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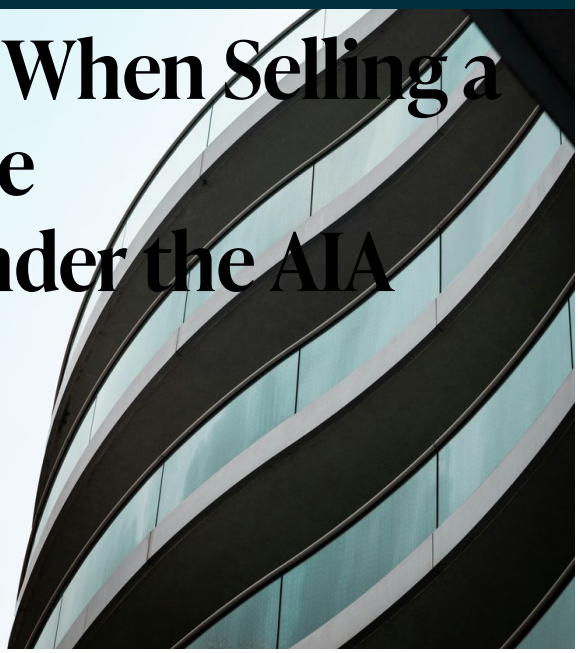
Over-Sweetening the Pot? When Selling a Product Bars Patenting the Manufacturing Process Under the AIA



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By: Matthew S. Murphy

The America Invents Act ("AIA") bars a person from obtaining a patent when the "claimed invention" had been "on sale" more than one year before the filing date of the patent. 35 U.S.C. § 102(a)(1).

Acesulfame potassium ("Ace-K") is an artificial sweetener used in foods, drinks, and medicines. In 2015, Celanese International Corporation ("Celanese") filed a patent claiming an improved method of preparing Ace-K. However, Celanese had secretly made Ace-K by 2011 using the claimed process and sold that Ace-K more than one year before filing its patent application. Based on these facts, the ITC issued a summary determination that the asserted patent claims were invalid pursuant to the AIA's on-sale bar provision.

Next week, the Federal Circuit in *Celanese International Corporation v. I.T.C.*, No. 22-1827, will hear Celanese's appeal. Celanese asserts that a plain reading of the statute requires that the "claimed invention" (i.e., the process) must have been on sale. It also asserts that textual differences between the on-sale bar provisions of pre-AIA 35 U.S.C. § 102(b) and AIA 35 U.S.C. § 102(a)(1) (e.g., changing "invention" to "claimed invention" and adding of "otherwise available to the public") show legislative intent to limit the on-sale bar to only the "claimed invention," and weighs against applying pre-AIA precedent to this dispute.

In contrast, the ITC and intervenor Anhui Jinhe Industrial Co. ("Anhui") assert that Congress did not modify the scope of the on-sale bar in enacting the AIA. In *Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.*, the U.S. Supreme Court affirmed that the AIA's on-sale bar applied where the claimed product had been the subject of a confidential sale. In considering whether the product had been "on sale," the Supreme Court stated that Congress "did not alter the meaning of 'on sale' when it enacted the AIA." Thus, the ITC and Anhui assert that pre-AIA on-sale bar precedent applies with equal force to the AIA and forecloses a patentee from patenting a process when a product made by the claimed process had been on sale. Celanese disagrees that *Helsinn* controls because that case ultimately addressed a different question than presented here.

Pre-AIA on-sale bar cases foreclosed a patentee from patenting a method of making a product when the product had already been offered for sale.[1] (Our prior article discussed the Federal Circuit's decision in *Quest Integrity* holding a method patent invalid where the patentee had earlier sold a service that secretly used the claimed method, and explained the risk that decision posed to cloud-based medical diagnostic patents.) The policy rationale is that a patentee should not be able to commercialize yet conceal the invention for later patenting and thereby extend a monopoly beyond the statutory term. Interestingly, Celanese points to a case refusing to apply the pre-AIA on-sale bar provision to invalidate a patent where a third party had sold tape made according to the patentee's process, but had not sought to secure its own patent on the process.[2] Celanese asserts that its reading of the AIA's on-sale bar provision would result in uniformity in the treatment of patentees and third parties.

If, as they say, the past is prologue, then the ITC and Anhui would appear to have the upper hand. Regardless, the Federal Circuit's decision could have far-reaching effects across industries, including in the life sciences, biotechnology, and pharmaceutical sectors where the process is often the product. Unlike pre-AIA 35 U.S.C. § 102(b), the AIA's on-sale bar provision is also not limited to sales in the U.S. Thus, domestic patents covering manufacturing methods and processes may be vulnerable to invalidity attacks based on foreign product sales. Further, even attempting to secure a patent on a process in the face of an invalidating product sale could also cause one to squander trade secret protection. Oral argument is scheduled for March 4.

1. *See, e.g.*, *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144 (Fed. Cir. 1983); *BASF Corp. v. SNF Holding Co.*, 955 F.3d 958, 969 (Fed. Cir. 2020); *Quest Integrity USA, LLC v. Cokebusters USA Inc.*, 924 F.3d 1220, 1227-28 (Fed. Cir. 2019); *Meds. Co. v. Hospira, Inc.*, 827 F.3d 1363, 1376 (Fed. Cir. 2016) (en banc); *ResQNet.com, Inc. v. Lansa, Inc.*, 594 F.3d 860, 866 (Fed. Cir. 2010); *In re Kollar*, 286 F.3d 1326, 1333 (Fed. Cir. 2002); *Brasseler, USA I, LP v. Stryker Sales Corp.*, 182 F.3d 888, 891 (Fed. Cir. 1999)

2. *W.L. Gore & Assocs., Inc. v. Garlock*, 721 F.2d 1540 (Fed. Cir. 1983).

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