

INFORMATION FOR USDA PLANT RESEARCHERS ON CONDUCTING OBSERVATIONAL RESEARCH WITH UTILITY PATENTED GERMPLASM

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Executive Summary and Background

Executive Order 14036 on “Promoting Competition in the American Economy” directed the U.S. Department of Agriculture (USDA) to examine ways to “ensure that the intellectual property system, while incentivizing innovation, does not also unnecessarily reduce competition in seed and other input markets beyond that reasonably contemplated by the Patent Act.” In response, USDA in March 2023 published a report, “More and Better Choices for Farmers: Promoting Fair Competition and Innovation in Seeds and Other Agricultural Inputs.” The report found that researchers and breeders faced significant challenges identifying the scope of research and breeding activities affected by patents on seeds and therefore faced difficulties navigating the contours of which activities are permissible. In some cases, they even faced difficulty precisely identifying which patents apply to particular seeds. Inability to clearly identify the scope of a patent’s coverage can frustrate research and innovation in plant breeding, as breeders decline to engage in certain lines of research rather than risk a patent infringement suit after investing time and resources in a new project.

USDA researchers, like all researchers, may be impacted by these challenges when they seek appropriate observational information. Researchers might, for example, need to grow the seed of a patented variety to physically observe the characteristics of the patented variety. In this example, two plants with identical genetics may display different characteristics if they are grown in different environments. Therefore, researchers, especially public researchers, often make observations of performance in experimental trials that compare multiple varieties in one or multiple environments. Variety trial data often includes characteristics most important to a grower’s purchasing decisions, including yield, disease resistance, resource use, and days to maturity, to name a few. The data are useful to understanding the efficacy of varieties in specific regions, climates, and environmental conditions. USDA has a long history, directly and through partnerships with universities, of providing critical information about comparative agronomic performance to farmers for the purposes of supporting and encouraging their success.

There may be a range of circumstances and methods in which researchers need to engage in observational research. This guidance encourages USDA plant researchers to consult with agency legal counsel when confronting concerns about the scope of particular patent claims. The guidance also affirms the ability for researchers to share the information they gather and conclusions they reach with others, including researchers, breeders, farmers, and consumers.

USDA underscores the importance of research access to germplasm for promoting competition, delivering more and better seed choices for farmers, and enhancing the resiliency of our nation’s

food and fiber supply and the bioeconomy more generally. With more than \$3 billion obligated for agricultural R&D, USDA has a vested interest in providing its researchers with legally-sound guidance for understanding their freedom to operate.¹ USDA will also remain attentive to whether any relevant contracts affecting seeds potentially give rise to unfair or anticompetitive practices under relevant laws.

Factors to Consider

The Patent Act defines infringement as the unauthorized making, using, offering to sell, or selling any patented invention within the United States, or importing into the United States any patented invention during the term of the patent.² In order to obtain protection under the Patent Act, a patent application must contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains to make and use the invention. The patent application also must contain one or more claims particularly pointing out and distinctly claiming the subject matter regarded as the invention.³

If a USDA plant researcher has questions or concerns about the scope of a patent's claims or their application to a particular product, or whether that product is otherwise legally available for research, a USDA plant researcher should consult USDA counsel before deciding to cease research concerning that product. Various factors may implicate the ability to conduct further research, including whether a biological deposition of a seed or plant tissue has been made to one of many International Depositary Authorities (IDA) as defined by the Budapest Treaty or whether the USDA plant researcher purchased the seed on the commercial marketplace.⁴

USDA recognizes the strong public interest in ensuring that USDA researchers can engage in observing seed germplasm in a manner that does not infringe on intellectual property rights.

Conclusion

Utilizing the help of USDA counsel to clarify the meaning and scope of patent claims provides USDA plant researchers more certainty to pursue cutting-edge research. USDA encourages non-USDA researchers and breeders that face similar challenges to contact their patent counsel, technology transfer office, and the USDA Agricultural Marketing Service's Farmer Seed Liaison at <https://www.ams.usda.gov/rules-regulations/seed-liaison>. The AMS Seed Liaison does not provide legal advice but does collect market intelligence to support an Interagency Working Group on Competition in Seeds and otherwise identify policy opportunities for improving the competitive landscape in seeds.

¹ National Center for Science and Engineering Statistics (NCSES). 2024. Federal Funds for Research and Development: Fiscal Years 2022–23. NSF 24-321. Alexandria, VA: National Science Foundation. Available at <https://nces.nsf.gov/surveys/federal-funds-research-development/2022-2023#data>

² Title 35 U.S. Code Section 271

³ Title 35 U.S. Code Section 112

⁴ Title 37 Code of Federal Regulations 1.803