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Helsinn Confirms Longstanding Law Concerning “On-Sale” Bar

January 25, 2019

US patent law has long held that inventions put on sale or placed in public use may not be patented if those sales or uses occurred more than one year before filing for patent protection. These rules apply to all forms of intellectual property,[1] including commercially valuable plant varieties which often undergo growth trialing, collaboration agreements and early demonstrations as part of the product development process. Creators of plant IP must be attuned to the "on sale" and "public use" bars to patentability to avoid losing the right to patent their varieties. The recent Supreme Court decision in *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 586 U.S. ____ (2019) underscores the potential legal implications to IP of these industry practices.

Helsinn confirms longstanding law concerning the “on-sale” bar

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 (public use and on-sale bars). Section 102 specifies an invention cannot be patented beyond the one year grace period if it is "in public use or on sale."[2] The redrafting of Section 102 added a new "catchall" closing phrase that bars the patenting of inventions "in public use, on sale, *or otherwise available to the public*."[3] 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.[4] A contrary holding in *Helsinn* would have disturbed this precedent.

Helsinn developed a drug to treat chemotherapy-induced nausea. Helsinn entered into a license agreement and "supply and purchase" agreement with a third party, which gave rights to sell the drug in exchange for upfront payments and a promise to purchase the drug exclusively.[5] Both agreements contained confidentiality provisions, but their existence was publicized.[6] When sued by Helsinn 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 as it was not a "public" sale. Helsinn won at the trial court but was reversed by the Federal Circuit.[7]

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.[8]

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 and contract-based relationships to support varietal development, these provisions are important to those developing 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.[9] 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.[10] Best practices for seed samples or trials with grower/customers involves careful contract drafting, and requirements for the grower to maintain confidentiality around the variety and prohibit public access to the land where the trial is running.

Helsinn could also have important consequences to the patenting of plant germplasms and strains in the rapidly emerging cannabis markets in the US, including for hemp and recreational marijuana. If illegal, such sales likely would be in secret, but *Helsinn* confirms this could still be a bar to patentability. Anyone seeking to purchase or license cannabis germplasms and strains who intends to seek formal IP protection should undertake careful diligence regarding such secret sales.

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."[11] 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 trialed in an indoor, controlled grow environment, valuable new plant inventions often must be grown outdoors in areas that are visible to public. This reality might lead a patent defendant to argue such "open air" trialing constitutes a "public use" that invalidates the right to later obtain a patent. Fortunately for developers of plant IP, courts have held that even though the experimentation is necessarily done within view of the public, no invalidating use has occurred because the public doesn't have actual access to the invention.[12] 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.[13] The *Helsinn* decision is important here because the Supreme Court confirmed 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 into the public domain, or more specifically, whether it would be reasonable for a member of the public to conclude the invention was not proprietary.[14] To answer this question, a court will examine 1) the nature of allegedly public activities; 2) the degree of public access and knowledge of use; and 3) whether confidentiality obligations existed. 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 their impact.[15] Those who develop new plant varieties and wish to demonstrate them to the market, for example during "Spring Trials," should take concrete steps to maintain expectations of confidentiality, and when feasible, have IP protections in place prior to such demonstrations.

The experimental use exception

Plant IP developers should also take advantage of the "experimental use" exception to the public use and on-sale bars. 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.[16] 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 a public use.[17] Finally, note that public use or commercial sales of products produced by a specific process puts both the product into the public domain and the process used to make the product.[18] 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.

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 trialing 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 trialing does not count as "public" use, even if the public theoretically can observe the trial. However, it is important to ensure access to the crop is limited by enforced (and ideally posted) property entry restrictions, and/or other contractual limitations. 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.
- 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. 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.

Notes

1. For a recent review of legal forms of IP protection for plants, see Pomeranz, M., Knauss, D., and Veitenheimer, E. "Shoots, leaves and money trees," Intellectual Property Magazine December 2018/January 2019, pp. 45-46.
2. 35 U.S.C. § 102(b) (pre-AIA).
3. 35 U.S.C. § 102(a)(1) (2011) (emphasis added).
4. *Helsinn*, slip op. at 6-7; *Pfaff*, 525 U.S. at 67; *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001); *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998).
5. *Helsinn*, slip op. at 2.
6. *Id.* at 2-3.
7. *Id.* at 4; *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, 855 F.3d 1356, 1360 (Fed. Cir. 2017).
8. *Helsinn*, slip op. at 8-9.
9. *See e.g. Medicines Co. v. Hospira, Inc.*, 881 F.3d 1347, 1351-52 (Fed. Cir. 2018).
10. For example, agreements between the 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. *See, e.g., Medicines Co. v. Hospira, Inc.*, 881 F.3d at 1353.

11. *See Barry v. Medtronic, Inc.*, No. 2017-2463 (Fed. Cir. Jan. 24, 2019), slip op. at 13-14.
12. *See Delano Farms Co. v. Cal. Table Grape Comm'n*, 778 F.3d 1243 (Fed. Cir. 2015).
13. *See Dey, L.P. v. Sunovion Pharm., Inc.*, 715 F.3d 1351 (Fed. Cir. 2013); *see also Invitrogen Corp. v. Biocrest Mfg.*, 424 F.3d 1374 (Fed. Cir. 2005).
14. *Delano Farms*, 778 F.3d at 1248.
15. *Id.*; *Dey*, 715 F.3d at 1355.
16. *See Polara Eng'g Inc. v. Campbell Co.*, 894 F.3d 1339, 1348-49 (Fed. Cir. 2018). *Polara* contains a detailed discussion *of* the experimental use exception and outlines 13-factor test of relevant considerations; *see also Barry v. Medtronic, Inc.*, No. 2017-2463, slip op. at *3 (Fed. Cir. Jan. 24, 2019)
17. *See Polara*, 894 F.3d at 1349, *citing City of Elizabeth v. Am. Nicholson Pavement Co.*, 97 U.S. 126, 133-34 (1877); *Manville Sales Corp. v. Paramount Sys., Inc.*, 917 F.2d 544, 551 (Fed. Cir. 1990).
18. *See Dippin' Dots v. Mosey*, 476 F.3d 1337, 1344 (Fed. Cir. 2007); *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC*, 911 F.Supp.2d 800, 804-05 (E.D. Wis. 2012) (even when process used is confidential, commercial sales of product made by that process can be invalidating).

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