its germplasm ownership share at 55%[iii] and 35% can be attributed to Corteva[iv] — a concentration far higher than in any other country. This means the concentration ratio of the top two companies, the CR2 is 90%.



Economist Dan Basse, of the AgResource Company in Chicago, noted in his presentation to the American Seed Trade Association's annual Corn, Soybean and Sorghum meeting in Chicago, that corn seed had become largely 'inelastic' since 2012[v], and no longer subject to the drivers of commodity pricing.

12) Is there evidence of contracting or sales practices locking a farmer into a mode of production and inhibiting them from entering other farm enterprises? To what extent do requirements or inducements to buy a main product (e.g., seed) with a second product (e.g., pest management chemical), bundle, stacked trait, or service impact the farmer or other agricultural input competitors? For instance, does such a practice lock a farmer into or out of certain product choices? Please offer specific recommendations for reforms.

As noted in **The Business Cycle of Independent Seed Companies**, these companies are farmers. Bundling at the farmer level and bundling at the seed company level have become common practice since 2018. Previously noted, Bayer CropScience holds above 55% genetic share in corn. This market share is the result of their branded business combined with their licensing business. Bayer licenses both corn genetics and biotechnology traits to Independent Seed Companies.

Bayer also licenses soybean genetics and biotechnology, including an herbicide tolerant package under the trade name Xtend. Xtend technology has come under fire nationally due to concerns over volatilization and drift of the corresponding herbicide, dicamba. Competing technology in soybeans is available from Corteva and Stine Seed, under the trade name Enlist, using the 2, 4-D herbicide.

Since 2018, Bayer introduced a bundling program that combined corn genetics and traits with soybean genetics and traits. For Independent Seed Companies, it meant they no longer had financial incentives just for selling more corn, now they had to sell more soybeans as well, or they would lose their incentives on corn. This program was branded the Premier Performance Program (PPP). It is still in effect today. This program meant that Independent Seed Companies could be penalized for selling soybeans with the Enlist trait.

The Premier Performance Program became more of a challenge in 2022 as Bayer enabled their branded dealers for the Channel brand to source Enlist soybeans and sell them – while holding Independent Seed Companies to the PPP.

11) What role do contractual or sales practices in seed and other agricultural input markets play with regard to a farmer's or business's autonomy, innovation, or ability to compete? How have contractual or sales practices changed over time? Do some firms' contracts require farmers to buy inputs from or sell exclusively to one or a few firms? What impacts do these contractual requirements have on competition?

As RR2 Xtend (Dicamba tolerant soybeans) drifting issues heightened, some IPSA members experienced increased pressure to sell those products by bundling them with other products, even where farmer customer demand was not there to support sales of RR2 Xtend. There are two different approaches to bundling – allowing or excluding licensing of technology and using reward programs to force licensing. This includes removing profitability of licensees and making it costly to switch, while rewarding loyalty at high levels.

Not only do Independent Seed Companies sacrifice profitability, but they also face barriers to switching to alternative technologies, due to the planning timelines of making investment decisions.

Additionally, unwritten programs that pay for "loyalty" can make the difference between profit and loss for a member company's yearly performance. Such programs can be handled entirely over the phone, without a paper trail and can make or break profitability year-over-year.

Independent companies like ours must provide a multinational corporation with a list of all our customers, (complete with addresses), the amount of seed purchased by product for each customer, as well as our complete company financials. After giving them all our company information, we need to try to compete against their company and owned brands. We also pay for a vast majority of our products early, holding risk often prior to receiving orders or payment from our customers. If an Independent Seed Company doesn't pay early, it may lose its license. We have examples of companies losing licenses over the past several years. Because of the dominant position on the corn side of the business, losing a license can push Independents out of business.

Threats of seed licenses being taken away are real.

15) Please comment on the presence of, and any concerns around, licensing restrictions in seeds or other agricultural inputs. Please comment on cross-licensing practices, including restrictions or exclusive cross-licensing permissions, and any related concerns. Do fees on the same type of license vary and if so under what circumstances? Do licensees have access to information on comparable licenses? Are some companies or organizations denied reasonable access to licenses and on what basis? What further guidance, if any, on appropriate licensing practices would be helpful?

Biotechnology traits could be considered an "essential facility" at least in crops like corn, soy, cotton, and canola. However, licenses are not available under conditions which could be considered fair, reasonable, and non-discriminatory. The most attractive combination of biotechnology traits are usually only cross-licensed between the trait developing companies and align the regulatory strategy of pyramid insect trait stacking. Other companies often have only access to trait packages with a limited value proposition at a price which leaves the vast amount of the trait value with the originator. Additionally, the owners of the traits have been using the "loyalty" programs with independent seed companies which make considering alternative traits punitive. Effectively, competition in the market is being impaired. Healthy competition benefits everyone. It provides growers with more options and drives innovation.

Bayer has entered into agreements with its competitors to refuse to deal with customers, except on terms acceptable to itself. Licensees must deal with this corporation and accept its terms to obtain rights to use its competitors' technology for seeds containing any of its genes or traits, where they control about 90% of biotech corn seeds sold, putting them in control of 90% of the markets for biotech corn and corn technology.

Prices that Independents must pay often change after seed is in the ground, leaving Independents committed to a changed price structure totally out of their control. During the 2021 planning and planting cycle, Bayer projected a royalty range between 5 to 10% increase, with a mid-range of 7.5%. When the crop plan was

planted, the actual royalty was announced. The royalty doubled over the projected range to 15%. Independents were locked into their plan. There was no way to change products. In 2022, guidance on trait royalty increases has already averaged up 22% and guidance on Roundup Ready technology is up 36%. This is indicative pricing on traited products that are nearing the end of their patent protection.

Reduced competition beyond reasonably contemplated in the Patent Act (35 U.S.C. 100 et seq. and 7 U.S.C. 2321 et seq.) through an intellectual property system and co-acting regulatory agencies.

4) Please share your views on whether, and if so how, the existing IP system— including plant patents, utility patents, and plant variety protection certificates— appropriately balances the need to incentivize innovation with the goal of ensuring public access to new and improved products at reasonable cost. Please explain why or why not and discuss in context of seeds or the particular agricultural input of concern. If you have concerns, please explain the concerns, and provide suggestions on how the IP system can be improved to address those concerns.

Seed and pesticide products intersect in a complicated regulatory landscape. One example is with regard to EPA Biopesticides and Pollution Prevention Division's proposed next steps regarding the September 9, 2020, Draft Proposal to Address Resistance Risks to Lepidopteran Pests of Corn and Cotton Containing *Bacillus thuringiensis* Plant-Incorporated Protectants and BPPD's proposed plans for industry negotiations. At issue is the need to find a regulatory pathway for genetics and trait technologies once they go off patent, which will increase competition, lower seed prices, and create opportunities for farmers. We are encouraged by recent conversations with EPA that it will pursue an additional policy approach to the one laid out for registrants and appreciate USDA's support for the role of Independent Seed Companies in the marketplace. This is critical, not only to promote effective stewardship based on local conditions, but also to avoid running counter to E.O. 14036. If the regulatory landscape only works for multinational corporations whose economic interests are in reducing sales of post patent products, then power in the corn genetic and trait technology marketplace is further solidified as consolidated.

5) For seeds in particular, is the patent side of the plant-related IP system appropriately reserving its grant of statutory patent monopolies to inventions that are of significant utility, novelty and non-obviousness? Do you have concerns about patent quality in the area of plant-related IP or plant-related technologies? If you have concerns, please explain.

IPSA will push for a simplified, streamlined, and cost-effective pathway for keeping post patent traits on the market. Taking them off the market inflates prices in trait packages, which is not in the best interests of farmers. We are talking about efficacious patent-expired traits, and our seed companies wish to obtain new registrations for them. Namely, that these single traits remain effective against primary pests like European Corn Borer (Ostrinia nubilalis - ECB) after being in the market for 25+ years. Secondly, there are 70 million acres of corn-only counties (i.e. non-cotton) and taking these traits out of the toolbox limits choices for farmers and ensures that they will pay higher seed prices for seed with traits they don't need. And lastly, EPA, working with registrants, is overly concerned about secondary insects that the single traits were never meant to control or had no effect on them (e.g. Corn Earworm (Helicoverpa zea - CEW) and Fall Armyworm (Spodoptera frugiperda - FAW)). Registrant seed guides also will show that many products with the VIP3A protein have only a single trait for ECB or have two single traits that are on EPA's phase-out plan.

Therefore, we want the resistance assessments to include specific geographic analyses when it comes to resistance management. The 2006 Scientific Advisory Panel and recommendation of natural refuge reduced block refuge in the cotton belt. This decision alone has caused the rise of current resistance problems in the

cotton belt that do not exist in the corn belt. Corn traits have been stewarded with refuge in a bag and block refuge that work. We see ways to move forward, including with different paths for different geographies, to not economically punish farmers and seed companies who have supported EPA's past stewardship decisions.

6) Does the existing IP system, as relating to seeds and other agricultural inputs, effectively meet the statutory goal of rewarding invention through protection from competition for a fixed term? Does it fairly and effectively promote competition and innovation, or does it inappropriately suppress competition and innovation? Please explain. If you believe the IP system inappropriately suppresses competition or insufficiently rewards innovation, please explain and provide concrete examples where possible.

IPSA supports innovation and believes in the patent system to reward companies that innovate. With biotechnology, because of the link between seed genetics and biotechnology traits, farmers and seed companies have not been able to enjoy the benefits of generic traited products on the market. Since the introduction of Roundup Ready soybeans in 1994, the cost to the farmer of those patents have continued to increase.

Let's look at a bag of corn seed as an illustration. Take a bag of VT Double Pro with good genetics. Let's price this from an Independent Seed Company that is licensing both genetics and traits from Bayer. That company would have to license from Bayer, because no other company can license the trait VT Double Pro. VT Double Pro was introduced in 2011. Today, a farmer will pay 64% of the cost of that bag of corn seed in intellectual property. That number does not flow back to the Independent Seed Company, it flows back to the trait and genetic provider.

For the Independent Seed Company, who produced, treated, conditioned and now owns the inventory, they are lucky to be able to manage their business to a 15% profit on that same bag. Competing against their supplier of traits and genetics can make that concept difficult.

Looking at Roundup Ready Corn in a similar situation, with the Roundup Ready event, NK603, coming off patent, the intellectual property cost is still 50% of that corn seed bag.

The intersection of intellectual property, antitrust, and other relevant laws, specifically FIFRA, must be assessed in combination. We don't want the U.S. Government to frustrate the public policy bargain inherent in granting patents whereby a 20-year monopoly is exchanged for making such inventions available for the public good. Now is the opportunity for farmers, other industry participants, and new market entrants to benefit from their broader availability of off-patent Plant Incorporated Protectants which will foster a more competitive marketplace for innovation, lowering costs for farmers and consumers.

We know that new technologies must continue to come into the marketplace. No single company nor individual owns the rights of this innovation that stretches back over 100 years in modern agriculture.

7) Do farmers, ranchers, and other stakeholders have sufficient access to off protection and generic options? If not, are regulatory tools, systems, or practices being utilized to inhibit access? For example, do you believe there is evidence of inappropriate strategies to extend the life of patents? Please explain and provide examples.

Independent Seed Companies are very concerned about adequate access to technology in the public domain. While it is appropriate that registrant companies have their voices heard, including the right to communicate with EPA, their economic interests do not align with those of future trait registrants and farmers interested in purchasing post-patent, traited products.

The first commercial biotechnology event in the United States went "off-patent" in 2014. However, no substantial post-patent use of biotechnology events has so far emerged.[vi] Some biotechnology event owners established the AgAccord® as a contractual framework for off-patent events in the US while ensuring that global regulatory commitments are maintained in the import countries. The AgAccord® comprises two separate agreements: The Generic Event Marketability and Access Agreement (GEMAA®), established in November 2012, has 10 signatories, and covers events under the governance of USDA (e.g., herbicide tolerance). So far, there seems to be no agreement established under the GEMAA®. The second agreement, the Data Use and Compensation Agreement (DUCA) would cover insect resistance traits. However, until today the minimum number of event holders necessary to activate the system has not yet been reached. The desirability and suitability of the GEMAA® and DUCA set up to promote post-patent use beyond the current incumbents is, at best, questionable.

The reasons for the limited post-patent use are "complex". Rüdelsheim finds that "*the conditions for Off-Patent Events are not available yet to form the basis for a new viable industry similar to the generic manufacturers of agrochemicals or pharmaceutical products, primarily because of (i) unharmonized global regulatory requirements for biotechnology organisms, (ii) inaccessibility of regulatory submissions and data, and (iii) potential difficulties to obtain seeds and genetic material of the unique genotypes used to generate regulatory data*".[vii] Schenkelaars also criticized that the lack of legal framework to maintain access to regulatory data after expiration of a patent on a biotechnology trait may interfere with the development of a market for generic biotechnology seeds.[viii] In addition, the following strategies and tactics may be involved:

- **Technology lifecycle management and raising the regulatory bar:** The technology to manage insect resistance and herbicide tolerance is becoming increasingly complex. There are meanwhile at least two modes of actions for above and below the ground insect pest and at least two modes of actions for herbicide tolerance proposed. Not always is there a clear technical requirement for higher level stacks. In most cases emerging issues of disease or weed resistance can be managed with application of chemical pesticides or selective herbicides. A "raising the bar" by requiring double or even triple mode of action may de facto preclude post-patent products with a single mode of actions.
- **Chain of custody:** While not part of the legal requirements, the regulatory authority in the U.S. and other countries require from a non-proprietor a proof for chain of custody i.e., evidence that the event has been obtained from the proprietor and is identical with the original event. Such a proof may require support from a proprietor which may be difficult to obtain for "generic" competitor.
- **Ever-greening strategies:** While the patent of the event is expired in some cases, other patents may still be in place. Such patents may relate to (i) detection methods (ii) stack combination, (iii) combinations with crop protection chemicals, (iv) refuge management and stewardship processes etc. To which extent such patents can effectively delay a post-market entry is also untested.
- **Limiting access:** Accessing a post-patent event in a "ready-to-use" form is a challenge. The patent deposit related to the event is often in a non-commercial germplasm which requires multiple cycles of backcrossing into a commercial germplasm. The use of commercial lines comprising the event is usually restricted by agreements and bag-tags which preclude the use even in a post-patent situation. Also, additional patents, such as on the variety, need to be considered.

One shall conclude that neither the regulatory nor other legislative frameworks are currently adapted to off-patent use scenarios. Legislators have an important role to pave the way instead of complicating the development of a post-patent biotechnology trait market in the interest of growers and breeders.

20) Please share any information relevant to regional needs, tribal and underserved communities, climate concerns, and product-specific matters, such as organic seeds, in relation to any of the concerns raised above.

We should not reduce choices in the market nor encourage an overuse of technology where it may not be needed, which can further contribute to resistance. We should look forward to a post-patent seed world where our members will provide lower-cost options that can serve farmers and drive their ROI.

Please see attached, a joint ASTA-IPSA letter to Mike Mendelsohn, EPA Emerging Technologies Branch Chief, dated March 17th, 2022.

22) Please comment on the strengths, weaknesses, effectiveness, and gaps in current USDA policies and programs to facilitate access to affordable seeds and other agricultural inputs for farmers, plant breeders, ranchers, and other stakeholders. Are information services, grow out services, and access to seed varietals that are not subject to IP protections sufficiently available? Do farmers, plant breeders, ranchers, and other stakeholders have sufficient voice within relevant agency decision-making, and if not, how could it be improved? How could labeling practices be improved? Please suggest actionable steps that USDA could take to help address any identified concerns.

Moving forward, we believe something must be done about the lack of competition in the seed industry and control by any small number of corporations over the industry. With a competition ratio (CR2) of 90%, there is no dispute that the seed market is too concentrated. New entrants are needed in the marketplace to make sure that farmers and seed companies can have alternatives, which ultimately drives food security and supports a vibrant agricultural economy, away from a monoculture.

This cannot be accomplished alone by USDA. This must be approached in a partnership with other government agencies:

- **USDA**: USDA, in a whole-of-government approach, can conduct retrospective reviews of approved mergers to assess whether they result in less innovation in the seed industry and higher seed prices for farmers. USDA can review the difference between brands and players. By looking at the rise of different branded alternatives owned by one company and price increases, farmers can have greater transparency. We need new entrants that can invest in genetics and technology to provide choices for farmers and the whole industry and creating space for them to operate is necessary. USDA should study the effects of bundling and other anticompetitive seed pricing practices, including the use of marketing dollars.

- **EPA**: EPA taking into consideration, including through support from USDA, how its current process exclusively tilts toward the companies with dominant market share remains critical. Allowing an efficient and affordable post-patent regulatory system will be important for a framework that accounts for geographic differences in where corn is grown. This process should include further clarity and consider economic impacts to Independent Seed Companies and to the availability, affordability, and diversity of seed choices to farmers.

- **DOJ**: DOJ should be vigilant for restraints of trade and mergers that can threaten competition, specifically focusing on licensing restrictions, anticompetitive bundling of different products and technologies, access to markets, endangered channels of distribution, and combinations of businesses that are actual or potential competitors.

In closing, we recognize the enormous value created by the biotechnology innovation brought forward in the mid 1990s by Bayer predecessor, Monsanto, and others. We believe this technology must be protected for future use and stewarded properly. We also believe in the innovation in plant breeding that has brought us to this point with an abundant food supply and food security. Innovators must be rewarded for that work. Many have built on the work of others in this noble endeavor, to continue to improve the crops that we grow.

There is a timeline on that reward. Patent laws must be shown to be reasonable and not perpetual. The ability to artificially extend patent life through legal manipulation must end, so that others may build new innovation on top of the current innovation.

Further, we propose that the current biotechnology traits have reached the point in the industry where there must be the freedom to access those traits by any company or organization without delay and under reasonable terms. Only by equalizing this biotechnology standard across the industry can we hope to see new genetic innovation and new development to propel us forward.

Thank you for your consideration of these comments.

Sincerely,

Todd L. Martin
CEO, Independent Professional Seed Association

Attachments

---

i. In 2015, the largest four sellers of corn and soybean seed accounted for 85 and 76 percent of U.S. corn and soybean seed sales, respectively, up from 60 and 51 percent in 2000. F. Ciliberto, G. Moshini, and E. Perry, "Valuing product innovation: genetically engineered varieties in US corn and soybeans," RAND J Econ 50 (2019): 615-644. See also https://edepot.wur.nl/141258;https://www.scielo.br/j/cbab/a/5knwVv7qCyQW4d69xwfNgQP/?format=pdf&lang=en; https://eu.boell.org/sites/default/files/agrifoodatlas2017_facts-and-figures-about-the-corporations-that-control-what-we-eat.pdf; https://eu.boell.org/sites/default/files/agrifoodatlas2017_facts-and-figures-about-the-corporations-that-control-what-we-eat.pdf; https://www.ers.usda.gov/webdocs/publications/42517/13606_aib786h_1_.pdf?v=0; https://farmaction.us//wp-content/uploads/2020/11/Hendrickson-et-al.-2020.-Concentration-and-Its-Impacts-FINAL.pdf

ii. USDA Crop and Seed Price Index from NASS; Crop-specific seed prices from USDA NASS for 1990–2015 (after which NASS discontinued its seed price series) and extended over 2016–2020 using USDA ERS Cost-of-Production estimates. Note, prices have fallen declined since 2015, with commodity price swings playing a significant factor

iii. See https://www.bayer.com/sites/default/files/2021-10/Crop Science Investor Webinar_2021-10-19_Presentation.pdf

iv. See https://investors.corteva.com/static-files/21e2aecd-3874-4797-b2d6-7d073a76336c

v. Dan Basse, AgResource Company, presentation to ASTA CSS, Chicago, December 2018

vi. The webpage of the AgAccord®/GEMAA® shows for certain events the expiration dates. These dates have not been independently verified and might be questionable for some events. In addition, all off-patent events of Syngenta are missing, as Syngenta is not a member of the GEMAA®. Generic Event Marketability and Access Agreement (GEMAA®). GEMAA® Notices. Available at: http://www.agaccord.org/?p=GEMAA#notices.

vii. Rüdelsheim P et al. (2018) Off-Patent Transgenic Events: Challenges and Opportunities for New Actors and Markets in Agriculture. Frontiers in Bioengineering and Biotechnology 6:71. doi:10.3389/fbioe.2018.00071. Available at: https://www.frontiersin.org/article/10.3389/fbioe.2018.00071.

viii. Schenkelaars P, de Vriend H, Kalaitzandonakes H (2011) Drivers of Consolidation in the Seed Industry and its Consequences for Innovation. Report commissioned by COGEM. Available at: https://www.lisconsult.nl/files/docs/consolidation_seed_industry.pdf.

March 17, 2022

Dear Mike,

Thank you and IRM Team for meeting with member companies of the American Seed Trade Association (ASTA) and the Independent Professional Seed Association (IPSA) that are currently non-registrants but have vested economic interests in the December 2021 Lepidopteran IRM Framework. We appreciate the frank conversation and your willingness to engage in further dialogue.

The companies represented understand and respect that EPA must limit the negotiation of the terms and conditions of registration for specific PIP products to their respective registrants. However, we maintain there should be no restriction for broader discussion on several measures in the 2021 Lepidopteran IRM Framework document that are broadly applicable to future registrants, as well as to independent seed companies that currently license technology from the registrants. We have included two diagrams explaining in brief the trait licensing, seed production and seed sale timeline. We strongly believe that it is important to establish a mechanism, independent from the Agricultural Biotechnology Stewardship Technical Committee (ABSTC), to hear from and consider input from the non-registrant companies on critical aspects of the Lepidopteran IRM Framework that will negatively impact independent seed companies and future registrants now and into the future.

As follow up to our meeting, the following are measures that we view as broad policy decisions that will have significant impact beyond just the current B.t. PIP registrants, and that warrant further discussion with the non-registrant companies.

- **Phase down of single mode of action products**

  Our understanding from the meeting is that the timetable for a possible phase down of currently registered single mode of action products will be negotiated with individual registrants. However, it is critical for EPA to understand that independent seed companies that hold licenses from the B.t. registrants will also be impacted by any possible phase down of these active ingredients and products. Like the registrants, independent seed companies produce and own seed inventory. Under the process that we understand EPA is currently considering, the independent companies will have no say on the timetable under which they would be required to sell impacted inventory.

  In addition, there are companies that intend to commercialize traits coming off patent to develop effective single mode action products. EPA cannot ignore the economic interests of these companies and their customers. These future registrants will provide new product options and may add a new layer of competition that will benefit farmers. In fact, FIFRA has strong protections for generic registrants that

are structurally incorporated into the statute. While this has not been an issue during the first phase of development and commercialization of the B.t. PIP products, such products are now entering into a second phase of commercialization where it will be possible to develop generic versions of these products. Generic versions of B.t. PIPs, as a matter of law, must be afforded the same statutorily guaranteed treatment as generic version of conventional pesticides. Moreover, it is a basic principle of FIFRA pesticide regulation that the benefits of the availability of generic pesticide products inure to a great extent to growers by making available to them providing lower cost pest control alternatives. These economic benefits to growers cannot be generally denied to them absent evidence-based measures that are limited to what is justified by actual evidence.

- **Registration timelines**

  In addition to concerns mentioned above regarding single mode of action PIPs, the December Framework document proposed new policy on registration timelines which establishes two new categories of pyramided PIPs, "non-functioning pyramids" and "low-functioning pyramids." The new policy for registration timelines impacts all future registrations, was not proposed in the August 2020 proposal, and therefore has not been subjected to public comment.

  Further, the definitions of "non-functioning pyramids" and "low-functioning pyramids" would be applicable to all future product registrations and could use refinement. Specifically, EPA's definitions take an unnecessarily broad approach and do not take into consideration that the functionality of a pyramided product may be different depending on geographies and pests. Under these suggested registration time limits, EPA may inadvertently incentivize commercialization and thus use of pyramided products that are more than what is indicated in any given geography and pest complex and more expensive for farmers. Further, this policy may inadvertently be detrimental to independent seed companies' access to wider ranges of pyramided traits, to provide a wider range of seed and traits options to growers. Any policy that has the ultimate effect of limiting grower choice must be limited to the extent that is supported by actual evidence. Limiting grower choice can have significant economic consequences.

- **Refuge compliance**

  As mentioned in our meeting, nearly 30% of traited seeds are produced, marketed, and sold by independent seed companies that license technology from registrants. The proposed requirement of co-packing refuge seed and verification of adequate refuge seed production would negatively impact independent seed companies that license technology.

- **Seed blend**

  The proposed increase from 5% to 10% RIB will impact independent seed companies that license technology from registrants. Like registrants, independent seed companies must sell any remaining 5% RIB inventory, modify current production practices, and ramp up production to commercial levels. Under the current structure, these companies do not have input in negotiating the grace period for dispatching remaining stocks or timetable for ramping up to 10% RIB.

- **Primary and Secondary Insect Pests in Corn**

  In addition, we note that, while intended to improve IRM of Lepidopteran pests of cotton and corn, the framework places undue and non-scientific emphasis on insects that are secondary in corn, and the management measures are disproportionally borne by the corn sector. The top 10 corn producing states, approximately 70 million acres of corn, do not have cotton production[1]; and yet are subjected to IRM requirements that are primarily focused on secondary pests of corn. We strongly recommend and request that EPA consider a wholistic review of IRM approaches so that the responsibility of resistance management is more equitably and appropriately distributed among the two crops. This review should include the participation of ABSTC, the non-registrant seed companies, future registrant seed companies, and the grower community.

Finally, we strongly support and believe in insect resistance management. We also believe in the importance of considering potential negative impacts of the December 2021 Lepidopteran IRM Framework on a more competitive market for traited seeds. We request a series of meetings to fully discuss the policy concern outlined in this letter. We look forward to working with you.

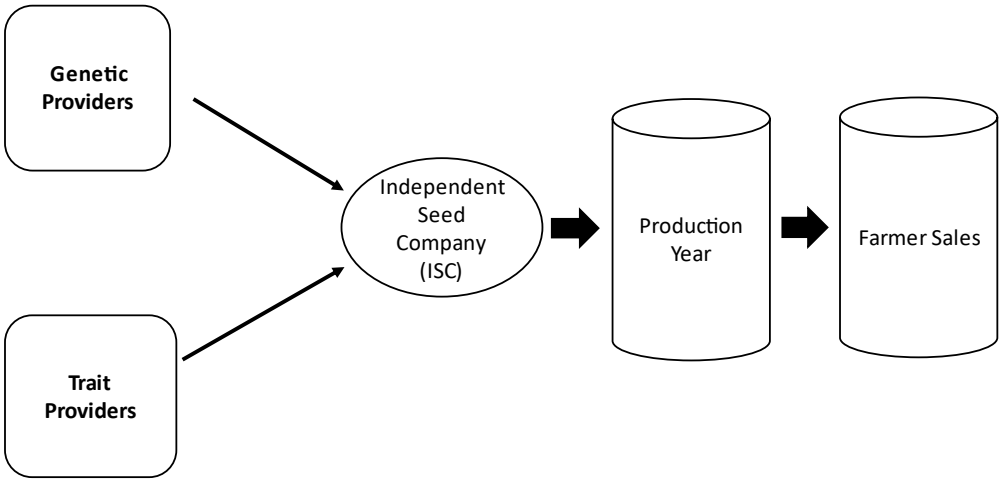
Sincerely,

Andrew W. LaVigne
President & CEO
American Seed Trade Association

Todd L. Martin
CEO
Independent Professional Seed Association

[1] https://www.nass.usda.gov/Publications/Todays_Reports/reports/acrg0621.pdf

Trait Licensing: From Providers to ISC



Timeline: Trait Licensing

Spring Year 1
Inbred Sold to ISC and Hybrid Product Produced

Fall Year 1
Product Packaged

Winter Year 1/2
Farmer Buys Seed

April Year 2
Farmer Plants

Fall Year 2
Farmer Harvests






TIME

USDA RFI on Competition and the Intellectual Property System:
Seeds and Other Agricultural Inputs

Submitted by Anonymous Family-Owned Seed Company and member of IPSA

May 12, 2022

This statement comes from a group of Independent Seed Companies and members of IPSA. We're writing this anonymously to tell our story. We wish we didn't have to be anonymous but feel we must tell the story of the unhealthy and uncompetitive side of the seed industry. Overall, over the last twenty years the seed industry has brought great tools to farmers in the form of improved genetics and helpful technology traits, but consolidation and buy-outs have driven the industry in an uncompetitive and unhealthy way. If something isn't done, independent companies will be driven out of business and farmers will pay much higher prices and have fewer technology options because of lack of competition.

The seed industry currently is controlled by three companies: Bayer CropScience, Corteva, and Syngenta. These three companies own most of the traits and genetics for corn and soybeans, which are the most widely grown crops in the United States. One company, Bayer CropScience, has a stranglehold on the corn industry with the largest combination of corn genetics and an estimated 90% of the corn technologies sold in the industry include at least one Bayer technology.

Many people don't understand how the seed industry works, because they see all the seed brands and think there must be competition, but all those brands pay royalties back to the large companies that own the genetics and traits and control the industry. Bayer CropScience, gets by far the largest amount of those royalty payments. Bayer uses their dominant position along with contracts and agreements with the rest of the industry to control pricing and the rules of engagement in non-competitive and unhealthy way.

For years, Bayer has had a dominant position in the soybean industry, like they currently do on the corn side, with their RR1 and RR2 soybean traits. Bayer is unhappy that they are losing this dominant position in soybeans and are using all measures necessary to get it back. Enlist E3 technology from Corteva has cut into Bayer's soybean position so much during the last three years that Bayer has signed an agreement with Stine Seed Co. to market Enlist E3 Technology in a Stine brand. Stine has a favorable position on E3 technology because they own a large share of soybean genetics. The agreement between Bayer and Stine appears to ensure that Bayer will regain its dominant position because now they can win by selling Bayer's own soybean technology or by selling Enlist E3 seed products through their own seed brands.

Much of the reason E3 technology has taken off is that there is very little drift to neighboring fields, unlike what we've seen with Bayer's dicamba technology. Farmer's like E3 technology, which has risen substantially in the last four years it has been on the market thanks to the

independent seed companies that are helping sell this technology. Bayer is extremely unhappy that independent companies have helped grow E3 technology, a direct competitor to them, and they have since worked to tighten the screws on independent companies that license from them by making it difficult for them with price increases and increasingly unfavorable contract terms.

These contracts are written by Bayer attorneys and are favorable only to Bayer. Independent companies like ours must provide Bayer with a list of all our customers, (complete with addresses), the amount of seed purchased by product for each customer, as well as our complete company financials. After giving them all our company information, we need to try to compete against Bayer's own company owned brands! We also must pay for a vast majority of our products with Bayer early, many times before we get orders or payment from our customers. If a company doesn't pay early, they may lose their license and many companies have lost their Bayer license over the past several years. Because of Bayer's dominant position on the corn side of the business, losing a Bayer license for many independents can push them out of business.

Bayer sets the royalties for its products and technologies, which essentially sets the price in the marketplace. While Bayer (and its predecessor Monsanto) have always had a price advantage, the spread has become much wider and our terms less favorable in recent years. Independent companies have very little power to negotiate. In recent years, our corn genetic royalties per unit have doubled and recently our corn trait royalties are going up significantly even on older technologies that are soon going off patent. Last year we were told our biggest selling corn technology would go up by a range that Bayer gave to us before planting; then after planting our seed we found out that our royalties would be going up 50% higher than the high end of the range they gave us before planting!

This year we are bracing for the highest trait increase we've ever seen – on every Bayer technology. These price increases are in addition to inflation costs and record-high fuel increases that we are facing. One Bayer executive has repeatedly told us, "You're just going to have to figure out how to get by on smaller margins." This is hard to take while Bayer just posted a 27% EBITA in the first quarter of 2022.

Most family-owned, independent companies are being forced to operate on a very thin profit margin. Bayer doesn't tell us what prices we will be charged before seed stock is planted each year for next year's sales. Imagine producing a product and having no idea how much your costs will be! If we select the wrong product to produce, we are on the hook for the inventory and many times we only get to look at Bayer's internal data to make a decision. Making the wrong choice on products has caused many independent companies to go out of business in the past. It appears that Bayer would like to push many independents out of business so the next new technology like E3, won't be able to get off the ground. Farmers will be the biggest loser if this is allowed to happen.

Bayer also has used bundling programs to punish us for selling competitive products. One specific bundling program was started in 2018 right before Enlist E3 technology went to market. This bundling program takes away corn rebates to independent companies if that company "isn't loyal" and doesn't maintain their Bayer soybean business. The irony is that Bayer signed a deal with Stine to sell competing E3, so Bayer isn't even 100% even loyal to its own products! They, like us, know that our customers want Enlist E3 technology. We should have the freedom to sell what is in the best interest of our customers without facing penalties.

Even though we face many obstacles, independent companies are providing U.S. farmers with seed choices and outstanding service. Farmers like that many seed company owners also are farmers and family businesses like them who live in rural America. We understand our customer's soils and environmental challenges because we also face them. We are committed to being good stewards of our land and environment, as well as keeping our rural communities strong and vibrant, because we also live in rural America.

We believe something must be done about the lack of competition in the seed industry and especially the control Bayer has over our industry. New entrants are needed in the marketplace to make sure that farmers and seed companies can have alternatives. We don't need more brands of corn and soybeans, because we have many different brand alternatives, but we need new entrants that can invest in genetics and technology to provide choices for farmers and the whole industry. We need true competition and not just the current situation with a few powerful companies controlling the industry behind the scenes for their own benefit.

Comment re: Doc No. AMS-AMS-22-0025

I am writing regarding Doc No. AMS-AMS-22-0025: *Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs*, specifically challenges related to the seed industry.

Through its owned brands and licensing, Bayer Crop Science (BCS) effectively controls a very large segment of the marketplace for corn traits and genetics. For licensees—Independent Seed Companies (ICS)- Bayer has a near monopoly position.

Over the course of the past decade, BCS has used that monopoly power to increase ISCs genetic royalties by as much as 5-fold, from less than $10 per unit to often more than $40 per unit.

They have also used that market power to increase the royalties for the most popular trait package (VT2P Pro) by as much as 25% in just the past two years.

To compound this issue, by not fully recognizing these increases in their own brands, which compete directly with ISCs, Bayer has significantly reduced competition and raised costs for farmers.

Although the ISCs have competed well in the market for the past 25 years, maintaining combined market share in the mid-20% range, this pricing pressure is truly unsustainable and is clearly reducing competition in the marketplace, forcing ISCs to either liquidate or operate at very low margins.

Finally, most of the GMO traits (both insect resistance and herbicide resistance) are nearing patent expiration, which should both spur new entrants into the marketplace. However, by tying these older traits to newer genetics, BCS is succeeding in maintaining their position.

Finally, Bayer's ability to use this market power is slowing innovation—why innovate when you can collect large royalties on old products—and making it difficult for new entrants to the marketplace.

It is clearly in farmer's interests to have healthy independent seed companies providing a check and balance on the handful of huge companies who dominate that marketplace. However, if current trends are allowed to continue, that will be impossible.

For the 2022 selling season, Bayer increased the trait royalty fee on corn seed by as much about 14%. Bayer's process for trait royalty pricing is to send an expected fee range in February/March and confirming the actual royalty in June. In 2021, Bayer sent out an expected range increase on trait fees of $7-$10. However, in June 2021, rather than confirm a trait fee within the range given in Feb/Mar, they actually increased that royalty by $15.00 (14.35%). Productions decisions are made well before the June timeframe, so this does not allow a company to make economically sound production plans.

For the 2023 sales year, Bayer has put out an expected trait fee increase of between $12 and $22. This represents a 25-35% increase in royalty costs in a two-year period.

These increases are more than ISC are able to pass on to their farmer customers, thus crushing margins for those Bayer "partners."

What makes this particularly difficult is that Bayer's owned brands (Dekalb, Channel, and regional brands) have not been supporting these increases in the marketplace

During the same year, it is our understanding that Bayer was able to buy-down the total royalty fees owed by their national retailers, selling DeKalb, causing a significant discrepancy in the marketplace in terms of pricing directly related to royalty fees. This allowed Bayer to increase the market share with their national brands and consequently, decreased market share for independent companies.
As an independent seed company licensed to sell Bayer products, we are not able to control the bottom-line cost to our customers because the trait pricing is determined by Bayer after decisions made to produce these same products, This becomes an untenable disadvantage in the marketplace when it is coupled with Bayer not requiring its own national brands to pay similar royalty fees.

Additionally, when the Corn States organization was dissolved within Bayer during the merger of Monsanto and Bayer, it eliminated a firewall of sorts between the licensing organization and the national Bayer brand groups. The licensing group is charged with servicing its licensees who sell Bayer products. If this licensing group is working in combination with the national brand groups within Bayer, there is an unequal balance of power being held by Bayer. Bayer's licensing group provides opportunities for additional funding to its licensing through marketing dollars, typically allocated by sales volumes. These sales volumes are often, and in most cases tied together between product types. For example, soybean trait sales are tied to corn trait sales for the licensee to receive agreed-upon marketing dollars. The consequence of tying product types to one another becomes a significant issue when Bayer can create imbalanced competition within a particular product type, as above with corn traits. When corn trait sales decrease, it affects the overall marketing funds provided for other products (i.e., soybean traits). These marketing dollars are often critical to the licensee being able to compete with farmgate prices, especially within these last two to three years of depressed market and commodity prices. These conditions have allowed Bayer to control their national brands' market share, the licensees market share, as well as the licensees margin opportunity.

The above are specific examples of the significant issue of one company having total control over both their own products and the products it licenses to its competition. The obvious solution to the lack of fair competition in this marketplace is to have the licensing group of Bayer separated out from the Bayer organization, to create a fair and impartial entity that can service its licensees, independently. If both the licensing group and the national brand group are allowed to operate within the same legal entity, there will be an imbalance of competition and a marketplace that is controlled by one entity.

6-13-2022

To whom it concerns pertaining to the matter of the following: Competition and the Intellectual Property System / Seeds and Other Agricultural Inputs:

As an Independent seed company that licenses traits and genetics from Bayer, we have a grave concern of the increase cost of doing business and being competitive with Bayer's own Brands.

The cost of traits alone for corn has increased 14% from the crop sales year 2021 to 2022. Now they have increased it again for corn for sales year 2023 another 17%. This does not include the steadily rising costs of genetics as each new class that comes out it increases 11% for corn.

The soybean traits have increased 10% for sales year 2023 from 2022.

The real concern we have is we are being priced out of the sales market as the Bayer Brands are selling these same traits with their Brands at previous year's levels. There was no cost increase to the customers we compete with from Bayer sales agents.

We have had good success using the traits and genetics we have been offered to license from Bayer but we feal the unrealistic charges for the traits going up each year and the Bayer Brands price remaining flat puts us at a severe disadvantage.

We also have concerns of newer offerings not being supplied to License's so we cannot remain competitive with performance in the field.

We are being pinched so we cannot cover our rising costs of production, freight, insurance, employee benefits, etc.

If this trend continues it will remove more independent competition for Farmers to by seed from. These Independent Seed Companies are closely tied to local communities and offer many other services to the community too numerous to mention.

We feel this is another anti-trust situation we ran into with Monsanto several years back of which Bayer purchased recently.

In the end this will remove Independent Seed Companies and give Farmers less competition and drive-up overall costs. Which can be used to fund the Bayer Branded to remove competition, so it is a less competitive market place controlled by a few large corporations.