

USDA and USPTO announce new partnership to beef up IP processes

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On March 6, 2023, the United States Department of Agriculture (“USDA”) released a new report: “More and Better Choices for Farmers: Promoting Fair Competition and Innovation in Seed and other Agricultural Inputs.” This report responded to President Biden’s July 9, 2021, Executive Order, “Promoting Competition in America’s Economy,” that asked the USDA and other federal agencies to analyze competition issues.

This article summarizes the USDA’s report, especially as it relates to intellectual property topics. In that regard, the report broadly addresses IP law protections, including for 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, and the multiple systems of IP protection available, including trademarks, plant variety protection (“PVP”) certificates, plant patents, utility patents, and even trade secrets.

The article provides an overview of the scope of public commentary and summarizes the USDA’s findings and recommendations in view of that input, including proposed working groups and federal agency coordination for next steps. To that end, for example, the USDA is establishing the Farmer Seed Liaison, tasked with tackling prior art issues, and the USDA and U.S. Patent and Trademark Office (USPTO) are partnering to enhance delivery of IP services to the public.

Ultimately, the USDA’s stated goal is to improve fair competition in the seed industry, enhance the resiliency of America’s food and agricultural supply chains, and provide economic opportunities in America’s agricultural communities.

Summary of public commentary

On March 17, 2022, the USDA 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. After the 90-day comment period, the USDA collected comments (40 by individuals; 9 by private entities; 26 by groups/organizations), hosted a public listening forum, and heard from interested parties to ensure as many perspectives were represented in the report.

In sum, commenters recognized the “push-and-pull” of intellectual property rights that is common in many industries. Many agreed

that a system that fairly protects IP is critical to continued innovation and investment in seed systems — but there were also concerns that the current system for protecting IP rights for plant innovations may not be promoting fair competition.

Specifically, common concerns include difficulty in assessing information on existing IP rights, proper application of patentability standards on plant innovations, the effects of utility patents on continued innovations, and the need for research and breeding exemptions.

Assessing information on existing IP rights

Many commenters expressed concerns about the difficulty in assessing information on existing IP rights, citing a lack of a consolidated information as a contributing factor. In fact, one commenter stated: “One of our biggest problems ... is that we find it impossible to get a list of the patented varieties that are available.”

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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 have to search multiple sources to identify the different ways a variety might be restricted by IP.

Application of patentability standards

Several commenters have taken issue with the seemingly improper application of patentability standards during the examination of plant-related innovations — including that incomplete prior art searching has led to patents that cover pre-existing plant varieties, methods of breeding, etc. For plants and plant genetics, prior art includes published patent and PVP applications, variety registrations, academic journals, public germplasm collections

(genetic resources in plant species from which new populations are developed), seed catalogues, and sales receipts.

Unsurprisingly, this represents an inherently complex search that requires significant time and resources that can be beyond the means of small seed companies and public institutions — e.g., not all plant breeders and seed companies have convenient access to freedom to operate advice — referring to convenient and cost-effective legal advice regarding one's ability to produce their product against the backdrop of the existing patent landscape, so they have the freedom to operate without the risk of being accused of infringing a patent.

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Similarly, commenters noted that patent applications may omit pedigree information (which describes the breeding history of the variety or trait) making it difficult for examiners or third parties to assess the enablement and novelty of claimed inventions. In other words, it is very difficult for the public to understand and avoid infringement or improve on the claimed invention.

Effects of utility patents on continued innovation

Many commenters were concerned that utility patents have been used to restrict their ability to save seed, conduct research, and develop new varieties. Further, there is still significant concern regarding patent eligibility for natural phenomena and traditionally bred plants.

Concerns often arising in the pharmaceutical industry have also come up. Some commenters 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 through continuing applications, in a process known as “evergreening.”

Research and breeding exemptions

Last, several commenters recommended that research and breeding should be exempt from plant patent infringement. Even if research and breeding were free from infringement, commenters also raised concerns about the growing use of contracts restricting use of seed apart from patent rights.

As an example, commenters noted that a plant breeder who has been unable to access unrestricted germplasm during the active life of a patent can only start innovating (1) after relevant patents expire, (2) only if the off-patent germplasm has seeds available that will germinate in sync with the research timeline, and (3) the germplasm is not covered by contracts that prohibit breeding.

Recommendations

Ultimately, the USDA is collaborating with the USPTO to ensure that the intellectual property system incentivizes innovation without unnecessarily reducing competition. Specifically, as it relates to intellectual property, they seek to ensure robust and reliable IP rights that enhance innovation and promote competition and ensure that IP owners exercise their rights within the scope of fair competition provided by law. To reach these goals, the USDA is establishing a Farmer Seed Liaison.

The Farmer Seed Liaison is tasked with addressing the prior art issues described above by facilitating communication between farmers, plant breeders, and the USPTO about prior art. As noted before, farmers and plant breeders are theoretically capable of reviewing the USPTO's docket, but as a practical matter, it's not happening.

Further, the Farmer Seed Liaison can facilitate outreach to farmers and plant breeders who may develop varieties but do not want to pursue formal IP protection. For example, outreach activities include expanding efforts to provide historically underserved and Indigenous communities with access to relevant resources, such as information on how to submit public varieties to the National Plant Germplasm System (NPGS). Coincidentally, this may also result in better documented information available to the USPTO for prior art searches.

The USDA and USPTO are also establishing a new partnership — the “Working Group on Competition and Intellectual Property” — to promote fairer competition and enhance their delivery of IP-related services to the public. As proposed, the Working Group will embark on the following initiatives:

- 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 spaces.
- Explore initiatives to enhance the quality of the patent examination process for agricultural products and processes, including opportunities for enhancing prior art search capabilities and providing additional guidance to patent examiners.
- Engage in a greater exchange of information regarding procedures used 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-patent germplasm.

- Consider and evaluate new proposals for incentivizing and protecting innovation in the seed and agricultural-related spaces, 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.

Last, the USDA also touched on the status of research and breeding exemptions and recommendations in the area. The USPTO continues to explore whether exemptions from utility patent infringement would strengthen innovation not only in the plant space, but also in other areas such as pharmaceuticals, and is working with the Food and Drug Administration (FDA) on those

efforts. The USDA suggested that, 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, among others.

In conclusion, the USDA's new initiatives aim to help all stakeholders — including plant breeders, farmers, and seed companies — understand and engage with the intellectual property system and the overlapping mechanisms that control how seed varieties and traits are developed, sold, and distributed. Ultimately, the agency hopes these initiatives will help foster more choices and increased innovation across crops and regions.

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