USDA Agricultural Marketing Service
U.S. DEPARTMENT OF AGRICULTURE

More and Better Choices for Farmers:

Promoting Fair Competition and Innovation in Seeds and Other Agricultural Inputs

A report directed by President Biden's Executive Order Number 14036: "Promoting Competition in America's Economy"

March 2023

Inari Exhibit 1025
Inari v. Pioneer

This report was prepared by the U.S. Department of Agriculture's Agricultural Marketing Service in consultation with relevant offices, agencies, and teams at USDA, as well as the Director of the United States Patent and Trademark Office and her team and other Federal partners. This collaboration was led by AMS academic cooperators Dr. Julie Dawson and Ms. Paulina Jenney of the University of Wisconsin-Madison, under the direction of Senior Advisor for Fair and Competitive Markets Mr. Andy Green. Its findings are comprehensively informed by the public input under a Request for Information issued in March 2022 as well as listening sessions, meetings, and other forms of consultation with farmers, seed businesses and trade associations, plant scientists, patent and competition experts, and other stakeholders. This report represents our best efforts, to date, to grapple with certain longstanding challenges associated with promoting competition and protecting intellectual property in relation to agriculture. USDA invites and encourages all stakeholders to continue the dialogue with us and with all our Federal partners to promote vibrant competition, a robust and reliable intellectual property system, and a continuing respect for science across all Federal policymaking.

Executive Summary

A well-functioning economy depends on businesses competing based on the merits of their products, including price, innovation, quality, privacy, and diversity. For years, American farmers and independent seed businesses have voiced concerns to the USDA about concentration and the consolidation of market power in agriculture, including in seeds and other agricultural inputs, and the resulting decline in healthy competition.[1] Competition in food and agricultural markets promotes the types of diversity farmers need to thrive: a diversity of choices that respond to the particular needs and priorities of farmers; a diversity of options to meet changing business, climatic, societal, and scientific needs; and a diversity of companies that are committed to the localities and regions they serve and can weather the storms and shocks of today and the future.

In the seed market, promoting fair and vibrant competition involves considerations of intellectual property (IP) law, antitrust and other fair business practices law, and public investment in our food system. These are complex and often confusing areas even for the most experienced farmers, plant breeders, small businesses, and others. Partly that flows from the nature of current varieties, where, building off of complex biological material, American ingenuity has produced incredibly advanced innovations. Adding to the complexity, business developments arising from multiple decades of mergers and acquisitions have led to an increasingly consolidated marketplace with complicated legal relationships among companies. Greater transparency, fairness, and investment—facilitated through better coordination and communication by government partners—are areas of progress that will benefit all in the marketplace.

To make that happen, on July 9, 2021, President Biden issued a historic Executive Order titled "Promoting Competition in the American Economy,"[2] which creates a whole-of-government approach to competition and includes initiatives across federal agencies to tackle some of the most pressing issues across our economy. Among other things, the Executive Order directs the Secretary of Agriculture, in consultation with the Under Secretary of Commerce for Intellectual Property and Director of the U.S. Patent and Trademark Office, to submit a report to the Chair of the White House Competition Council on concerns and strategies for ensuring "that the intellectual property (IP) system, while incentivizing innovation, does not also unnecessarily reduce competition in seed and other input markets beyond that reasonably contemplated by the Patent Act."[3]

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1. As defined in Federal Register Notice requesting for public comment on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs," 87 *Fed. Reg.* 15198 (March 17, 2022), at www.regulations.gov/document/AMS-AMS-22-0025-0001.
2. Executive Order Number 14036, "Promoting Competition in America's Economy," at https://www.whitehouse.gov/briefing-room/presidential-actions/2021/07/09/executive-order-on-promoting-competition-in-the-american-economy/.
3. See 35 U.S.C. 100 et seq. and 7 U.S.C. 2321 et seq.

As a response to the Executive Order, on March 17, 2022, the USDA-AMS published a request for public comments and information that included 25 multi-part questions about competition and market power, intellectual property, and other business practices in the seed industry that might be affecting the American farmer's ability to participate in a fair and competitive market.[4] After a 90-day comment period, we (USDA staff and cooperators) collected comments, hosted a public listening forum,[5] and heard from an array of interested parties to ensure that as many perspectives as possible were represented in this report.[6]

Comments and input were diverse, nuanced, and multifaceted. Many commenters agreed that a system that fairly protects IP is critical to continued innovation and investment in seed systems.[7] Because plant breeding takes time and resources, many plant breeders and seed companies need a return on their investment. At the same time, we heard concerns that the current system and practices for protecting and enforcing IP rights for plant innovations may not be promoting fair competition. Those concerns broadly fall into several areas.

First, some commenters expressed concerns about the difficulty in accessing information on existing IP rights associated with a particular plant variety. Due to the various IP systems for protecting plant-related innovations, a lack of a consolidated source of information was noted as a contributing factor.

Second, several commenters focused on the application of patentability standards on the examination of plant-related innovations. To determine whether a claimed invention is novel and non-obvious, the USPTO must conduct a thorough search of the existing prior art. For plant technologies, this often requires searching numerous non-patent sources, such as publicly available scientific literature and datasets. These commenters believe incomplete searching has led to patents that covered existing plant varieties, characteristics, and methods of breeding.

Third, several commenters raised concerns with how IP rights for plant-related inventions are being used and enforced, noting the growing use of licenses that override research and breeding exemptions guaranteed by certain types of IP rights. Some plant breeders expressed having difficulty determining whether their ongoing work would infringe upon a newly granted IP right. These commenters noted that if faced with a lawsuit, small to mid-sized plant breeding programs may be led to discontinue those lines of innovation even if they believed they would likely not be found liable in court.

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4. 87 *Fed. Reg.* 15198 (March 17, 2022), www.regulations.gov/document/AMS-AMS-22-0025-0001.
5. *Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs*, (Aug. 2022), www.zoomgov.com/rec/play/h4r0AJXwFkYRbfUr6zDMELCKte7_77Meo-W1fnl9VrbKFGdr0QIig-qAovK4WqxAuiq8HDNkOnTPxXW8.WwQpath9AqKkafH_?continueMode=true.
6. In this report, we use "commenters" to refer to people who submitted public comments, people who participated in listening forums, or people who participated in interviews.
7. In this report, when we refer to seed, we also include other planting stock for crops not propagated by seed (tubers, bulbs, cuttings, etc.).

Commenters that primarily license IP from larger companies were concerned about the effects of consolidation on their choice of products. These commenters described farmer, plant breeder, and seed retailers' increasing dependence on the few companies that control most of the IP for seed. They also observed that this dependence is more pronounced for farmers, plant breeders, and retailers in commodity crops than in specialty crops. Commenters described situations in which companies on whom they are dependent for seed or technology could impose contractual terms that seem to extend patent rights beyond the scope contemplated by law. Small businesses expressed concern that these companies may offer retail incentives that disadvantage competitors, new entrants, farmers, and consumers.

Finally, many commenters called for greater investment in public infrastructure around seed systems and plant breeding. This public infrastructure, largely a partnership between the states and federal government, involving USDA research locations, Land Grant Universities, and State Agricultural Experiment Stations, has long supported fair competition among private entities by releasing cultivars that small and mid-sized companies can use, and by being a key provider of traits and varieties for underserved crops and geographies. Decades of underinvestment have significantly reduced that capacity. With fewer choices, and without varieties tailored to local circumstances, farmers may lose potential revenue. In addition, the loss of decentralized capacity for variety development and production of seeds and other planting stock means that supply chains are vulnerable to disruption. Commenters pointed out that increased investments could mitigate climate-related disruptions to food and agricultural systems, could encourage new market entrants, and could establish a fairer and more competitive market.

Addressing these concerns is not a straightforward task (see methodological note below). The concerns of farmers, businesses, plant breeders, and market participants—those who grow the food we eat, as well as the general public—span IP law, antitrust law, and public investment in our food system. Moreover, federal authorities that tackle these issues are complex and overlapping. Ultimately, the following report defines three key topic areas in which the Executive Order's whole-of-government approach to promoting competition can be used to address these challenges:

1. ensure robust and reliable IP rights that enhance innovation and promote competition
2. ensure that IP owners exercise their rights within the scope of fair competition provided by law, and
3. rebuild critical national infrastructure for variety development and the provision of seed and other planting stock to create resilient seed supply chains.

In each of these sections, we analyze the current situation and make recommendations for the U.S. Government to promote fair competition and innovation, focused on actions available to the executive branch and leaders of involved federal agencies, including the Department of Agriculture (USDA), Patent and Trademark Office (USPTO), the Department of Justice (DOJ), and the Federal Trade Commission (FTC). Our goal is to improve fair competition in the seed industry, enhance the resiliency of America's food and agricultural

supply chains, and provide economic opportunity and choice for America's agricultural communities.

Methodological note. The commentary discussed in this report represents views that existed at the time the comments were submitted. Where, in the intervening months, USDA, the USPTO, or other agencies, under the Biden Administration, has made a number of improvements, we make note of that progress while preserving the commenters' views. Additionally, some comments may represent the commenter's perspective which may be in conflict with others' views, data, or market understanding. We have preserved the comments as presented and provide additional clarification as needed without seeking to conclusively evaluate their relationship to existing law, practices, or data in all circumstances. Our purpose is simple: the USDA, USPTO, and other Federal partners take seriously the concerns of all involved in the seeds and other agricultural input markets and are committed to taking a whole-of-government approach to addressing any and all concerns.

Summary of key recommendations

This is a brief summary of the recommendations given in the report. Detailed, complete recommendations are given in specific sections of the full report.

- **A voice for farmers and plant breeders.** To enhance transparency, reduce confusion, and otherwise help farmers, small and mid-sized seed businesses, and plant breeders successfully navigate a complex seed system, AMS is establishing a Farmer Seed Liaison. Among its responsibilities will be to facilitate communication between farmers, plant breeders, and relevant agencies that touch on the IP system, more generally coordinate implementation of the recommendations described in this report, and otherwise promote fair competition in the seed industry. In consultation with the USPTO and modeled on AMS's Transportation Services Division, the Farmer Seed Liaison will particularly facilitate engagement and public input into existing public USPTO input processes regarding prior art.
- **A new partnership between USDA and USPTO**. A new Working Group on Competition and Intellectual Property will focus on a number of initiatives such as: 1) to explore joint USPTO-USDA opportunities for collecting broader stakeholder input from researchers, plant breeders, farmers, and others in the seed and agricultural input markets; 2) to explore initiatives to enhance the quality of the patent examination process for innovations related to agricultural products and processes, including opportunities for enhancing prior art search capabilities and providing additional training and guidance to patent examiners; 3) to collaborate on initiatives that enhance the transparency of IP information for agricultural-related innovations and assess availability and viability of patented and off-patented germplasm; and 4) to consider and evaluate new proposals for incentivizing and protecting innovation in the seed and agricultural-related space, including the addition of research or plant breeders' exemptions for U.S. utility patents.
- **Enhanced transparency for farmers.** Enforce label requirements under the Federal Seed Act (FSA), to ensure that farmers have access to all legally required information at

the earliest opportunity, usually at the time of purchase and no later than the commencement of shipment. Additionally, enforce false advertising provisions under the FSA to avoid representations that may claim or give the impression that seed brand names add diversification for a grower when that representation is false or misleading. Enhance the accessible filing of complaints and tips on potentially unlawful seed practices.

- **Interagency coordination to promote fair competition.** USDA and USPTO, together with the Department of Justice (DOJ) and the FTC, contemplate a number of actions to promote fair competition in the seed industry, including 1) expand farmerfairness.gov to include seeds and other inputs, 2) assess the impact of seed business consolidation and IP on pricing, choice, and availability of adapted varieties and the impact of reduced competition on food security, genetic diversity, and regional production capacity, and 3) coordinate and consult on actions related to practices in the seed industry that may harm competition.
- **Investment in innovative and resilient local and regional food systems.** Every day USDA invests in science and innovation in agriculture. Following the pandemic, USDA has already begun pivoting to meet the needs of a more diverse and resilient food system, which incorporates equity and respects Indigenous food systems. More can be done to create enhanced diversity and resiliency in seeds and other agricultural inputs, including 1) explore and highlight opportunities where additional funding, if provided, may encourage public sector plant breeders to work in crops or regions that are currently underserved by the private sector and where innovation is needed for farmer choice and resilience, 2) promote broader adoption of IP strategies that enable continued research and breeding with commercialized cultivars from federally funded research, 3) encourage and strengthen partnerships between public entities, small and mid-sized businesses, and non-profit organizations, and ongoing outreach and support to historically underserved groups, including indigenous peoples who originally stewarded and continue to care for important varieties, and 4) explore options to invest in education around agriculture, plant breeding, and seed systems at all levels.

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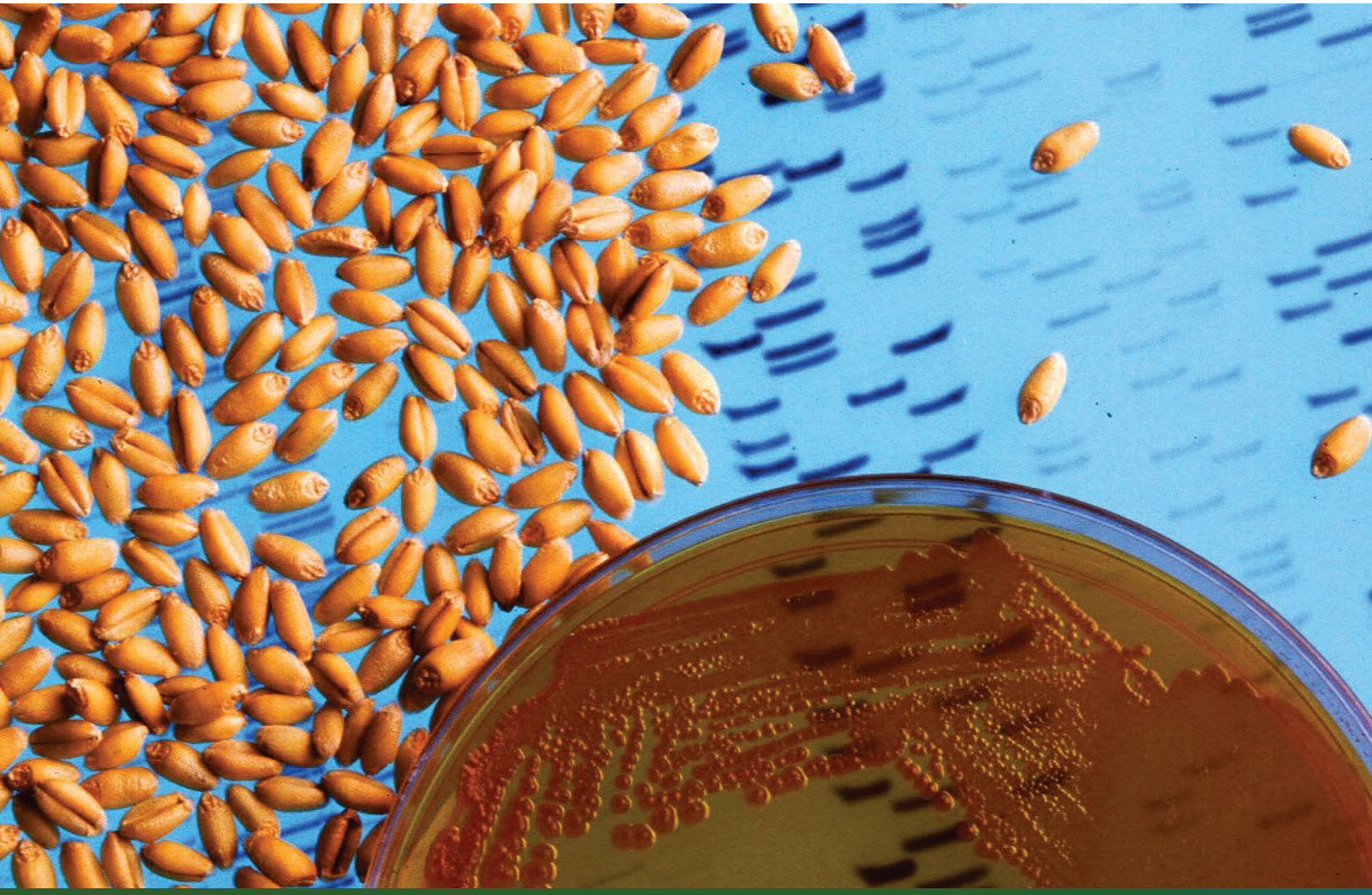

Introduction

American agriculture has undergone significant transformation over the past one hundred years. Plant breeding innovation has contributed to this transformation, delivering improved varieties to farmers across crops, regions, and production systems. Variety development and seed systems engage a wide range of innovators, including farmers, universities and research organizations, seed and nursery businesses of all sizes, independent plant breeders, and large vertically integrated companies. Over the same time period, the opportunities, limits, and challenges of intellectual property (IP) rights have come to play a central role in plant breeding. Robust and reliable IP rights and their fair enforcement are a critical component to ensure equitable opportunities for all actors engaged in variety development. This, in turn, is key to sustaining ongoing innovation to ensure the resilience of America's agricultural production in the face of new and evolving challenges.

The U.S. Constitution grants Congress the power "to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."[8] In response, Congress has crafted a patent system to provide adequate incentives to individual inventors while encouraging innovation for public benefit. The system strikes this balance in three important ways. First, stringent requirements for patent protection seek to assure that ideas and inventions already in the public domain remain available for the public to use. Then, patents incentivize innovation by granting a period during which no one else can make, use, offer to sell, sell, or import an invention without the permission of the patent owner. Finally, in exchange for this exclusive right, the inventor fully discloses the invention in their application and grants public access to the patented invention for further innovation, so long as the patent is not infringed upon during the limited duration of the patent. By design, this system provides limited-in-time exclusivity to the claimed invention in order to deliver innovations to the public. By requiring disclosure of the methods of creating innovations, it allows for others to build on them.

Research shows that the patent system, generally, spurs innovations in the private sector. A recent economic study published by the U.S. Patent and Trademark Office (USPTO) shows that IP-intensive industries play a significant role in the U.S. economy in terms of both output—measured as gross domestic product (GDP)—and employment.[9] IP protection may be especially important to new market entrants, individual inventors, and small businesses that do not have market share and rely on their IP to compete. Research and development spending and new plant variety introductions by the private seed industry have generally grown in recent decades. At the same time, some have expressed concerns that dominant companies in research-intensive markets, such as pharmaceuticals, technology, and

8. U.S. Constitution, art. 1, sec. 8, cl. 8.
9. USPTO, *IP and the U.S. Economy: Third Edition*, by Andrew A. Toole, Richard D. Miller, Nicholas Rada, (2022). www.uspto.gov/sites/default/files/documents/uspto-ip-us-economy-third-edition.pdf

agriculture, are tipping the careful balance struck by Congress to use the intellectual property system in ways that protect market power at the public's expense.

In agriculture, ongoing consolidation has resulted in a global seed industry dominated by just a few companies.[10] Farmers, plant breeders, businesses, and others have expressed growing concern about the implications of this continuing consolidation. Their concern has been heightened given the potential interplay between industry consolidation, anticompetitive behaviors, and the exclusive rights conferred by the utility patent system, which has increasingly been used for seed-related IP following court decisions expanding the scope of patentable material.[11] The tension is due in part to the fact that the IP system, which provides a limited-in-time exclusivity to claimed inventions, coexists with antitrust laws, which prohibit specific behaviors that restrict competition in the marketplace.[12]

On July 9, 2021, President Biden issued an Executive Order titled "Promoting Competition in the American Economy," which creates a White House Competition Council and directs Federal agency actions to enhance fairness and competition across America's economy. Among other things, the Executive Order directs the Secretary of Agriculture, in consultation with the Director of the USPTO, to submit a report on concerns and strategies for ensuring that the intellectual property (IP) system, while incentivizing innovation, does not also unnecessarily reduce competition in seed and other agricultural input markets. As a response to the Executive Order, on March 17, 2022, the USDA's Agricultural Marketing Service (AMS) published a request for public comments and information that included 25 multi-part questions about competition and market power, intellectual property, and other business practices in the seed industry that might be affecting the American farmer's ability to participate in a fair and competitive market. After a 90-day comment period, we (USDA staff and cooperators) collected comments, hosted a public listening forum, and heard from an

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10. In its 2018 assessment of global seed markets, OECD writes that "Bayer-Monsanto is the largest player, with roughly equal shares of sales coming from seeds and biotech versus agricultural chemicals. ChemChina-Syngenta is second, at about a third smaller than Bayer-Monsanto, but mostly focused on agricultural chemicals. DowDuPont is the third major player, with a roughly equal split between seeds and biotech. Following the acquisition of Bayer assets, BASF has become the fourth player in the sector, although its total sales are less than half of those of Bayer-Monsanto. Finally, both Limagrain/Vilmorin and KWS, while important players, are small in comparison with the market leaders. Each firm has less than one-tenth the sales of Bayer-Monsanto." OECD, "New Evidence on Market Concentration," *Concentration in Seed Markets: Potential Effects and Policy Responses,* (OECD Publishing, Paris, 2018), 57.
11. See, e.g., Department of Justice (DOJ). *Competition and Agriculture: Voices from the Workshops on Agriculture and Antitrust Enforcement in our 21st Century Economy and Thoughts on the Way Forward.* 2012. www.justice.gov/atr/page/file/1534736/download.
12. The Sherman Act of 1890 authorizes the Department of Justice to prohibit all contracts, combinations and conspiracies that unreasonably restrain interstate and foreign trade. The Sherman Act also makes it a crime to monopolize any part of interstate commerce. The Clayton Act (1914) further prohibits mergers or acquisitions that are likely to lessen competition, as well as other business practices, such as discriminatory pricing and exclusive dealing, that may harm competition under certain circumstances. The Federal Trade Commission, established through the FTC Act (1914), is empowered to prevent unfair methods of competition and deceptive practices affecting commerce, and joins the DOJ in enforcing the Clayton Act.

array of interested parties to ensure that as many perspectives as possible were represented in this report.

Public comments generally addressed concerns about consolidation and market power; IP mechanisms and how they are used; business practices that may restrict competition including trait stacking, bundling, and licensing terms; information resources including farmer access to information and farmer rights to data collected by digital platforms; and additional matters including right-to-repair and regulatory burdens for bringing new products to market. The comments submitted to the *Federal Register* reflected a range of commenter types. Forty comments were submitted by individuals, including anonymous commenters, the public-at-large, farmers, independent plant breeders, and university-affiliated researchers. Nine comments were submitted by private entities, ranging in size from small businesses to multinational corporations. Twenty-six comments were submitted by groups or organizations. Ten of these were nonprofits or advocacy groups, ten were trade associations, and six were farmers' organizations. Groups that claimed to represent individuals claimed anywhere from one thousand to two million members; however, because not all groups explicitly stated their membership, these numbers could not be accounted for in a systematic way.

Of the public comments posted to the *Federal Register*, the majority expressed concern about the negative effects of business consolidation and market power of large companies. Some of these comments were from individuals and focused on single aspects of the inquiry, such as consolidation, patents, or prices of seeds and other inputs. Some comments that described concern about concentration detailed licensing practices they consider anticompetitive. Others voicing concern about these issues included farmers' organizations such as the National Farmers Union. In addition, this group of comments included organizations representing consumer, economic, and environmental advocates such as the American Antitrust Institute, the Center for Food Safety, Friends of the Earth, and the Open Markets Institute.

Many commenters were concerned that utility patents have been used to restrict their ability to save seed, conduct research, and develop new varieties. Some commenters focused on fair licensing, especially when it comes to the ability to develop generic versions of genetically engineered traits, and/or pricing and labeling that may be deceptive or unfair to consumers. Many of these commenters, especially those that advocated for a balance between reasonable IP protection to sustain plant breeder livelihoods while preserving an ability for subsequent innovation, were submitted by individual plant breeders (both public sector and independent), breeding companies, and groups that include plant breeders in their membership, such as the Independent Professional Seed Association and Organic Seed Alliance.

Some trade associations including the American Seed Trade Association, American Soybean Association, U.S. Chamber of Commerce, and seed companies such as Bayer and Corteva, expressed support for the current IP system, recognizing the importance of IP in promoting

and protecting investment in research and variety development. Some of these comments also called for a stronger IP enforcement regime. Many indicated significant concern about international regulatory situations that may delay approval of products for reasons not related to public safety. These commenters also requested clarity on regulations of new breeding technologies and pointed out that ensuring a fair playing field in the international sphere is important for domestic competition and investment.

In response to the request for information published earlier this year and listening sessions held through 2022, a number of commenters shared concerns about behavior in the seed industry that may be anticompetitive. We also heard from commenters and others, either directly or through their organizations, that they cannot publicly oppose incumbents in the market for fear of retaliation. For example, the Organic Seed Alliance and the Rural Advancement Foundation International noted that farmers in their network have been routinely subject to legal and financial intimidation.[13] The Center for Food Safety submitted a 50-page report documenting "stories of harassment and intimidation by seed companies."[14] And the Independent Professional Seed Association, the largest national organization of independent retailers, which describes itself as representing roughly 22% of the market share across corn and soybeans sold in the United States, noted that its comment was submitted on behalf of its members, who "fear retaliatory actions in the marketplace should they choose to comment individually."[15]

Therefore, while we have carefully considered all the information provided during the request for information and in subsequent conversations with agency staff, academic experts, industry employees, and farmers, we note that commenters' fear of retaliation and lack of information about firm sales data and contracts leads to an incomplete picture of the dynamics in the seed industry. It is not within the purview of the USDA to conduct such investigations; we believe further scrutiny of concerns about anticompetitive behavior in the industry by the relevant agencies is appropriate.

To help facilitate understanding of the discussion in this report, there is a glossary of terms starting on page 14. Figure 1 (page 17) shows a simplified schematic of the variety development process as well as an illustration of some of the different types of business structures that exist within the seed industry.

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13. Organic Seed Alliance, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs," (June 15, 2022), 22. www.regulations.gov/comment/AMS-AMS-22-0025-0073
14. Center for Food Safety, Comment on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs," in "Seed Giants vs. U.S. Farmers," (2013), 7. www.regulations.gov/comment/AMS-AMS-22-0025-0076.
15. Independent Professional Seed Association, Comment on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs," (June 15, 2022), 2. www.regulations.gov/comment/AMS-AMS-22-0025-0061.

Glossary

Note: These terms and definitions are intended as general descriptions to assist a non-expert reader of this document only. They may reflect a degree of simplification for the purposes of this report and are not intended to replace any definitions currently in use in any U.S. Government laws or regulations, nor are they legally binding on the actions of any Government agency. For specific definitions that apply to any law or regulation of any Government agency, please consult directly with that agency.

Plant Breeding

Asexual reproduction: A method of plant propagation using vegetative material (other than seed) from a single parent, including cuttings, grafting, tissue culture, and propagation by root division.[16]

F1 hybrid varieties are the result of crossing two inbred lines. The sudden introduction of genetic diversity creates "**hybrid vigor**," leading to a high-performance population that is also genetically uniform (all individuals have the same parents). Seeds saved from F1 hybrids do not produce the same characteristics as those displayed by the hybrid parent; they may display any range of genetics from either of the inbred parents.

Genetic engineering: Manipulation of an organism's genes by introducing, eliminating or rearranging specific genes using the methods of modern molecular biology, particularly those techniques referred to as recombinant DNA techniques.

Genome: All the genetic material in all the chromosomes of a particular organism.

Genome editing, or **gene editing**, is a type of genetic engineering that inserts, deletes or replaces a specific sequence of DNA in the organism. There are a number of methods of gene editing, of which CRISPR is the most well-known to the public at this point.

Inbred lines are plant populations developed by self-pollination that are genetically uniform and display uniform characteristics. Seed saved from inbred lines will have the same genetics and characteristics as the parent plant.

Plant breeding: The use of cross-pollination, selection, and certain other techniques involving crossing plants to produce varieties with particular desired characteristics (traits) that can be passed on to future plant generations.

16. PVP Act, Chapter 4, Sec. 41, USDA, Agricultural Marketing Service (AMS), 2013.

Plant germplasm: The sum total of the genetic resources in a plant species from which new populations are developed.

Stacks are typically combinations of genetically engineered traits that provide different functionalities, such as multiple plant incorporated protectants targeting different insect families, or multiple herbicide tolerance traits for different herbicide modes of action.

Traits are individual characteristics determined by a plant's genetics. Traits may be naturally occurring, such as having red fruit, identified through conventional plant breeding, or they may be genetically engineered, such as herbicide tolerance.

Variety: A subdivision of a species for taxonomic classification also referred to as a "cultivar." A variety is a group of individual plants that is uniform, stable, and distinct genetically from other groups of individuals in the same species.

Crop groups

Commodity crops are defined by the U.S. Farm Bill.[17] Wheat, corn, sorghum, barley, oats, cotton, rice, certain pulses, soybeans/other oilseeds, peanuts and sometimes sugar are considered commodities, with different crops being considered eligible commodities for different programs.

Specialty crops are defined as fruits and vegetables, tree nuts, dried fruits and horticulture and nursery crops, including floriculture.[18]

Plant-related Intellectual Property Rights and Business Practices

Bag tags are licenses affixed to seed packaging that stipulate how the seed may be used. The buyer agrees to, or "signs," the contract by opening the package.

License agreements rely on contract law to stipulate how seed can be used. License agreements may be based on patent, PVP, or trademark protection; companies also use licenses to restrict the use of seed that is not protected by any other form of intellectual property right.

Material Transfer Agreements (MTAs) are documents that stipulate how seed can be used when transferred (but usually not sold) from one party to another. MTAs are often used by researchers and germplasm collections.

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17. 7 U.S.C. § 9011
18. Specialty Crops Competitiveness Act of 2004 (7 U.S.C. §1621 note), amended under section 10010 of the Agricultural Act of 2014, Public Law 113-79. More information at https://www.ams.usda.gov/services/grants/scbgp/specialty-crop

Plant Variety Protection certificates (PVPs) are administered by the USDA and protect a new and distinct variety. Varieties protected by PVP may be used in research and breeding but may not be used to create a commercially available F1 hybrid or essentially derived variety without a license. PVP varieties may not be exported from the U.S. by anyone without the authorization of the certificate holder. The term of protection for seed-propagated crops is 20 years from issuance of the certificates and 25 years for trees and vines.

Plant patents are administered through the USPTO and provide exclusive rights to an asexually propagated plant and any of its parts. Plant patents consist of only one claim, which refers to the description of a novel plant in the application. A plant patent expires 20 years from the earliest filing date of the patent application.

Utility patents are administered through the USPTO and are issued for inventions that are patent eligible, new, non-obvious, and useful. Utility patents can claim plant germplasm, plant varieties, genetically modified traits, and breeding methods. Utility patents permit the patent holder to exclude others from using the claimed invention in research (with limited exceptions), breeding, planting saved seed, and from otherwise using, making, offering to sell, selling, or importing the invention. Utility patents expire 20 years from the earliest filing date of the patent application.

Figure 1: Simplified schematic of variety development process that delivers seed to farmers. This represents many seed-propagated crops; however, there is considerable variation by crop type. Asexually propagated crops have similar variety development stages but more biological complexity in systems delivering planting stock to farmers.

1. Intellectual Property in the Seed Industry

The IP system, by design, is meant to incentivize innovation through exclusive rights in exchange for disclosure for public benefit. A goal in promoting fair competition is to ensure that exclusive rights are tailored and used in such a manner to arrive at a socially advantageous balance between exclusivity and competition. This balance is struck along multiple dimensions. In the first instance, which we discuss in this section, this balance is reflected in the different type of IP rights and the way they can be challenged and used.

In agriculture, IP law can protect seeds, plants, plant varieties, parts of plants, methods of breeding, methods for identifying or isolating naturally occurring traits, specific modified gene sequences, and genetically engineered traits. There are multiple systems of IP protection available, depending on the type of invention claimed and the amount of restriction sought by the inventor: trademarks, plant variety protection (PVP) certificates, plant patents, and utility patents (See Glossary). Additionally, trade secret protection, both at the state and federal level, may protect parent lines of hybrid crops. Plant breeders and seed companies can also use contract law to control the exchange of plants, seeds, and other propagation material. These contracts, generally governed by state law rather than federal law, interact with patents, PVP, technology licenses, and copyright in various ways. The overlap of different IP regimes and contract law on the same variety can create difficulty in determining farmers' rights to save seeds or plant breeders' ability to experiment with the protected variety.[19]

The differences in each form of intellectual property protection are central to any discussion about their effects on innovation in plant breeding (see Table 1, page 19). Both plant patents and PVP are *sui generis* intellectual property systems established by Congress to address the tension between the biological features of plants (that plants reproduce naturally, their improvement and adaptation is iterative, and farmers have historically saved seed and other propagation material) and plant breeder and seed companies' need to recoup development costs to sustain ongoing research. Utility patents are used widely across industries and are not tailored specifically to plants. PVP certificates can protect all types of plant varieties,[20] while plant patents protect only asexually propagated plant varieties. Importantly, utility patents are the only mechanism to protect plant traits (including genetically engineered traits) and breeding methods. The PVP system provides both research and breeding exemptions. The patent system does not provide a breeding exemption and allows a research exception that encompasses only "very narrow" experimental uses "solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." It does not include uses that have

19. See, for example, Mark D Janis, "Intellectual Property Issues in Plant Breeding and Plant Biotechnology," Articles by Maurer Faculty, 2560, (2002). www.repository.law.indiana.edu/facpub/2560.
20. The 2018 Farm Bill added asexually propagated crops to those eligible for PVP. 7 U.S.C. § 2402(a).

the "slightest commercial implication" and has been interpreted to exclude academic research.[21]

In general, plant breeders have diverse perspectives on the effects of utility patents on continued innovation. Some are of the opinion that utility patents on genetically engineered traits are appropriate subject matter, while patents on varieties and traits from traditional breeding are not. Some express the view that utility patents on varieties are appropriate subject matter but that patents on traits produced by traditional breeding are not. Others think that patents on traits from traditional breeding are necessary to protect their investment from appropriation and to allow them to cross-license other patented traits but contend that varieties should only be protected through PVP. Finally, some believe that the current system of allowing utility patents on both varieties and traditionally bred traits is appropriate.

Table 1: Comparison of different forms of intellectual property protection for plants [22]

FORM (AGENCY)	CRITERIA	ELIGIBLE CLAIMS	SAVED SEED EXEMPTION	BREEDING EXEMPTION	RESEARCH EXEMPTION
Plant Variety Protection (USDA)	Plants that are new, distinct, uniform and stable[23]	A described new plant variety	Yes, up to the amount purchased	Yes	Yes
Plant Patents (USPTO)	Asexually propagated plants that are new, distinct and completely described	One claim that describes a new plant variety	No	No	Restricted
Utility Patents (USPTO)	Eligible subject matter, novel, nonobvious, definite and enabled	Any number of claims that describe a variety, modified genetic trait, method of identifying a trait, or method of breeding	No	No	Restricted

21 Madey v. Duke University, 307 F.3d 1362

22. Chart based on Table 1 from Mojdeh Bahar and Robert J. Griesbach, "To Protect or Not to Protect: Guide for Deciding on Public Release or Intellectual Property Protection of New Plant Cultivars and Germplasm," *HortScience* 54, no. 4 (April 1, 2019): 764, https://doi.org/10.21273/HORTSCI13528-18.

23. Plant Variety Protection includes the right to prevent others from commercializing "essentially derived" varieties without permission of the owner of the PVP certificate. Utility patents and plant patents do not include the concept of essential derivation.

Patents Are Used Widely Across Crop Markets

In 2013, researchers noted that the rate of issuance of utility patents on new crop varieties has, in recent years, generally outpaced the rate of PVP applications.[24] In a preliminary analysis of PVP certificates and patents mentioning crop names, we found that PVPs accounted for 61% of IP developed in 1990 and only 38% in 2020 (See Appendix B). Across all crops, IP composition generally shifted from mostly PVP certificates in the 1990s to a higher percentage of utility patents in 2020 (See Figure 2, page 22).[25] This trend was more pronounced for crop markets dependent on genetically engineered varieties, such as corn, soybean, and cotton, in which PVPs made up most IP in the 1990s and less than half in 2020. In contrast, for wheat and forage species, which are crops with significant public sector funding and whose IP ownership is less concentrated, IP composition tended to remain mostly PVPs, with slight increases in numbers of patent certificates awarded in 2020.[26]

For specialty crops, utility patents often focus on improvements on traits such as disease resistance or aspects of quality. Some plant breeders with whom we spoke noted that some crops—mostly self-pollinated vegetables such as green beans or lettuce—rely heavily on utility patents. There are also many vegetable varieties without IP on the variety itself that are sold as F1 hybrids or with licenses. These may not be protected as a variety but may contain patented modified gene(s) that confer traits such as specific disease resistances. Plant patents have been the predominant form of IP for many asexually propagated specialty crops, although there is growing use of utility patents and, more recently, PVP. The trend toward utility patent protection for all crop types makes critical the consideration of its mechanisms of protection and impacts on the seed market in the future.

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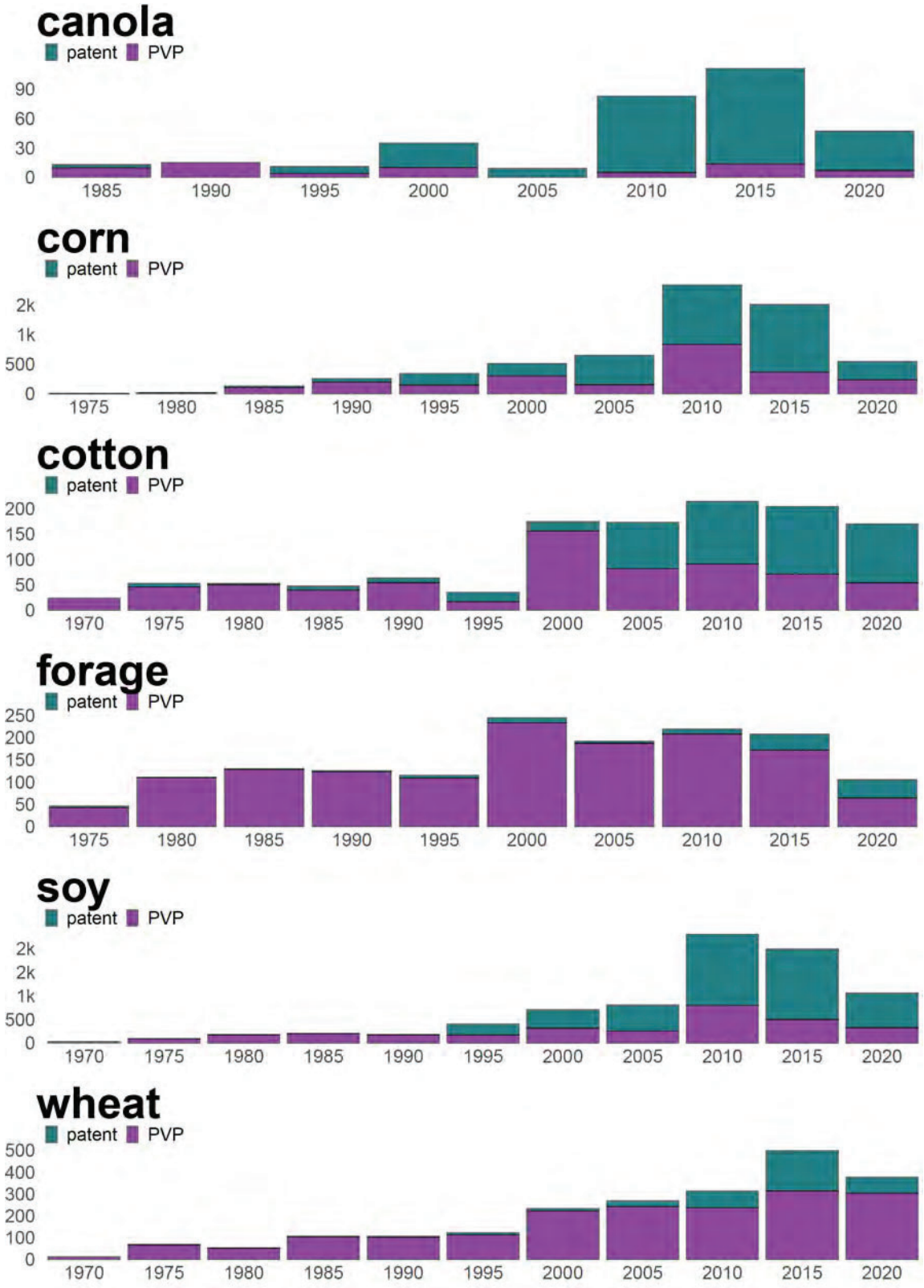
24. Philip Pardey, Bonwoo Koo, Jennifer Drew, Jeffrey Horwich, and Carol Nottenburg, "The evolving landscape of plant varietal rights in the United States, 1930–2008." *Nature Biotechnology* 31, no. 1 (2013): 25-29.
25. From 1970 to 2020, the composition of IP for plants shifted from mostly PVP to utility patent, particularly for soy, corn, and cotton, whose IP ownership by the top four firms also dramatically concentrated during that time period. For example, for soybean, PVPs accounted for 97% of IP in 1990 and only 31% in 2020 with the rest being utility patents. For corn, IP was 68% PVP in 1990 and 44% in 2020. For cotton, IP was 86% in 1990 and 32% in 2020.
26. PVPO Application Status Report, accessed November 3, 2022. www.ams.usda.gov/sites/default/files/media/PVPOApplicationStatus.xlsx.

Figure 2: IP by PVP (purple) vs. patents (green) from 1970 – 2020 for crops with the highest numbers of certificates. Each bar represents a 5-year time period, centered around the year labeled on the x-axis.



Plants Pose Unique Challenges for Patent Examination

The patent system can provide an important benefit to businesses by protecting their investment and efforts in developing new varieties, traits, or breeding methods. To get a utility patent, the invention must meet the statutory requirements of being patent eligible subject matter, useful, novel, and non-obvious. Since 1980, the Supreme Court has issued a series of decisions that have changed the way that the USPTO examines applications on plants (See Appendix A). In 2019, the USPTO published updated guidance to clarify practices for patent examiners in determining subject matter eligibility as it relates to laws of nature, natural phenomena, and abstract ideas,[27] and in 2021 issued a request for comments regarding patent eligible subject matter.[28] Commenters noted that there is still significant concern regarding patent eligibility for natural phenomena and traditionally bred plants.[29] This leads to concerns about utility patents negatively affecting innovation and new variety development. One avenue for ensuring that the IP system effectively incentivizes innovation is to ensure issued patents satisfy each statutory requirement.

Challenges: novelty and non-obviousness

To ensure that a claimed invention is novel and non-obvious, patent examiners conduct a "prior art" search of previously published patents, literature, and other types of public information to ensure that the invention was not previously known or used. Some commenters believe incomplete searching has led to patents that covered existing plant varieties, characteristics, and methods of breeding.[30] The scope of prior art is vast and includes subject matter that has been patented, named in a patent application, described in a printed publication, in public use, on sale, or otherwise publicly available before the filing date of the claimed invention.[31] For plants and plant genetics, prior art includes evidence of public use of the variety or trait in question, including plant and utility patents, patent application publications, published PVP applications, variety registrations in other jurisdictions, academic journals, public germplasm collections, seed catalogues, and sales receipts that adequately describe the claimed invention. This represents an inherently complex search that requires significant time and resources, as prior art for plants may not be as immediately accessible as for other types of inventions. In fact, when Congress passed the

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27. 2019 Revised Patent Subject Matter Eligibility Guidance, 84 *Fed. Reg*. 50 (Jan. 7, 2019), www.federalregister .gov/documents/2019/01/07/2018-28282/2019-revised-patent-subject-matter-eligibility-guidance.
28. Patent Eligibility Jurisprudence Study, 86 Fed. Reg. 36257 (July 9, 2021), www.federalregister.gov/documents/2021/07/09/2021-14628/patent-eligibility-jurisprudence-study
29. For example: "There are an extensive number of patent protections, including Utility Patents, on native traits in plants conferred through traditional breeding and selection." Anonymous, Comment on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs," (June 15, 2022), 1. www.regulations.gov/comment/AMS-AMS-22-0025-0063
30. See, for example, Jim Myers, Comment on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs," (June 15, 2022), 4. www.regulations.gov/comment/AMS-AMS-22-0025-0060
31. 7 U.S.C. § 102.

Plant Patent Act in 1930, the law made special provisions for the USDA to provide input to the USPTO during the examination process,[32] acknowledging that the Department would have access to agricultural records that could support a prior art search.[33]

As a practical matter, the literature most often cited by patent examiners in patent applications is previously issued patents, which contain disclosures that can often be more easily mapped to the claims in patent applications.[34] Because many plant breeders may choose not to use the patent system,[35] their work may not be as readily accessible to patent examiners. These gaps likely require establishing more comprehensive common prior art sources used by all parties.

In 2011, the America Invents Act changed the third-party prior art submission rules for pending patent applications, indicating an opportunity for the public to help improve the prior art search and, consequently, the quality of patents. Now, the public can submit evidence of prior art to pending applications for up to six months after they are published. Unfortunately, this provision has seen little use.[36] In the plant space, this may be because some plant breeders are unaware that such an option exists, or because of the prohibitive amount of time and cost it would take to monitor pending patent applications. The USPTO publishes pending patent applications every Thursday via a recently redesigned web-based search tool called PubSearch. Some commenters reported difficulty using this search tool to effectively search for pending patent applications.[37] Since the time that comments closed and

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32. "The President may by Executive order direct the Secretary of Agriculture, in accordance with the requests of the Director, for the purpose of carrying into effect the provisions of this title with respect to plants (1) to furnish available information of the Department of Agriculture, (2) to conduct through the appropriate bureau or division of the Department research upon special problems, or (3) to detail to the Director officers and employees of the Department." 35 U.S.C. § 164

33. In its 1967 report, the President's Commission on the Patent System noted that in practice, "[plant] patents are granted if the Department of Agriculture notifies the Patent Office that, as far as it can determine, the plant variety is new, and the examiner finds no art indicating the contrary." *To Promote the Progress of Useful Arts in an Age of Exploding Technology: Report of the President's Commission on the Patent System.* Washington, D.C: The President's Commission on the Patent System, (1967), 21.

34. Christopher A. Cotropia, Mark A. Lemley, and Bhaven Sampat, "Do Applicant Patent Citations Matter?," *Research Policy* 42, no. 4 (2013): 844–54, https://doi.org/10.1016/j.respol.2013.01.003.

35. "Most freelance plant breeders draw part of their motivation for plant breeding from a deeply held belief that the rights of farmers, gardeners, and others to grow seeds, sell them, and breed from them should not be infringed." Carole Deppe, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" in "Freelance Plant Breeding," (June 15, 2022), 138. www.regulations.gov/comment/AMS-AMS-22-0025-0075.

36. USPTO letter to FDA, (2022), 7. www.uspto.gov/sites/default/files/documents/PTO-FDA-nextsteps-7-6-2022.pdf

37. "While purported to be more user-friendly, the application still requires the user to have a computer that can run the program as well as working knowledge of field codes, Boolean, and proximity operators, as well as the time to search for pending applications pertinent to their crops." Organic Seed Alliance, Comment on "Competition," page 32. www.regulations.gov/comment/AMS-AMS-22-0025-0073.

in response to public feedback, the USPTO designed and deployed a simplified, guided search interface, Patent Public Search Basic, in December of 2022.[38]

Some commenters noted that many plant breeders do not have the time and resources to monitor such applications, let alone to put together a third-party prior art submission, even if their work could render an application's claims invalid. According to a public sector vegetable breeder, the third-party prior art submission process "is still rather opaque to those not versed in patent law and requires a substantial time commitment to obtaining and reading patent applications when they first issue. These requirements are generally beyond the means of small seed companies and public institutions."[39] Additionally, some public institution technology transfer offices with whom we spoke also do not advise plant breeders to submit prior art because the patent examiner is likely to find relevant prior art anyway, especially when initial claims are particularly broad. Though the USPTO offers resources for the public to provide submissions,[40] there still may be other reasons why parties do not submit relevant prior art. Overall, this feedback suggests that the USDA and USPTO could enhance outreach to farmers, plant breeders, businesses, and others in the seed and agricultural markets.

Some commenters wrote that it is a common practice for patent applicants to initially submit the broadest possible claims in patent applications. For example, in their public comment, the Farmers Business Network wrote: "It is standard practice among plant breeders now to evaluate dozens or a hundred attributes of the new germplasm to be able to find some obscure differences from existing germplasm, as a way to avoid the issue of prior art."[41] In a review of nine patents commenters brought to our attention, three of the respective patent applications were filed with broad claims on naturally occurring traits, and as they moved through prosecution, the patent examiner gradually cancelled claims in order to ultimately result in a patent that only covers a specific hybrid or single variety. In these instances, it appeared that responsibility was on the examiner to determine what aspects of the claims were patentable. The language included in the original specification of the application that

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38. The USPTO notes that with the new Patent Public Search Basic interface, users do not have to learn new syntax, and the search results can readily be reviewed with a preview of the first page or a link to the full document. Training on the Patent Public Search tool is available on demand as a web-based tutorial and through videos found on the YouTube @USPTOvideo channel. Users can also attend livestream Patent Public Search training hosted by the Patent and Trademark Resource Center (PTRC). Initial user feedback seen by the Customer Service (CX) team, the PTRC, and Public Search Facility (PSF) shows that these changes have helped to address customer concerns.
39. Jim Myers, Comment "Competition," 8.
40 See, e.g., USPTO, Quick Start Guide and FAQs available at: https://www.uspto.gov/patents/initiatives/preissuance-submissions/resources; Basic Guidelines and Helpful Hints available at: https://www.uspto.gov/patents/initiatives/preissuance-submissions/about; and Detailed guidance in MPEP § 1134.01 available at https://mpep.uspto.gov/RDMS/MPEP/current#/current/d0e121605.html.
41. Farmer Business Network, Comment on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs," (June 15, 2022), 7. www.regulations.gov/comment/AMS-AMS-22-0025-0071.

concerned plant breeders, who encountered difficulty determining whether what was ultimately claimed would have impeded their breeding projects.

Challenges: disclosure

Patent law requires an applicant to fully disclose their invention by providing a written description and the manner of making and using the invention, such that one of skill in the art can make and use the invention without undue experimentation.[42] Commenters noted that patent applications may omit pedigree information (which describes the breeding history of the variety or trait) that they believe is critical to understanding the process of creating a new variety or incorporating a trait into a variety.[43] According to these commenters, without this information, it is difficult for examiners or third parties monitoring applications to find relevant prior art. For example, a variety that appears in a pedigree for a new patent application might have a PVP certificate, or publication, or commercial sale associated with it that documents prior art on a specific trait.

Some plant breeders with whom we spoke noted that in practice, disclosure may only provide information that the patenting firm would be able to understand. For a stylized example, one plant breeder noted that a "detailed description of the invention" included in a patent application for a hybrid variety might read: "The F1 hybrid was created by crossing two proprietary lines. The F1 was grown in plot number 2X6754 under the stake number N1987."[44] The person noted that the patent examiner may then request pedigree information, but that the applicant can request the pedigree to be classified as confidential business information. By contrast, the PVP application requires a variety's "genealogy (back to and including public and commercial varieties, lines, or clones used)," such that a person skilled in the art could, given enough time, recreate a similar invention from identifiable and available varieties. Although only certain types of information must be disclosed in the patent system, applicants have general duties of good faith, candor, and disclosure associated with the patent prosecution process.[45] At present, pedigree information may be needed to meet specification requirements.[46] Those requirements can also be met by depositing a sample of biological material in a public depository, which is discussed in more detail below.[47] Taken together, such comments suggest that more fulsome disclosure of pedigree may be beneficial in future prior art searches and to enable follow-on innovation for some patented varieties.

In summary, plant breeding is a lengthy and resource intensive endeavor; sometimes, it takes decades to develop a marketable product with significant public value. Some commenters

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42. 35 U.S.C. §112
43. "One concern about patent quality is that some patents do not contain sufficient information and detail such that another developer could replicate the invention in order to improve upon it." Breakthrough Institute, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (May 16, 2022), 3. www.regulations.gov/comment/AMS-AMS-22-0025-0038.
44. This is a stylized example based on an active patent. The plot and field numbers have been changed.
45. 37 C.F.R. 1.56
46. 35 U.S.C. 112.
47. 37 C.F.R. 1.802.

noted that the long development period is a strong argument for the current IP system. For example, KWS Seeds, headquartered in Germany, wrote: "It requires years, and sometimes decades, to produce seeds and other agricultural inputs... The existing IP system enables access to new and improved products which are based on the needs of farmers and the growing challenges they face."[48] Others noted that the resources required to develop new varieties are also an argument for rigorous examination of claims to ensure that they meet stringent criteria for subject matter eligibility, reduction to practice, novelty, non-obviousness and utility. For example, one commenter outlined four separate instances when an issued patent affected research and breeding programs for which the commenter believed there was documented prior art at the time the patent was filed.[49] While we did not evaluate any particular case, a terminated breeding project due to an invalid patent represents a significant loss of investment and may deprive growers of plant varieties and traits that would have resulted from that line of research.

Consumers, farmers, and the seed breeding industry alike have an interest in assuring that patents issued maintain high standards of novelty and non-obviousness, as a baseline of a robust and reliable patent system. Enhanced interagency cooperation, as well as increased engagement with all farmers, plant breeders and seed companies, can help increase certainty and confidence in this process.

Post–Issuance Proceedings for Challenging Patent Validity

The USPTO offers three avenues for challenging granted patents. An *ex parte* reexamination can be requested after a patent has been granted, with the scope of the challenge limited to novelty and non-obviousness. In an *ex parte review,* the requester submits patents and printed publications that may invalidate the patent. If the USPTO determines that there is a "substantial new question of patentability," the office will order reexamination and the application is reassigned to a new examiner.[50] The filing cost for requesting a reexamination is $6,300, with discounts, bringing the cost down to $2,560 for small entities and $1,260 for micro entities.[51] Because the proceedings are *ex parte*, there is no participation by third parties after the initial filing, keeping legal fees to those challenging patents down.

Under the America Invents Act of 2011 (AIA), a challenger also may pursue two avenues more akin to litigation by involving the Patent Trial and Appeal Board (PTAB).[52] One avenue involves a petition for post-grant review (PGR), which must be filed within the first nine months after the patent has been granted. In another avenue, a challenger can request an *inter partes* review (IPR) after the post-grant review period has expired. In an *inter partes*

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48. KWS Seeds, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (June 15, 2022), 2. www.regulations.gov/comment/AMS-AMS-22-0025-0055.
49. Jim Myers, Comment on "Competition," 4.
50. 37 C.F.R 1.510
51. USPTO, "Fee Schedule," www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule.
52. USPTO, "What are AIA proceedings," https://www.uspto.gov/patents/patent-trial-and-appeal-board/about-ptab/what-are-aia-proceedings.

review, the scope of the challenge is limited to novelty and non-obviousness, and only on the basis of prior art consisting of patents or printed publications.[53] Small businesses may find the cost prohibitive: the base fee to request a post-grant or *inter partes* review from the PTAB is over $19,000, with fees totaling over $40,000 if the request is instituted, with no discounts provided for by Congress for small and micro entities. These fees do not account for the legal fees incurred while challenging a patent.[54] The USPTO under the Biden Administration is working to help those who are under-resourced have access to pro bono legal counsel.[55]

If a plant breeder or seed firm chooses not to challenge a patent but continues their line of research, they may be liable for infringement should the patent holder assert their IP rights. Litigation often involves differences in interpretation of patent claims. Though the patent may still be challenged at the USPTO once litigation commences or in the litigation itself (or both), when litigation occurs in such cases, there may be an imbalance in resources between the patent holder and the party accused of infringement. Small businesses challenging the patent of an incumbent may find that the patent holder is bringing more legal expertise and staff time to the case than the parties accused of infringement, making settlements more likely.[56] Though the USPTO under the Biden Administration is working on measures to reduce the uncertainty in patent claims, there is currently no process for an entity affected by a patent to request clarification of claims from the USPTO in order to determine if their activities are infringing. This means that plant breeders and seed companies working in an area potentially covered by a patent would be advised to seek legal advice on their freedom-to-operate in light of the patent or may be subject to an unknown amount of liability from patent infringement. Though various legal resources are available on a pro bono or fee basis, not all plant breeders and seed companies have convenient access to freedom to operate advice.

In many instances, a patent holder generally cannot obtain damages for infringement if they do not give notice by marking their product or notifying the infringer that their product is patented.[57] While this may be the case, a plant breeder who did not obtain the claimed innovation from the patent owner may not be given notice because the patent owner may not know what research the affected party is conducting, and the affected party likely does not want to reveal their current research and development activities to a potential competitor in order to obtain clarification from the patent owner on whether the owner considers those activities an infringement. As a practical matter, plant breeders may already

53. USPTO, "*Inter Partes Review*," www.uspto.gov/patents/ptab/trials/inter-partes-review.
54. USPTO, "Fee Schedule," www.uspto.gov/learning-and-resources/fees-and-payment/uspto-fee-schedule.
55. UPSTO, "USPTO launches PTAB Pro Bono Program," https://www.uspto.gov/about-us/news-updates/uspto-launches-ptab-pro-bono-program.
56. For example: "Litigating a patent infringement action is extremely costly, and the high cost favors large corporations. Farmers accused of infringement may feel pressured to settle because defending themselves in court may drive them to bankruptcy." Organic Seed Alliance, Comment on "Competition," 25.
57. 35 U.S.C. § 287

have invested significantly in a line of research and breeding before IP rights are granted to a competitor and before they are likely to be notified regarding these IP risks.

In summary, commenters reported that the difficulty of monitoring pending patent applications, the expense of challenging a patent post-issuance, and the steep risk of liability for patent infringement have created a situation in which small and mid-sized programs are more likely to decide to either pay a licensing fee for an innovation they may already have commercialized, or to discontinue that line of research and breeding entirely rather than to challenge a patent, even if the outcome would help resolve legal uncertainties. In October 2022, as a response to the executive order on "Promoting Competition in the American Economy," the USPTO under the Biden Administration published a request for public comments regarding several of the topics outlined above.[58] The request seeks input on additional sources for prior art, third party avenues for participation in the prosecution process, and alternative fee structures that may encourage higher quality patent applications. Previously, the USPTO under the Biden Administration has stated its intention to provide more time for patent examiners to review patent applications and to collaborate with other federal agencies to ensure robust and reliable patent rights. This initiative is ongoing and there are several identified areas for coordination between the USDA and the USPTO.

Continued Innovation as Impacted by Disclosure, Germplasm Accessibility, Research and Breeding Exemptions

Commenters raised concerns that the utility patent system may need to better accommodate plant-specific features that make them different from other patentable inventions. Fully addressing the barriers to continued innovation may require legislative or judicial action; however, there are areas in which it is possible to improve the current system to achieve a better balance of both providing needed IP protection for innovations and encouraging continued innovation that builds on protected varieties and traits.

Continued innovation: disclosure

Patent law requires that, in exchange for a limited period of exclusivity, the patent applicant must adequately disclose their invention, such that any person skilled in the art could make or use the invention without undue experimentation.[59] As mentioned above, information such as pedigrees may not be disclosed in published patents. In the words of one plant breeder we interviewed, "It used to be that you could go back and read a patent and understand what they did to create the variety. Now, the patents don't tell you anything." The

58. USPTO, "Request for Comments on USPTO Initiatives to Ensure the Robustness and Reliability of Patent Rights," 87 *Fed. Reg.* 60130, https://www.federalregister.gov/documents/2022/10/04/2022-21481/request-for-comments-on-uspto-initiatives-to-ensure-the-robustness-and-reliability-of-patent-rights.
59. 35 U.S.C. § 112.

commenter expressed concern that if a plant breeder wants to improve upon the steps taken by the inventor during the active term of the patent, they would have no point for reference for its origin, and thus be unable to utilize the disclosure. The commenter's concern is that if the published patent does not trace pedigree back to known and available parents, and seed of the patented plant is not accessible, the public cannot understand and improve on the claimed invention.

While a pedigree gives enough detail to understand the development of a new variety, disclosing a plant in sufficient detail in writing to recreate it from scratch is, in general, not possible due to its biological nature. To create a new variety or incorporate a new trait into a breeding program, it is necessary to have access to germplasm, i.e., seeds or other propagation material, which contain the source genetic material.[60] New varieties can be created from non-IP protected germplasm, but follow-on innovations on patented material are constrained by restrictions which limit access to that germplasm. In other industries, innovators may be able to look at descriptions of inventions described in patent applications, then design around the claimed invention. In contrast, plant varieties and the genetic traits they contain are the product of evolutionary history, domestication, and breeding. Withholding access to IP-protected seed or other propagation material prevents access not only to the trait or variety in question, but also to the prior innovation that led to its development. This limits the ability of other innovators to make follow-on improvements.

Accordingly, PVP and utility patents often require seed deposits of the protected plant. These deposits serve as part of the disclosure and are intended to be available for continued innovation. For PVP varieties, the assumption is that one could procure seed on the commercial market and make use of the research and breeding exemption to continue innovation. As discussed later, these varieties are increasingly often only available with licenses that restrict research and breeding. For utility patents, seed deposits may be available, but without a broader research or breeding exemption, such deposits may be insufficient to allow for continued innovation during the life of the patent. We recognize, of course, the importance of enabling plant breeders of protected varieties to recoup their investment, particularly in view of the rapid development of new breeding technologies, such as genome editing.

Continued innovation: germplasm accessibility

If there are closely related varieties on the market that are not utility patented, research and breeding restrictions may not be severe; however, once a large percentage of varieties are subject to patents, it could be difficult for new entrants to gain access to commercially relevant germplasm. The large wave of business consolidation that has occurred in the past few decades is evidence that sometimes, the fastest way for a variety developer to enter the

60. "Plant breeders must not only know how the current variety was developed and its characteristics, but also have access and the right to use the current variety in breeding. Consequently, patent disclosures alone do not allow other inventors to benefit from the patented lines when creating new plant varieties." Farmer Business Network, Comment on "Competition," 4.

market may be to purchase a breeding program from another firm or to acquire a smaller breeding firm with its own germplasm. Commenters note that without access to germplasm, entering the market is nearly impossible. For example, Farmers Business Network, a farmer-to-farmer network and e-commerce platform wrote, "Many competitive breeding programs have closed, and new entrants are very rare. This consolidation will only continue to intensify, as new germplasm must be bred from existing germplasm that is owned and controlled by a few dominant companies."[61]

Continued innovation: research and breeding exemptions

Developing a commercial variety takes multiple growing seasons and sometimes a decade or more of careful selection. For perennial crop varieties, many of which are protected by plant patents, the plants themselves can take a decade to mature and breeding timelines are extremely long. For both perennial and annual crop varieties, a competing plant breeder who has been unable to access germplasm during the active life of a patent cannot simply release a new variety with the patented traits as soon as the patent expires or release a variety that builds on a patented variety through traditional breeding. They can only start innovating after the relevant patents expire, and only if the off-patent germplasm has seeds available that will germinate and are not covered by contracts that prohibit breeding.[62] In most countries, plant varieties are ineligible for patent protection, with only a few exceptions: among them the United States, Australia, Japan, and South Korea. Most other countries have adopted the Plant Breeders' Rights framework set forth by the International Union for the Protection of New Plant Varieties (UPOV), which allows for breeding during the active life of the IP protection (see below).

International IP protection for plant varieties

UPOV: The International Union for the Protection of New Varieties of Plants (*Union interationale pour la protection des obtentions végétales*) is an intergovernmental organization based in Geneva, Switzerland. UPOV was established in 1961 by the International Convention for the Protection of New Varieties of Plants (the "UPOV Convention"). It came into force in 1968 after ratification by Germany, the Netherlands and the UK and was revised in 1972, 1978 and 1991. The U.S. is a signatory to the 1991 convention. According to UPOV, its mission "is to provide and promote an effective system of plant variety protection, with the aim of encouraging the development of new varieties of plants, for the benefit of society."[63]

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61. Farmer Business Network, Comment on "Competition," 3.
62. "Plant breeding, whether done by traditional methods or relying on modern molecular biology techniques, is somewhat unique in the context of cumulative innovation. Specifically, production of an improved variety is not possible without physical access to the relevant germplasm. Information per se, such as that disclosed by utility patents, is just not enough to provide the blueprint for an improved variety without access to the relevant biological material." Matthew S. Clancy and GianCarlo Moschini, "Intellectual Property Rights and the Ascent of Proprietary Innovation in Agriculture," *Annual Review of Resource Economics* 9, no. 1 (October 5, 2017): 61, https://doi.org/10.1146/annurev-resource-100516-053524.
63. USPTO, "International Convention for the Protection of New Varieties of Plants," www.uspto.gov/ip-policy/patent-policy/international-convention-protection-new-varieties-plants.

Currently, there are 78 member countries and intergovernmental organizations.[64] The UPOV convention principles are similar to those in the U.S. PVP Act in several important ways, including the presence of a breeding and research exemption and the concept of essentially derived varieties (EDV).

EDV: The concept of an essentially derived variety (EDV) in the PVP Act recognizes the need to balance research and breeding exemptions with the protection of investment in the development of new varieties, by preventing the commercialization of an EDV without a license from the original PVP owner. The UPOV Council issued the non-binding Explanatory Notes on EDVs in 2017.[65] However, the rapid development of new breeding technologies has brought the EDV concept to the forefront of discussions. Because new breeding technologies such as genome editing allows a plant breeder to make precise changes in a genetic sequence without altering the rest of the genome of the initial variety, many plant breeders of the initial varieties and PVP owners are concerned that the competitors would use a new breeding technology with their protected varieties to develop new varieties with fewer costs and less time. While genome editing would appear to be included in the definition of EDV under the U.S. PVPA[66] and is currently included in the definition of an EDV in non-binding guidance from UPOV,[67] seed industry actors have asked UPOV Council to re-examine their definition of EDVs in light of new technologies. While an agreement among the UPOV members has not been reached, some plant breeder groups have developed crop-specific professional agreements. For example, the Wheat Workers Code of Ethics governs conduct when working with experimental lines from other wheat breeders and lists categories of variety derivation methods where written approval is needed from the originator. [68]

TRIPS: The World Trade Organization's (WTO) **Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS)**, negotiated during the 1986-94 Uruguay Round, introduced intellectual property rules into the multilateral trading system. According to the WTO, TRIPS is "an attempt to narrow the gaps in the way intellectual property rights are protected and enforced around the world, and to bring them under common international

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64. Union for the Protection of New Varieties of Plants, https://www.upov.int/overview/en/upov.html.
65. UPOV, "Explanatory Notes on Essentially Derived Varieties." www.upov.int/meetings/en/doc_details.jsp?meeting_id=64149&doc_id=550033.
66. 7 U.S.C. § 2401 (4)
67. UPOV, "Explanatory Notes on Essentially Derived Varieties." www.upov.int/meetings/en/doc_details.jsp?meeting_id=64149&doc_id=550033.
68. National Wheat Improvement Committee, "Wheat Workers Code of Ethics for Distribution of Germplasm," (November 5, 1994). www.ars.usda.gov/ARSUserFiles/30421000/wheatcode.html. "Uses for which written approval of the owner/breeder is required include: (a) Testing in regional or international nurseries; (b) Increase and release as a cultivar; (c) Reselection from within the stock; (d) Use as a parent of a commercial F1 hybrid, synthetic, or multi-line cultivar; (e) Use as a recurrent parent in backcrossing; (f) Mutation breeding; (g) Selection of somaclonal variants; or (h) Use as a recipient parent for asexual gene transfer, including gene transfer through molecular genetic techniques."

rules." It establishes minimum standards of protection and enforcement that each government must provide citizens of all 164 WTO member countries.[69]

To address this, many plant breeders have recommended an exploration of research and breeding exemptions for utility patents in the plant breeding space. The International Seed Federation, which did not submit comments but is widely regarded for its role in the global seed industry, notes that "certain exceptions from patent rights are necessary in the field of plant breeding to maximize the potential for innovation" and suggests that "both a general research exception and a specific plant breeders' exception in patent laws should be considered."[70] Some countries which allow patent protection on plant traits have adopted research exemptions within their patent system.[71] Additionally, in public comments and interviews conducted for this report, several plant breeders from both large companies and small start-ups emphasized the need to maintain access to seeds for continued innovation. One commenter, a plant breeder and seed company founder, suggested that "all patented and IP protected varieties" should be available for breeding with a "fair royalty system."[72] Farmers Business Network wrote that "plant breeders, seed companies, farmers, and consumers in the United States would benefit from legislation creating a research exemption for patented germplasm."[73]

Currently, the USPTO is exploring whether research exceptions in utility patents would strengthen U.S. innovation not only in the plant breeding space, but also in other areas such as pharmaceuticals and drugs, and is working with the FDA on those efforts. In plant breeding, exemptions could include, for example, a research exemption to allow pre-commercial use of the innovation in research and breeding and enable more rapid post-patent entry, and a null-breeding exemption to allow plant breeders to work with the genetics in a variety that contains a patented genetically modified trait if the variety to be commercialized no longer includes that trait.

In addition to research and breeding restrictions, utility patents also restrict others from making the patented product. Seed-bearing plants are organisms whose multiplication is the natural result of using them as the seller intends and thus, they are different from other industrial products. If a grower purchases patented tomato seeds, the tomato grown from those seeds will naturally contain more seeds, although patents technically restrict others

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69. World Trade Organization, "Intellectual property: protection and enforcement," https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm.
70. International Seed Federation, "ISF View on Intellectual Property," (2021), 4, 27. www.worldseed.org/wp-content/uploads/2021/08/ISF-View-on-Intellectual-Property-2012-amended-2021-1.pdf
71. France: Article L. 613-5-3 of the Intellectual Property Code adopted in 2004; Germany: Section 11.2.b of the Patent Act adopted in 2005; the Netherlands: Article 53.2.b of the Dutch Patent Act; Switzerland: Article 9 (e) of the Federal Act on Patents for Inventions, adopted in 2008.
72. Ken Owens, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (May 15, 2022), 1. www.regulations.gov/comment/AMS-AMS-22-0025-0028
73. Farmer Business Network, Comment on "Competition," 3.

from recreating the invention without a license. Some commenters note that this self-replicating nature of seeds is a strong argument for seed-saving restrictions, particularly in the international arena. Corteva, a major seed firm in the United States, wrote, "Strong and enforceable IP protection incentivizes and safeguards U.S. investment. It also helps reduce the risk of theft and misappropriation of U.S.-funded innovation by overseas competitors. Major agricultural technologies, such as seeds or DNA-encoded traits, are self-replicating and especially vulnerable to misappropriation."[74] Others argued that this characteristic of seeds makes them an unnatural fit for the patent system, and describe the great lengths required to avoid unintentionally violating patent restrictions. For example, one farmer and corn breeder commented: "Over the years as we've put in the hard work of development, the hardest part has been avoiding contamination by patented genes in our neighbor's GMO corn planting. We have to wait until they've planted, then wait a few weeks to sow our own corn [to avoid cross pollination] …If they are late in their sowing, there may not be enough time left for us to get a crop, and we may miss a year of development and selection."[75]

The PVP system provides for research and breeding exemptions. These exemptions allow the use of a protected variety for continued breeding or research, without prior authorization of the PVP holder. However, if this work results in a variety that falls under the category of "essentially derived variety (EDV),"[76] commercializing the EDV requires the authorization of the PVP owner of the initial variety. The concept of EDV is currently under discussion at the international level within UPOV (see note on EDV on page 31).

In the modern seed industry, it is common for plant breeders to use multiple IP mechanisms to protect plant-related innovations. The exceptions under the PVP system can be superseded by the restrictions under the patent system, or by contract law in different forms of licensing agreements, such as bag tags or Material Transfer Agreements (MTAs). A bag tag is an agreement that is printed directly onto seed packaging. Upon opening the seed package, the purchaser is deemed to have agreed to the terms of the bag tag, which may include restrictions on seed saving and use for breeding and research purposes. In some cases, it is difficult for plant breeders or researchers to access commercial seeds without bag tags, which means that they are not able to take advantage of the breeding/research exceptions under

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74. Corteva, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (June 14, 2022), 4. www.regulations.gov/comment/AMS-AMS-22-0025-0053.
75. Jason Myers-Benner, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs," (May 15, 2022), www.regulations.gov/comment/AMS-AMS-22-0025-0027.
76. "Essentially derived variety: (A) In general; The term "essentially derived variety" means a variety that— (i) is predominantly derived from another variety (referred to in this paragraph as the "initial variety") or from a variety that is predominantly derived from the initial variety, while retaining the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety; (ii) is clearly distinguishable from the initial variety; and (iii) except for differences that result from the act of derivation, conforms to the initial variety in the expression of the essential characteristics that result from the genotype or combination of genotypes of the initial variety. (B) Methods; An essentially derived variety may be obtained by the selection of a natural or induced mutant or of a somaclonal variant, the selection of a variant individual from plants of the initial variety, backcrossing, transformation by genetic engineering, or other method." 7 U.S.C. § 2401

the PVP law. The PVP variety may also be an inbred used to produce a commercial hybrid. The inbred would not be commercially available, necessitating that the plant breeder request seed from the PVP holder, who may decline to provide it or only provide it with an MTA that does not allow breeding activities. Altogether, this means that PVP certificates can be, and often are, coupled with licensing restrictions that enable them to function in essentially the same ways as utility patents. In contrast, when Congress passed the PVP Act,[77] any commercialized seed with a PVP certificate would have immediately been available for breeding, because plant breeders could purchase commercial seed without additional restrictions. Several commenters noted that such restrictions increasingly narrow the available working gene pool and limit plant breeders' ability to innovate.[78]

Continued innovation: Access to protected varieties and traits after IP rights expire

Essential to a balanced IP system is that most formal methods of IP expire (with the exception of trade secrets and trademarks), after which the claimed innovation becomes part of the public domain. While farmers and plant breeders can legally use varieties and traits that are no longer protected by IP rights, we heard from commenters that there may be difficulty in accessing seed if a firm has taken these varieties off the market, or if they are restricted with other IP or licenses from the original owner.

In the case of PVP varieties, the issue of seed access after the expiration of the PVP certificate was addressed in the enabling legislation. Upon receiving a PVP, the applicant deposits seeds in the USDA-National Plant Germplasm System (NPGS), where seed is maintained for the duration of the PVP, and then multiplied for distribution for any research and breeding purpose. When the PVP certificate on a protected variety expires, the NPGS distributes research quantities of seed to plant breeders who request it. This is a distinct feature of the PVP system, which offers access to ex-PVP seeds in the public domain, even if the company that originally commercialized the variety has removed it from sale. This is also a unique aspect of the U.S. system, and one that commenters said was a critical advantage to the PVP system over similar systems in other countries. There is widespread support for the U.S. PVP system and for NPGS serving this role, and many commenters noted the excellent quality of NPGS services.

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77. 7 U.S.C. 57

78. "This tendency to the narrowing of the working genepool of breeders is antithetical to the very core of productive and innovative plant breeding which depends on free access to genetic diversity." Jack Kloppenburg, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (June 15, 2022), 4, https://www.regulations.gov/comment/AMS-AMS-22-0025-0024; *See also* Deppe, Comment on "Competition" in "Freelance Plant Breeders," 138: "An additional threat to the freedom to operate of freelance and other plant breeders is the increasing tendency of the major retail seed companies to sign or accept contracts, licenses, bag-tag agreements, and language on invoices from their major wholesale suppliers that put serious restrictions on seed."

While some patented varieties also have PVP certificates and are thus stored with the NPGS, some commenters in public comments and interviews mentioned that there may be logistical barriers to accessing off-patent germplasm that is not stored with NPGS.[79] In the process of applying for a patent on biological material, applicants must deposit a sample of the claimed invention (in this case, seed samples) in an approved International Depository Authority (IDA) or a depository recognized by the USPTO.[80] Some plant breeders we interviewed noted having received non-viable seeds from a depository which may not be as well-equipped as the NPGS to maintain the viability of deposited seeds, so that research samples, when distributed, do not always germinate. A facility equipped to maintain seed viability over long periods of time, followed by regeneration before distribution, would help facilitate the use of off-patent varieties and traits by distributing viable germplasm once a patent expires.

Enhanced Transparency for a More Level Playing Field

Some commenters noted that information about the specific IP mechanisms applied to each type of seed is diffuse and difficult to find. Because there is not a comprehensive source of information about different types of restrictions on specific seeds, people who are interested in working with or developing new varieties of seeds must resort to researching multiple sources to identify the different ways a variety might be restricted by IP, including the PVP database, patent databases (such as Patent PubSearch, Espacenet, or other third-party aggregators), and individual seed company websites.

Within certain crops or sectors with well-established norms, plant breeders may know what sources they need to check. The Texas Seed Trade Association wrote that "information concerning what is, and what is not, a protected variety is widespread and well-understood."[81] While it may be possible to determine whether a variety has a PVP, and varieties which are patented often come with a license agreement, some commenters stated that it is difficult to find information on which specific patents apply to a particular variety and reported significant challenges in accessing and navigating information on utility

79. For example, "In the one case where I requested patented germplasm after the patent expired, the depository was unable to provide me with the germplasm. So if there is an improvement that needs to be made in the IPR [intellectual property rights] of germplasm, it would be that the depositories for germplasm must make the germplasm available as required by law." Peter Baenziger, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (April 28, 2022), 2. www.regulations.gov/comment/AMS-AMS-22-0025-0018:

80. Article 7 of the Budapest Treaty of the World Intellectual Property Organization defines the criteria for acquiring International Depository Authority status. *See also* 37 C.F.R. 1.808 (a)(2) and MPEP 2403 Deposit of Biological Material [R-07.2015]. Currently there are only three IDAs in the United States. The American Type Culture Collection (ATCC) is the principal IDA for most crop seeds. The National Center for Marine Algae and Microbiota (NCMA) also accepts seed and plant tissue deposits.

81. Texas Seed Trade Association, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (May 15, 2022), 2. www.regulations.gov/comment/AMS-AMS-22-0025-0023.

patents.[82] During the public listening session held in August 2022, the executive director of the Heritage Grain Alliance stated: "One of our biggest problems…is that we find it impossible to get a list of the patented varieties that are available."[83] In her public comment, one freelance plant breeder described the situation as such:

> "There is often also no indication of the presence of a patent on the seed packaging or in the description of the variety in a seed catalog. There is often not even any information about the existence of a patent on the website of the breeder of the variety... Sometimes the patent applications refer to the variety only by internal firm numbers or codes, and there is no mention anywhere of the name that the variety is actually to be sold to the public under. In these cases, even if a prospective plant breeder spends weeks looking up and reading patents on the crop of interest, there is no way they can tell whether the varieties they are hoping to use to breed from are patented or not."[84]

One plant breeder interviewed for this report mentioned that companies might sometimes exploit the lack of transparency to extend the scope of their patent beyond what the application claimed. For example, some plant breeders we interviewed noted that companies have acquired patents on traits such as disease resistances, then retroactively claimed to have IP rights on varieties that contain those traits, even though the varieties have been on the market for many decades. A plant breeder and founder of an independent seed company commented that he has encountered bag tags on an heirloom variety that was not protected by any form of IP at all. He wrote that this practice, "in the absence of a publicly available list of patented varieties, creates the impression that 'everything is patented'... This leads to people restricting their own fair use of public domain varieties, a kind of self-censorship, for fear of legal consequences."[85]

Because there is a lack of clarity about which restrictions apply to certain varieties or traits, large companies can intimidate smaller companies or seed growers with fewer resources into licensing contracts or agreements that restrict rights to which they may be legally entitled. In their comments, the Organic Seed Alliance referenced an instance in which one large company had sent letters to hundreds of small companies, many of whom had not ever done

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82. For example, "Before beginning a breeding program, the breeder must undertake a study of whether the plant materials intended for use in the program are covered by IPR [intellectual property rights] encumbrances of some sort. This exploration of the parameters of "freedom to operate" are time, energy, and resource intensive and are a major disincentive for use of the material in question. The effect is to push breeders into silos in which they work only with material they already know to be unencumbered." Kloppenburg, Comment on "Competition," 4; *See also* Morton, Comment on "Competition," 2: "I have grown a lettuce with IPR with the intention of offering it for sale, because I had no way to know the status of that variety. In each of these cases neither the catalog nor the packaging informed the seed "user" that collecting seed from the variety would be an IPR infringement."
83. USDA, "Listening Session on Competition and Intellectual Property Rights," (August 24, 2022). www.zoomgov.com/rec/play/h4r0AJXwFkYRbfUr6zDMELCKte7_77Meo-W1fnl9VrbKFGdr0QIig-qAovK4WqxAuiq8HDNkOnTPxXW8.WwQpath9AqKkafH_?continueMode=true.
84. Deppe, Comment on "Competition," 2.
85. Morton, Comment on "Competition," 2.

business with the sender, listing both granted and pending utility patent applications, stating that using traits claimed in any of the applications would be a violation of IP rights.[86] Some of the patents listed covered only specific hybrids, although the list and letters were written in such a way that the broad traits given as patent titles might have confused seed growers without access to a patent attorney. As noted above, the USPTO under the Biden Administration is working to help those who are under-resourced have access to pro bono legal counsel.

Overlapping IP mechanisms become even more confusing to farmers, plant breeders, or retail buyers when manufacturers sell seed in bulk and retailers repackage it, if the agreements are not conveyed to subsequent purchasers. As noted above, identifiers used in commercial sale, such as variety names and numbers, may be different from those used in applications for utility patent protection, obscuring the link between the patent and the marketed product. Labeling and seed packaging from different companies marketing the same variety further complicates the search for intellectual property rights that apply to a particular variety.

Many farmers plan to plant multiple varieties of the same crop to provide resilience in the event that any particular variety succumbs to environmental or pest pressures over the course of the season.[87] However, commenters wrote that it is sometimes difficult for farmers to verify that they are purchasing distinct varieties because of the way that commodity seeds are branded and marketed.[88] One company might market their seeds under different brand names, which may be difficult to distinguish from the variety names of the seed, and which may be different from the company name of the seed retailer. The same variety might also be sold under different brand names by different retail companies, but it is difficult to find this information without a careful reading of the label on the seed bag.

A 2021 report from the Farmers Business Network (FBN) found that about half of the corn and soybeans on the market are hybrids that have been "relabeled," referring to single varieties that have been marketed under different brand names, such that the consumer may believe they are buying different varieties.[89] Some commenters pointed out that relabeling can be pro-competitive by giving farmers more retailer options, but only if it is easy for farmers to find the information about what companies and brands carry a particular variety in order to compare prices, quality, customer service, or other aspects of the brands when deciding

86. Organic Seed Alliance, Comment on "Competition," 17.
87. Cathleen McCluskey and William F. Tracy, "Engaging Farmer Stakeholders: Maize Producers' Perceptions of and Strategies for Managing On-Farm Genetic Diversity in the Upper Midwest," *Sustainability* 13, no. 16 (2021), https://doi.org/10.3390/su13168843. *See also*, Dan Fromme, "Examine bag tag on seed carefully to avoid planting same hybrid," *CornSouth,* (2020), https://cornsouth.com/production/examine-bag-tag-on-seed-carefully-to-avoid-planting-same-hybrid/.
88. See, for example, Organic Seed Alliance, Comment on "Competition," 29-31
89. AgDaily, "Seed Relabeling Report Highlights Transparency Gap," AgDaily.com, (2021). www.agdaily.com/crops/seed-relabeling-report-highlights-transparency-gap.

which seed to buy. Others contend that the practice can also facilitate price discrimination.[90] A company selling one variety might charge more in a different region, under a different brand. Further, several farmers and seed retailers noted that some companies selling commodity seeds list *only* the brand name (and not the variety) in the information sources that farmers use to make purchasing decisions, such as online catalogs. This means that a farmer may not discover the variety they purchased until the order arrives, as the variety identifier is only printed on the physical seed tag attached to the seed bag. In a survey conducted by FBN, only 31% of member farmers believed they bought relabeled seed, while 73% actually had.[91] The Organic Seed Alliance commented that the practice of relabeling serves to "bolster the illusion that diverse options [are] being maintained," even when companies are consolidating or are reducing the diversity of choices available to the consumer.[92] The practice, if not transparent to farmers, may also impede strategies to mitigate potential environmental risks by planting multiple varieties of the same crop.[93]

Intellectual property rights offer significant incentives for investments in research and development but may also be used to hinder innovation in some instances. USDA and USPTO have crafted recommendations for relevant information sharing for examining patent and PVP applications and to increase outreach to the public to make the patent process and enforcement more widely understood. Still, not all of the issues presented here are under the jurisdiction of either agency. We heard significant concerns about consolidation of the seed and agricultural input industry and the effects of concentrated market power on farmers, independent plant breeders, and small seed companies. These concerns are explored in the next sections.

Recommendations On Intellectual Property Protections in The Seed Industry

The USDA is collaborating with the USPTO to help ensure that the IP system, while incentivizing innovation, does not unnecessarily reduce competition in seed and other agricultural input markets. Outlined below are a number of policy and program actions, some underway and others proposed here, to promote robust and reliable IP and enhance fair competition.

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90. "Additionally, there is evidence that seed companies wield their market power through price discrimination. For example, companies may label the same seed variety differently and offer different prices in different geographies and for different farms sizes." National Farmers Union, Comment on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs," (June 15, 2022), 3. www.regulations.gov/comment/AMS-AMS-22-0025-0064.
91. AgDaily, "Seed Relabeling."
92. Organic Seed Alliance, Comment on "Competition," 29.
93. McCluskey and Tracy, "Engaging Farmer Stakeholders," *Sustainability* 13, no. 16 (2021), https://doi.org/10.3390/su13168843.7/5/2023 10:29:00 AM

Farmer Seed Liaison. Under the America Invents Act of 2011, USPTO maintains a public input process where members of the public may submit to USPTO information regarding prior art that may be relevant to the USPTO's determination of a particular pending patent application that has been published and is publicly available. While farmers and plant breeders are theoretically capable of reviewing the USPTO's docket, as a practical matter they have neither the time nor capacity to do so on a regular basis. With the invitation of USPTO, USDA will help fill that gap. AMS will develop a Farmer Seed Liaison which, as part of its role in implementing the recommendations in this report, can facilitate engagement of the USPTO with farmers and plant breeders. This initiative could help communicate to farmers and plant breeders the availability of public third-party input processes for patents and collect and transmit to USPTO relevant information from farmers, plant breeders, and other members of the public. This would not be a novel function for the USDA, which historically provided information to the USPTO for plant patent applications when requested. The USDA currently fulfills a similar role in other industries. The Transportation Services Division of AMS, under statutory authority from the Agricultural Marketing Act of 1946, represents the views of farmers and agricultural shippers before the transportation regulatory agencies, such as the Surface Transportation Board and the Federal Maritime Commission. The Farmer Seed Liaison can also facilitate outreach to farmers and plant breeders who may develop varieties but not want to pursue formal IP protection regarding how to submit public varieties to the National Plant Germplasm System (NPGS) for consideration of inclusion in the collection, which may result in better documented information available to the USPTO for prior art searches. Outreach activities could also expand current efforts to provide historically underserved and Indigenous communities with access to relevant resources and culturally significant accessions in the NPGS (discussed in Section 3).

Partnership between USDA and USPTO. In working together on this report, USDA and USPTO recognized that there was much that the two could do together. To promote fairer competition and enhance their delivery of services to the public, USDA and USPTO propose to establish an ongoing Working Group on Competition and Intellectual Property. Within USDA, this will be coordinated by the Farmer Seed Liaison. As currently envisioned, the agencies will explore taking a number of steps as follows.

- Explore joint USPTO-USDA opportunities, including issuing requests for comments and hosting roundtables, for collecting broader stakeholder input from researchers, plant breeders, farmers, and others in the seed and agricultural input space.
- Explore initiatives to enhance the quality of the patent examination process for innovations related to agricultural products and processes, including opportunities for enhancing prior art search capabilities and providing additional training and guidance to patent examiners.
- Engage in a greater exchange of information regarding processes and procedures at USPTO and USDA, including providing joint training and informational sessions on IP protection for seeds, varieties, and other agricultural inputs.
- Collaborate on developing materials and conducting outreach to better educate plant breeders and farmers on IP protection and enforcement.

- Collaborate on initiatives that enhance the transparency of IP information on existing IP rights for agricultural-related innovations.
- Engage with recognized depositories to assess availability and viability of patented and off-patented germplasm.
- Conduct a comparative analysis of the protection and enforcement of seed and agricultural-related IP in the U.S. with other jurisdictions, including underlying policies and practices. In addition, the USPTO plans to conduct an analysis to evaluate whether additional initiatives or changes will strengthen our intellectual property system.
- Consider and evaluate new proposals for incentivizing and protecting innovation in the seed and agricultural-related space, including the addition of research or breeding exemptions for U.S. utility patents, to ensure that our IP laws continue to incentivize innovation without unduly delaying competition and new market entrants.

Enhance Transparency for Farmers. The USDA underscores that farmers and seed businesses should know the variety and brand of the seed they are purchasing. As part of USDA's and the Administration's whole-of-government efforts to enhance transparency and promote fair competition across the supply chain, the USDA reiterates its commitment to the following measures:

- Enforce label requirements under the Federal Seed Act (FSA), to ensure that farmers have access to all legally required information at the earliest opportunity, usually at the time of purchase and no later than the commencement of shipment.
- Additionally, enforce false advertising provisions under the FSA to avoid representations that may claim or give the impression that seed brands add diversification for a grower when that representation is false or misleading.
- Enhance the accessible filing of complaints and tips on problematic seed practices.

2. Competition and Innovation

Many commenters agreed that a system that fairly protects IP is critical to continued innovation and investment in seed systems. Plant breeding is an endeavor that takes time and resources, and breeding companies need to be able to realize a return on this investment in order to continue to operate. However, a range of commenters noted that in the current market, which has experienced consolidation over the past several decades, companies may be extending their market power in a way that exceeds IP law's careful balance between the rights of the inventor and the encouragement of invention for public good. These commenters are concerned that when there are only a few companies dominating closely related industries, those companies may leverage their IP rights in combination with market power to create barriers to competition. Numerous comments raised concern over both the vertical integration of seed supply chains, as well as the horizontal consolidation of seed, pesticide, fertilizer, and data platforms.[94] In this section, we look at commenter concerns about their ability to operate in the seed market. This includes the terms of licensing technologies for commercial sale and access to technologies for continued research and breeding, both before and after IP protection expires.

The seed sector is generally discussed as two distinct but broad markets: commodity crops and specialty crops. Commodity seeds are staple crops, such as corn, soy, and cotton that cover large acreage, and specialty crops are generally fruits, vegetable, and ornamentals grown on smaller acreages (see Glossary). Commodity crop seed markets have experienced more consolidation than specialty crop seed markets,[95] although there have been recent periods of consolidation in vegetable seed markets as well.[96] The increase in concentration in companies that produce genetically engineered crops is even more pronounced.[97] For these companies, the impetus to consolidate is often attributed to the higher costs of biotechnological research and development, as well as the added cost of acquiring regulatory approval for genetically engineered traits. Genetic engineering also offers the potential for companies to combine products with commercial herbicide and pesticide platforms. Since

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94. For example, "The advent of integrated proprietary traits, seeds, and agrochemical systems has transformed the sector. Indeed, there is now less emphasis on competition in markets for seeds and traits and more focus on control of vertically-integrated markets for entire "systems." The American Antitrust Institute, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (May 16, 2022), 1. www.regulations.gov/comment/AMS-AMS-22-0025-0034. *See also* Friends of the Earth, Comment on "Competition," 1. www.regulations.gov/comment/AMS-AMS-22-0025-0057: "[T]ightly integrated platforms have locked farmers into using products from only a single platform, in many cases, and they give these few agrichemical companies unprecedented anticompetitive power in these markets."
95. James M. MacDonald and John Crespi, "Concentration in Food and Agricultural Markets," in *Handbook of Agricultural Economics*, vol. 6 (Elsevier, 2022), 4781–4843, https://doi.org/10.1016/bs.hesagr.2022.03.003.
96. For example, in its analysis of the Bayer - Monsanto merger in 2018, the Department of Justice noted that at the time, the two companies controlled 94% of the carrot market and 90% of the market for cucumber seeds. Crespi and MacDonald, "Concentration," 4805.
97. "For GM traits, market concentration appears much higher than for seed markets. While several medium-sized regional players are active in seed markets, the market for GM traits is dominated almost exclusively by large multinational firms." OECD, *Concentration in Seed Markets*, 150.

the early 1990s, when the first genetically engineered traits were introduced to the seed market, over 200 companies selling commodity seeds were either acquired or went out of business.[98] The Organization for Economic Co-operation and Development (OECD) estimates that in 2016, four companies controlled 91% of the U.S. market value in cotton seed, 82% in maize seed, and 69% in soybean seed markets.[99]

Several studies have characterized the consolidation of patent ownership. For example, Pardey et al. considered the cumulative percentage of IP rights held by a given number of applicants over the period from 1930 – 2008 to demonstrate an increasing concentration of varietal rights applications.[100] Clancy and Moschini updated this data to quantify utility patent and PVP ownership on varieties from 2011 – 2015, noting that, at the time, DuPont (now Corteva) owned over half of all PVP rights for maize and soybean varieties, and 39% and 30% of utility patents for maize and soybean varieties, respectively.[101] At the time, Monsanto (now Bayer), owned around 30% of PVPs and nearly half of all patents for maize and soybean varieties.[102] This research indicated that at the time, even before the major mergers of Dow/ DuPont and Bayer/ Monsanto, the top two companies held around 80% of all patents and PVP rights for maize and soybean varieties.

To our knowledge, there has been no consistent analysis of IP ownership that considers both protections on new varieties and patent protection on traits, gene sequences, marker identification, and breeding methods. We undertook an analysis to estimate seed company ownership of granted Plant Variety Protection (PVP) certificates and patents mentioning crop names in the abstract or title from 1970 – 2022 (see Appendix B for methods).[103] Our results show that the top four companies dramatically increased their share of IP ownership since the 1990s (Figure 3). For example, for corn, the top four companies owned 41% of IP in 1990, with Pioneer making up 38%. By 2000, this share had increased to 77% with Pioneer acquired by DuPont (33%) and Monsanto emerging as a significant IP owner (26%). In 2010, top four ownership increased to 93%. Today, the top four (Bayer, Corteva, ChemChina and BASF) own 97% of canola, 95% of corn, 84% of soybean, 51% of wheat, and 74% of cotton IP. Bayer owns the highest percentage of utility patents, including 71% of corn patents, while Corteva owns the highest percentage of PVP certificates, including 53% of corn PVPs.

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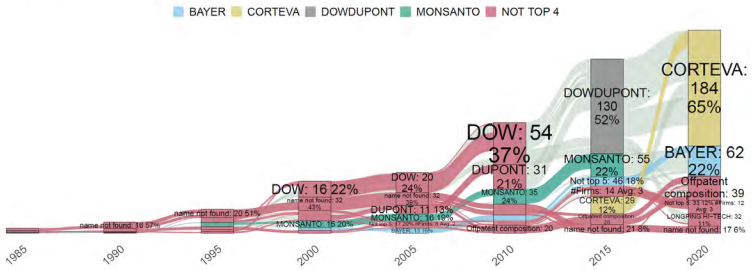
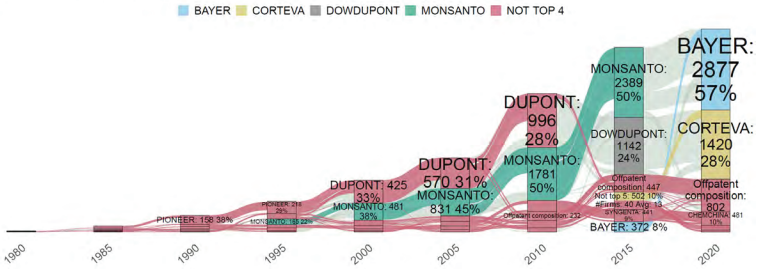
98. Philip H Howard, *Concentration and Power in the Food System: Who Controls What We Eat?*, Revised Edition (Bloomsbury Academic, 2021), 109.
99. OECD*, Concentration in Seed Markets,* 119-128.
100. Philip Pardey et al., "The Evolving Landscape of Plant Varietal Rights in the United States, 1930-2008," *Nature Biotechnology* 31, no. 1 (January 2013): 25–29. https://doi.org/10.1038/nbt.2467.
101. Clancy and Moschini, "Intellectual Property Rights and the Ascent of Proprietary Innovation," 68.
102. Clancy and Moschini, "Intellectual Property Rights and the Ascent of Proprietary Innovation," 68.
103. We included the following patent types in our analysis: PVP, utility, plant, design, or other patents. PVP and utility patents accounted for more the vast majority—more than 95 percent—of IP for canola, corn, cotton, forage, soybean, and wheat certificates analyzed.

Figure 3 on following page: Estimated firm ownership of PVP and patent certificates from 1980 – 2020 by crop. For canola, Corteva owns 65% of IP, followed by Bayer (22%). For corn, Bayer owns 57% of IP, Corteva owns 28%, and ChemChina owns 10%. For forage, non-top-five companies own 53%. For soybean, Corteva owns 33%, Bayer owns 43%, and ChemChina owns 7%. For wheat, Corteva owns 23%, Bayer owns 17%, and ChemChina owns 11%. The width and color of each rectangular panel represents the number of certificates and parent firm name, respectively. Years shown signify the 5-year interval: for example, 2020 refers to 2018 through 2022. Ribbons that connect firm names from year to year represent the transfer of IP: if the labeled firm name and color remains the same from one year to the next, the firm retains the IP; if the firm name changes and the ribbon color is the light green shade, the new labeled parent firm has acquired the IP. See Appendix B for detailed methods. Companies with certificate counts that total the top four for all time are labeled with their firm name while the rest are labeled "Not Top Four."

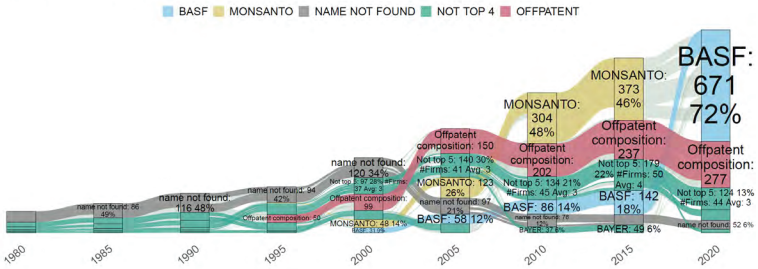
CANOLA: Firm IP Ownership: 1980–2022



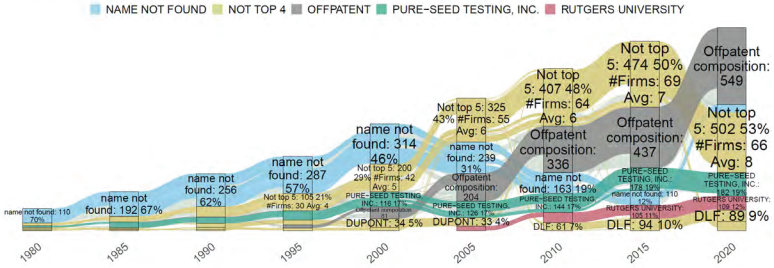
CORN: Firm IP Ownership: 1980–2022



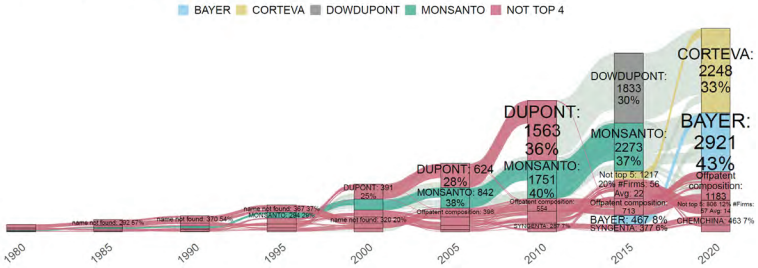
COTTON: Firm IP Ownership: 1980–2022



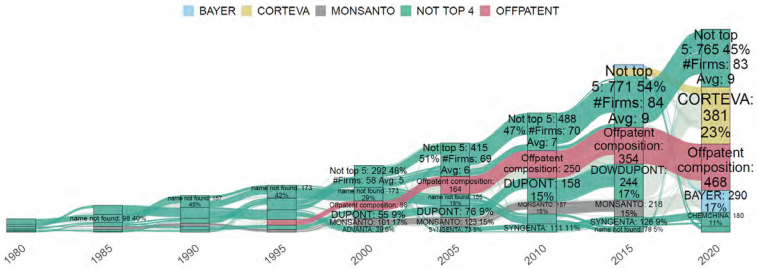
FORAGE: Firm IP Ownership: 1980–2022



SOY: Firm IP Ownership: 1980–2022



WHEAT: Firm IP Ownership: 1980–2022



In the past, some scholars have reasoned that while prices remain low and mergers maintain or increase system efficiency, consolidation can represent a benefit to the public.[104] Other scholars have renewed interest in different ways to measure the effects of concentration, especially as it increases or decreases competition, innovation, and structural inequalities.[105] While there are many analyses of the impacts of concentration on prices, there has been less research on the impact of concentration on innovation.[106] If increased concentration causes newly merged companies to consolidate breeding programs to serve higher volume seed markets, regional specificity may be lost in some geographic areas or crops. In the case of seeds, varieties are not interchangeable among regions. Focusing on seed prices exclusively may fail to capture differences in seed quality in terms of factors such as regional adaptation, market differentiation, or the benefit of diversity *per se*, (i.e., having choices available for farmers to plant multiple adapted varieties to manage within-season risk on their farms). These factors look to the potential *revenue* that farmers can make, or not make, from the crop based on the choice of seeds to which they have access.

In 2012, USDA-Economic Research Service studied growing concentration in agricultural input markets since the 1990s.[107] The report noted that fewer companies are responsible for the innovations that enter the market. In this sense, the presence of fewer decision makers may narrow the scope of inquiry and innovation in the market. In addition, the report described how larger companies increased their spending on R&D as they raised prices for farmers, which reflected, at least in part, the improved quality and productivity of the new varieties they developed. The report also questioned whether, under the current market and policy environment, increased economies of scale in crop biotechnology may imply that "only very large companies can hope to compete in these sectors."[108] Taken together, the increased concentration and economies of scale for dominant companies may pose significant barriers to entry for small and medium-sized enterprises and reduce innovation.

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104. See, e.g., Robert H. Bork, *The Antitrust Paradox: A Policy at War with Itself*. (New York: Basic Books, 1978).
105. Lina Khan, "The New Brandeis Movement: America's Antimonopoly Debate," *Journal of European Competition Law & Practice* 9, no. 3 (March 1, 2018): 132, https://doi.org/10.1093/jeclap/lpy020.
106. MacDonald and Crespi, "Concentration in Food and Agricultural Markets,"7/5/2023 10:29:00 AM 4823.
107. Keith Fuglie et al., "Rising Concentration in Agricultural Input Industries Influences New Farm Technologies," *Amber Waves*, 2012, https://doi.org/10.22004/ag.econ.142404.
108. Keith Fuglie et al., "Rising Concentration," 2012.

Representative types of companies in the seed industry

The seed industry is complex and there is no standard type of business enterprise. However, there are some representative types of companies which fill different roles. Appendix C provides graphical representations of these types of companies.

Some companies are *vertically integrated*, from the beginning of the breeding process to the delivery of seed directly to farmers. Most of the dominant industry players fall in this category and sell some proportion of their seed to farmers either directly or through exclusive licenses with branded retailers. Many of these companies are also *horizontally integrated* with other agricultural input enterprises. They also license varieties (and sometimes germplasm) and traits to other entities within the seed industry. There are also companies and public institutions that specialize in the development of varieties (*cultivar developers*) or traits (*trait developers*) and then license these to other seed businesses for commercialization. These are all different types of plant breeding companies.

There are seed businesses that do not have their own breeding programs, but instead license varieties and patented traits from breeding companies. These businesses receive stock seed and scale production, clean and condition the seed, apply seed treatments (which may also be licensed if proprietary), and package the seed for farmers. They may then either sell seed directly to farmers or sell it to other retailers. These companies are usually referred to as *seed dealers.* Seed dealers typically test new varieties from breeding companies to determine which varieties they would like to license. Some seed dealers also test new hybrid combinations (licensing inbred lines of a crop like corn from breeding companies), but this is declining as breeding companies increasingly prefer to license finished hybrids and not inbred lines. Seed dealers must forecast demand and contract with specialized seed farmers for seed production the year prior to offering the seed for sale commercially. After the seed harvest, they are responsible for cleaning, conditioning and quality testing the seed in order to sell it to farmers the following spring. They are usually responsible for the risks associated with seed production and unsold inventory. The seed dealership model is more common in commodity crop sales than other types of crops. However, even in commodity sales, dealers are being increasingly replaced with branded retailers. Branded retailers carry seed and other inputs from a single breeding company rather than testing and carrying varieties and other inputs from several breeding companies.

Other seed businesses may primarily purchase commercial seed wholesale from breeding companies or seed dealers and offer it for retail sale to farmers. These types of businesses are typically called *seed retailers*. This is a more common model for vegetable crops, and vegetable seed retailers typically also test many different varieties from different breeding companies and decide what to purchase for their customers.

Increased Prices are Felt Acutely by Independent Small to Mid-Sized Companies

Industry leaders contend that as costs for research and development have risen, especially with the widespread adoption of genetic engineering in commodity crops, mergers have allowed businesses to invest in variety improvement while keeping prices relatively low.[109] Indeed, innovations by major companies have led to increased yields, which many farmers understand to be commensurate with the increased prices resulting from private investment.[110] In their public comment, the American Seed Trade Association notes that the cost of bringing a new genetically engineered trait through the research, development, regulatory and commercialization process is significant—estimated at about $115 million.[111] A single trait may then be incorporated into many varieties for sale to farmers. For some farmers, "the yields of modern seeds easily justify the cost of seed."[112] While seed prices rose around 700% for genetically engineered crops and around 218% for other field crops between 1990 and 2013,[113] the new varieties increased farm productivity by billions of dollars annually.[114] However, as research and development in agricultural inputs has become increasingly dominated by the private sector, economists note that "much of benefits from private R&D may not accrue to the farm sector at all but accrue as profits to the input supply industries."[115] A recent study shows that farmers retain less than half of the surplus revenue generated by genetically engineered varieties, with the majority of the surplus revenue accruing to the companies that originate those varieties.[116]

While some may consider increased seed prices to be justified by improvements in the seed, others note that farmers see little price transparency due to the complex nature of technology licensing agreements that dictate the price of genetically engineered traits in seeds. The American Antitrust Institute wrote that these "technology fees, which in the past were a line item on the bill, are now rolled into the total cost of the seed."[117] The Independent Professional Seed Association (IPSA) stated that their members, who do see these technology fees, pay separately for individual traits and varieties from dominant companies. They then often compete directly with the branded retailers of

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109. For example, "Pricing in the agricultural input marketplace is competitive, reflecting the increased value that farmers receive from technology innovations delivered as a result of significant investment in technology advancements and testing," Corteva, Comment on "Competition," 4.
110. "The relative stability of seed prices contrasts with the tremendous value gained by farmers from planting professionally-produced improved varieties." American Seed Trade Association, Comment on "Competition," 4.
111. American Seed Trade Association, Comment on "Competition," 7. Data on the return on this investment in terms of revenue generated by a commercialized genetically engineered trait is not provided.
112. Boyce Kluting, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (May 15, 2022), 4. www.regulations.gov/comment/AMS-AMS-22-0025-0031.
113. 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.
114. Federico Ciliberto, Giancarlo Moschini, and Edward D Perry, "Valuing Product Innovation: Genetically Engineered Varieties in US Corn and Soybeans," *The RAND Journal of Economics* 50, no. 3 (Fall 2019): 615–44.
115. Keith Fuglie et al., "Research, Productivity, and Output Growth in U.S. Agriculture," *Journal of Agricultural and Applied Economics* 49, no. 4 (November 2017): 533, https://doi.org/10.1017/aae.2017.13. In this paper, "input supply" refers to industries that "provide seeds, chemicals, machinery, etc."
116. Ciliberto, Moschini, and Perry, "Valuing Product Innovation," 640.
117. The American Antitrust Institute, Comment on "Competition," 13.

the same companies and have had to absorb the brunt of the increased cost.[118] Seed businesses are fairly diverse in their strategies and may combine different stages of the development-to-delivery process (page 47). The degree to which seed businesses are affected by IP is dependent on the stages of development in which they are involved.

Loss of Independent Small to Mid-Sized Companies Raises Concerns about Farmer Choice and Access to Independent Product Information

Commenters noted that the increase in royalties paid by licensees is only one explanation for the loss of independent retailers. They also raised concerns about the licensing of IP. The number of independent seed dealers that test their own hybrid combinations or have some small variety development programs in-house has declined significantly in recent decades. During the same period of time, commodity farmers have increased their use of patented, genetically engineered seed traits. Because those seeds traits are owned by very few companies, seed dealers do not have very many breeding companies to choose from when licensing these traits and varieties. Therefore, breeding companies have power to dictate terms which may be unfavorable to independent dealers.

For example, the Independent Professional Seed Association (IPSA) commented that in order to license patented traits and varieties, "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."[119] This creates a situation in which the licensor knows the licensee's costs and profit margins, as well as complete information on their market and customers. In another example, IPSA also notes that independent seed dealers must accept licensing contracts from a dominant firm before being told the royalty amounts they will pay, a transaction that sometimes happens entirely over the phone.[120] They may not find out these amounts until they have already started seed production for the following season with licensed material and cannot change their course of action.[121]

Some commenters raised the concern that dominant market players can exercise power over independent retailers by threatening to deny them a license should the retailer behave in a manner contrary to the interests of the licensor, such as by trying to combine traits from one firm with germplasm from another or selling generic chemical inputs with seeds that incorporate patented traits. A comment submitted by Cape Law Firm, which represents clients in the input industry, states

118. "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... This year we are bracing for the highest trait increase we've ever seen." Independent Professional Seed Association, Comment on "Competition," 17.
119. Independent Professional Seed Association, Comment on "Competition," 6.
120. "Such programs can be handled entirely over the phone, without a paper trail and can make or break profitability year-over-year." Independent Professional Seed Association, Comment on "Competition," 6.
121. "Bayer doesn't tell us what prices we will be charged before seed stock is planted each year for next year's sales." Independent Professional Seed Association, Comment on "Competition," 17.

that "licensees live in constant fear of the prospect of license termination, an event which can (and has) [brought] about the end of a licensee's business."[122] IPSA's public comment also noted that "because of the dominant position on the corn side of the business, losing a license can push independents out of business."[123]

We also heard from a number of interviewees that farmers' options may be constrained in certain geographic regions based on local regulations or on the technology adoption of neighboring farmers, leading to even fewer licensing choices or opportunities for independent retailers. For example, according to seed dealers interviewed for this report, the extensive use of crops tolerant to volatile herbicides has led some farmers to plant these tolerant crops not necessarily because the varieties are superior, but because planting herbicide-susceptible seeds carries an unacceptable risk of having crops damaged by volatilized herbicides from neighboring sprayers. The Center for Food Safety wrote that "besides the costs of resistant weeds, herbicide-resistant crop systems are inherently anti-competitive, in that they force farmers to buy these crops, where available, in self-defense, or suffer the drift-damaging consequences."[124] Although there has been no systematic data collection on the subject, the Environmental Protection Agency (EPA) assumes that such "defensive" planting has contributed some portion of the rapid adoption rates for dicamba-tolerant seeds,[125] which accounted for 43% of all soybean acres in 2018,[126] and about 66% of all planted acres in 2020.[127] The rapid increase in use may also impact the development of alternatives. For example, some companies may not be able to successfully commercialize a new variety in some regions unless it has the tolerance trait, unless they obtain a license from the primary tolerance trait owner.

One of the most recurrent concerns raised in public comments described exclusion payments, which encourage seed dealers and their customers to buy more of the breeding company's patented products. IPSA described a bundling program that combines corn genetics and traits with soybean genetics and traits. To obtain the manufacturer's financial incentives for corn, seed dealers must also meet benchmarks for soybeans.[128] These payments, which are often unwritten and not transparent, bring up concerns about exclusive dealing, which can violate antitrust law if its effect is

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122. Cape Law Firm, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs," 10. www.regulations.gov/comment/AMS-AMS-22-0025-0062.
123. Independent Professional Seed Association, Comment on "Competition," 6.
124. Center for Food Safety, Comment on "Competition," 10.
125. Environmental Protection Agency, "Dicamba Use on Genetically Modified Dicamba-Tolerant (DT) Cotton and Soybean: Incidents and Impacts to Users and Non-Users from Proposed Registrations," EPA-HQ-OPP-2020-0492-0003. (2020), 43-45. https://www.regulations.gov/document/EPA-HQ-OPP-2020-0492-0003.
126. Seth J Wechsler et al., "The Use of Genetically Engineered Dicamba-Tolerant Soybean Seeds Has Increased Quickly, Benefiting Adopters but Damaging Crops in Some Fields," *Amber Waves,* (USDA-ERS), October 1, 2019). https://www.ers.usda.gov/amber-waves/2019/october/the-use-of-genetically-engineered-dicamba-tolerant-soybean-seeds-has-increased-quickly-benefiting-adopters-but-damaging-crops-in-some-fields/.
127. Environmental Protection Agency, "Status of Over-the-Top Dicamba: Summary of 2021 Usage, Incidents and Consequences of Off-Target Movement, and Impacts of Stakeholder-Suggested Mitigations," EPA-HQ-OPP-2020-0492. (2020), 10-11, https://www.regulations.gov/document/EPA-HQ-OPP-2020-0492-0021.
128. "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," Independent Professional Seed Association, Comment on "Competition," 5.

to unreasonably restrain trade or function as an unfair method of competition, for example. The Open Markets Institute noted that in a 2018 survey of over 950 U.S. farmers, "44% reported that one or more of their seed retailers or distributors had switched to offering seeds from just one manufacturer in the five years before the survey."[129] Pivot Bio, a company that offers a microbial alternative to synthetic fertilizer, expressed difficulty entering the market due to these programs: "By creating incentives, rebates, discounts and other incentives, [input manufacturers] attempt to box out competition and protect brand loyalty. These marketing programs are expanding to now include seed, fertility, and sustainability programs. Again, these new sustainability bundles will further block grower choice around sustainability by not allowing mixing and matching practices and products that best serve a farming operation's unique needs."[130]

Independent seed companies are an important component in a competitive seed market. Historically, these providers have independently evaluated varieties to build out their product offerings, and have competed on seed prices and quality to ensure that farmers were offered the best varieties for their region and production system. Some independent field trial networks (which do not sell seed) remain, both public and private. However, they do not cover all regions or crops, and originating companies determine the varieties which should be compared. The rising cost to enter such trials is borne by the companies themselves, which may represent a barrier to entry for emerging competitors.

Potential Loss of Innovation Due to Changing IP Landscape and Reduction of Small to Mid-Sized Businesses

Plant breeding is a resource-intensive endeavor that demands significant investment in order to innovate. The American Seed Trade Association, which represents both small and large seed companies, wrote that its members spend, on average, 15% of revenue on R&D,[131] a rate much higher than that of other industries.[132] Some commenters claim that these expenditures are made possible by the increasing concentration of technology assets that mergers provide, and that sustained investments in research and development are evidence that companies continue to innovate even after merging. For example, Bayer wrote that "the combination of Bayer and Monsanto brought together world-class expertise and capabilities in biologics, breeding, chemistry, data, germplasm,

129. Open Markets Institute, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (May 16, 2022), 5. www.regulations.gov/comment/AMS-AMS-22-0025-0033, *citing* Maurice E Stucke and Allen P Grunes, "An Updated Antitrust Review of the Bayer-Monsanto Merger," (The Konkurrenz Group, 2018).
130. Pivot Bio, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (June 14, 2022), 2. www.regulations.gov/comment/AMS-AMS-22-0025-0052.
131. American Seed Trade Association, Comment on "Competition," 7.
132. OECD, *Concentration in Seed Markets,* 37.

and other agricultural disciplines." [133] Merger proponents often argue that such combinations create efficiencies and reduce redundancies in research. However, recent studies from the Federal Reserve show that merger and acquisition activity across all U.S. industries in general is associated with an increase in consumer prices, but not with increases in productivity or efficiency.[134]

Recent discussion from USDA Economic Research Service (ERS) noted that "there is good reason to think that increases in concentration do not persistently lead to greater incentives to innovate; rather, beyond some high level of concentration, further increases could actually reduce the incentive to innovate."[135] ERS has also concluded that increasing levels of concentration, as large companies merge with large companies, has not had much effect on the average intensity of industry R&D.[136] A study on the effects of patent ownership and innovation noted that when measuring R&D by new varieties released, mergers do not seem to have a significant effect on the production of new varieties.[137] As noted below, the quantity of varieties released alone, without a measure of the quality or distinctiveness of those varieties, is not a perfect measure of innovation rates. Still, these points, taken together, question whether increased concentration always results in more effective and efficient investments in innovation.

Importantly, the overall high level of investment in research and development is in part due to the biological nature of seed innovation. Evolving pests and diseases mean that varieties can relatively quickly fail to perform as well as they did when they were first released. For example, varieties succumb to pressures such as new diseases spreading internationally or changing pest pressure due to warmer winters. These are often regionally specific; therefore, it is important to look not only at overall R&D spending in comparison to other industries, but the diversity of focus areas within R&D programs, and whether key areas of concern for farmers are being addressed.

The vertical and horizontal integration of the seed and agricultural input industries also presents challenges for sustaining R&D investment and for new entrants into these markets. When genetic engineering technology was first introduced to the market, different companies competed in different parts of the seed development industry. Some companies were dominant in genetically

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133. Bayer, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (June 14, 2022), 1. www.regulations.gov/comment/AMS-AMS-22-0025-0051; *See also* Corteva, Comment on "Competition," 2: "The merger of the agricultural companies of Dow AgroSciences and E. I. du Pont de Nemours & Company into Corteva Agriscience has resulted in a more effective global competitor that has immediately provided new and innovative products in the marketplace."

134. Bruce A. Blonigen and Justin R. Pierce, "Evidence for the Effects of Mergers on Market Power and Efficiency," *Finance and Economics Discussion Series* 2016, no. 082 (October 2016), (Washington: Board of Governors of the Federal Reserve System), https://doi.org/10.17016/FEDS.2016.082.

135. James MacDonald, "Mergers and Competition in Seed and Agricultural Chemical Markets." *Amber Waves*, 2017. https://www.ers.usda.gov/amber-waves/2017/april/mergers-and-competition-in-seed-and-agricultural-chemical-markets/

136. Keith Fuglie, Paul Heisey, John L. King, Kelly Day-Rubenstein, David Schimmelpfennig, Sun Ling Wang, Carl E. Pray, and Rupa Karmarkar-Deshmukh, "Research investments and market structure in the food processing, agricultural input, and biofuel industries worldwide," *USDA-ERS Economic Research Report* 130 (2011):15.

137. H. Phoebe Chan, "Do Firms with Larger Patent Portfolios Create More New Plant Varieties in the U.S. Agricultural Biotechnology Industry?" *Economics of Innovation and New Technology* 20, no. 8 (November 2011): 749–75. https://doi.org/10.1080/ 10438599.2010.531915.

engineered traits and others were dominant by holding access to high-quality germplasm. These companies then licensed technologies to other companies such as seed dealers. The American Antitrust Institute commented that such rivalry in agricultural biotechnology innovation is "essential for maintaining incentives to continue existing and prospective product development programs."[138] Increasing concentration, especially as companies have come to own both germplasm development programs and IP rights on genetically engineered traits, makes it even more difficult for small and medium companies to enter the market.

Companies can enter cross-licensing agreements for access to IP that they do not own. In some ways, cross-licensing can be seen as a pro-competitive alternative to mergers and acquisitions. When competing companies need access to traits or germplasm in order to innovate, cross-licensing allows companies to access other IP without having to buy the competition outright.[139] In their public comment, KWS Seeds wrote that cross-licensing "support[s] even greater access to innovative technologies."[140] However, some have noted that companies negotiate these licensing agreements by offering to trade access to different IP rights that are comparable in value.[141] Small companies and independent plant breeders who are not a part of the network of dominant companies and do not have valuable patents to trade may face significant licensing costs which represent a barrier to entry. Competition agencies have noted that while cross-licensing has the potential to generate significant efficiencies, they may also generate anticompetitive effects such as the foreclosure of innovation or the facilitation of market division.[142]

As a note, some commenters pointed to the increasing number of patents on plants as evidence that innovation has not stagnated. However, according to several interviewees, a company's primary motivation to pursue patents may not primarily be to protect the company investment in particular genetics or traits, but rather to build up an IP portfolio whose size and scope in and of itself is attractive to investors or useful for cross-licensing. In this way, it is difficult to conclude that an increasing number of patent rights on plants necessarily advance overall innovation without analyzing the contents of the patent claims. Some commenters wrote that companies may focus research in areas where they are able to make incremental, protected improvements on existing patentable material rather than investing in new lines of research.[143]

Finally, a primary concern voiced by many commenters, especially those that represent farmers, is that the absence of a seed saving exemption in an IP-dominated seed system removes an important

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138. The American Antitrust Institute, Comment on "Competition," 12.
139. Clancy and Moschini, "Intellectual Property Rights and the Ascent of Proprietary Innovation," 68.
140. KWS Seeds, Comment on "Competition," 2.
141. Ioannis Lianos and Alexey Ivanov, "The Global Seed Market, Competition Law and Intellectual Property Rights: Untying the Gordian Knot," *Concurrences: Competition Law Review* 2, (2016): 72, https://doi.org/10.2139/ssrn.2773422.
142. U.S. Department of Justice and Federal Trade Commission, "Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition," (2007), 8. www.ftc.gov/sites/default/files/documents/reports/antitrust-enforcement-and-intellectual-property-rights-promoting-innovation-and-competition-report.s.department-justice-and-federal-trade-commission/p040101promotinginnovationandcompetitionrpt0704.pdf.
143. For example, "Increasingly privatized research and development (R&D) favor defensive research that guards corporate profits over risky innovation into the new, more sustainable production systems the world needs to meet global food demand in the face of climate change." Open Markets Institute, Comment on "Competition," 1.

driver of innovation from the system. The National Family Farm Coalition wrote: "In the context of user-innovation, agriculture has been a field where farmers substantively contributed to developing and improving existing and new plant varieties."[144] Proponents of farm-saved seed argue that such practices also provide an important impetus for seed firms to innovate, as those companies had to regularly introduce valuable genetic improvements that would incentivize farmers to return to the market to purchase new seed, rather than save the previous year's seed. The National Farmers Union also argues that even while genetically engineered varieties, which cannot be developed in the field, have delivered benefits to many farmers, an outsize focus on such technologies has "also reduced farmers choice of seeds, including for conventional and locally and regionally adapted options."[145]

Public Availability of Patented Innovations after IP Protection Expires

An important feature of the IP system is that after a patent expires, the patented material enters the public domain. However, some commenters described factors that delay competition from companies using off-patent material, including anti-competitive practices leveraged by patent holding companies, plant breeders' inability to access unrestricted germplasm from public depositories, and regulatory burdens which may represent a barrier to entry for genetically engineered varieties.

Patent-holding firms may delay competition after patents have expired

Commenters stated that patent holders may engage in conduct that may inappropriately extend exclusivity beyond the life of their patent. For example, the Breakthrough Institute commented that "some companies use reach-through clauses in licensing and Material Transfer Agreements (MTAs) that lay claim to inventions developed using the material, or to the material itself after the patent has expired."[146] In addition, commenters have described licensing schemes that effectively remove seed from the market when it is set to come off-patent, prohibiting would-be innovators or generic growers from accessing the seed.[147]

Some commenters also allege that patent-holding firms are able to extend exclusivity beyond the life of their initial patents by making minor modifications to the original patent claims and re-filing the application, in a process known as "evergreening." According to a comment from the Breakthrough

144. National Family Farm Coalition, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (June 15, 2022), 7. www.regulations.gov/comment/AMS-AMS-22-0025-0066.
145. National Farmers Union, Comment on "Competition," 2.
146. Breakthrough Institute, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (May 16, 2022), 4. www.regulations.gov/comment/AMS-AMS-22-0025-0038.
147. One example of this is BASF's LibertyLink (LL), a patented gene that provides tolerance to the herbicide glufosinate. As the patent is set to expire in 2023, BASF has executed a strategy to remove those seeds from the market that includes 1) allowing LL licenses to expire in 2021, 2) prohibiting all production of the seed in 2022, and 3) requiring sell-off and disposal of all unsold seed inventory as grain, such that when the patent expires in 2023, a generic seed supply will not exist. *See* Cape Law Firm PLC, Comment on "Competition," 3.

Institute, "these variations can include only slight changes that do not effectively improve the quality or functionality of the product."[148] Minor modifications may be patentable if they meet the statutory requirements of novelty, non-obviousness and utility. In this case, the expired patented invention should be available for public use.

In the seed industry, there are genetically engineered traits that have come off-patent which could potentially be used for the development of generic products. However, there have been barriers to the development of generics including difficulty accessing traits in germplasm without other patents and difficulty gaining regulatory approval for new combinations of off-patent traits. In addition, the growing herbicide tolerance of weeds, and the evolution of insect resistance to some plant incorporated protectants means that the deployment of these off-patent traits must usually be done in combination with other control mechanisms or additional herbicide tolerance traits or plant incorporated protectants, which have largely been developed by the currently dominant firms.[149] We also heard concern that farmers are not able to select only the traits they want or need, but usually must select from a limited number of combinations which may include traits that they cannot use.[150] The addition of newly-patented traits to that combination may also function to block access to the older, off-patent traits.

Plant breeders encounter difficulty accessing off-patent seed from public repositories

As described above, plant breeders may have difficulty accessing seed that will germinate from the depository which collects patented seeds as part of the patent application process. In addition, without a meaningful research exemption, plant breeders must wait until germplasm or traits are off-patent to begin experimentation and breeding, whether these traits are genetically engineered or naturally occurring. At that point, the off-patent traits that are accessible for breeding are in off-patent varieties that are quite old compared to the current elite varieties. It is not possible to take an off-patent trait and move it directly into a new variety; it has to be incorporated into a breeding program, meaning that it takes years to deploy off-patent traits in varieties that are competitive on the market. In countries that do not allow patents on plant varieties, and which permit research and breeding with patented traits,[151] plant breeders have access to patented traits for pre-commercial

148. Breakthrough Institute, Comment on "Competition," 4.
149. The American Antitrust Institute, Comment on "Competition," 3.
150. "One of the main reasons for this small acreage of PIPs on the list for potential phase-down is that the current registrants have been combining the post-patent PIPs with currently patented PIPs and selling these "stacks" in their branded seed as well as licensing them to other companies, regardless of a licensee's or the ultimate corn farmer's need for the additional traits. This practice has multiple negative impacts by increasing the costs to licensees and their seed customers while also stifling competition from potentially new registrants." Farmers Business Network, Comment on "Competition," 9.
151. France: Article L. 613-5-3 of the Intellectual Property Code adopted in 2004; Germany: Section 11.2.b of the Patent Act adopted in 2005; the Netherlands: Article 53.2.b of the Dutch Patent Act; Switzerland: Article 9 (e) of the Federal Act on Patents for Inventions, adopted in 2008.

research and breeding and can develop elite varieties ready for the market when the patent expires.[152]

Biotechnology regulation may delay commercialization of new products and generics

The coordinated regulatory framework that determines which genetically engineered products are able to enter the market plays an important role in the development of a generic industry. EPA, FDA and USDA-APHIS all have regulatory authority over certain products of biotechnology. Some commenters noted that the extensive investments required by seed companies to bring new genetically engineered products through the regulatory process are untenable for small and medium sized entities. The American Seed Trade Association wrote that regulatory expenses, and the amount of time spent in the regulatory approval process, has increased dramatically in recent years. "While other costs of research and development may vary between companies and plant species," they wrote, "the cost and time of regulation is applied equally regardless of the size of the company, the plant species, commercial market potential, or even the safety risk assessment of the gene target(s)."[153]

At the same time, generic producers of genetically engineered traits have faced significant obstacles to accessing the seeds and information required to produce generics that will meet regulatory standards. Concerns have been raised with companies allowing registrations to expire for the off-protection technology and setting high prices to share data necessary for regulatory compliance, which may allow patent owners to prevent competitors from using technologies that should ostensibly become a part of the public domain.[154] A voluntary framework for addressing this issue, called the AgAccord, has been developed by the private sector.[155] The White House Office of Science and Technology, along with the EPA, FDA, and USDA-APHIS are currently conducting a review of the coordinated framework on the regulation of biotechnology.[156] While this report is focused on intellectual property and consolidation, a dedicated review of current regulatory requirements is likely imperative to a vibrant and competitive agricultural biotechnology market.

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152. These countries only require plant breeders to have a license when they decide to commercialize a variety, and only if the variety contains traits that are still subject to patent claims. Viola Prifti, *The Breeder's Exception to Patent Rights: Analysis of Compliance with Article 30 of the TRIPS Agreement*, International Law and Economics (Cham: Springer International Publishing, 2015), https://doi.org/10.1007/978-3-319-15771-9.
153. American Seed Trade Association, Comment on "Competition," 6.
154. "Finally, companies can in effect extend the life of a patent by making it difficult for other developers to commercialize products that use the off-protection technology by neglecting stewardship of the off-protection technology, maintenance of regulatory authorizations, and sharing of data and studies necessary for regulatory compliance." Breakthrough Institute, Comment on "Competition," 4. (In consultation with the USPTO, we underscore that the life of a patent cannot actually be extended, but also acknowledge that practices may give that appearance.)
155. http://www.agaccord.org
156. Office of Science and Technology Policy, "Request for Information: Identifying Ambiguities, Gaps, and Uncertainties in the Coordinated Framework for the Regulation of Biotechnology," 87 *Fed. Reg*. 77900, (2022). https://www.federalregister.gov/documents/2022/12/20/2022-27599/request-for-information-identifying-ambiguities-gaps-inefficiencies-and-uncertainties-in-the

In summary, the most recent round of seed industry mergers has resulted in an industry structure that has essentially combined multiple markets into platforms which include genetically engineered traits, improved varieties, other inputs and digital tools all from the same company.[157] One of the challenges of consolidation of multiple markets and IP ownership is that smaller companies seeking to move into these markets may not be able to gain access to a market in one part of the platform because they lack access to other parts of the platform, such as protected germplasm and patented traits. Additionally, existing independent seed dealers have little choice but to maintain license agreements from the dominant players because adding third party products might mean they could lose access to multiple product lines for which there are very few alternative sources.[158] New entrants, such as small biotechnology firms, see the value of patents to protect their innovations and spoke in favor of maintaining strong patent protections for truly innovative developments in interviews, listening sessions, and the public comments.[159] However, they also recognized the need for access to elite varieties to deploy new technologies, which means being able to license their technology to breeding companies or being able to license germplasm from breeding programs.[160] A strategy to increase competition in seeds and other inputs will necessarily examine the effects of horizontal integration and common licensing practices in the industry, while increasing access to elite germplasm for small and independent companies.

Recommendations To Improve Competition and Innovation

The USDA recognizes the leading role of antitrust and fair business practice enforcement by Federal partners including the DOJ and the FTC. Through their interagency working group, USDA and USPTO will collaborate to promote competition in the seed industry. Specific actions could include the following:

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157. Lianos and Ivanov, “The Global Seed Market, Competition Law and Intellectual Property Rights,” 75.
158. “Additionally, the owners of the traits have been using the "loyalty" programs with independent seed companies which make considering alternative traits punitive.” Independent Professional Seed Association, Comment on “Competition,” 6.
159. “In the context of plant seeds and other living organisms (e.g., microbes) where the product is easily reproduced, patent protection and the adherence to the Supreme Court’s holdings in Bowman v. Monsanto are important to incentivize the significant investment needed to bring these products to market.” Pivot Bio, Comment on “Competition,” 3.
160. An issue occurs where an owner of a platform technology (e.g., a plant seed or operating system) can use their position to limit access to a technology which operates on the platform (e.g., in the case of a plant seed, a biological treatment, or in the case of an operating system, an application). While patents are, in their very nature, anti-competitive, this can become impermissibly anti-competitive when a patent holder uses their patent rights to gain an advantage over a technology not covered by their patents. This can include limiting access to a platform (e.g., a plant seed) to developers of technology that operate on that seed (e.g., a biologicals company), especially where the owner of the platform technology uses their IP rights to slow the development of technology to allow them to develop their own competing technology or to show preference for particular technologies over others (e.g., their own technologies or technologies from their preferred vendors).” Pivot Bio, Comment on “Competition,” 3.

- Expand *farmerfairness.gov* to include seeds and other inputs, and conduct outreach and education to farmers, plant breeders, seed businesses, and the public, including around potentially anticompetitive behavior and how to file confidential tips and complaints.[161]
- Educate farmers about the rights conferred by the sale or voluntary exchange of seed that are subject to bag tags, licenses, and MTAs so that farmers and others better understand when use of those products is and is not subject to IP protections.
- Assess the impact of reduced competition and IP on pricing, choice, and availability of adapted varieties of commodity and specialty crops across growing regions.
- Coordinate and consult on actions related to practices in the seed industry that may harm competition or adversely affect consumers. Provide information related to food security, genetic vulnerability, and regional production issues for consideration by DOJ and FTC in the context of competition matters that may come before them, including as they may relate to the appropriateness of providing non-exclusive licenses for IP to address anticompetitive practices and market structures.
- Explore opportunities for promoting the development of generic competition when appropriate.

161. Tips and referrals regarding criminal antitrust matters are protected under the Criminal Antitrust Anti-Retaliation Act. See "Fraud and Financial Issues" at www.whistleblowers.gov.

3. Seed System Resilience

In 2018, the National Defense Authorization Act recognized the global food system as a national security concern. As the world becomes increasingly dependent on fewer food-growing regions, countries are more susceptible to acute environmental and political shocks.[162] The occurrence of global disruptions, as demonstrated by the COVID pandemic and the war in Ukraine, have compounded these vulnerabilities, as countries with constrained food supplies have been unable to simply purchase food elsewhere. The USDA's Food System Transformation framework, announced this year, includes working toward a more resilient food supply chain by increasing capacity of distributed and local food producers. The framework builds upon USDA's Agri-food Supply Chain Assessment,[163] carried out under E.O. 14017, which highlights the need for "resilient, diverse, and secure chains" across all industries in order "to ensure our economic prosperity and national security."[164] Because all production starts with seeds, domestic seed research, development, and production should be considered critical national security infrastructure.

Resilience is a concept used in many fields and is generally understood as the ability to adapt to or recover from change. Seed systems include both biological and human systems, and resilience in both types of systems relies on their buffering capacity, physical and functional redundancy of components, decentralization of functions, and the flexibility of components to take on different roles as conditions change.[165] Buffering capacity is probably the most well-known component of resiliency, and in biological systems, including agriculture, this can be increased by the incorporation of diversity at multiple levels, from genetic diversity within crops, to the diversity of crops grown on the landscape and the agricultural systems present. In terms of the human side of seed systems, this buffering capacity can be achieved by diversifying enterprises and spreading risk across multiple breeding programs and seed production regions. Physical and functional redundancy is more difficult to advocate for, as it often goes against economic concepts of efficiency and specialization, but it is equally important. Similarly, decentralization of functional components often is seen as less efficient than centralized, standardized systems. However, the vulnerability of hyper-specialized supply chains to disturbance has renewed interest in more resilient essential supply systems. The final component of resilience, flexibility, is perhaps the hardest element of resiliency to plan for, and relies mostly on people having enough knowledge to fill multiple roles in the seed system, enough information to adapt, and enough choices of seed and germplasm to make adaptation possible.

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162. Anthony Janetos et al., "The Risks of Multiple Breadbasket Failures in the 21st Century: A Science Research Agenda" (Boston, MA: The Frederick S. Pardee Center for the Study of the Longer-Range Future, 2017).
163. USDA, "USDA Agri-Food Supply Chain Assessment: Program and Policy Options for Strengthening Resilience," (2022). https://www.ams.usda.gov/sites/default/files/media/USDAAgriFoodSupplyChainReport.pdf.
164. Executive Order 14017 of February 21, 2021, "America's Supply Chains," 86 *Fed. Reg.* 11849. https://www.federalregister.gov/documents/2021/03/01/2021-04280/americas-supply-chains.
165. Julie Dawson, "Building Resilient Seed Systems: Implications for Germplasm Conservation, Plant Breeding, and the Organic Seed Community," *Proceedings of the 8th Organic Seed Growers Conference*, (Corvallis, OR: Feb. 4-6, 2016), 136-138. https://seedalliance.org/publications/proceedings-8th-organic-seed-growers-conference.

In many ways, ensuring fair competition is the most direct way to enhance seed system resilience. Providing equitable access to markets will allow companies of all sizes to thrive by focusing on crops, agricultural systems, and regions where they see opportunities. New companies will be able to emerge where there are gaps in product offerings and small companies can serve regions that are otherwise overlooked. Most importantly, a seed sector with many actors will decentralize and diversify decision-making, so that people responding to local and regional contexts will make the decisions that affect the future of our food system. It also will mean that many people will have the knowledge needed to step in and help the system recover if faced with a crisis. To accomplish this goal, in addition to addressing issues related to IP rights and anti-competitive behavior, there is also a need to reinvest in seed system infrastructure and engage future seed system leaders by supporting education and training.

It has long been recognized that there is an important role for the public sector to play in medical research, for conditions that do not have a large drug market or for issues related to public health and the prevention of illness. A similar approach is needed to achieve food system security and domestic national security in agricultural production. Public investment can support both critical seed system infrastructure for national security and fair competition in the seed industry, providing choices to farmers in all regions. Historically, the USDA-Agricultural Research Service (ARS) and State Agricultural Experiment Stations (SAES) supported by both state and federal funds have worked cooperatively to develop new varieties of both regionally and nationally important crops. States also typically have foundation seed programs to ensure that farmers have access to high quality, certified seed of varieties developed in the public sector. These programs are especially important for crops that have high social value but lower private returns, like some small grains and tubers, organic seeds, and regionally adapted varieties.[166]

Funding for these programs has declined at both the state and federal level over the last several decades, meaning that this infrastructure may be at immediate risk of being privatized or dismantled. One plant breeder who spent most of their career in the private sector wrote that due to increasing consolidation, "tied into the concomitant decrease in funding and activities at the USDA and State Universities on fruit and vegetable research and breeding programs, we have significantly less chance of innovation now than in the past. For example, when I started working in 1982, there were 6 or 7 public programs on peppers in the U.S. Now there are maybe two."[167] A recent study by USDA-ERS researchers shows that while major trade competitors, including China, the European Union, India, and Brazil, are increasing public spending on agricultural R&D, the United States is falling behind. The report states that "present trends may affect the U.S. role as a global leader in agricultural sciences" and could lead to reduced trade competitiveness if national productivity

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166. "Underinvestment is likely to be greatest when there is a large gap between private and social returns. Underinvested areas may include, for example: Identification and characterization of unique genetic traits from plant germplasm resources (such as from the NPGS) for breeding new cultivars; Applied research for technologies that are especially difficult to patent or appropriate, such as breeding new varieties of "orphan" crops that include some small grains, root and tuber crops, tree crops, and others; Breeding cultivars to be grown outside current major production areas or for small markets such as organic." USDA, "Roadmap for Plant Breeding," (2015).
www.nifa.usda.gov/sites/default/files/resources/usda-roadmap-plant-breeding.pdf
167. Ken Owens, Comment on "Competition," 1.

growth is slowed.[168] This echoes findings in several studies that declining public funding is endangering our capacity to conduct plant breeding and agricultural research to respond to critical needs throughout the country.[169]

The decrease in public support for agricultural R&D may be due in part to an expectation that the private sector will fill gaps in research needs. In 1950, public agencies (including federal programs, Land Grant Universities, and State Agricultural Experiment Stations) outspent the private sector in agricultural research by 34%. By 2011, the private sector was outspending the public sector by 73%.[170] The Bayh-Dole Act, signed in 1980, allows public universities to retain title to market innovations developed using federal research funds, and was intended to help fund public research. However, in 2015, the National Genetic Resources Advisory Council (NGRAC) acknowledged that the Bayh-Dole Act may have resulted in the "development of varieties suitable for the largest economic markets and thus have had an unintended negative impact on the ability of public breeding programs to deliver commercially available organic and non-GE varieties for GE-sensitive markets."[171]

Other studies have analyzed the impact of private-sector funding on public breeding programs.[172] In 2017, researchers conducted a survey of nearly 200 public plant breeders in the United States, in which over 70% indicated that their cultivars were "always" or "most of the time" protected by IP. [173] In the same survey, only 4% reported that IP mechanisms currently employed by the public sector improve their freedom to operate, while over half responded that the public sector's IP system "somewhat" or "strongly" restricts their freedom. In the same survey, 70% of respondents said that

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168. Nelson, Kelly, and Keith Fuglie. "Investment in U.S. Public Agricultural Research and Development Has Fallen by a Third Over Past Two Decades, Lags Major Trade Competitors." *Amber Waves: The Economics of Food, Farming, Natural Resources, and Rural America* (2022). https://www.ers.usda.gov/amber-waves/2022/june/investment-in-u-s-public-agricultural-research-and-development-has-fallen-by-a-third-over-past-two-decades-lags-major-trade-competitors.
169. President's Council of Advisors on Science and Technology, "Report to the President on Agricultural Preparedness and the Agriculture Research Enterprise" (Washington DC: Executive Office of the President, December 2012).;
See also Adrienne C. Shelton and William F. Tracy, "Cultivar Development in the U.S. Public Sector," *Crop Science* 57, no. 4 (2017): 1823–35, https://doi.org/10.2135/cropsci2016.11.0961.;
See also Michael T. Coe et al., "Plant Breeding Capacity in U.S. Public Institutions," *Crop Science* 60, no. 5 (September 1, 2020): 2373–85, https://doi.org/10.1002/csc2.20227.
170. Philip G Pardey and Jason M Beddow, "Revitalizing Agricultural Research and Development to Sustain U.S. Competitiveness" (Farm Journal Foundation, 2017), 3. www.instepp.umn.edu.
171. NGRAC, "Report and Recommendations of The National Genetic Resources Advisory Council," (2015), 11. nareeeab.ree.usda.gov/sites/default/files/2017-07/2%202015%20NGRAC%20Report%20Final.pdf.
172. The idea that Bayh-Dole may be restricting access to elite germplasm was noted as early as 2007 by the Government Office of Accountability: "Regarding barriers to accessing plant germplasm, plant breeding researchers with whom we spoke said that intellectual property laws can limit access to elite germplasm. For example, the University and Small Business Patent Procedures Act, also known as the Bayh-Dole Act, allowed nonprofit organizations, such as universities, to retain title to and market the inventions they created using federal research funds. As a result, universities now restrict their sharing of germplasm, according to these plant breeding researchers." U.S. Government Accountability Office, "Information on Classical Plant and Animal Breeding Activities," GAO-07-1171R. (Washington, DC, 2007) www.gao.gov/assets/gao-07-1171r.pdf.
173. Shelton and Tracy, "Cultivar Development in the U.S. Public Sector," 1829.

funding from private industry impacts the focus of their breeding work in varying degrees.[174] Some scholars argue that decreasing funding from public sources raises the concern that university scientists may need to pursue crop development programs that generate revenue and may have difficulty supporting under-represented crops.[175] Still, the fact is that for most breeding programs, even highly successful ones, royalties represent a small share of their overall operating budget.[176] Even in the private sector, breeding programs are funded by a combination of royalties and seed sales, not royalties alone.

Importantly, studies conducted by independent scientists provide unbiased information on new technologies for farmers. Public researchers have traditionally been responsible for conducting independent trials that compared seed variety efficacy, safety, and performance. A decline in funding, coupled with stricter intellectual property rights and cross-licensing agreements, has meant that farmers are increasingly dependent on product information generated by the seed companies themselves, from sales representatives, seed dealers or branded retailers who conduct trials, company trial reports, and company websites. Testing conducted by larger well-resourced companies in multiple locations may be highly accurate due to the large quantity of data generated. Still, public sector trials are an important point of comparison across multiple companies for growers, and small to mid-sized companies or new entrants are able to demonstrate their variety performance in comparison to varieties from dominant firms. Without this data and visibility, market entry can be very difficult for smaller companies.

Risks of Declining Public Investment in Our Seed System

There is growing interest in increasing domestic food production capacity; however, foreign ownership of seed and chemical input manufacturers, as well as the globalized nature of seed production, complicates this proposition. While foreign investment in seed systems contributes to global seed system resilience, it is important that this be balanced with U.S. domestic investment and domestic capacity. Today, three of the top four companies currently dominating the seed market in the Unites States are foreign-owned.[177] In 2017, researchers estimated that German-owned

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174. Shelton and Tracy, 1831.
175. "[W]hen compared to agribusiness scientists, university crop scientists have tended to focus on minor crops and minor crop traits. The public sector has funded this research because a healthful, environmentally friendly and diverse food supply is important for societal well-being… The concern, then, is that reducing public investment in research funding, encouraging universities to conduct research while pursuing intellectual property, and encouraging universities to collaborate with the private sector will blur distinctions between research cultures and undermine the university's social obligations." Leland Glenna, Sally Shortall, and Barbara Brandl, "Neoliberalism, the University, Public Goods and Agricultural Innovation: University, Public Goods, Agricultural Innovation," *Sociologia Ruralis* 55, no. 4 (October 2015): 446, https://doi.org/10.1111/soru.12074.
176. Shelton and Tracy, "Cultivar Development in the U.S. Public Sector," 1831.
177. Howard, *Concentration and Power in the Food System: Who Controls What We Eat?*, 110.

Bayer Crop Science and Chinese state-owned Syngenta group accounted for over half of all ownership of U.S. patent rights for maize and soybean varieties.[178]

While the specialty crop industry is not as consolidated as that of corn, soy, and cotton, foreign entities still control much of the plant breeding and seed production. Bayer, BASF and Syngenta are leading companies in vegetables as well as in agronomic crops, along with Vilmorin/Limagrain (France). Other leading players include Rijk Zwaan (Netherlands), TAKII (Japan) and Sakata (Japan), Bejo (Netherlands), Enza Zaden (Netherlands) and Ball (U.S.). Most of these companies do have breeding and trialing programs in the U.S., with U.S.-based plant breeders and research stations. Seeds, however, are often grown outside of the U.S. due to labor availability and the possibility of counter seasonal production. Specialty crop seed tends to be higher value per unit volume, which makes transportation costs less significant. In addition, specialty crop seed may require very specific environmental conditions for successful production, which constrains where large-scale seed production occurs. In specialty crops, the seed producing regions may be different from the crop producing regions because the conditions for the best quality seed may be different from the conditions where the crop can be grown. This is different than commodity crops where the marketed product is often the seed (as grain). Most specialty seed companies have a presence in both seed producing and crop producing regions.

As consolidation has resulted in fewer and larger companies, those companies have concentrated research and development in higher volume and higher value seed markets.[179] Smaller scale seed companies and public sector programs often do not have the same volume or dollar value thresholds for a variety to be considered profitable and can focus on more regional production or smaller acreage crops or agricultural systems. Reductions in the number of breeding companies and breeding programs, and the potential decreases in the number of crops being developed for each region of the country, increases our vulnerability to major shocks in two ways.

First, it concentrates production of crops in the regions where there is the most support for those crops. If production becomes highly concentrated in certain regions, such as specialty crop production in California,[180] it puts the country at risk of shortages should a disruption occur to production, processing, or distribution from that region. For example, lettuce production is highly concentrated geographically, which creates a positive feedback loop for lettuce breeding efforts to focus on those areas of California. A severe drought in that area would affect the national supply in the short term. In the longer term, this concentration of production and breeding efforts reduces our ability to adapt to climate change or other more substantial disruptions, because it would take a decade or more to restart breeding programs in regions of the country which are not currently major

178. Clancy and Moschini, “Intellectual Property Rights and the Ascent of Proprietary Innovation,” 68.
Notably, both Chinese and German intellectual property systems permit a broader scope of breeding allowance on IPR-protected crops. Germany has incorporated a specific breeding exemption into their IP legislation, while China does not grant patents on plant varieties. See: Zhiqian Wan and Mark Perry, “Breeding Exemption in Plants Under Intellectual Property Regimes,” in *Free Trade Agreements* (Singapore: Springer Singapore, 2019), 99–117. https://doi.org/10.1007/978-981-13-3038-4_6.
179. USDA, “Agri-food Supply Chain Assessment,” 13-14.
180. USDA, “Agri-food Supply Chain Assessment,” 13-14.

production areas. In particular, the Great Lakes region is expected to become an even larger region for specialty crop production in the future, but mergers have resulted in the closure of several breeding stations in the region, with personnel relocated to California.

Second, commodity farmers are at high risk of disruptions because of decreased on-farm genetic diversity in major crop-growing regions for corn, soy, and cotton. Recent studies on genetic diversity have shown that the global food system is dependent on increasingly fewer crops.[181] The lack of diversity may be more pronounced in the U.S. than in other agricultural centers, where even diversity within crops has been increasingly narrowed by the proprietary nature of seeds.[182] A study of county-level crop data across the U.S. shows that overall crop diversity decreased from 1978 - 2012, with the biggest decrease in diversity reported in the Heartland Resource Region, comprising most of the Corn Belt where both crop types and the companies that market them are the most consolidated.[183] Intellectual property rights that restrict research prevent analysis of the genetic composition of corn hybrids on the market,[184] but some analyses on publicly available and non-research restricted seeds suggest that a majority of corn on the market is derived from just a few genetic lines.[185] We heard from several people knowledgeable about the industry that essentially all the genetic diversity in our current maize crop is available in off-patent lines, meaning that there has been little to no introduction of new genetic diversity to the germplasm pools of the largest companies for at least 20 years. The current genetics have just been continuously recombined and introduced traits that offer different types of pest and herbicide resistance, with an increasingly narrower genetic base.[186] Genetic uniformity lends a high degree of performance and predictability to crop systems, but also means that the entire maize industry might be at an increased risk of novel pathogens or climatic stressors.[187] For years, the USDA's Maize Crop Germplasm Committee has listed an assessment of the genetic health of the standing U.S. maize crop as a matter of national security, but as of yet, such a

181. Colin K. Khoury et al., "Increasing Homogeneity in Global Food Supplies and the Implications for Food Security," *Proceedings of the National Academy of Sciences of the United States of America* 111, no. 11 (March 18, 2014): 4001–6, https://doi.org/10.1073/pnas.1313490111.
182. "Nevertheless, most of the developed countries derive all of their diversity from this narrow germplasm and the effect of economic and IP policy on innovation in agriculture is continuing to narrow the germplasm." Jack A. Heinemann et al., "Sustainability and Innovation in Staple Crop Production in the U.S. Midwest," *International Journal of Agricultural Sustainability* 12, no. 1 (January 2014): 71–88, https://doi.org/10.1080/14735903.2013.806408.
183. Jonathan Aguilar et al., "Crop Species Diversity Changes in the United States: 1978–2012," ed. John P. Hart, *PLOS ONE* 10, no. 8 (August 26, 2015): e0136580, https://doi.org/10.1371/journal.pone.0136580.
184. "The proprietary nature of commercial corn hybrids complicates determination of their composition and diversity." Mark A. Mikel, "Genetic Diversity and Improvement of Contemporary Proprietary North American Dent Corn," *Crop Science* 48, no. 5 (September 2008): 1687, https://doi.org/10.2135/cropsci2008.01.0039.
185. "Our results revealed that, on average, 81.6% of an ex-PVP's genome is shared with at least 1 of these 12 founder lines and more than half when limited to B73, Mo17 and 207." Stephanie M. Coffman et al., "Haplotype Structure in Commercial Maize Breeding Programs in Relation to Key Founder Lines," *Theoretical and Applied Genetics* 133, no. 2 (February 2020): 547, https://doi.org/10.1007/s00122-019-03486-y.
186. Researchers documented this trend as early as 2006: "Review of the pedigree derivations in this study suggests that plant breeders have been most successful in developing new products when they recombine the most elite material available. The propensity of breeders to work elite related material in recycling of inbred lines may over the long-term decrease genetic diversity." Mark A. Mikel and John W. Dudley, "Evolution of North American Dent Corn from Public to Proprietary Germplasm," *Crop Science* 46, no. 3 (May 2006): 1204, https://doi.org/10.2135/cropsci2005.10-0371.
187. McCluskey and Tracy, "Engaging Farmer Stakeholders: Maize Producers' Perceptions of and Strategies for Managing On-Farm Genetic Diversity in the Upper Midwest," 2.

study has not been performed.[188] The NPGS conserves a large collection of genetic resources for maize, and an ongoing public-private partnership, the Germplasm Enhancement of Maize (GEM) project, seeks to increase the genetic diversity available in commercially viable lines.[189] However, the landscape-level genetic diversity of maize and other crops is still currently unknown.

Infrastructure and Capacity Building to Strengthen Seed System Resilience

Significant gaps in crop development investment include regions outside the primary production area, crops with environmental benefits such as cover crops or perennials, the development of generic versions of patented traits in genetic backgrounds adapted to particular regions, and crop development for reduced input requirements or organic production. The public sector may also take on research that is farther upstream from commercialization or that has a long time horizon before a commercial product will be available. This could include identifying resistances for emerging diseases in un-adapted varieties or wild species and incorporating them into well-adapted germplasm, developing perennial crops, and adapting crops to the effects of climate change. Renewed public investment in pre-breeding activities would additionally provide high-quality germplasm to small and mid-sized regional companies which may not have the capacity to run a full breeding program on their own, but which can work from public releases to develop more regionally adapted cultivars at a competitive price for farmers.

There is wide support for increasing funding for public breeding programs and agricultural research stations. In the request for information, responses that differed substantially on the topic of intellectual property rights agreed on the call for increased public investment in crop development programs. For example, the American Seed Trade Association recommended "strong public sector research investments in the plant sciences."[190] Friends of the Earth supported "more funding and research from land grant universities and HBCUs [Historically Black Colleges and Universities] for seeds and climate mitigation strategies that stay in the public domain."[191] A comment from the Breakthrough Institute named "insufficient public research funding" as one of the most important factors in "discouraging innovation or preventing public access to new and improved crop varieties at reasonable cost."[192] In 2016, a national summit on intellectual property rights and public plant breeding listed "capacity funding for public cultivar development" a top priority.[193]

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188. USDA-ARS Maize Crop Germplasm Committee, "Maize Crop Vulnerability Statement Recommendations," 1. https://www.ars-grin.gov/npgs/cgc_reports/maizevuln2016.pdf.
189. USDA-ARS, "Germplasm Enhancement of Maize: Utilizing diverse maize genetic resources from around the globe," https://www.ars.usda.gov/midwest-area/ames/plant-introduction-research/home/germplasm-enhancement-of-maize/
190. American Seed Trade Association, Comment on "Competition," 10.
191. Friends of the Earth, Comment on "Competition," 1.
192. Breakthrough Institute, Comment on "Competition," 2.
193. J. C. Dawson, V. M. Moore, and W. F. Tracy, "Establishing Best Practices for Germplasm Exchange, Intellectual Property Rights, and Revenue Return to Sustain Public Cultivar Development," *Crop Science* 58, no. 2 (March 1, 2018): 470, https://doi.org/10.2135/cropsci2017.05.0320.

The conservation and use of genetic diversity of crops is also a role which the public sector has led, and still leads, although currently without sufficient funding. For thousands of years, America has been home to incredible agricultural diversity due to the work of Indigenous seed keepers, whose cultivation domesticated some of the world's most important crops. European settlers and enslaved African people brought seeds from other continents. Agricultural productivity was dependent on the knowledge of Indigenous and African farmers. Many of the seeds in our public germplasm collections come from Indigenous sources. In the U.S., the 1890 and 1994 Land Grant institutions have not historically had the same level of investment as 1862 Land Grant Universities, where most public plant breeding programs are located. Increased federal funding for HBCUs, Tribal Colleges, and Tribal Governments to build capacity and infrastructure for seed stewardship and seed sovereignty initiatives is critical to building an equitable, diverse, and resilient food system. The public sector also has a key role to play in education and empowerment of talented individuals who will be the next generation of plant breeders, scientists, entrepreneurs, and seed stewards. While several 1862 Land Grant Universities have graduate programs and undergraduate programs in plant breeding and related agricultural sciences, this should be expanded to engage 1890 and 1994 Land Grants, Technical and Community Colleges and high schools who may reach a much broader and more diverse group of students interested in agriculture and food security.

Recommendations to Improve Seed System Resilience

The USDA plays a vital role in seed system resilience by conducting and funding public research and breeding programs. Declining resources in recent decades have constrained the ability for the public system to support choices for farmers and ranchers—risks that the pandemic revealed all too clearly. USDA has already begun pivoting to meet the needs of a more diverse and resilient food system, which incorporates equity and respects Indigenous food systems. Yet more remains to be done. Below we highlight several project areas, proposed and ongoing, and funding gaps where additional investment could create more diverse and robust supply chains.

- Explore and highlight opportunities where additional funding, if provided, may encourage public sector plant breeders to work in crops or regions that are currently underserved by the private sector and where innovation is needed to increase the choice of cultivars available to farmers and to improve seed system resilience. In particular, continue to build capacity at 1890 and 1994 Land Grant Universities for plant breeding, seed stewardship and research, in addition to rebuilding 1862 Land Grant University infrastructure and capacity.
- Promote broader adoption of IP strategies that enable continued research and breeding with commercialized cultivars resulting from federally funded research programs. As a model of IP policies, USDA-AMS cultivar release practices usually allow for continued research, breeding, and seed saving.
- Support robust genetic diversity and innovation potential through the exchange of experimental germplasm between plant breeders, by promoting adoption among federally funded research programs of material transfer agreement (MTA) best practices that provide for research and breeding exemptions.

- Work with the USPTO and National Institute of Standards and Technology (NIST) to examine how the Bayh-Dole Act can appropriately support plant breeding programs and further cultivar development.
- Encourage and strengthen partnerships between public entities, small and mid-sized businesses, and non-profit organizations to support seed systems; for example, through the USDA-NIFA Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) programs. These offer competitively awarded grants to qualified small businesses to support high quality research related to important scientific problems and opportunities in agriculture that could lead to significant public benefits.
- Encourage and strengthen ongoing outreach and support to historically underserved groups, including Indigenous peoples who originally stewarded and continue to care for important varieties, among which are those held in public collections.
- Explore opportunities to invest in education for agriculture, plant breeding and seed systems at all levels, including high schools, community colleges, technical colleges, 1994, 1890 and 1862 Land Grant Universities to cultivate the next generation of agricultural innovators.

Conclusion

Farmers know that the key to resilience in agriculture is diversity. Farmers plant multiple varieties so that when one exhibits a weakness—to insects, or pests, or environmental conditions—other varieties can contribute to continued productivity.[194] Consolidation in agriculture has resulted in less diversity at all levels of the value chain: today, fewer companies produce a larger share of inputs than ever before, including seeds and related technologies.[195] While this consolidation might lead to greater theoretical efficiency in the food system, it can also lead to higher levels of vulnerability to disturbances.[196] Seed systems combine aspects of both biological and human systems, and so can draw from research on resilience in both types of systems. Resilient systems typically have a degree of redundancy, diversity, decentralization and flexibility, meaning components are not so specialized that if one component fails the entire system goes down. In addition, the complexity and scope of the issues facing agriculture and food systems require a critical mass of people and infrastructure to adequately respond.

The intersection of intellectual property and antitrust is complex, made even more so by the overlapping mechanisms that control how seed varieties and traits are developed, sold, and distributed. Helping all actors—including plant breeders, farmers, and seed companies—understand and engage with these systems provides a clear benefit to all who depend on the crops they grow. Many of the recommendations in this report will draw on the new Farmer Seed Liaison, an initiative that can help bridge the gaps and enhance transparency in a complicated environment. In doing so, it will help to foster more choices and increased innovation across crops and regions. In a time of increasing disruption, the American food system must find ways to increase its resilience.[197] Promoting transparency, fair competition, and innovation among many actors in the seed system is the first step to accomplishing this goal.

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194. Brenda B. Lin, "Resilience in Agriculture through Crop Diversification: Adaptive Management for Environmental Change," *BioScience* 61, no. 3 (March 2011): 183–93, https://doi.org/10.1525/bio.2011.61.3.4.
195. James M MacDonald, Robert A Hoppe, and Doris Newton, "Three Decades of Consolidation in U.S. Agriculture" (USDA - ERS, 2018), https://www.ers.usda.gov/webdocs/publications/88057/eib-189.pdf?v=610.5.
196. Michael S. Crossley et al., "Recent Collapse of Crop Belts and Declining Diversity of U.S. Agriculture since 1840," *Global Change Biology* 27, no. 1 (January 2021): 151–64, https://doi.org/10.1111/gcb.15396.
197. Mary K. Hendrickson, "Resilience in a Concentrated and Consolidated Food System," *Journal of Environmental Studies and Sciences* 5, no. 3 (September 5, 2015): 429, https://doi.org/10.1007/s13412-015-0292-2.

Appendix A. History of IP for Plants in the U.S.

Agriculture in the present-day United States has been fueled by the exchange of seeds and local selection. For millennia, Indigenous people have cultivated crops, growing with and alongside wild plants to create varieties that filled different environmental, culinary, and cultural niches.[198] Early exchange of seeds across the continent and with Central and South America resulted in the domestication and widespread cultivation of some of America's most important crops – crops like corn, beans, potatoes, squash, peppers and tomatoes. However, the diversity cultivated has been subject to extensive pressures over the last several centuries, including the intentional destruction of Indigenous seeds as a form of displacement and war.[199]

In the nineteenth century, colonization expanded across North America and settlers introduced other crops to the agricultural system present on the continent. In 1839, the United States Patent Office obtained congressional funding to collect and distribute seeds and plants to settler farmers across the country, to determine the varieties best suited to their new environment.[200] The Patent Office, through its Division of Agriculture, sent millions of free seeds to farmers each year, including both foreign seeds and high-quality domestic varieties. The free seed program was so robust that in 1862, Congress elevated the Division to department status, and directed the newly founded Department of Agriculture to "procure, propagate, and distribute among the people new and valuable seeds and plants."[201] In the same year, the Morrill Act created "Land-Grant Universities" to teach agricultural and mechanical arts to farming families across the country.[202] Soon after, the Hatch Act created state Agricultural Experiment Stations (SAES), which partnered with the Universities to carry out research and breeding projects.[203] The improved cultivars, which were optimally adapted to each station's specific region, were then delivered to local farmers that could use them.

Many of the seeds that were collected during the 19th and 20th centuries were also deposited into what is today known as the National Plant Germplasm System (NPGS), a public repository of over 600,000 plant accessions whose stated purpose is to "safeguard the genetic diversity of agriculturally important plants" and to "support agricultural production by acquiring, conserving, evaluating, documenting, and distributing crop germplasm."[204] NPGS genebanks maintain this seed collection and distribute, at no cost, small quantities to researchers and plant breeders looking for

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198. See Rowen White, "Planting Native Seeds in a Modern World," Devon A. Mihesuah and Elizabeth Hoover, eds. *Indigenous Food Sovereignty in the United States: Restoring Cultural Knowledge, Protecting Environments, and Regaining Health*, (University of Oklahoma Press, 2019), 186-197.
199. See *White,* "Planting Native Seeds in a Modern World," 189-190.
200. Jack Ralph Kloppenburg Jr., *First the Seed: The Political Economy of Plant Biotechnology*, 2nd ed. (Madison, WI: University of Wisconsin Press, 2004), 50- 60.
201. 7 U.S.C. § 2201
202. 7 U.S.C. 321 et seq.
203. 7 U.S.C. 361 et seq.
204. USDA – ARS GRIN, "Plant Germplasm," https://www.ars-grin.gov/Collections.

new traits to incorporate into their projects. NPGS collections include wild crop relatives, varieties developed over centuries by farmers, varieties developed with traditional breeding and varieties which may contain traits from genetic engineering.

The past century has brought changes that have moved plant breeding firmly into the realm of industry. In the late 1800's, early plant breeders began making controlled crosses between plants with different characteristics and tracking the performance of progeny to improve varietal performance. This included plant breeders working on staple crops, such as the work of the French company Vilmorin in wheat, and the work of Luther Burbank in California in specialty crops. The turn of the 20th century brought with it advances in the understanding of genetic inheritance and statistics, which shifted crop improvement to a professional discipline of its own. Seed companies and nurseries for planting stock of horticultural crops became established. With the advent of controlled hybridization in staple crops like maize, companies could recoup costs of breeding investment by selling seed to farmers each year. Other crops, such as wheat and beans, are not easily hybridized, and reproduce by self-pollinated seed, so farmers could still save reliable seed from season to season. Many horticultural crops were reproduced by grafting or other vegetative methods, meaning that varieties could be easily cloned. For both clonal and self-pollinated crops, this meant that potential competitors could reproduce and sell the variety without any compensation to the plant breeder who originated it. Over the next several decades, the seed industry began to call for forms of IP protection that could provide plant breeders mechanisms for recouping the costs of research and development. The nascent private seed trade also viewed the government's free seed program as competition, and lobbied Congress for the USDA to cease the distribution of free seeds to farmers.[205]

In 1930, Congress established the first form of intellectual property protection for plants in the Plant Patent Act (PPA).[206] Because individual fruit trees and ornamentals like roses could be "cloned" by making cuttings, nurseries could establish business by offering highly stable and uniform populations to their customers in unlimited quantities. However, these propagation methods also meant that competitors could quickly develop exact replications of unusual or superior varieties.[207] This meant that a plant breeder who produced a unique variety was at risk of quickly having competitors selling exactly the same variety without having made any investment in its development. Compelled by concerns from trade groups like the American Association of Nurserymen, lawmakers passed the PPA, which stated that "whoever invents or discovers and asexually reproduces any distinct and new variety of plant… may obtain a patent."[208] When it was passed, the law protected the plant only, and not its fruit or flowers, presumably to assure farmers and consumers that the Act was designed to cover methods of reproduction and not the food

205. Kloppenburg Jr., *First the Seed: The Political Economy of Plant Biotechnology*, 71.
206. 35 U.S.C. 15
207. Cary Fowler, "The Plant Patent Act of 1930: A Sociological History of Its Creation," *Journal of the Patent and Trademark Office Society* 89, no. 9 (2000): 625.
208. 35 U.S.C. § 161 (1930).

itself.[209] At the time, Congress was unwilling to extend the scope of patentable material to staple crops, and so specifically excluded sexually-reproduced (seed-propagated) plants and tuber propagated plants such as potatoes, specifically because potatoes are "propagated by the same part of the plant that is sold as food."[210] As the Act was being debated, Representative LaGuardia asked Congress to consider a hypothetical situation: "A man patents a new plant or tree and then the seeds get out into the market. The seeds are patentable in some way, and farmers plant those seeds. Then they are subject to all the penalties imposed by the patent law, and they may be enjoined from harvesting their crops," alluding that such a measure would disrupt farmer livelihoods. The authors of the Act assured him that the hypothetical he presented would not manifest, "because seeds have been exempted, for the reason that seeds…usually produce plants varying in many respects."[211] The Act was passed, but due to rapid advances in plant breeding, which created more genetically-uniform varieties, the question posed by LaGuardia soon gained relevance in the debate about patents and plants.

During most of the early 20th century, plant breeding relied heavily on federal and state government support afforded to public breeding programs at Land Grant Universities.[212] Breeding programs in each state worked on the development of regionally adapted varieties of important crops for their state. Seed companies would license varieties or inbred lines for hybrid production from state foundation seed programs. At the same time, a growing private seed industry was also developing breeding programs, most heavily in hybrid crops such as maize which will not produce true to type. Hybridization prevented competitors from commercializing the same variety and required farmers to purchase seed each year, which allowed for a recovery of the investment into plant variety development. Other than the plant patent system for protection of asexually propagated plants, no other form of IP was available for plant varieties for most of the 20th century. The seed of inbred lines that were used to make successful hybrids were maintained as trade secrets. In part because of this lack of IP protection, many self-pollinated and clonally propagated food crops, including wheat, soybeans, beans, and potatoes, relied mainly on public sector breeding programs.

The seed industry, both in the U.S. and internationally, pushed for the development of IP protection for seed-propagated crops so that they could protect the investment they made in the development of improved varieties. This effort was largely targeted at preventing competitor seed companies from reproducing and selling seed of the protected variety at lower cost than the IP holders. The International Convention for the Protection of New Varieties of Plants (UPOV) was approved in 1961 after a convention in Paris, France (See page 30). In the U.S., similar discussions were underway, and legislation was passed in 1970 with the Plant Variety Protection Act (PVPA) establishing a form of

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209. Today, the plant patent law provides for exclusive rights to the whole plant and any of its parts: "In the case of a plant patent, the grant shall include the right to exclude others from asexually reproducing the plant, and from using, offering for sale, or selling the plant so reproduced, or any of its parts, throughout the United States, or from importing the plant so reproduced, or any parts thereof, into the United States." 35 U.S.C. § 163.
210. Hearings before the Committee on Patents, House of Representatives, 71st Cong., 2nd sess., on H.R. 11372, a bill to provide for plant patents. (1930), 15. https://hdl.handle.net/2027/umn.31951d035832922.
211. Hearing on HR. 11372: A Bill to Provide for Plant Patents, 71st Cong., 2nd sess., (1930), 8391. https://www.congress.gov/bound-congressional-record/1930/05/05/house-section.
212. Kloppenburg Jr., *First the Seed.*

intellectual property protection for seed-propagated plants, including most plants grown for food. The PVPA affirmed the role and potential of private industry to innovate new crop varieties by providing market incentives in the form of a limited period of exclusivity, much like the patent system. Several years prior to the passage of the PVPA, the President's Commission on the Patent System acknowledged "the valuable contribution of plant and seed breeders, [but did] not consider the patent system the proper vehicle for the protection of such subject matter."[213] Thus, the PVPA explicitly provided exemptions that allow farmers to save seeds for on-farm use, and for plant breeders to use protected varieties for use in their own breeding programs, so long as the result of their efforts is a new variety with enough distinction from the original variety that it is not considered "essentially derived." The concept of "essentially derived" is well established for some species such as cereals, where a professional code of ethics has governed exchanges among breeding programs for several decades and is part of non-binding guidance documents for UPOV.[214] The PVP also allows the owner to prevent the export of seeds of the protected variety, a right not specifically mentioned in patent law.

In essence, these exemptions balanced the needs of the seed industry while justifying the creation of an alternative to the utility patent system, which allows patent holders to prohibit others from making, using, or selling the claimed invention in any way. In the 2018 Farm Bill, many asexually propagated species were added to the list of crops eligible for plant variety protection though the PVPA, meaning that these crops are now able to be protected by both plant patents and PVP certificates.[215] This was done partly due to concerns from the horticultural industry about the ability of essentially derived varieties to be commercialized by a competitor under a plant patent, while the PVPA protects plant breeders from third parties commercializing an essentially derived variety without a license.

In the 50 years following the passage of the PVPA, the Supreme Court issued a series of decisions in patent-related cases that had the effect of gradually expanding the ability of companies to use utility patents to protect novel varieties and other plant breeding innovations, including by allowing the "dual protection" of both PVP certificates and utility patents on seed-bearing crops and their associated traits.[216] The extension of utility patent subject matter eligibility to living organisms began with *Diamond v. Chakrabarty* in 1980, which allowed for utility patents on living organisms, and was reinforced by the U.S. Patent and Trademark Office (USPTO) decision in *Ex parte Hibberd* (1985), which ruled that maize seed was patentable subject matter. The Supreme Court, in *J.E.M. Ag Supply, Inc v. Pioneer Hi-Bred* (2001), held that utility patents could be issued for sexually-reproducing plants. In *Asgrow Seed Co. v. Winterboer* (1995), the Court narrowed the farmers' exemption in the PVPA by curtailing the amount of seed a farmer could save and resell, and in *Bowman v. Monsanto* (2013), the Court ruled that the patent exhaustion doctrine does not permit a farmer to save and replant

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213. *To Promote the Progress of Useful Arts in an Age of Exploding Technology: Report of the President's Commission on the Patent System*, (Washington, D.C: 1967), 20-21. https://catalog.hathitrust.org/Record/001511264.
214. National Wheat Improvement Committee, "Wheat Workers Code of Ethics for Distribution of Germplasm," (November 5, 1994). www.ars.usda.gov/ARSUserFiles/30421000/wheatcode.html.
215. 7 U.S.C. § 2402(a).
216. *Diamond v. Chakrabarty*, 447 U.S. 303, (1980); *Asgrow Seed Co. v. Winterboer*, 513 U.S. 179 (1995); *J.E.M. Ag Supply, Inc v. Pioneer Hi-Bred, Inc.,* 534 U.S. 124 (2001); *Bowman v. Monsanto Co.*, 568 U.S. 1151 (2013)

patented seed. This series of decisions resulted in an IP system in which plant breeders can apply for utility patents on plant varieties, plants with new traits developed through traditional breeding, genetically engineered traits, and methods of plant breeding, which expands the scope of IP protection for plants beyond the Plant Variety Protection Act and the Plant Patent Act.

In the 2010s, the Supreme Court revisited the subject of patent eligibility in a series of cases that challenged previous decades' "common-law" approach to defining the scope of patentable inventions.[217] Two of these cases are of importance to plant breeding and agricultural inputs because, while "laws of nature" and "natural phenomena" were already categorically unpatentable, advancements in genetic technology had raised new questions about where the boundaries of nature were drawn. The first case, *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, (2012) ruled that a claim for a method for optimizing pharmaceutical drug dosage based on a measure of metabolites in a patient's blood was directed to a "law of nature" without any inventive step.[218] Theoretically, the same test could be applied to marker-assisted plant breeding, where plant breeders identify particular trait-conferring genes and develop methods to create new varieties based on the presence of those genes. A second case, *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.* (2013), addressed the issue of patents on gene sequences more directly, deciding that isolated, naturally-occurring human gene sequences are unpatentable "natural phenomena," but that synthetic cDNA is patent-eligible.[219] Responses to these court cases have been mixed, with some arguing that the vagueness of the *Mayo* framework makes patent rights unpredictable and others arguing that the established limits of patentability protect access to important biological technologies.[220]

Some public comments to the USDA's request for comments also referenced *Mayo* and *Myriad*. Pivot Bio, a small microbial fertilizer company, argues that "these decisions have left a cloud over the validity of patents in this space, even patents which had long-been believed to be valid."[221] Another commenter noted that the decisions "make sense" but are not being uniformly applied to patents on plants, claiming that "despite this ruling and the longstanding judicial exemptions, there are an extensive number of patent protections, including utility patents, on native traits in plants conferred through traditional breeding and selection."[222] In 2019, the USPTO published updated guidance to clarify practices for patent examiners in determining subject matter eligibility as it relates to laws of nature, natural phenomena, and abstract ideas,[223] and in 2021 issued a request for comments

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217. U.S. Library of Congress Congressional Research Service, *Patent-Eligible Subject Matter Reform: Background and Issues for Congress*, by Kevin J. Hickey. R45918. (2022). https://crsreports.congress.gov/product/details?prodcode=R45918
218. 566 U.S. 66 (2012).
219. 569 U.S. 576 (2013).
220. USPTO, "Patent Eligible Subject Matter: Public Views on the Current Jurisprudence in the United States," (2022), ii. https://www.uspto.gov/sites/default/files/documents/USPTO-SubjectMatterEligibility-PublicViews.pdf.
221. Pivot Bio, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs" (June 14, 2022), 2. https://www.regulations.gov/comment/AMS-AMS-22-0025-0052.
222. Anonymous, Comment Letter on "Competition and the Intellectual Property System: Seeds and Other Agricultural Inputs." https://www.regulations.gov/comment/AMS-AMS-22-0025-0063.
223. USPTO, "2019 Revised Patent Subject Matter Eligibility Guidance," 84 *Fed. Reg.* 50, (Jan. 7, 2019), www.federalregister.gov/documents/2019/01/07/2018-28282/2019-revised-patent-subject-matter-eligibility-guidance.

regarding patent eligible subject matter.[224] The criteria for patents granted on plants, traits, and methods of breeding remains under considerable discussion and will likely continue to evolve in the coming years.

224. USPTO, "Patent Eligibility Jurisprudence Study," 86 *Fed. Reg.* 36,257, (July 9, 2021), www.federalregister.gov/documents/2021/07/09/2021-14628/patent-eligibility-jurisprudence-study.

Appendix B. Methods of Analysis of IP Ownership

We undertook an analysis to estimate seed firms' ownership of granted Plant Variety Protection (PVP) and patent certificates from 1970 – 2022. To produce the compiled list of certificates, we appended the historic PVP certificates record (13.8K issued between 1973 - 2022) with a dataset of patent certificates mentioning any of 230 crop names in the patent title or abstract,[225] retrieved using the Patents Viewer API (20K issued between 1976 - 2021).[226] We verified the consistency of IP owner names across patent and PVP certificates.

For many patents, the listed applicant organization name, i.e.: inventor, may have been acquired under a new parent company, so we appended a new field with the likely new parent name based on merger data. For example, for a certificate listing "Monsanto" as its inventor that was approved in 2019, we appended a new field with "Bayer," which had acquired parts of Monsanto in 2018. To do this, we matched the certificate's assignee organization name to the possible new parent name from data on 492 historic mergers between 1975 – 2022, provided by Phil Howard. Methods of his analysis are described in a 2009 paper,[227] and we were provided data on mergers up to 2022, described in a recent release.[228] Data noted major cases in which the new parent company acquired a specific crop division of the acquired firm. We tracked acquisitions by crop when this was noted. Most of the 492 mergers documented were either not annotated by crop (221) or were recorded as 100% acquisitions (90), with 21 being joint ventures. For the mergers noted as joint ventures or partial acquisitions, e.g.: 40% ownership by Company A – 60% ownership by Company B, we treated each transaction as a 100% acquisition.

This process was done for each year from 1970-2022, which ensured that we created a historic timeline of ownership for each patent from the year invented to present. For each year, we counted IP ownership in terms of numbers of patents and numbers of PVP certificates for each firm by crop.

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225. For PVP certificates, we retained the entire set for the analysis and assigned the crop name as that designated in the publicly available AMS PVP table. For the patents dataset retrieved, we found it difficult to determine the assigned crop name based on the available fields or if they invention was actually related to plant variety or cultivar. We therefore assigned a patent to a crop if the text of the abstract or title mentioned the crop name as a text string. We further filtered the resulting dataset for only patent titles and abstracts that contained the words plant, seed, cultivar, or variety. Overall, our method of cropname assignment for patents does not necessarily obtain the actual crop invention claimed in the certificate. Our method also does not necessarily obtain certificates pertaining to new crop varieties solely; the method simply identifies any invention whose abstract or title mentions the crop name and "plant", "seed", "cultivar", or "variety." "PVPO Application Status Report." 2023. https://www.ams.usda.gov/services/plant-variety-protection/application-status.
226. Christopher Baker, *patentsview*: An *R* Client to the '*PatentsView*' API. *R* package version 0.3.0, (2022). https://docs.ropensci.org/*patentsview*/index.html.
227. Philip H. Howard, "Visualizing Consolidation in the Global Seed Industry: 1996-2008," *Sustainability* 1, no. 4 (2009): 1266–87, https://doi.org/10.3390/su1041266.
228. Amos Strömberg and Phil Howard, "Recent changes in the global seed industry and digital agriculture industries." (2023), philhoward.net/2023/01/04/seed-digital/.

To account for IP expiring and becoming part of the public domain, we appended “Offpatent” to firm names in the year the IP expired. We were then able to graph ownership based on type (PVP vs. Utility Patent) or by crop and firm.

We recognize a few limitations of the analysis. In our analysis, we do not calculate an actual economic value of IP, i.e.: identify and weight for high-value or low-value IP owned; instead, we weight all IP certificates equally. We did not distinguish between utility patents on varieties, traits or methods, or other technology. We also do not have full data on which IP ownership transferred to new parent companies for each merger so have made assumptions that IP ownership follows company ownership exactly. We have focused the scope of this analysis on estimating the likely ownership of IP and describing trends in IP acquisitions/mergers. Evaluating these relationships more fully might be appropriate for future analyses.

In the figures below, we show historic ownership and acquisition of utility patent (p) (blue) or PVP (v) (yellow) certificates for the crops receiving the highest numbers of certificates. Each ribbon represents numeric quantity of IP certificates in each five-year interval that passed from one firm to the same firm or to another firm. Y-axis values denote number of patents or PVP certificates. X-axis values denote the five-year interval. For example, 2020 refers to 2018 through 2022. Each label in the chart displays the parent firm name, followed by total non-expired IP owned in that year, followed by percent ownership of IP.

Figure B1: For canola, which includes rapeseed, most IP owned were patents. Corteva (74%) and Bayer (24%) altogether own 87% of IP, which includes 98% of non-expired canola patents. Corteva acquired its IP primarily through Dow and DuPont. Bayer acquired Monsanto around 2018. In contrast, non-top four companies tended to own PVPs.

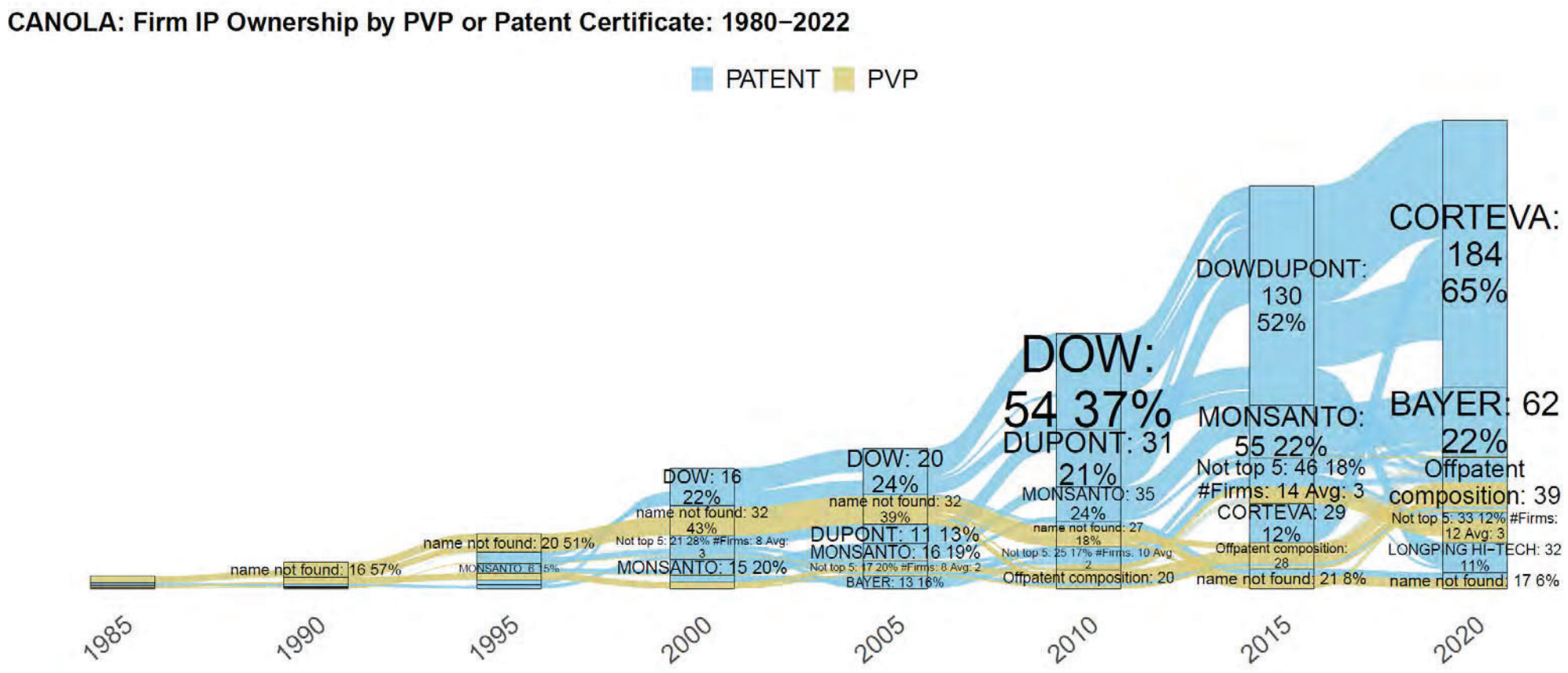


Figure B2: For corn, the top four account for 95%of IP ownership. Bayer is the top patent holder, while Corteva is the top PVP holder. Bayer owns 57% of IP, which includes 71% of corn patents and 36% of PVP, followed by Corteva (28% of total, including 53% of PVP and 13% of patents), and ChemChina (10% of total, including 10% of PVP and 9% of patents) through its acquisition of Syngenta around 2016.

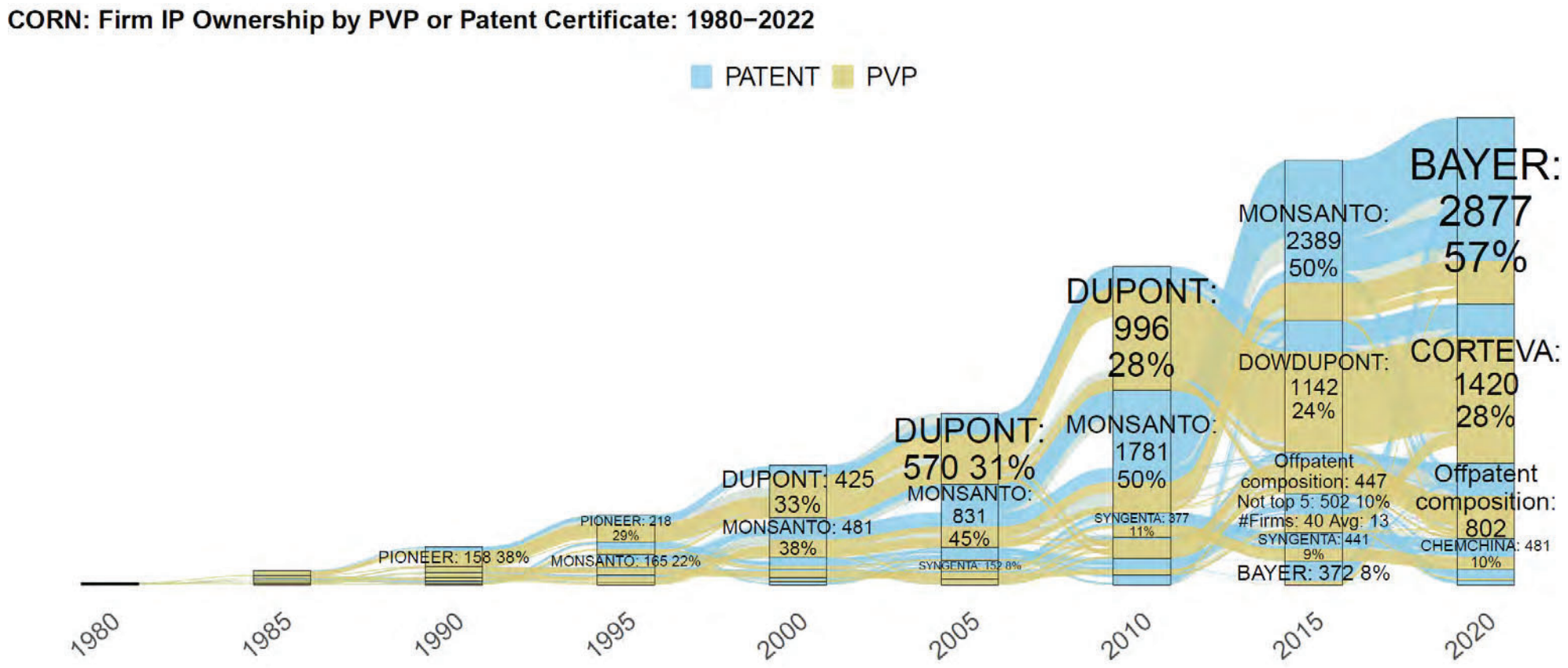


Figure B3: For cotton, BASF owns 72% of IP, which includes 70% of patents and 75% of PVP, followed by Phytogen Seed Company (7% of total, including 11% of patents and 2% of PVP). As part of the Bayer-Monsanto acquisition and divesture in 2018, BASF acquired Monsanto, which had owned 46 percent of cotton IP.

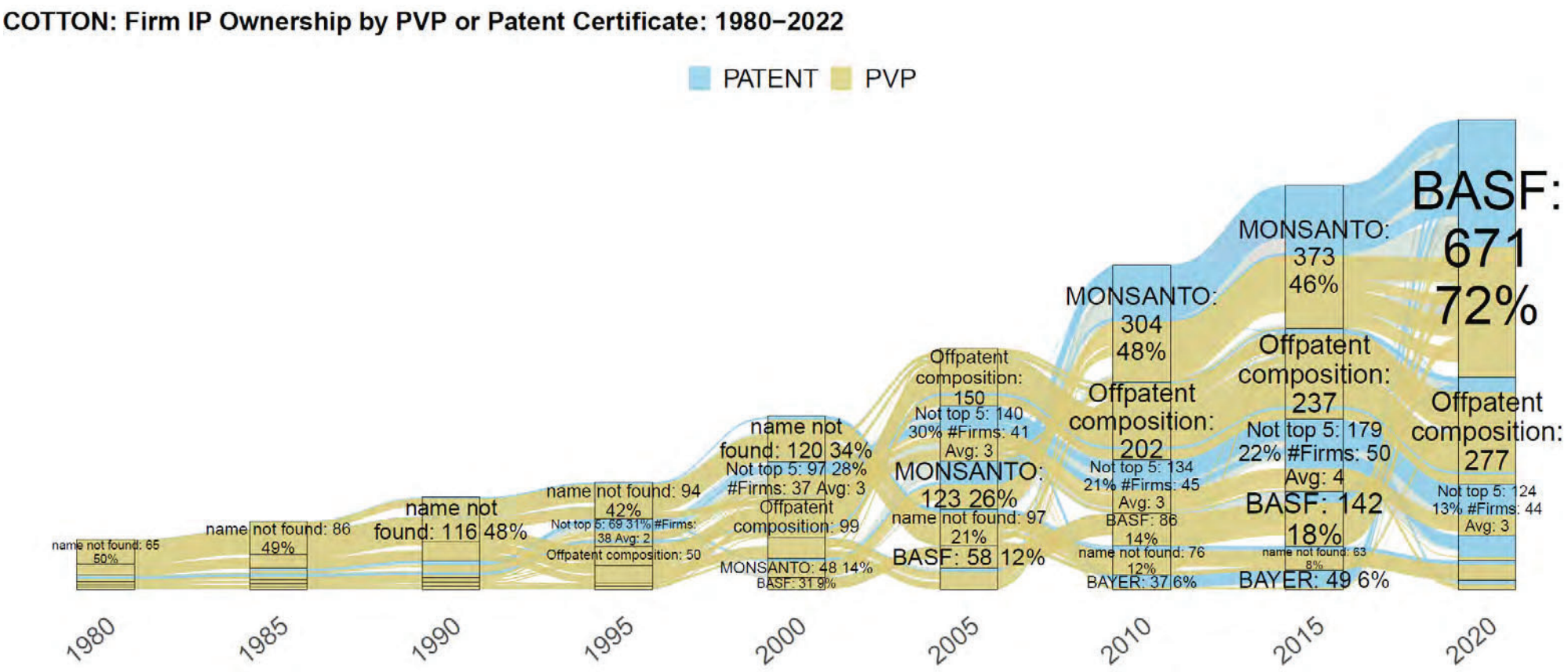


Figure B4: For forage, which includes alfalfa, most IP owned were PVP certificates, with fewer acquisitions, i.e.: labeled firm name tends to be the same from one year to the next. Non-top 12 firms currently own the largest share (27%), followed by Pure-Seed Testing (19%), Rutgers University (12%), DLF (9%), Peak Forage Genetics International (57% of patents), and Corteva (18% of patents).

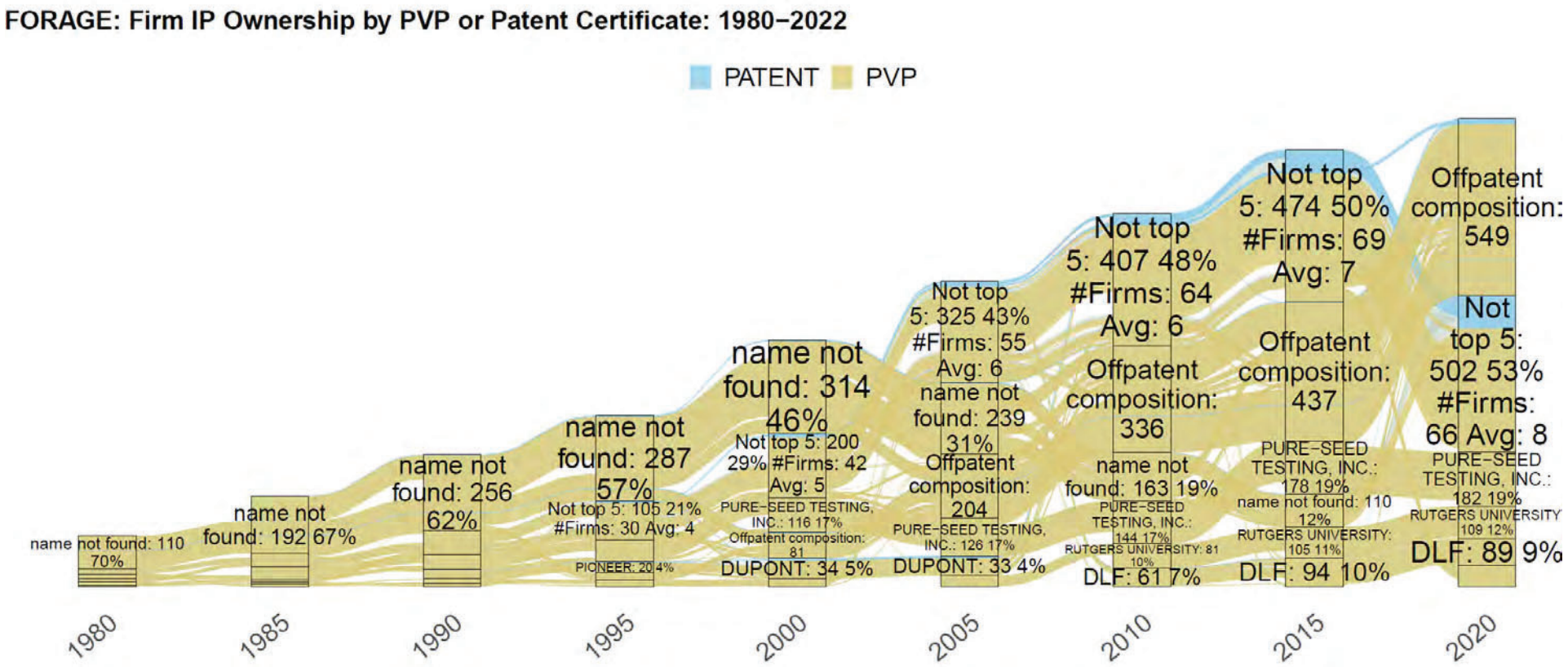


Figure B5: For soybean, the top four firms own 84% of IP. Corteva owns 33% of IP, which includes 51% of PVP and 25% of patents, followed by Bayer (43%, including 46% of patents and 37% of PVP), and ChemChina (7%, including 7% of patents and 6% of PVP).

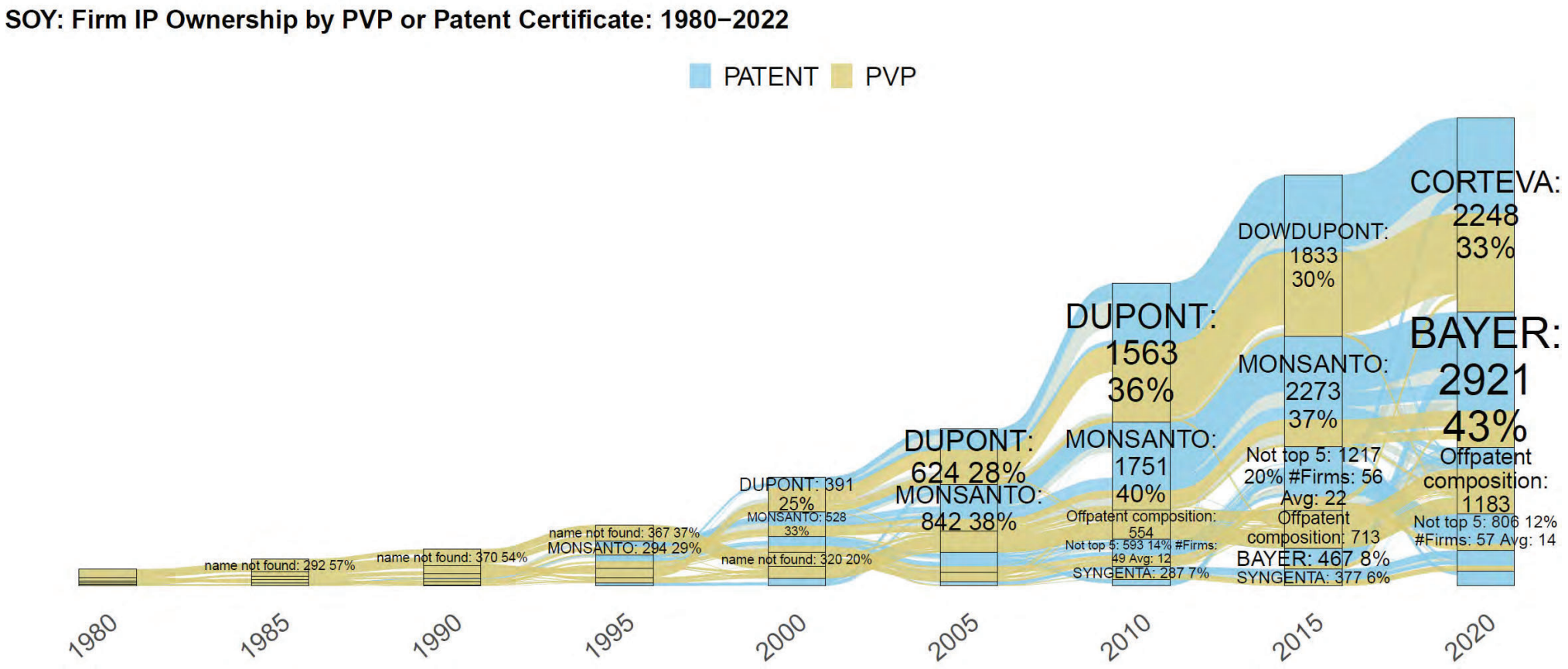
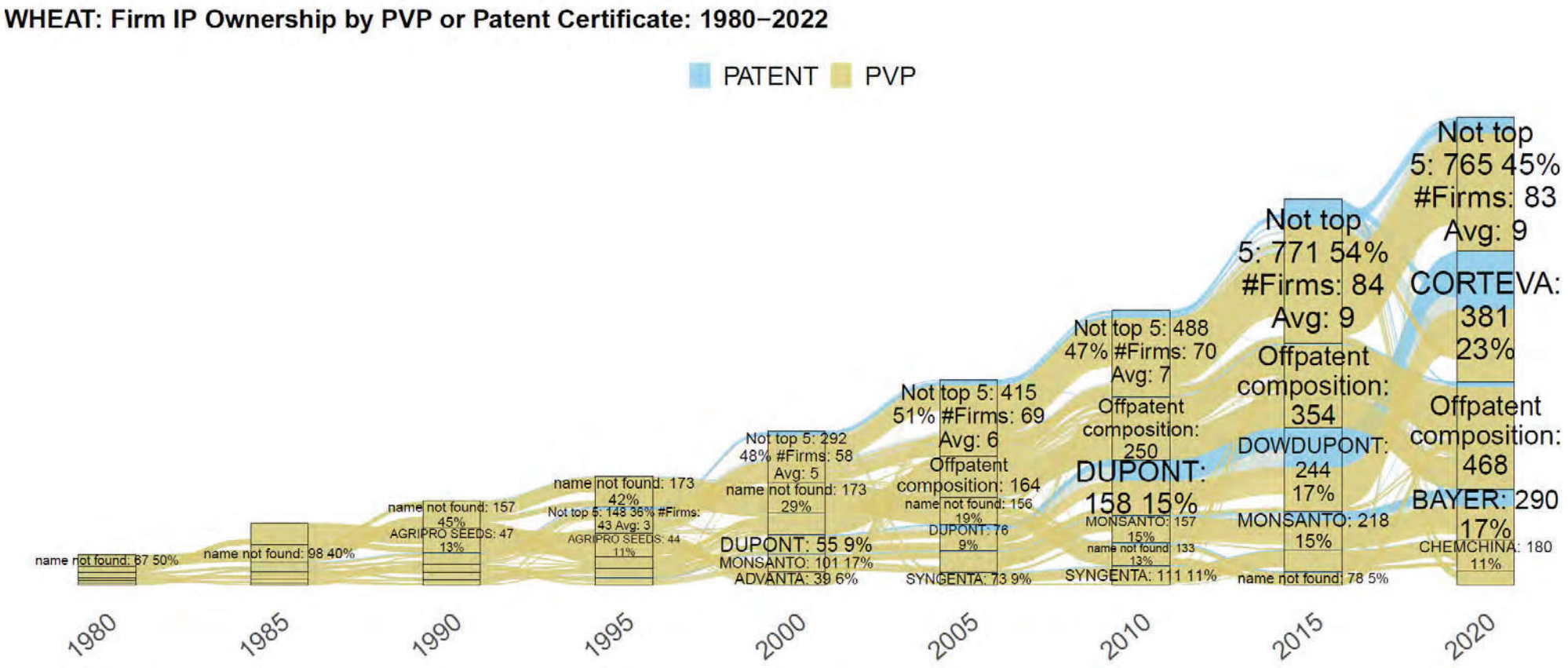


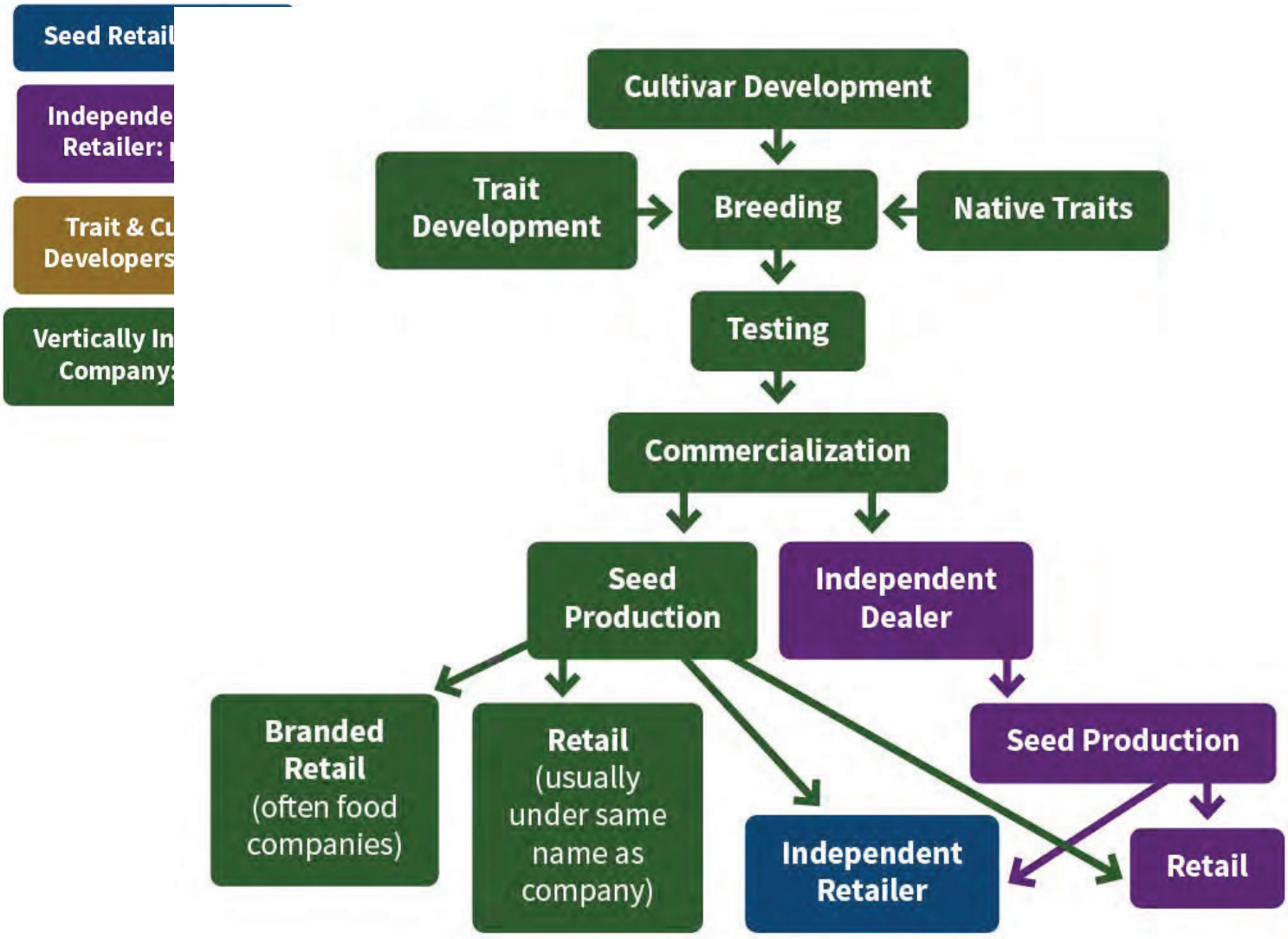
Figure B6: For wheat, most IP owned were PVP certificates. The top four account for 51%ownership. Corteva owns 23% of wheat IP, including 47% of patents and 16% of PVP. Bayer owns 17%, including 27% of patents and 15% of PVP. ChemChina owns 11%, including 13% of PVP.



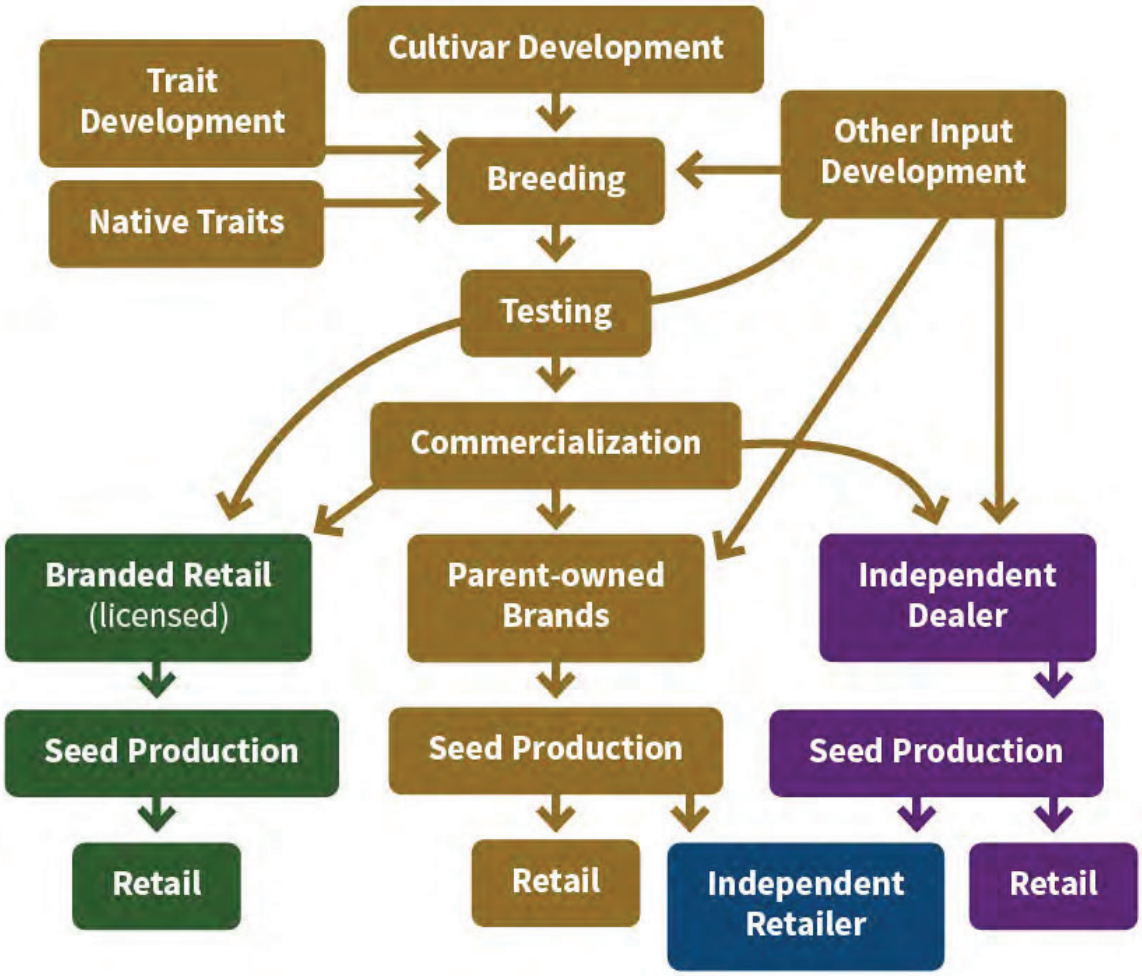
Appendix C: Seed Industry Diagrams

See page 47 for an explanation of the different types of seed companies.

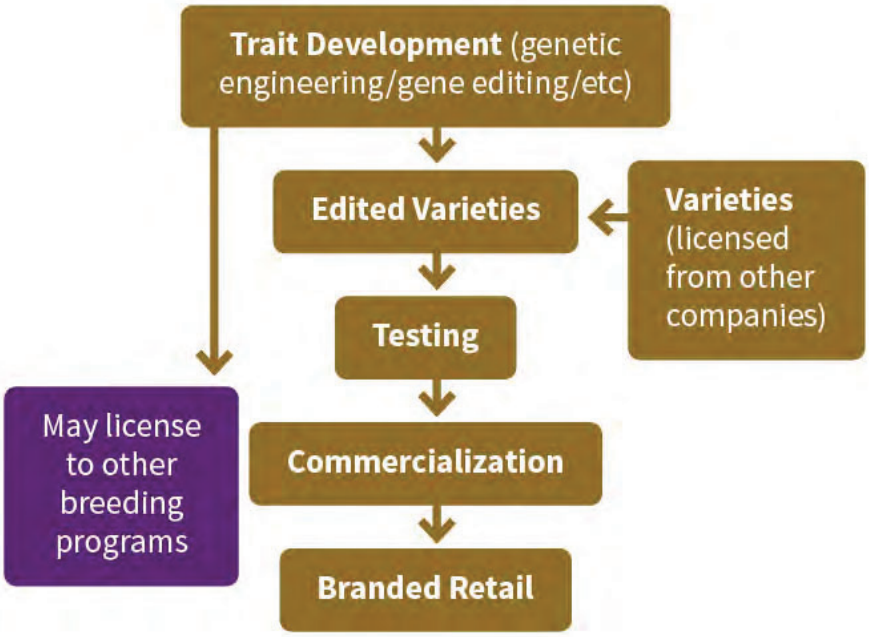
Diagram Color Chart (left) and Vertically Integrated Seed Company (right)



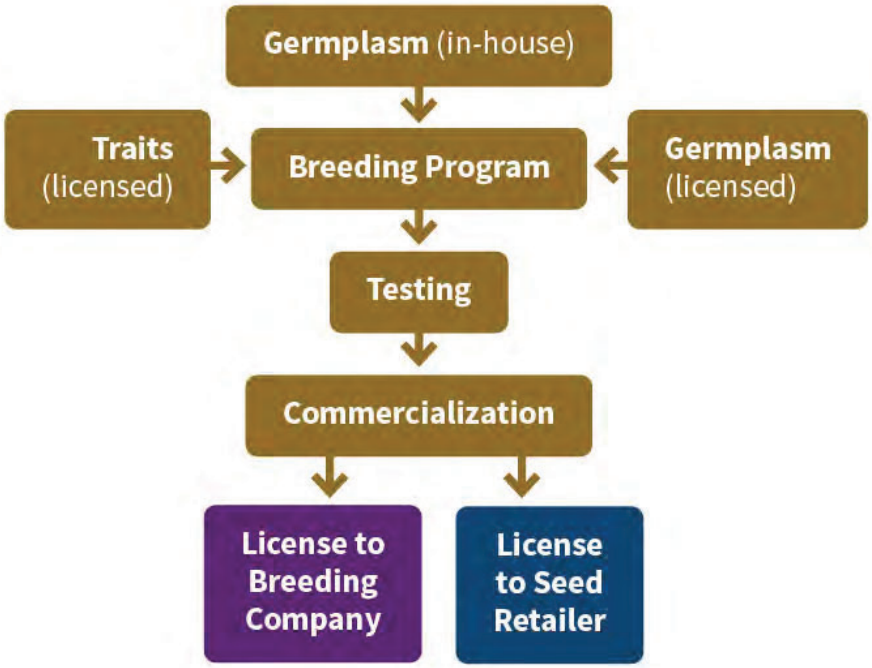
Vertically and Horizontally Integrated Seed Company



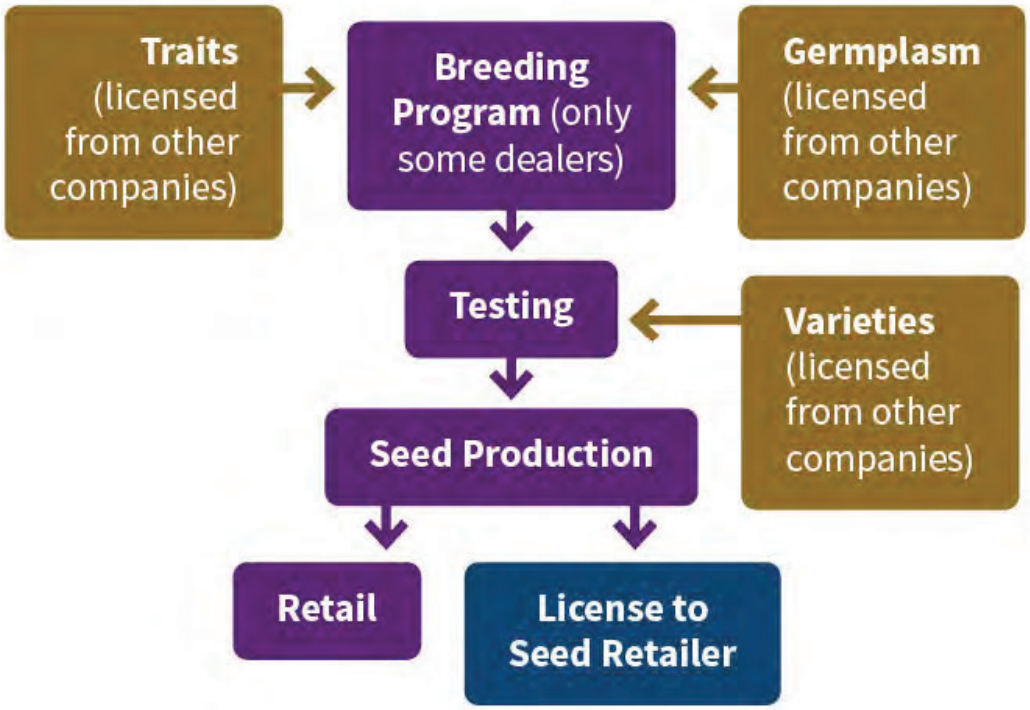
Trait Developer



Cultivar Developer



Seed Dealer



Seed Retailer

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