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ON-SALE BAR RAISED BY FEDERAL CIRCUIT?

What is a "sale" versus what is extended product development? That appears to be a core question dogging the Federal Circuit as it re-examines the on-sale bar.

Under pre-AIA Federal Circuit precedent, virtually *any sale*–whether private or public–will trigger the on-sale bar. Under the AIA, the on-sale bar may be *limited to sales that make the invention available to the public*. But, the old rule is not going out without challenges. The Federal Circuit just agreed to consider whether, for pre-AIA applications, there should be a "supplier" exception to the on-sale bar that could narrow the definition of an invalidating sale.

Pre-AIA "On Sale" Bar

Before passage of the AIA, an inventor could obtain a patent unless, "the invention was . . . on sale in this country, more than one year prior to the date of the application for patent in the United States."[1] This provision continues to apply to most patent applications filed prior to March 16, 2013,[2] and similar language appears in the AIA and governs applications filed after that date, but with one key difference.[3]

The Supreme Court provided definitive parameters for the pre-AIA "on-sale" bar in *Pfaff v. Wells Elec., Inc.*[4] After rejecting the "totality of the circumstances" test, the Court announced two prerequisites for application of the bar.[5] Under *Pfaff*, the on-sale bar applies if, more than one year before the date of the application (the "critical date"), the claimed invention was (1) the subject of a commercial offer for sale; and (2) ready for patenting.[6]

The Medicines Corp. v. Hospira, Inc.

The Medicines Co. (TMC) sued Hospira, Inc. for infringement of two patents.[7] TMC sold a bivalirudin drug product under the trade name Angiomax™ and listed the two patents-in-suit in the U.S. Food and Drug Administration (FDA) "Orange Book." TMC alleged infringement based on

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1 35 U.S.C. §102(b).
2 *See* Leahy-Smith America Invents Act, Publ. L. No. 112-29, 125 Stat. 335 (Sept. 16, 2011).
3 35 U.S.C. § 102(a)(1) ("the claimed invention was . . . in public use, **on sale, or otherwise available to the public** before the effective filing date of the claimed invention.") (emphasis added).
4 525 U.S. 55 (1998).
5 *Id.* at 66, n. 11; *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1357 (Fed. Cir. 2001).
6 *Id.* at 67; *The Medicines Co. v. Hospira, Inc.*, 791 F.3d 1368, 1370 (Fed. Cir. 2015).
7 *The Medicines Co. v. Hospira, Inc.*, Civil Action No. 09-750-RGA, 2014 WL 1292802, *1 (March 31, 2014 D. Del.).

Hospira's Abbreviated New Drug Application (ANDA) seeking approval to market a generic drug.[8]

Hospira contended TMC's asserted patent claims were invalid under the on-sale bar because, before the critical date, TMC (1) paid a contract manufacturer to prepare validation batches of Angiomax™ using the patented method and (2) offered to sell the resulting product to its exclusive distributor.

"Federal Circuit case law applies the on-sale bar where the "inventor commercially exploited the invention" before the critical date, even when title was not transferred.[15]"

After a bench trial, the district court rejected Hospira's argument, saying it had failed to prove invalidity by clear and convincing evidence.[9] The district court reasoned TMC's product was not sold or offered for sale before the critical date because:

- The contracted manufacturer sold manufacturing services only, not pharmaceutical batches;[10]
- The batches were not prepared for commercial purposes, but were instead experimental – made to verify that the invention worked for its intended purpose;[11] and
- The exclusive distribution agreement was not a sale. It was merely a contract to enter into a contract, which could have been rejected.[12]

On appeal, a panel of the Federal Circuit reversed the district court, holding both patents were invalid under the § 102(b) on-sale bar.[13]

"To find otherwise would allow TMC to circumvent the on-sale bar and be inconsistent with the "no supplier" exception for the bar set forth in Special Devices v. OEA, Inc.[17]"

The Federal Circuit panel decided that while the district court correctly concluded the manufacturer had invoiced only for services and that title to the batches had not passed, the transaction did not end the inquiry.[14] Federal Circuit case law applies the on-sale bar where the "inventor commercially exploited the invention" before the critical date, even when title was not transferred.[15] The sale of manufacturing services to TMC resulted in batches worth more than $10 million each, enabling TMC to obtain FDA approval. Therefore, the batches provided a commercial benefit before the critical date.[16] To find otherwise, the panel reasoned, would allow TMC to circumvent the on-sale bar and be inconsistent with the "no supplier" exception for the bar set forth in *Special Devices v. OEA, Inc.*[17]

The panel also said the district court erred in finding the experimental use doctrine precluded application of the on-sale bar to the batches. Experimental use cannot occur after the invention is reduced to practice, as it was when the batches were produced for TMC.[18] Conception is not required

8 *Id.*
9 *Id.*
10 *Id.* at *9; *The Medicines Co. v. Hospira, Inc.,* 791 F.3d 1368, 1370 (2015).
11 *Id.* at *11.
12 *Id.* at *12.
13 *The Medicines Co. v. Hospira, Inc.,* 791 F.3d 1368, 1369 (2015).
14 *Id.* at 1370.
15 *Id.*
16 *Id.* at 1371.
17 *Id., citing Special Devices, Inc. v. OEA, Inc.,* 270 F.3d 1353, 1357 (Fed. Cir. 2001).
18 *Id.,* at 1372, *citing, in re Cygnus Telecomm. Tech., LLC Patent Litig.,* 536 F.3d 1343, 1356 (2001).

to establish reduction to practice when the invention is on sale, so the sale of the invention obviates any need for inquiry into conception.[19]

Last month, the Federal Circuit granted TMC's motion for rehearing *en banc* and requested briefs on several issues, including, "Should this court overrule or revise the principle in *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353 (Fed. Cir. 2001), that there is no "supplier exception" to the on-sale bar of 35 U.S.C. §102(b)?"[20]

"The Federal Circuit first announced its "no supplier exception" to the on-sale bar in *Special Devices, Inc. v. OEA, Inc.*[21]"

No Supplier Exception

The Federal Circuit first announced its "no supplier exception" to the on-sale bar in *Special Devices, Inc. v. OEA, Inc.*[21] In a strongly worded opinion, the court wrote there was no supplier exception to the on-sale bar because "neither the statutory text, nor precedent nor the primary purpose of the on-sale bar" allowed the court to recognize a "supplier" exception to the on-sale bar. The court believed such an exception would allow inventors to "stockpile" commercial embodiments of the patented invention before the critical date.[22]

In reaching this decision, the Federal Circuit said: (1) the text of section 102(b) "makes no room for a 'supplier' exception;"[23] (2) Congress indicated it does not matter who places the invention "on sale," so the "seller" can be the inventor, supplier or a third party;[24] (3) Federal Circuit precedent precludes a "supplier" exception;[25] and (4) there is a policy of encouraging an inventor to enter the patent system promptly.[26] Thus, "If such an exception is to be created, Congress, not this court, must create it."[27]

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Arguments to Eliminate or Limit "No Supplier" Exception

Against this back drop, attempts to limit or eliminate the *Special Devices* rule appear to face a steep uphill battle. Those opposed to a "supplier" exception to the on-sale bar will merely point to the language of *Special Devices,* and its express invocation of Congress as the sole source of any modification.

But consider the following arguments for why the court could trim the rule.

The § 102(b) on-sale bar as currently construed creates an opportunity for anomalous results. Under § 102, there is no "secret" prior art.[28] Secret, personal use does not constitute a §102(b) sale.[29]

19 *Id., citing Scaltech, Inc. v. Reted/Tetra, LLC,* 269 F.3d 1321, 1331 (Fed. Cir. 2001); *Abbott Labs. v. Geneva Pharm.,* 182 F.3d 1315, 1318-19 (Fed. Cir. 1999).
20 *The Medicines Co. v. Hospira, Inc.,* No. 2014-1469, 2015 WL 7077193, *1 (Nov. 13, 2015 Fed Cir.).
21 270 F.3d 1353, 1357 (Fed. Cir. 2001).
22 *Id.* at 1355, 1354.
23 *Id.* at 1355.
24 *Id.*
25 *Id., reviewing, Brassler, U.S.A. I, L.P. v. Stryker Sales Corp.,* 182 F.3d 888 (Fed. Cir. 1999); *Zacharin v. U.S.* 213 F.3d 1366 (Fed. Cir. 2000).
26 *Id.* at 1357.
27 *Id.*
28 *See Vulcan Eng'ing Co., Inc. v. FATA Alum., Inc.,* 278 F.3d 1366, 1372 (Fed. Cir. 2002); *D.L. Auld Co., v. Chroma Graphics Corp,* 714 F.2d 1144, 1147-48 (Fed. Cir. 1983).
29 *Special Devices, Inc. v. OEA, Inc.,* 270 F.3d at 1362.

While there are no "secret" sales,[30] "[i]nventors can request another entity's services in developing products embodying the invention without triggering the on-sale bar."[31] Services provided by a contract manufacturer are generally considered secret and provide only an indirect commercial benefit to the inventor, even if the service involves performing the steps of a product-by-process patent. Unless a product containing or derived from the invention is sold to the public, the inventor is unlikely to recognize a financial gain from the patented invention.

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Given this framework, and assuming no other prior art issues exist, a patent owner or its employee may produce and stockpile patented products or products made using a patented product-by-process method without implicating § 102(b) and risking an on-sale bar. The same patent owner may not, however, contract with a third party to provide manufacturing services. Arguably, there is no policy justification for the difference.

AIA § 102(a)(1)

The language of the AIA suggests a different result. For applications filed after March 16, 2013, a patent will issue unless "the claimed invention was . . . in public use, **on sale, or otherwise available to the public** before the effective filing date of the claimed invention."[32]

Under the AIA, if "or otherwise available to the public" modifies "on sale," the new statute substantially limits the scope of the existing on-sale bar. The legislative history suggests that is the case. Former Sen. Jon Kyl (Ariz.) specifically noted that "or otherwise available to the public" should modify "on sale" in the statute.[33] Advocates of the "supplier" exception now have a sound statutory basis for the proposal.

"Under the AIA, if "or otherwise available to the public" modifies "on sale," the new statue substantially limits the scope of the existing on-sale bar."

In supporting this premise, the MPEP states, "The phrase 'on sale' in AIA 35 U.S.C. § 102(a)(1) is treated as having the same meaning as 'on sale' in pre-AIA § 102(b), **except that the sale must make the invention available to the public**."[34]

CONCLUSIONS

Given these shifting sands, is there a sound policy reason for a difference in the scope and application of the on-sale bar for self-made v. contracts-made products for applications before and after March 16, 2013? It seems the Federal Circuit may be leaning toward a requirement that, even under the pre-AIA law, the product must be available *to the public* to trigger the on-sale bar, shielding the inventor's ongoing product development using a contract manufacturer.

30 *Id.* at 1357; *Hamilton Beach Brands, Inc. v. Sunbeam Products, Inc.*, 726 F.3d 1370, 1375 (Fed. Cir. 2013).
31 *Trading Tech., Int'l, Inc. v. Espeed, Inc.*, 595 F.3d 1340, 1361-62 (Fed. Cir. 2010).
32 35 U.S.C. §102(a)(1) (emphasis added).
33 Cong. Rec. S1370-71 (daily ed. Mar. 8, 2011).
34 Manual of Patent Examining Procedure, § 2152.02(d) (Rev'd 11.2013) (emphasis added).