

# Ensuring a bountiful IP yield from plant sales

Daniel Knauss, Sarah Moore, and Erich Veitenheimer from Cooley discuss the public use and on-sale bars to patent protection and focus on their impact on the protection of commercially valuable plant varieties

## Helsinn confirms longstanding law concerning the on-sale bar

Patent rights are lost when an invention is placed in the public domain through commercial sale or public use. These bars to patentability have been a feature of the US patent system for nearly two centuries. In 2011, Congress enacted the America Invents Act, the first significant overhaul of codified patent law since the 1950s. Included in these changes was a redrafting of Section 102, which specifies that an invention cannot be patented beyond a one year grace period if it is “in public use or on sale.” The redrafting of Section 102 added a new catch-all closing phrase that bars the patenting of inventions “in public use, on sale, or otherwise available to the public.” The meaning and scope of this new phrase was the topic of much discussion prior to the *Helsinn* decision, as its limits were unclear and there was little case law to provide direction.

The key question in *Helsinn* was whether “or otherwise available to the public” modified the preceding phrases, such that only public sales could be invalidating sales. Prior to *Helsinn*, Supreme Court cases consistently implied (and the Federal Circuit specifically held) that secret sales are still invalidating if they qualify as commercial sales of an invention ready for patenting. A contrary holding in *Helsinn* would have disturbed this precedent.

The underlying facts of *Helsinn* are straightforward. Helsinn developed palonosetron (Aloxi) as a drug to treat chemotherapy-induced nausea and vomiting. It partnered with MGI Pharma for marketing of the drug. MGI and Helsinn entered a licence agreement and supply and purchase agreement. These agreements gave MGI the right to sell the drug in exchange for upfront

## 1 MINUTE READ

Commercially-valuable plant varieties are often developed through the use of third party collaborations, industry demonstrations, seed samples, and experimental trials in outdoor areas visible to the public. The recent Supreme Court decision in *Helsinn Healthcare S.A. v Teva Pharmaceuticals USA, Inc.* underscores the potential legal implications of these industry practices for plant IP. This article discusses the “on sale” and “public use” bars to patentability as applied to plant IP and offers take home lessons for developers of new varieties in view of IP concerns and legal precedent, including *Helsinn*.

payments and a promise to purchase the drug exclusively from Helsinn. Both agreements contained confidentiality provisions as to their specific terms, but the existence of the agreements was made public through a press release and other public statements. (Note that other Federal Circuit and Supreme Court precedent strongly suggests that the publicity of the contracts is not important for the inquiry. These cases are clear that the key issue for the on sale bar is commercial exploitation, not publicity.) Teva sought to bring generic palonosetron to market, and Helsinn sued for patent infringement. Teva argued that these contracts were proof of an invalidating prior sale. Helsinn argued the new language of Section 102 modified the preceding statutory phrases, such that the sale in question could not be invalidating because it was not a public sale. Helsinn won at the trial court, but the decision was reversed by the Federal Circuit.

Writing for a unanimous Court, Justice Thomas succinctly affirmed the Federal Circuit. The new language in Section 102 does not depart from the long-settled precedent: even secret sales can be invalidating. Thus, before and after the redrafting of Section 102, any bona fide commercial sale of an invention ready for patenting (made more than one year prior to filing) will extinguish the right to a patent in that invention.

## Avoiding the loss of patent rights for commercially valuable plant varieties

*Helsinn* affirms the bar against patenting commercially sold or publicly used inventions under the revised Section 102. Given the frequent need for growth trials, industry demonstrations, and contract-based relationships to support varietal development, these provisions are important to those creating valuable new plant varieties and related agricultural inventions (and who want patent protection). Under these provisions, the on-sale bar requires *both* that a sale has occurred *and* that the invention was “ready for patenting” at the time of the sale.

## What constitutes a commercial sale of a plant invention?

The rule for commercial sale generally tracks whether the transaction constitutes a sale under the Uniform Commercial Code. For example, contracts or transactions that set product price, a purchase schedule, and provide for transfer of title in the product qualify as sales, even if the amount of product to be sold is not specified. However, as the *Helsinn* case shows, other complex commercial arrangements, including agreements for sales to occur at a future date can qualify as invalidating sales. For example, agreements between an inventor-company and its own customers and distributors may still create an on-sale bar, if they meet the requirements of the cases discussed in this article. The character of the transaction, not the identity of the parties to that transaction, will be controlling.

What about free seed samples, trial packs etc.? Although each case must be evaluated on its particular facts, as a general rule, giving away free seed samples could still constitute a sale under this provision. The seed producer obtains a valuable benefit from providing samples to growers, who will report back on

their impressions of the variety. This can be a key driver in determining which varieties should be subject to patent protection. (The precedent on these issues is very old in American law. Even a single instance of giving away or selling the invention, if done without restriction, is sufficient to invalidate.) Even if a court found that a particular sample giveaway was not a sale for patent law purposes, the open trialling of the variety from the seed sample by a grower without restriction could potentially give rise to a separate ground of invalidity under the public use rule discussed below. Best practices for seed samples or trials with growers/customers involves careful contract drafting, and the inclusion of requirements for the grower to maintain confidentiality around the variety and prohibit public access to the variety and the land where the trial is running.

The Court’s affirmation that secret sales still act as a bar to patentability could also have important consequences for the patenting of plant germplasm and strains in the rapidly emerging cannabis markets in the US, including for hemp and recreational marijuana. Due to their illegality at the time of the sale, any such sales most likely were in secret. This could still be a bar to patentability if they occurred more than one year prior to filing for formal IP protection. Anyone seeking to purchase or license cannabis germplasm and strains, who intends to seek formal IP protection, should undertake careful diligence to ascertain if such secret sales occurred and, if so, when they happened.

In situations in which a variety is discussed in a printed publication and also placed on sale in foreign jurisdictions, it is also important to bear in mind the unique case law for plant patents. *In re Elsner* held that a printed publication that did not contain sufficient details to enable the public to practise use of the variety, could be combined with foreign sales of the variety to find invalidity in the US. This case has continuing relevance for plant patents filed before the AIA took effect; for patents governed by the current patent laws, the foreign sale is by itself sufficient to invalidate the patent (the revised patent law expanded the on-sale bar to include both foreign and domestic sales). The reasoning in *Elsner*, and cases like it, further suggests that the key inquiry for courts will be whether the public can propagate the variety in determining if a sale (or public use) has occurred.

## When is a plant invention “ready for patenting”?

An invention is ready for patenting when it is “reduced to practice” (meaning sufficiently developed to be put into use) or when it is “depicted in drawings or described in writings of sufficient nature to enable a person of ordinary skill in the art to practice the invention.” In the context of a plant-related discovery, inventions are likely to be considered ready for patenting at least when the variety is fixed and stable, and possibly earlier for a given variety if it is understood to reliably function for its intended purpose.

## When is a plant invention in public use?

Except for those varieties that can be fully trialled in an indoor, controlled growth environment, valuable new plant inventions

often have to be grown outdoors in areas that are visible to the public. This might lead a patent defendant to argue such open air trialling constitutes a public use that invalidates the right to later obtain a patent.

Fortunately for developers of plant IP, courts understand the need for outdoor trials. Courts have held that even though the experimentation is necessarily done within view of the public, no invalidating use has occurred because the public does not genuinely have access to the invention. This is an important distinction between the on-sale and public use bars: while secret sales can be invalidating, secret (or controlled-access) uses are not.

For example, in *Delano Farms Co. v California Table Grape Commission*, plant patents on two novel table grape varieties were challenged under the public use doctrine. More than two years before filing for a patent, the varieties were on display at a USDA experimental open house at Cal. State Fresno. Only the mature fruit was displayed, not the vines or wood. Audience members were not permitted to take samples or to view the full plants in the field. However, some growers requested samples of the new varieties. A USDA employee, acting without authorisation, provided them in early 2002 – more than a year before the patents were filed. By 2003 these samples were grafted and propagated to over 100 growing vines, although no vines or fruit had been sold or transferred. These plantings (on private property) were visible from a public road, but they were not labelled or freely accessible to the public.

The trial court held (and the Federal Circuit affirmed) that there was no invalidating public use. The transfer of the samples and demonstration to a third party were not public uses. The transfers were done without authorisation and the variety previews were made under an expectation of confidentiality. Indeed the evidence showed the inventor had tried (without success) to maintain secrecy and to prevent dissemination. It is of key importance for developers of new plant varieties that the fact the vines were grown in view of the public did not transfer the invention to the public domain. Simply viewing the vines did not put the public in possession of key features of the invention as claimed. No invalidating public use occurred. The *Helsinn* decision is important here because the Supreme Court confirmed that the newly added to §102 phrase (“or otherwise available to the public”) did not change the interpretation of prior, relevant case law.

In assessing public use, the key question is whether the invention was placed in the public domain, or more specifically, whether it would be reasonable for a member of the public to conclude the invention was not proprietary. To answer this question, a court will examine 1) the nature of the allegedly public activities; 2) the degree of public access and knowledge of use; and 3) whether confidentiality obligations existed. As *Delano Farms* shows, even if the use in question is done by a third party, the court will focus its attention on whether a confidentiality obligation existed. Thus, even though third party use can qualify as public use, secrecy or confidentiality agreements will negate its impact. Other cases with even simpler facts confirm the reasoning in *Delano Farms*. Those who develop new plant varieties and wish to demonstrate them to the market, for example during “Spring Trials,” should take concrete

### Take home lessons for developers of new varieties

- Be cautious of the on-sale bar, especially when working with third parties like customers and distributors during the trialling and product development process. Even secret sales can be invalidating. Do not enter into agreements that would qualify as commercial sales until after executing an IP protection plan. Maintain the strictest possible confidentiality.
- Open air trialling does not count as public use, even if the public theoretically can observe the trial. However, it is important to ensure that access to the crop is limited by enforced (and ideally posted) property entry restrictions, and/or other contractual limitations. Use variety codes to conceal the name of the variety being field trialled from public view.
- Keep accurate and complete records of all sales and public uses of any plant inventions that you might want to protect via formal IP protection. Free samples or trials given without restriction to growers will create public use issues if they precede patent prosecution efforts by more than one year. Note and track the dates of any such occurrences in relationship to the one-year grace period to file for protection.
- Conduct thorough diligence on the prior sales and public uses of any plant inventions to be purchased or licensed if the intention is to seek formal IP protection on such inventions. In some instances, it may be extremely difficult to obtain all such relevant information from the seller or licensor.

steps to maintain expectations of confidentiality, and when feasible, have IP protection in place prior to such demonstrations.

Plant IP developers should also take advantage of the experimental use exception to the public use bar. Under this doctrine, use of the invention in public will not invalidate if it is done for the specific purpose of testing important features of the invention and/or to determine if the invention will work for its intended purpose. If there is a tight nexus between the need for the experimentation and the design of the experiment (in terms of features that are important for the invention) courts are hesitant to deem the product development process as a public use.

Finally, note that public use or commercial sales of products made by a specific process put both the product into the public domain and the process used to make the product. For example, a patent on methods for making Dippin’ Dots ice cream was invalidated based (in part) because the Dippin’ Dots product had been commercially exploited before the filing date of the methods patent. (Even when the process used is confidential, commercial sales of a product made by that process can be invalidating.) Therefore, method claims covering specific steps needed to create a valuable plant variety can be at risk if the variety is on sale or in public use before those method steps are protected.



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Scientists or lawyers?  
We're hard to label.

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