NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

HELSINN HEALTHCARE S.A.,
Plaintiff-Appellee

v.

TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICAL INDUSTRIES, LTD.,
Defendants-Appellants

2016-1284, 2016-1787

Appeals from the United States District Court for the District of New Jersey in Nos. 3:11-cv-03962-MLC-DEA, 3:11-cv-05579-MLC-DEA, 3:13-cv-05815-MLC-DEA, Judge Mary L. Cooper.

ON PETITION FOR REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, MAYER*, LOURIE, DYK, MOORE, O'MALLEY, REYNA, WALLACH, TARANTO, CHEN, and HUGHES, *Circuit Judges*.**

O'MALLEY, *Circuit Judge*, concurring in the denial of panel rehearing.

PER CURIAM.

O R D E R

Appellee Helsinn Healthcare S.A. filed a petition for rehearing en banc. A response to the petition was invited by the court and filed by appellants Teva Pharmaceuticals USA, Inc. and Teva Pharmaceutical Industries, Ltd. The petition was first referred as a petition for rehearing to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on January 23, 2018.

FOR THE COURT

January 16, 2018 /s/ Peter R. Marksteiner
Date Peter R. Marksteiner
Clerk of Court

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* Circuit Judge Mayer participated only in the decision on the petition for panel rehearing.

** Circuit Judge Stoll did not participate.

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O'MALLEY, *Circuit Judge*, concurring in the denial of panel rehearing.

Helsinn Healthcare S.A. ("Helsinn") petitions the court for rehearing, arguing that the America Invents Act ("AIA") changed the meaning of the on-sale bar under 35 U.S.C. § 102 so as to disturb settled law. Helsinn contends that, under the new standard established by the AIA, the Supply and Purchase Agreement ("Agreement") between Helsinn and MGI Pharma, Inc. ("MGI") does not trigger application of the on-sale bar with respect to U.S. Patent No. 8,598,219. Because I believe the panel decision correctly concluded that the AIA did not change longstanding precedent governing the on-sale bar, and that the Agreement triggers the on-sale bar under that precedent, I agree that panel rehearing is not warranted and therefore concur in the denial of Helsinn's petition.

I write separately because I believe Helsinn's petition and various amici briefs filed in support thereof mischaracterize certain aspects of our panel opinion and advance policy-based criticisms about aspects of the law that this court is not at liberty to change. I believe those points merit response.

I.

I begin with the mischaracterizations. There are three: (1) we concluded that every time the fact of a sale is disclosed to the public, regardless of the nature of the disclosure, the on-sale bar in 35 U.S.C. § 102 will be triggered; (2) our decision implies that all supply-side agreements with third-party distributors will constitute invalidating transactions; and (3) our holding is inconsistent with our *en banc* decision in *Medicines Co. v. Hospira, Inc.*, 827 F.3d 1363 (Fed. Cir. 2016).

First, Helsinn and some amici believe the panel decision concluded that all public sales will trigger the on-sale bar. To support that contention, they place undue weight on a single sentence in the decision that states, "after the AIA, if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale." *Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc.*, 855 F.3d 1356, 1371 (Fed. Cir. 2017).

This sentence does not suggest that publicly announced agreements will always trigger the on-sale bar, nor does it suggest that secret sales never will. As we explained in *Medicines*, the confidential nature of a transaction is just one of several factors for determining whether the transaction rises to the level of a commercial sale such that the on-sale bar would apply. 827 F.3d at

1376 ("Like the absence of title transfer, the confidential nature of the transactions is a factor which weighs against the conclusion that the transactions were commercial in nature."); *Helsinn*, 855 F.3d at 1364 (explaining that, in *Medicines*, "[w]e noted that the absence of the passage of title, the confidential nature of a transaction, and the absence of commercial marketing of the invention all counsel against applying the on-sale bar"). That single factor, however, is not dispositive of the analysis. Indeed, other factors may counsel in favor of finding that a publicly announced transaction is insufficient to trigger the on-sale bar, depending on the circumstances. *See, e.g.*, *Linear Tech. Corp. v. Micrel, Inc.*, 275 F.3d 1040, 1050 (Fed. Cir. 2001) (holding that promotional activity was insufficient to trigger the on-sale bar).

All that our panel opinion held was that the *particular* agreement at issue triggered the on-sale bar, in part—but not exclusively—because it was made public. Helsinn did not just disclose the fact that it had entered into a supply agreement with MGI; a partially-redacted copy of the Agreement itself was included with MGI's Form 8-K filing. *Helsinn*, 855 F.3d at 1361. As the panel noted, the Agreement described the claimed drug formulation "in detail." *Id.* at 1366. The Agreement also "expressly contemplated" the passage of title, and made clear that Helsinn "commercially marketed its invention before the critical date." *Id.* at 1364. All of these factors weighed strongly in favor of finding that the on-sale bar was triggered. *Id.* at 1364–65, 1371.[1]

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[1] Some amici assert that Congress intended to abrogate the standard governing secret sales set forth in *Metallizing Engineering Co. v. Kenyon Bearing & Auto Parts Co.*, 153 F.2d 516 (2d Cir. 1946), and urge us to use this case as a vehicle to acknowledge that fact. *See, e.g.*, Amicus Br. of Naples Roundtable, Inc. 12–16. Because

Second, we did not hold that all supply-side arrangements for future sales will invalidate a later-filed patent. In fact, we expressly held otherwise. *See id.* at 1371 ("We do not find that distribution agreements will always be invalidating under § 102. We simply find that this particular Supply and Purchase Agreement is."); *see also Medicines*, 827 F.3d at 1381 ("We hold . . . that a contract manufacturer's sale to the inventor of manufacturing services where neither title to the embodiments nor the right to market the same passes to the supplier does not constitute an invalidating sale under § 102(b)."). As we explained in *Medicines*, inquiries under § 102's on-sale bar provision are fact-intensive and require the application of a variety of commercial law principles to the allegedly triggering transaction at issue. *See Medicines*, 827 F.3d at 1375–76. While it may be difficult to structure such transactions to avoid the tests set forth in *Medicines* and applied in *Helsinn*, nothing we said in the panel decision would make it impossible to do.

Third, Helsinn and its amici contend that, because we recognized in *Medicines* that our holding there would avoid disadvantaging small companies who do not otherwise have the resources to manufacture products inhouse, it is inconsistent for us not to strive to protect

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the Supreme Court seems to have endorsed the general principles articulated in *Metallizing*, *see Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68 (1998) (quoting *Metallizing* for the proposition that an inventor "shall not exploit his discovery competitively after it is ready for patenting"), it is questionable whether we could depart from them now. As we stated in our panel opinion, moreover, the rule in *Metallizing* simply is not implicated by the facts of this case; the Agreement was not a "secret sale." *See Helsinn*, 855 F.3d at 1368–69 (declining "the invitation by the parties to decide th[e] case more broadly than necessary").

those same companies with respect to their distribution needs. That we refused to find in *Medicines* that the mere stockpiling of a patented invention constitutes an invalidating activity does not lead to the conclusion that distribution agreements, regardless of their commercial character, are also not invalidating. We held in *Medicines* that, where a transaction does not bear the hallmarks of a commercial sale—even where the transaction results in stockpiling of product for future potential sales—the on-sale bar will not be triggered. *See id.* at 1377–79. In other words, we declined to base our decision about the application of the on-sale bar on a policy desire to avoid stockpiling. Where, as here, however, the tests laid out in *Medicines* lead to the conclusion that a transaction carries all indicia of a commercial sale, we cannot shield the transaction from the reach of § 102 merely because that conclusion would make it more difficult for certain companies to establish a distribution chain for those same products. The fact that we did not allow the policy implications of our decision in *Helsinn* to overcome our analysis of the commercial nature of the Agreement is entirely *consistent* with *Medicines*. Congress may decide that certain commercial sales or offers for sale should be exempted from the reach of § 102 for policy reasons; we may not do so, however.

II.

I turn now to the criticisms of our conclusion that the AIA had no impact on the application of the on-sale bar to these facts.

While Helsinn and its supporting amici say much about why they think the law relating to the on-sale bar should be narrower than it traditionally has been, and point to the statements of a few legislators who expressed similar views, they make few legal arguments to support the conclusion that Congress actually changed that aspect of patent law.

Helsinn's only argument directed to the text of the statute is that the new phrase "or otherwise available to the public" appearing in post-AIA § 102(a) modifies the preceding phrase "on sale," and therefore alters the traditional concept of what constitutes a "sale" for purposes of the on-sale bar. Helsinn argues that we should apply the "series-modifier" doctrine, which dictates that, "[w]hen a modifier is set off from a series of antecedents by a comma, the modifier should be read to apply to each of those antecedents." *Finisar Corp. v. DirecTV Grp., Inc.*, 523 F.3d 1323, 1336 (Fed. Cir. 2008) (internal quotation marks omitted). According to Helsinn, "otherwise available to the public" restricts every preceding phrase in § 102(a), including the phrase "on sale," to activities that make the claimed invention fully available to "the public."

There are several problems with Helsinn's argument, however. First, the use of the series-modifier doctrine only applies in limited circumstances not present here.[2] Second, the Supreme Court has explained that terminal

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[2] The series-modifier rule is applicable only when "several words are followed by a clause which is applicable as much to the first and other words as to the last." *Paroline v. United States*, 134 S. Ct. 1710, 1721 (2014) (quoting *Porto Rico Ry., Light & Power Co. v. Mor*, 253 U.S. 345, 348 (1920)); *see also Lockhart v. United States*, 136 S. Ct. 958, 963 (2016) (explaining that the doctrine is most appropriate when it would not "take[] more than a little mental energy to process the individual entries in the list" so as to "carry the modifier across them all"). Here, "otherwise available to the public" is not equally applicable to all preceding phrases because each phrase—i.e., "patented," "printed publication," and "public use"—recites a disclosure that is necessarily public. Helsinn's reading of the statute would therefore create redundancies within § 102(a) itself.

limiting clauses or phrases ordinarily should be read to modify only the noun or phrase that immediately precedes them—known as the "last antecedent" doctrine. *See Barnhart v. Thomas*, 540 U.S. 20, 26 (2003). This is especially true where, as here, the phrase at issue is separated from the preceding phrases with a comma, followed by use of the word "or," implying that what follows the comma is something different from and independent of the preceding concepts. This doctrine implies that "to the public" limits only "otherwise available." In other words, "otherwise available to the public" is a catch-all provision that encompasses means by which the claimed invention can be disclosed to the public that are not otherwise accounted for in § 102(a).

Helsinn's grammatical argument also must compete with numerous other legal arguments that support a contrary conclusion—i.e., that Congress meant to leave the on-sale bar intact:

- Congress chose not to modify the term "on sale," as it had previously appeared in § 102(b), suggesting that Congress intended for that term to take on the meaning that courts had attributed to it for well over a century. "[I]t is a cardinal rule of statutory construction that, when Congress employs a term of art, it presumably knows and adopts the cluster of ideas that were attached to each borrowed word in the body of learning from which it was taken." *FAA v. Cooper*, 566 U.S. 284, 292 (2012) (internal quotation marks omitted); *Bruesewitz v. Wyeth LLC*, 562 U.S. 223, 243 (2011) ("When all (or nearly all) of the relevant judicial decisions have given a term or concept a consistent judicial gloss, we presume Congress intended the term or concept to have that meaning when it incorporated it into a later-enacted statute." (internal quotations marks omitted)).[3]

- Helsinn's reading of post-AIA § 102(a) renders the "on sale" provision superfluous because that reading would equate "on sale" with "public use," which is already provided for in the statute. Such a reading is disfavored. *See Hibbs v. Winn*, 542 U.S. 88, 101 (2004) ("A statute should be construed so that effect is given to all its provisions, so that no part will be inoperative or superfluous." (internal quotation marks omitted)).

- Post-AIA § 102(b)(1) provides a grace period where (in paragraph (A)) a "disclosure" is made by the inventor, or (in paragraph (B)) the subject matter disclosed by a third party had, before such disclosure, been "publicly disclosed" by the inventor. If all prior art events—i.e., all "disclosures"—recited in § 102(a) were already public disclosures, the word "publicly" in § 102(b)(1)(B) would be redundant, and there would be no need for a separate rule for third-party disclosures. This suggests that not all prior art events in § 102(a) are public events. *See United States v. Alaska*, 521 U.S. 1, 59 (1997) ("The Court will avoid an interpretation of a statute that 'renders some words altogether redundant.'" (quoting *Gustafson v. Alloyd Co.*, 513 U.S. 561, 574 (1995)).

As the panel opinion noted, "[i]f Congress intended to work such a sweeping change to our on-sale bar jurisprudence . . . , it would [have done] so by clear language."

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[3] Notably, post-AIA § 102 recites *all* of the key terms that appeared in pre-AIA § 102—i.e., "patented," "described in a printed publication," "in public use," and "on sale"—verbatim, and in the same order.

Helsinn, 855 F.3d at 1371 (quoting *Dir., OWCP v. Perini N. River Assocs.*, 459 U.S. 297, 321 (1983)). It would not have done so in a manner that is at odds with so many principles of statutory interpretation.

Helsinn's legislative history arguments do not fare much better. As we stated in the panel opinion in this case, the legislative statements to which Helsinn cites are at best equivocal. *See id.* at 1368–71.[4] And numerous other aspects of the legislative history indicate both that Congress's primary focus when amending § 102 was on the nature and content of prior art printed publications, not on the on-sale bar, and that Congress several times considered, but rejected, the very changes to the on-sale bar Helsinn urges us to conclude were actually made. *Compare* S. Rep. No. 111-18, at 60 (2009) (Senator Kyl and others urging the Senate to remove from the precursor bill "patent-forfeiture provisions that apply only to non-public prior art"), *with* Comm. on the Judiciary, Markup of H.R. 1249, at 101 (Apr. 14, 2011) (Representative Lofgren offering an amendment to prevent the elimination of "public use" and "on sale" from the definition of prior art, citing "strenuous concerns" about "the deletion of specific categories of prior art with well established

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[4] It is a stretch to characterize floor statements by individual Senators made the day after the bill was passed as legislative "history." If anything is reflective of what Congress intended, beyond the words used in the enacted statute, it would seem that the House Report accompanying the 2007 bill—which reintroduced the "public use" and "on sale" language—would be. That report confirms that the Committee used "the current § 102(b) as the template from which to define the scope of prior art in the Act, primarily because of how the terms 'in public use' and 'on sale' have been interpreted by the courts." H.R. Rep. No. 110-314, at 57 (2007).

meanings”); *see also* Br. Opp’n Reh’g En Banc at 10–12 (describing evolution of bill); *Hamdan v. Rumsfeld*, 548 U.S. 557, 579–80 (2006) (“Congress’ rejection of the very language that would have achieved the result the Government urges here weighs heavily against the Government's interpretation.”).

III.

That leaves us with the policy-based criticisms of the panel opinion. Helsinn and amici criticize the panel decision for failing to properly consider what they characterize as the key policy underlying the on-sale bar—the “policy against removing inventions from the public domain which the public justifiably comes to believe are freely available due to commercialization.” *In re Caveney*, 761 F.2d 671, 676 (Fed. Cir. 1985). They argue that a sale between an inventor and a supplier does not place the invention in the public domain in the first place, and that allowing a patent on the invention after such a sale therefore does not remove the invention from the public domain. Because this is true, they assert, the on-sale bar should not be triggered by distribution agreements.

As an initial matter, this policy goal is not the only one that animates the on-sale bar. Both the Supreme Court and this court have recognized that another concern underlying the on-sale bar—and in fact, the “overriding” concern—is the risk that an inventor will commercially exploit his invention beyond the statutory term. *See Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 64 (1998) (noting that § 102 “serves as a limiting provision” insofar as it “confin[es] the duration of the [patent] monopoly to the statutory term”); *STX, LLC v. Brine, Inc.*, 211 F.3d 588, 590 (Fed. Cir. 2000) (“The overriding concern of the on-sale bar is an inventor’s attempt to commercialize his invention beyond the statutory term.”); *cf. Kendall v. Winsor*, 62 U.S. (21 How.) 322, 328 (1858) (“[T]he inventor who designedly, and with the view of applying it indefinitely and exclusively for his own profit, withholds his invention from the public, comes not within the policy or objects of the Constitution or acts of Congress.").

We have described other policy goals as well, including promoting the early filing of patent applications, for example. *See Medicines*, 827 F.3d at 1372; *see also Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829) (noting that allowing an inventor to "hold back from the knowledge of the public the secrets of his invention" and thereafter file for a patent application "would materially retard the progress of science and the useful arts, and give a premium to those who should be least prompt to communicate their discoveries"). These policy concerns do not always align and may at times lead to a conclusion that is contrary to the conclusion reached by considering *only* whether a sale injects the invention into the public domain.

Whatever the various policy goals behind the on-sale bar might be, the Supreme Court's rigid two-part test articulated in *Pfaff v. Wells Electronics, Inc.*, prevents us from expressly considering and balancing such goals. Prior to *Pfaff*, we applied a "totality of the circumstances" test that took into account the policy goals underlying the on-sale bar. *See, e.g.*, *Evans Cooling Sys., Inc. v. Gen. Motors Corp.*, 125 F.3d 1448, 1451 (Fed. Cir. 1997) ("[T]he totality of the circumstances and the policies underlying the bar must be considered in determining whether a definite offer for sale triggering section 102(b) has been made."), *abrogated by Pfaff*, 525 U.S. 55; *Ferag AG v. Quipp Inc.*, 45 F.3d 1562, 1566 (Fed. Cir. 1995) ("The underlying policies are what drives the section 102(b) analysis."), *abrogated by Pfaff*, 525 U.S. 55; *Medicines*, 827 F.3d at 1372. In rejecting that test, the *Pfaff* Court made clear "that we are not to look to broad policy rationales in assessing whether the on-sale bar applies." *Medicines*, 827 F.3d at 1377; *Pfaff*, 525 U.S. at 65–67 & n.11. Instead, "we are to apply a straightforward two-step process—one which permits an inventor to 'both understand and control the first commercial marketing of his invention.'" *Medicines*, 827 F.3d at 1377 (quoting *Pfaff*, 525 U.S. at 67). And, in doing so, we are to focus on the commercial nature of the transaction at issue. The now-governing test therefore leaves little room for policy-based inquiries. Unless and until the Supreme Court articulates a more flexible test that allows courts to expressly consider the policies that animate the on-sale bar, and to give priority to one of those goals over others, our on-sale bar jurisprudence will not necessarily promote any given policy goal.

It is fair to question whether such distribution agreements *should* fall within the scope of the on-sale bar in light of the policy goals discussed above. Parties enter into distribution agreements for the purpose of making preparations to sell products to the public in the *future*, but these agreements do not themselves effectuate consummated sales to end users. And there is often a need to make distribution agreements public to induce investors to supply funding for product development. But when the activity shifts from pre-commercial to commercial activity, the § 102 calculus shifts as well.

We also must remember that "on sale" in § 102 covers not only consummated sales, but mere offers for sale as well.[5] Thus, an offer for sale between a supplier and

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[5] Our "offer for sale" law is well established, and the Supreme Court has confirmed that "on sale" encompasses mere offers to sell. *See Pfaff*, 525 U.S. at 67 (stating the on-sale bar applies if, among other things, "the product [is] the subject of a commercial offer for sale"); *Helsinn*, 855 F.3d at 1370–71; *see also D.L. Auld Co. v. Chroma Graphics Corp.*, 714 F.2d 1144, 1150 (Fed. Cir. 1983) ("That no sale was actually made to International Crest is irrelevant. An offer to sell is sufficient under the policy animating the statute, which proscribes not a sale,

distributor can trigger the on-sale bar even though the transaction is several steps removed from the consuming public *actually* acquiring the invention. It is difficult to see how Helsinn's theory of § 102, and its belief that the invention must be made available to the public before the on-sale bar is triggered, squares with years of case law regarding the invalidating nature of mere offers for sale. Congress or the Supreme Court could redefine "on sale" to exclude mere offers for sale; again, we cannot.

The on-sale bar's applicability to commercial agreements entered into for the purpose of preparing to make future sales has provoked criticism long before *Helsinn*. *Cf. McCreery Eng'g Co. v. Mass. Fan Co.*, 195 F. 498, 502 (1st Cir. 1912) (noting that "there is reason to doubt whether an offer to deliver an article at a future time is in substance a putting on sale before the time of actual delivery"). Until Congress amends § 102 to exclude such agreements from its scope, or the Supreme Court changes the analysis we are to employ when considering such transactions, these criticisms will continue.

For these reasons, I concur in the denial of panel rehearing.

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but a placing 'on sale.'"); *Dittgen v. Racine Paper Goods Co.*, 181 F. 394, 398 (E.D. Wis. 1910) ("[A] device will be on sale within the meaning of the law, if it is offered for sale, whether any specimen of it is actually sold or not." (internal quotation marks omitted)); *Covert v. Covert*, 106 F. 183, 188 (W.D.N.Y. 1901) ("The offer to sell the wagon jack more than two years before filing application is enough. Actual sale is not necessary."), *aff'd*, 115 F. 493 (2d Cir. 1902).