APPEAL NOS. 2014-1469, 2014-1504

IN THE
UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

THE MEDICINES COMPANY,

Plaintiff-Appellant

v.

HOSPIRA, INC.,

Defendant-Cross-Appellant.

Appeal from the United States District Court for the District of Delaware
Case No. 09-cv-750-RGA, Judge Richard G. Andrews

DEFENDANT-CROSS-APPELLANT HOSPIRA, INC.'S OPPOSITION TO PETITION FOR REHEARING EN BANC

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September 8, 2015

CERTIFICATE OF INTEREST

Counsel for Defendant-Cross Appellant Hospira, Inc. certifies the following:

1. The full name of every party or amicus represented by me is:

Hospira, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

None.

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Pfizer, Inc., of which Hospira, Inc. became a subsidiary on September 3, 2015.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court are:

Jenner & Block LLP: Bradford P. Lyerla, Aaron A. Barlow, Sara T. Horton, and Jamie K. Lord.

Morris James LLP: Richard K. Herrmann and Mary B. Matterer.

Sutherland Ashbill & Brennan LLP: William F. Long and Tara Stuart (subsequently moved to McKenna Long & Aldridge LLP), and Kristin E. Goran.

September 8, 2015 /s/ Bradford P. Lyerla

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INTRODUCTION

MedCo's petition offers no reason for the Court to rehear this case en banc.[1] *First*, MedCo paid Ben Venue to manufacture batches of Angiomax valued at more than $10 million each. The panel's holding that the on-sale bar was triggered does not break new ground; instead, it reflects careful application of the established principle that, once an inventor commercially exploits an invention, failure to apply for a patent promptly may jeopardize the inventor's expected right to exclude.

Second, MedCo's argument for experimental use has no factual basis. According to MedCo's own documents, the first three batches were to be "filled for commercial use." A14884. Although they were also used to satisfy the FDA's validation requirement, that validation process was not "experimental," nor did it transform MedCo's stated commercial purpose into an experiment.

Third, the panel's holding that the invention was ready for patenting does not conflict with the Supreme Court's decision in *Pfaff* or with any decision of this Court. Instead, that holding acknowledges what is plain: because Ben Venue actually delivered batches manufactured using MedCo's revised process, and because the inventors realized that the batches had impurities well below the levels claimed in the patents, the claimed invention necessarily was reduced to practice.

[1] Although MedCo filed a single petition for panel rehearing and rehearing en banc, the notice dated August 24, 2015 invites a response only to the petition for rehearing en banc. Out of an abundance of caution, Hospira states that the arguments in this response equally warrant denial of the petition for panel rehearing.

The panel's decision does not conflict with any decision of this Court or the Supreme Court, nor does it involve any precedent-setting question of exceptional importance. Instead, it represents a straightforward and correct application of well-settled precedent. The petition should be denied.

BACKGROUND

Prior to the July 27, 2007 critical date, MedCo paid Ben Venue Laboratories for three batches of Angiomax made with the process recited by the patents-in-suit. A17177-78; A16852-53. This arrangement was straightforward: MedCo arranged for the active pharmaceutical ingredient to be provided to Ben Venue. A16053-54. Ben Venue, in turn, produced the Angiomax using MedCo's revised process. A16867-68; A14959-60; A15210-11; A15452-53; A16838; A16850. Ben Venue then released the Angiomax to MedCo in exchange for $347,500. A16058; A17177-78; A16852-53.

From the start, MedCo made extensive commercial use of these batches. Each of them was given a commercial product code and was "[r]eleased for commercial and clinical packaging." A14959-60; A15210-11; A15452-53. Before the critical date, MedCo placed these three batches of Angiomax in its commercial pipeline for ultimate sale to the public. *Id.*; *see* A16837-51. Regardless of whether those sales took place after the critical date, MedCo's commercial benefit from having a well-stocked pipeline of commercially packaged Angiomax was enor-

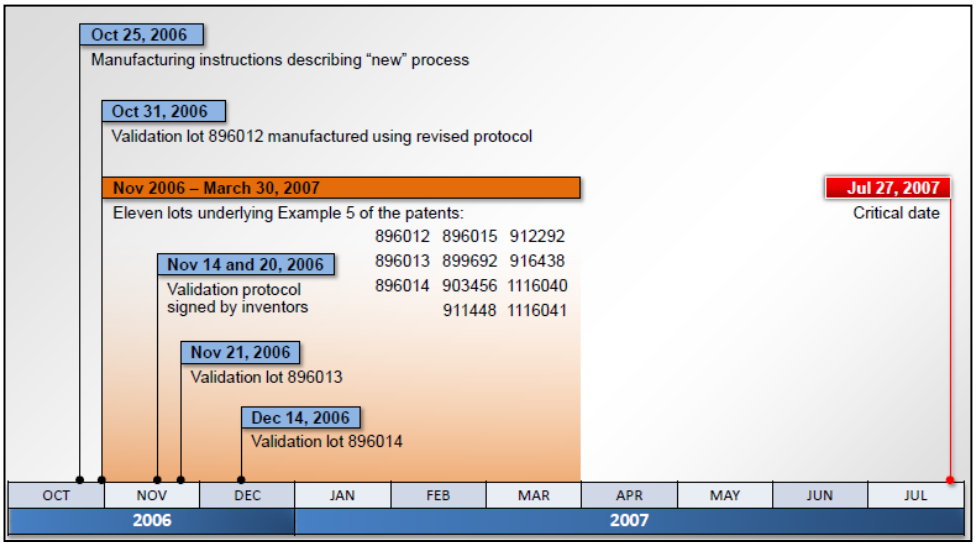
mous: as MedCo admitted, a typical batch has a market value of $10 million to $20 million. A15986; A16055-56.

MedCo also used these batches to "validate" its revised process. A14883-89. This "validation" was required by FDA regulations. 21 C.F.R. § 211.110. It was not, however, an experiment: the inventor-approved protocol described it as "confirmational validation" that was "intended to verify and validate the effectiveness of the process optimization steps." A14883; *see* A14884 (describing objectives as "to confirm that all in process specifications and critical parameters are maintained during the manufacturing of the product . . . with the implementation of the process improvements" and "to ensure that the process optimizations indeed minimize the risk of high levels of Asp9 impurity in the final product"); *see also* A17178 (Ben Venue invoice "to manufacture [the] bivalirudin lot").[2] The protocol made equally clear that the Angiomax produced would be sold commercially: "The solution," it explained, "will be filled for commercial use." A14884.

Subsequent to validation—but still before the critical date—MedCo paid Ben Venue to manufacture eight *more* commercial batches of Angiomax with the revised process. A16678-79. Each batch, again, was valued at more than $10 mil-

[2] By contrast, an invoice for earlier experimentation described that work as "product and process development" and "performance of pilot formulation studies to support investigation of Asp9 impurity." A17175.

lion. A15986. The table below (A15898) shows the manufacture of the lots relative to the critical date:



Applying well-settled precedent, the panel determined that the on-sale bar of 35 U.S.C. § 102(b) invalidated MedCo's patents.[3] MedCo's petition identifies no reason why the panel's decision warrants rehearing en banc.

ARGUMENT

I. REHEARING EN BANC IS UNWARRANTED ON WHETHER A COMMERCIAL SALE TOOK PLACE.

The on-sale bar serves important purposes. It "encourages an inventor to enter the patent system promptly" and thus disclose his or her invention to the public. *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F.3d 1368, 1370 (Fed. Cir. 1998). At the same time, it ensures that a patentee cannot extend its commercial monopo-

[3] Hospira's briefing to this Court also raised other reasons why MedCo cannot prevail here, including the fact that—as the district court found—Hospira's generic bivalirudin will not infringe. The panel did not reach any of these arguments.

ly for more than the prescribed term by delaying filing for a patent. *See, e.g.*, *D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1148 (Fed. Cir. 1983).

Accordingly, what triggers the bar is commercial exploitation of the invention. As this Court has held, the bar "preclude[s] attempts by the inventor or his assignee to profit from commercial use of an invention for more than a year before an application for patent is filed." *Id.*; *see Plumtree Software, Inc. v. Datamize, Inc.*, 473 F.3d 1152, 1163 (Fed. Cir. 2006) (explaining that "[p]erforming the steps of [a] patented method for a commercial purpose is clearly an attempt to profit from the commercial use of an invention" and thus constitutes a "sale").

Because the on-sale bar encompasses any sort of commercial benefit from the invention, this Court has repeatedly made clear that it is not limited to sales made by the patentee itself. *See, e.g.*, *Special Devices, Inc. v. OEA, Inc.*, 270 F.3d 1353, 1355-56 (Fed. Cir. 2001); *Zacharin v. United States*, 213 F.3d 1366, 1371 (Fed. Cir. 2000); *Evans Cooling Sys., Inc. v. Gen. Motors Corp.*, 125 F.3d 1448, 1453-54 (Fed. Cir. 1997). The bar applies even to sales made by a supplier *to* the patentee. *Special Devices*, 270 F.3d at 1355-56. Sales that enable the patentee to stockpile the invention commercially are of particular concern: in *Special Devices*, the Court rejected a rule that "would allow inventors to stockpile commercial embodiments of their patented invention via commercial contracts with suppliers more than a year before they file their patent application." *Id.* at 1354.

It is also well-settled that the commercial benefit triggering the bar may flow from any commercialization of the invention, regardless of whether an embodiment of the invention is itself sold. Thus, in *D.L. Auld Co.*, the Court held that the sale of *products* made with the patented *process* triggered the bar. *See* 714 F.2d at 1147. It explained: "If Auld produced an emblem by the method of the invention and offered that emblem for sale before the critical date, the right to a patent on the method must be declared forfeited." *Id.*; *see Scaltech, Inc. v. Retec/Tetra, LLC*, 269 F.3d 1321, 1328 (Fed. Cir. 2001) (applying the bar where "the process itself was not offered for sale but only offered to be used by the patentee").

The panel's ruling here reflects an unremarkable application of these principles to conclude that MedCo's transactions with Ben Venue constituted a triggering commercial exploitation of the invention. MedCo paid Ben Venue hundreds of thousands of dollars. In exchange, Ben Venue provided MedCo with batches of Angiomax made using MedCo's revised process. *See supra*. MedCo received a substantial commercial benefit, in the form of tens of millions of dollars' worth of Angiomax that it added to its commercial pipeline. These circumstances are more than sufficient to trigger the on-sale bar. *See Special Devices*, 270 F.3d at 1355-57; *compare Brasseler U.S.A. I, L.P. v. Stryker Sales Corp.*, 182 F.3d 888, 890 (Fed. Cir. 1999) (envisioning that the bar might not apply where an inventor orders

"a few sample products" from a supplier).[4] And they take this case well outside *Trading Technologies Int'l, Inc. v. eSpeed, Inc.*, 595 F.3d 1340 (Fed. Cir. 2010), which held that the inventor's "own secret, personal use" of the claimed invention was not barring.

Although the panel here did hold that the on-sale bar can apply even without title passing, that holding is consistent with this Court's precedent and does not warrant en banc review. The panel did not hold that title (or rights of property) *never* needs to pass for the on-sale bar to apply. It merely held that, in *this* case, passage of title was unnecessary because MedCo had so clearly exploited its invention commercially before the critical date. Op. 4-5. MedCo's petition, for its part, cites no case refusing to apply the on-sale bar simply because title did not pass.

To the contrary, it is well-settled that the on-sale bar can apply even where there is no passage of title to the invention's commercial embodiment. *See D.L. Auld Co.*, 714 F.2d at 1147. Subsequent cases have reaffirmed this principle. *See In re Kollar*, 286 F.3d 1326, 1333 (Fed. Cir. 2002); *Plumtree*, 473 F.3d at 1163 (stressing that "performing the patented method for commercial purposes before

[4] MedCo's argument (Pet. 7) that it received no "commercial benefit" from the transactions before the critical date ignores reality. The product that MedCo received from Ben Venue was not, as MedCo claims (Pet. 7), "an unproven new pharmaceutical product." It was *the same* Angiomax product that MedCo had sold before, just manufactured with a revised process. A19; A16055-56; A16075. MedCo has pointed to no reason why it could not have sold this product to the public before the critical date, other than its own decision not to release it from a quarantine routinely imposed on all batches stockpiled in the company's pipeline.

the critical date constitutes a sale under § 102(b)"). Here, the panel applied *D.L. Auld Co.* and properly concluded that there was "no principled distinction" between that case and "the commercial sale of services that result in [MedCo's] patented product-by-process." Op. 5.[5]

MedCo's unprecedented proposed rule, by contrast, would provide a road map to escape application of the on-sale bar. Even a few months of pharmaceutical exclusivity can be worth hundreds of millions of dollars, creating overwhelming incentives to maximize a patent's duration. Yet under MedCo's proposed new rule, an inventor could readily skirt the on-sale bar by recharacterizing a transaction as a mere "manufacturing contract"—even where, in economic substance, the transaction constitutes a highly lucrative commercial exploitation of the invention.

Finally, MedCo's argument about unfairness to smaller companies (Pet. 10) rings hollow. As an initial matter, the on-sale bar is hardly draconian. It does not prohibit an inventor from having an invention manufactured however it wishes, in-

[5]MedCo's argument based on the Uniform Commercial Code (UCC) amounts to mere grasping at straws. *See* Pet. 5. Prior to its petition, MedCo had never argued that the UCC controls the scope of the on-sale bar enacted by Congress. Nor is it even clear whether (as MedCo now argues) its transactions with Ben Venue encompassed no "sale" within the meaning of the UCC. And the sole case MedCo now cites merely looked to the UCC for guidance in determining whether particular communications rose to the level of a sufficiently firm "offer"—a question not at issue here. *See Group One, Ltd. v. Hallmark Cards, Inc.*, 254 F.3d 1041, 1047 (Fed. Cir. 2001); *see also Scaltech*, 269 F.3d at 1328 (characterizing the UCC as "an important relevant source of general contract law" for purposes of that determination, and citing *Group One*). MedCo's new UCC argument thus provides no reason to grant the petition.

cluding by another entity. Instead, it merely dictates that *if* an inventor chooses to commercially exploit the product in this fashion, then the inventor must file a patent application—even a provisional one—within the one-year grace period permitted by statute. And in all events, the purported unfairness that MedCo identifies has existed at least since the Court's decision in *Special Devices* that an inventor's purchases from a supplier can trigger the on-sale bar. MedCo's quarrel is not with the panel's decision, but with the long line of cases holding that the bar covers ay commercial exploitation of the invention. *See supra* pp. 5-6. MedCo offers no reason why this line of settled precedent should be revisited.

II. REHEARING EN BANC IS UNWARRANTED ON WHETHER THE EXPERIMENTAL USE EXCEPTION APPLIES HERE.

MedCo's petition also fails to demonstrate that rehearing en banc is warranted on whether the experimental-use exception to the on-sale bar applies here. MedCo had the burden of proving that exception. In particular, MedCo had to prove—with evidence—that the transaction constituting the sale was merely "incidental to the primary purpose of experimentation." *Allen Eng'g Corp. v. Bartell Indus., Inc.*, 299 F.3d 1336, 1354 (Fed. Cir. 2002) (quotation marks omitted).

Although MedCo's petition repeatedly asserts that Ben Venue's production of the batches in question was for experimental purposes, it cites *zero* evidence to that effect. For instance, MedCo proclaims that "[t]he primary purpose of the validation batches was to ensure that they would meet FDA requirements and were

[sic] thus experimental in nature." Pet. 9. For support, the petition cites to a later section of the petition—which, in turn, cites nothing from the record, other than the fact that MedCo "follows CGMP requirements" (Pet. 13) and initially asked Ben Venue to manufacture only three batches using its revised process (Pet. 14). *See also* Pet. 13 (statement, without record citation, that the batches "were made to determine whether the inventions worked for their intended purposes").

MedCo's inability to point to evidence of experimental use is unsurprising. MedCo did not even argue experimental use in the district court; instead, the court addressed the experimental-use exception sua sponte. And it is easy to see why MedCo did not argue experimental use: documentary evidence amply established that, at the time of validation, Medco *expected* the process to work as intended, and that the transactions' commercial purpose was far more than "incidental." *Allen Eng'g*, 299 F.3d at 1354; *see* A14884 ("The solution will be filled for commercial use."); A14883 (describing process validation as "confirmational validation" that was "intended to verify and validate the effectiveness of the process optimization steps"); A14884 (describing objectives as "to confirm that all in process specifications and critical parameters are maintained during the manufacturing of the product . . . with the implementation of the process improvements" and "to ensure that the process optimizations indeed minimize the risk of high levels of Asp9 impurity

in the final product"). Indeed, it defies belief to suppose that MedCo put many millions of dollars' worth of its product at risk in an experiment.

MedCo cannot surmount these massive evidentiary hurdles by suggesting that validation batches, such as those made here, are inherently experimental (an argument it never made in the district court). The FDA's regulations do not characterize process validation as "experimental," nor do they otherwise have anything to do with the experimental-use exception. And the FDA's description of validation as "testing" (Pet. 13) does not mean that it is "experimental." *Every* batch of pharmaceutical product must be "tested" before it is made available for sale, *see* 21 C.F.R. § 211.110(a)—but that does not turn it into an experimental batch.[6]

Nor did the panel hold that the manufacture of validation batches can *never* constitute an experimental use for purposes of the on-sale bar. It held only that, on

[6] Even if the validation batches *were* experimental, the experimental-use exception still would not save MedCo from the on-sale bar. Subsequent to the three validation batches, but before the critical date, MedCo purchased eight *more* commercial batches of Angiomax made using the revised process. *See supra*.

While MedCo has claimed that Hospira waived this argument by failing to present it to the district court, MedCo's contention ignores the course of proceedings below. MedCo never argued experimental use below, presumably because it realized that the facts could not support the exception. Although the record contained evidence of all eleven sales, Hospira chose to argue only that the three validation batches were barring because, in the absence of an experimental-use argument, there was no need to argue the other eight. Only in its post-trial decision did the district court raise the issue sua sponte, holding that the three validation batches were experimental. Had MedCo (or the district court) raised the issue earlier, Hospira would have included the other eight batches in its on-sale argument.

the facts of this case, Medco had not shown that its use was experimental. As the panel explained: "This is not a situation in which the inventor was unaware that the invention had been reduced to practice, and was experimenting to determine whether that was the case. The batches sold satisfied the claim limitations, and the inventor was well aware that the batches had levels of Asp^9-bivalirudin well below the claimed levels of 0.6%." Op. 7. In the end, Medco's argument is not really about any question worthy of en banc review; it is just a flawed plea to overturn the application of settled law to the evidence in this case.[7]

Alternatively, MedCo argues that en banc review is necessary because of two statements in the panel's opinion that supposedly conflict with each other. Specifically, MedCo highlights that the panel first stated that "experimental use cannot occur after a reduction to practice," but then stated that "the experimental use defense may be available even if the invention had been reduced to practice if the inventor was unaware that the invention had been reduced to practice (i.e., worked for its intended purpose) and continued to experiment." Pet. 10-11; Op. 7.

[7] Contrary to MedCo's contention, there is no conflict between this conclusion and the Supreme Court's decision well over a century ago in *City of Elizabeth v. American Nicholson Pavement Co.*, 97 U.S. 126 (1878). *City of Elizabeth* articulated the experimental use exception, stating that an inventor's use of the invention "by way of experiment, and in order to bring the invention to perfection," does not implicate the on-sale bar. *Id.* at 134; *see id.* at 137 (no on-sale bar "when the delay is occasioned by a bona fide effort . . . to ascertain whether it will answer the purpose intended"). The panel here did not ignore this rule; instead, it held that as a factual matter, the inventor "was well aware" that the invention would serve its intended purpose and was not experimenting. Op. 7.

MedCo's attempt to manufacture confusion fails. Fairly read, the first statement is a recitation of the general rule, while the second statement is an exception to that rule. And in all events, the supposed conflict to which MedCo points is immaterial to this case. As the panel correctly concluded, "the inventor was well aware" that the revised process served its intended purpose, Op. 7, and MedCo's petition points to no respect in which the inventor "continued to experiment." Thus, even if there were some conflict between the two panel's two statements, MedCo could not establish its defense regardless of which statement prevails.

III. REHEARING EN BANC IS UNWARRANTED ON WHETHER MEDCO'S INVENTION WAS READY FOR PATENTING.

Finally, MedCo urges that rehearing en banc is warranted on whether its claimed invention was ready for patenting. Again, MedCo is incorrect: the panel's decision is fully consistent with *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), and with this Court's own precedent.

Pfaff provides that the on-sale bar applies if, prior to the critical date, the invention is "the subject of a commercial offer for sale" and "is ready for patenting." 525 U.S. at 67. The second of these requirements may be satisfied in "at least two ways: by proof of reduction to practice before the critical date, or by proof that prior to the critical date the inventor had prepared drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Id.* at 67-68.

Here, the panel concluded (as did the district court) that this second requirement had been satisfied because the claimed invention had been reduced to practice. Op. 8. That was the only permissible conclusion: Ben Venue manufactured and delivered batches of Angiomax in exchange for payment by MedCo. As instructed by MedCo, Ben Venue manufactured those batches pursuant to MedCo's revised process. And as the panel observed, those batches "satisfied the claim limitations." Op. 7. Under these circumstances, it defies logic to say that the invention had not been "reduced to practice." The panel's decision succinctly encapsulated this conclusion: "[B]ecause the invention was sold, for the reasons described *supra* Section II(A), we find that the Ben Venue batches reduced the invention to practice." Op. 8.

The panel's holding did not, as MedCo claims, improperly turn *Pfaff*'s two-part test into a one-part test. As an initial matter, in holding that the invention had been reduced to practice, the panel referred back to the portion of its decision in which it had discussed reduction to practice at length. In all events, however, a conclusion that a sale implies reduction to practice in no way undermines *Pfaff*. When a product is merely *offered* for sale—one way to satisfy the first part of the *Pfaff* test—the invention may not yet have been reduced to practice or otherwise become ready for patenting. Accordingly, the second part of *Pfaff*'s test requires a showing that the product *was* ready for patenting. But where a product embodying

the invention not only has been *offered* for sale, but has *actually* been sold and delivered, by definition it has been reduced to practice for purposes of the on-sale bar. *See, e.g.*, *Pfaff*, 525 U.S. at 57 n.2 (explaining that "[a] process is reduced to practice when it is successfully performed," and "[a] composition of matter is reduced to practice when it is completely composed").

Nor is there anything aberrant about the panel's holding that conception of the invention is not required for the invention to have been reduced to practice. Pet. 14. To the contrary, this Court has repeatedly rejected the argument that conception is necessary. *See Abbott Labs. v. Geneva Pharms., Inc.*, 182 F.3d 1315, 1318 (Fed. Cir. 1999) (explaining that "[t]he fact that the claimed material was sold under circumstances in which no question existed that it was useful means that it was reduced to practice"); *Scaltech*, 269 F.3d at 1331 ("[W]here an invention is on sale, conception is not required to establish reduction to practice.").[8] The evidence that MedCo cites—purportedly showing that "the inventors did not appreciate the claimed maximum Asp^9-bivalirudin impurity levels," Pet. 15—is irrelevant.

CONCLUSION

The petition for rehearing en banc should be denied.

[8] MedCo's effort to distinguish *Abbott Laboratories* falls flat. MedCo claims that *Abbott* is off-point because "in that case it was undisputed that the claimed product was commercially sold prior to the critical date." Pet. 14-15. MedCo nowhere explains why the standard that applies to the second part of the *Pfaff* test depends on whether the first part's result is disputed.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on September 8, 2015, I caused the foregoing Opposition to Petition for Rehearing En Banc to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the CM/ECF system, which also caused a copy of the foregoing to be delivered by electronic means to the counsel of record listed below.

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