October 15, 2022

Kathi Vidal
Under Secretary of Commerce for Intellectual Property and
Director of the United States Patent and Trademark Office
600 Dulany Street
Alexandria, VA 22314

Docket: PTO-P-2022-0026

RE: Patent Subject Matter Eligibility Guidance

Dear Director Vidal,

Thank you for the opportunity to submit comments regarding guidance on patent subject matter eligibility limits. Organic Seed Alliance (OSA) is a mission-driven organization that works nationally to ensure farmers have access to the seed they need to be successful, and we achieve this mission through plant breeding and research, practical education, and policy advocacy.

To begin, we are surprised that the current USPTO guidance to examiners includes no discussion or examples relating to agriculture. Patent eligibility limits are especially important for plant genetics because so much subject matter in the field is naturally occurring and/or results from applying natural laws. In addition, there were no utility plant patents until recently, so there is a dearth of patent prior art in this field. Simply applying other sections of the patent law is especially inadequate in this field.

We are concerned about the immediate and long-term impacts of utility patents on plant varieties and genetic traits given that patent holders enjoy far-reaching control over access and use of their protected plant products. A single patent on plant genetics typically covers a plant, seed, tissue cultures, future generations, crosses with other varieties, and the methods used, making important plant material inaccessible to plant breeders, researchers, and farmers due to seed-saving and research restrictions.

The patent system fails in its mission to strike a balance between benefiting inventors and benefiting the public when eligibility limits are not appropriately applied to plant genetics.

The guidance needs to change because it is leading the PTO to grant patents that are ineligible. We find patent claims on plant genetic traits and phenotypes that exist in nature and/or were

Headquarters: PO Box 772 • Port Townsend, WA 98368 • (360) 385-7192
Regional Offices: Arcata, CA • Madison, WI • Missoula, MT
www.seedalliance.org

sourced from the National Plant Germplasm System (NPGS) particularly problematic. For example:

- There are patents that claim exclusive access over the ability to cross varieties in NPGS known to have desirable disease and pest resistance. Seminis patent U.S. Patent No. 8,859,859B2 claims "a method of producing a cucumber plant having resistance to Downy Mildew (DM) comprising the steps of (a) crossing a cucumber plant of accession PI197088 with a second cucumber plant having at least one desired trait; and (b) selecting at least a first progeny cucumber plant resulting from the crossing that comprises resistance to Downy Mildew and the desired trait." PI197088 is an accession (a group of related plants from a single species which are collected at the same time and location) in the NPGS that, prior to the Seminis application, was being used by public breeding programs specifically for its high level of DM resistance. In other words, this is a method of producing a cucumber plant with DM resistance by crossbreeding a cucumber plant from a group known for its DM resistance with another cucumber plant. Nothing about it is inventive.

- U.S. Patent No. 9,173,355B2 claims "carrots having high lycopene content" (very red carrots, which exist in nature without human intervention) through the very common (and age-old) practice of crossing plant varieties to make hybrids. Plants with the same characteristics as products of nature are not eligible for patent protection, especially when they are created using practices humans have used for a very long time.

- Similarly, there is a patent claiming "red lettuce" (U.S. Patent No. 8,143,487B2). Red lettuce is a head lettuce variety that is red to the heart. This trait occurs in nature without human intervention but challenging to breed for because the red pigment in lettuce typically requires the leaves be exposed to the sunlight's UV-radiation for the anthocyanin that causes the color to synthesize. Since sunlight does not reach the center leaves of a dense head of lettuce, breeders are developing varieties that are more likely to yield red lettuce by selecting for traits that result in a red-to-the-heart lettuce without depending on light reaching the core. The red lettuce patent covers a color change in lettuce that is bred using conventional and generic breeding practices. Neither the practices of establishing red-to-the-heart lettuce nor the idea of breeding for such a trait is inventive. The fact that you can select for this trait demonstrates it is a naturally occurring genetic trait.

- There are patents on "heat-tolerant broccoli" (such as U.S. Patent No. 7,829,763B2) that cover broccoli plants bred to produce commercially acceptable heads under warmer growing conditions. Broccoli is a cool weather crop, so identifying plants that perform well under heat stress allows these plants to be grown across a wider range of geographies. The heat-tolerant broccoli patent makes broad claims to broccoli traits for heat tolerance by including all phenotypic characteristics in its description. By describing phenotype as opposed to genotype, the observable physical characteristics of the broccoli are claimed, making for a markedly broad sweeping claim to the ownership of a trait that

Headquarters: PO Box 772 • Port Townsend, WA 98368 • (360) 385-7192
Regional Offices: Arcata, CA • Madison, WI • Missoula, MT
www.seedalliance.org

is naturally occurring. As a result, the claims cover practically any broccoli plant with observable heat-tolerance, regardless of how it is bred or what its genotype is.

The protected traits and plant lines described above are naturally occurring. The material and methods used to produce them are conventional, routine, and well-understood. They contain nothing inventive that could make them eligible for patent protection. These are just a few examples out of many.

We recommend the USPTO start over with this guidance and include accurate and effective instruction regarding claims on plants and plant genetics. For starters, we recommend that USPTO:

1. **Remove parts of the guidance that are inconsistent with the law—in particular, the "practical application" test—which have allowed patents on products of nature when integrated into practical applications regardless of whether they are markedly different from products of nature or contain inventive concepts.**

2**. Include instructions on plants that occur in nature and/or are produced by using laws of nature (e.g., crossing plants will produce offspring with a varying range of traits found in the crossed plants).**

3. **Work with the USDA to develop more detailed instructions on the application of Section 101 to agriculture-related patent applications.**

The PTO and USDA should work together to develop guidance that prevents ineligible agriculture-related patents. As a starting point, they should partner to establish a coordinator position and office to serve as a liaison between the two agencies. This would improve transparency and monitoring of plant genetics protected by patents, address complaints and concerns from affected individuals, organizations, and communities, and gather useful information for crafting more effective policies and guidance in the future. The office should also collaborate on providing the public with information it needs, such as a regularly released newsletter and easily navigable database specific to plants/genetic traits that are under review for a utility patent or already protected by law.

There is an urgent need for this kind of assistance and resources. The PTO's existing databases continue to be challenging to navigate. We regularly hear from seed growers, farmers, plant breeders, and seed savers who are concerned about the dearth of information about IP protections on the seed they buy and worried about saving, breeding, or growing that seed to sell without that knowledge. We also hear from plant breeders who struggle to navigate the IP system when they want to release a variety they have developed. For plant breeders and seed growers not affiliated with or connected to a university program or a commercial seed company, it is very difficult to understand what they should to do identify and respect the IP rights of others or obtain and enforce IP protections for their own advances.

Headquarters: PO Box 772 • Port Townsend, WA 98368 • (360) 385-7192
Regional Offices: Arcata, CA • Madison, WI • Missoula, MT
www.seedalliance.org

The public must be protected from patent claims that ultimately hinder innovation, independent research, and the resiliency and security of our seed and food supplies. The balance of power is currently tipped toward the rights of powerful companies with extensive IP portfolios and away from the public interest, particularly the interests of independent seed growers, farmers, plant breeders, and seed savers. Patent applications claiming agriculture-related products of nature and natural laws require rigorous scrutiny when determining patent eligibility.

Thank you again for the opportunity to provide comments regarding the guidance on patent subject matter eligibility limits. Please let us know how we can further support your efforts.

Sincerely,

Kiki Hubbard
Director of Advocacy & Communications
(406) 544-8946
kiki@seedalliance.org