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The Murky World of IP Protection for Gene-Edited Plants

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Agribusiness is currently experiencing both a technological revolution and a corresponding increase in intellectual property uncertainty and disputes.

A recent example is the *Corteva Agriscience LLC v. Inari Agriculture Inc.*, lawsuit filed in the U.S. District Court for the District of Delaware on Sept. 27.

There, major germplasm owner Corteva has accused plant trait developer Inari of using a front company to get access to Corteva seeds kept at a public seed bank to do gene-editing trait development for commercial production.

Corteva has brought claims for patent infringement, breach of material transfer agreements, unfair competition and conversion. Inari has not yet answered, but one can expect its defense will shed light on the current uncertainties in IP rights and ownership for gene-edited plants.

Gene Editing Changes the Game in Plant Development, Creates More Uncertainty

Advancements in gene-editing technology are transforming agribusiness. The development of new plant traits through traditional breeding programs has typically involved years or even decades of work.

Now, new biotechnology tools enable plant trait development in just a fraction of that time.

These advancements are also presenting new legal challenges and uncertainty for the agricultural and food technology sectors.

Through partnerships between owners of plant varieties and germplasms, created through traditional breeding or otherwise; and trait development companies that use gene editing and other molecular biology tools, new plant varieties can be developed and brought to market more quickly than ever before.

But these collaborations are complex, and U.S. law has yet to clearly establish IP rights for newly derived plant varieties resulting from such collaborations.

For example, is a gene-edited version of an already patented variety separately patentable? And who would own it, the germplasm owner or parties involved in the gene editing?

This lack of clarity under U.S. law is creating challenges when it comes to protecting and determining ownership of new plant varieties produced by gene editing, and must be carefully navigated by parties entering into joint development arrangements.

These challenges are even more acute when a trait developer gets access to another's germplasm without permission, such as the scenario presented in the *Corteva vs. Inari* lawsuit.

Methods for IP Protection for Plant Varieties

Any time two parties are involved in creating a new plant variety by using gene-editing technology on an existing germplasm, a first consideration is how to protect newly created plant varieties.

While there are multiple, overlapping, avenues for plant protection under U.S. law, there is little precedent with respect to how such protections apply to gene-edited varieties developed from an existing germplasm, regardless of whether the preedited germplasm has IP protection.

The basic framework for protection of plant IP involves any one or combination of protections administered through

- The U.S. Patent and Trademark Office, i.e., plant patents and utility patents; and
- The U.S. Department of Agriculture, i.e., plant variety protection certificates.

Trademark protection from the USPTO is yet another form of plant IP protection, e.g., branding of ornamentals.

Plant Patents

With a plant patent issued by the USPTO, an applicant can obtain exclusive rights to propagate and sell a plant with specific traits that distinguish it from other plants, such as a leaf color or shape. However, the IP protection offered by a plant patent is limited in specific and important ways. The protection is only for a specific plant, and it does not restrict a plant from being used by others to create new varieties, which is known as a breeder's exception.

Plant patent protection is a useful IP tool for gene-edited varieties, where the edited plant has a newly distinguishable trait from the original plant.

PVP Certificates

Plant owners can also apply for plant variety protection, or PVP, at the USDA's Plant Variety Protection Office, provided the plant variety is distinct, uniform and stable. The IP rights granted through a PVP certificate gives commercial exclusivity to the plant owner, but like a plant patent administered through the USPTO, is limited by a breeder's exception. This allows others to develop new varieties using the protected variety.

There are recent examples of the USDA granting a PVP certificate for new varieties possessing gene-edited traits, with the gene-edited traits providing the distinctness required for PVP. In other words, gene editing of an existing plant variety, whether protected or not, creates a new PVP IP right in the eyes of the USDA.

Some may view this perspective of the USDA as a direct challenge to the rights of traditional breeders and owners of valuable germplasms. If the USDA continues this practice, breeders and germplasm owners could lose rights to gene-edited versions of their varieties.

Utility Patents

Utility patents issued by the USPTO offer the broadest of all the plant IP protections, and are used to protect, for example, plant traits themselves — independent of any specific plant — germplasms, and methods, such as breeding techniques. To qualify, the inventive subject matter must be new, nonobvious and have a specific utility.

Unlike the other plant IP protections discussed here, utility patents are not subject to a breeder's exception, meaning others are prohibited from using the invention without the patent owner's consent. Utility patents have also been used to protect gene-editing tools, germplasms developed through gene editing, and traits imparted by gene editing.

IP Considerations in Collaborations

With these plant IP protection regimes in mind, any scenario where gene-editing companies (trait developers) and germplasm owners (breeders) are in collaborations or disputes requires careful consideration of existing IP and ownership rights, as well as any potential future IP protections sought for resulting gene-editing activities.

Parties in collaborations need to address the following IP considerations in any collaboration agreement:

Assessing Existing IP Protections

Clearly acknowledge existing ownership of traits and germplasms. In collaborations, trait owners may have IP protection on a trait (e.g., a utility patent) and the breeder may have IP protection on the germplasm (e.g., a plant patent or a PVP certificate).

Determining What IP Protections Will Be Pursued

The parties should contemplate the goal of the collaboration and clearly decide what types of IP protections will be pursued on jointly developed subject matter. Since IP protection can be costly, collaborators should contractually agree on how the cost-burden is allocated, how decisions pertaining to IP protection are made, how disputes are resolved and how IP rights are controlled, if granted.

Establishing Ownership of Resulting IP

Since ownership is derived from inventorship — or breeding activity, in the case of plant patents and PVP certificates — collaborative activities should be clearly stated. Often one party will contribute a valuable germplasm

and the other party will contribute know-how regarding gene editing or a particular trait. If the collaboration involves moving a proprietary trait into a proprietary germplasm, then co-ownership of resulting plant IP may be the result.

However, competing interests will exist in such circumstances. Germplasm owners who have invested years of breeding effort into developing a robust germplasm will be reluctant to lose control or ownership of their germplasms.

On the other hand, trait owners will look to avoid being treated as mere vendor of gene-editing services, with no resulting rights in a new inventive variety. These tensions need to be openly discussed and accommodated in a collaboration agreement.

If joint ownership in a newly created variety is not possible, then the parties will want to agree to express license rights so that they can share in commercial opportunities. A joint venture entity to produce and commercialize the new variety arising from a collaboration is yet another way to pursue shared commercial benefit.

International IP Protection

The parties should also consider that IP and ownership in the U.S. may vary from international legal schemes. For any collaboration with an international reach, there could be additional IP and ownership considerations that must be addressed.

For example, in the European Union, the only protection available for a new plant variety is an exclusive right granted by the Community Plant Variety Office, although utility patent protections are available for some plant-related inventions.

IP Considerations in Disputes

The *Corteva vs. Inari* lawsuit highlights the claims germplasm owners will raise when a trait developer uses a proprietary germplasm for gene editing without permission. Corteva has asserted infringement of both PVP certificates and utility patents, along with common law and state statutory claims.

However, since the USDA has been issuing PVP certificates for new gene-edited varieties to parties other than the germplasm owners, there is an unresolved question on who has rights in and ownership of those gene-edited varieties. As this lawsuit unfolds, maybe the courts will start to offer some clarity on this issue.

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