United States Patent and Trademark Office

Under Secretary of Commerce for Intellectual Property and
Director of the United States Patend and Trademark Office

January 14, 2025

Jennifer Moffitt
Under Secretary
Marketing and Regulatory Programs
U.S. Department of Agriculture
Washington, D.C. 20250

RE: Increasing Research Access to Germplasm | Recommendations of the USDA (Oct. 8, 2024)

Dear Under Secretary Moffitt,

Thank you for your October 8, 2024 letter of recommendations to the USPTO.

The USPTO shares your vision of encouraging balance between incentives for inventors and innovation promotion for the public benefit by clarifying the information needed for inventors to fully disclose their inventions and ensuring that technology in the public domain remains available to the public.

The USPTO has reviewed its existing guidance and concluded that additional guidance relating to breeding histories and/or deposit of biological materials is not needed at this time. One requirement to patentability is a written description under 35 U.S.C. § 112. That statute, *inter alia*, requires "a written description of the invention, and of 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, or with which it is most nearly connected, to make and use the same." When a utility patent to a claim on a plant variety or plant part is pursued—not unlike other biological technologies—one way to satisfy § 112 is through statements in the written description of a patent application that the plant-related matter (i.e., biological material) is both known and readily available to the public. *See* Manual of Patent Examining Procedure (MPEP) § 2404.01.

For plant-related innovations, this may be achieved by disclosing breeding histories back to known and publicly available varieties. However, the USPTO also allows applicants to satisfy § 112 by making a deposit of material (e.g., seeds, tissue cultures, etc.). MPEP 2403 *et seq*. With one possible exception (37 CFR 1.808(b)), all restrictions on the accessibility by the public of the deposited material are irrevocably removed by the applicant upon the granting of the patent. Thus, in those instances in which a deposit was required to satisfy § 112, the public may access the patent protected material from the applicable depository. It is from that deposit that the public would be enabled to make and use the claimed invention as required by § 112.[1]

1 That a depository may require a material transfer agreement to access patented material does not alter this analysis. Activities done by third parties with accessed, patented material and undertaken merely to understand the patent's claim scope are no different than the public reading any other patent specification that does not require a deposit (*i.e.*, one that is fully enabled via the written description alone). Of course activities beyond this, for example those taken with commercial intention, would not be considered equivalent to reading a patent application.

Moreover, the USPTO has addressed the public accessibility of any required deposit (i.e., not just plant-related biological deposits). Section 2404.01 of the MPEP is instructive:

> By showing that a biological material is known and readily available or by making a deposit in accordance with these rules, applicant does not guarantee that such biological material will be available forever. Public access during the term of the patent may affect the enforceability of the patent. Although there is a public interest in the availability of a deposited biological material during and after the period of enforceability of the patent, there should not be any undue concern about continued access to the public. See 37 CFR 1.806 (the term of deposit is "at least thirty (30) years and at least five (5) years after the most recent request" for a sample; the agreement sufficiently ensures that the deposit will be "available beyond the enforceable life of the patent"). Unless there is a reasonable basis to believe that the biological material will cease to be available during the enforceable life of the patent, current availability would satisfy the requirement. The incentives provided by the patent system should not be constrained by the mere possibility that a disclosure that was once enabling would become non-enabling over a period of time through no fault of the patentee. *In re Metcalfe,* 410 F.2d 1378, 161 USPQ 789 (CCPA 1969).

We look forward to continuing our collaboration among our agencies. Any objective data the USDA accrues on these topics may help serve as a useful basis for further consideration. The robustness of America's agricultural ecosystem is critical to the prosperity of all Americans.

Respectfully Submitted,

Derrick Brent
Acting Under Secretary of Commerce for Intellectual Property
and Acting Director of the United States Patent and Trademark Office