Nos. 2019-1067, -1102

In the United States Court of Appeals for the Federal Circuit

AMGEN INC., AMGEN MANUFACTURING, LIMITED,

Plaintiffs-Cross-Appellants,

v.

HOSPIRA, INC.,

Defendant-Appellant.

Appeals from the United States District Court
for the District of Delaware, Case No. 1:15-cv-00839-RGA,
The Honorable Richard G. Andrews

RESPONSE TO PETITION FOR REHEARING EN BANC OF PLAINTIFFS-CROSS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING, LIMITED

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Counsel for Plaintiffs-Cross-Appellants Amgen Inc. and Amgen Manufacturing, Limited, certifies as follows:

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   AMGEN INC. and AMGEN MANUFACTURING, LIMITED

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:

   n/a

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

   AMGEN INC.

4. The names of all law firms and the principals or associates that appeared for the party now represented by me in the trial court or are expected to appear in this Court (and who are not already listed on the docket for the current case) are:

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5. The title and number of any case known to counsel to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b).

   None.

6. Statement of related cases. *See* Fed. Cir. R. 47.5(a).

   The following interlocutory appeal from the same civil action in the district court was previously before this Court: *Amgen Inc. v. Hospira, Inc.*, Appeal No. 16-2179, before Judges Dyk, Bryson, and Chen, opinion by Judge Dyk on August 10, 2017 reported at 866 F.3d 1355.

Date: February 27, 2020

/s/ John R. Labbé
John R. Labbé

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INTRODUCTION

After making five batches of its biosimilar EPO drug substance for clinical trials and process validation, Hospira made an additional twenty-one batches for "commercial inventory." Faithfully implementing the express language of the Safe Harbor statute, 35 U.S.C. § 271(e)(1), and consistent with Supreme Court and this Court's precedent, the jury was instructed:

> If you find that an accused activity was reasonably related to the development and submission of information to the FDA for the purpose of obtaining FDA approval, then Hospira has proved its Safe Harbor defense as to that activity. If Hospira has proved that the manufacture of a particular batch was reasonably related to developing and submitting information to the FDA in order to obtain FDA approval, Hospira's additional underlying purposes for the manufacture and use of that batch do not remove that batch from the Safe Harbor defense.

(Panel Op. at 13 & Appx139 (full Safe Harbor instruction).) The jury found that Hospira proved that the Safe Harbor applied to the manufacture of seven of those twenty-one batches, and awarded damages for Hospira's infringing manufacture of the remaining fourteen batches.

The panel decision in this case does not warrant en banc review. Reading the instruction as a whole, including the portion excerpted above, the panel correctly concluded that the Safe Harbor jury instruction was not legal error. The instruction gave Hospira the rightful protection of the Safe Harbor to the extent Hospira proved that the accused act of infringement, here the manufacture of any given

batch of drug substance, was for uses reasonably related to developing information for FDA approval. Hospira's contention that the panel and the district court improperly focused on "underlying purposes" is refuted by the jury instruction itself. (Petition at 8, 9.) The only reference to "underlying purposes" in the instruction told the jury that "underlying purposes for the manufacture and use of [a] batch would *not* remove that batch from the Safe Harbor defense." (Panel Op. at 13 & Appx139 (emphasis added).) This instruction was consistent with the statute and all precedent of this Court and the Supreme Court.

The panel did not announce a special Safe Harbor rule for process patents. Instead, the panel said that the Safe Harbor *would* apply if an "act of manufacture" (that is, an infringing act) "was *for uses* reasonably related to submitting information to the FDA." (Panel Op. at 15 (emphasis added).) This tracks the language of the statute and is consistent with binding precedent.

The panel applied the appropriate standard of appellate review to the district court's denial of JMOL, on an issue on which Hospira bore the burden of proof, and correctly found that substantial evidence supported the jury's decision rejecting the Safe Harbor defense for Hospira's manufacture of certain batches of EPO. In stating the issue of "exceptional" importance for en banc review, Hospira ignores the factual nature of the Safe Harbor defense and the jury's verdict, and improperly reframes the statutory inquiry to read "reasonably related" out of the

inquiry. (Petition at 1.) The panel decision contains an extensive list of the substantial evidence supporting the verdict. (Panel Op. at 17-18.) And as the panel noted, "[t]he fact that the jury found some of the 'commercial inventory' batches nonetheless protected by the Safe Harbor defense supports the conclusion that the jury did not reject the defense simply because Hospira made the batches for commercial inventory." (Panel Op. at 18.) The jury, whose province is to assess credibility and weigh the evidence, was entitled to accept Amgen's evidence that the "uses" that Hospira argued brought its infringing manufacture within the Safe Harbor defense were not reasonably related to seeking FDA approval, but were instead part of routine testing requirements for commercial manufacturing. There was sufficient evidence for the jury to reasonably conclude that these uses were not reasons for Hospira to make the batches, but were instead tests Hospira was required to perform only because it made the batches for commercial inventory.

The panel decision affirming the district court's construction of claim 27 does not read a limitation out of claim 27. Hospira admits, as it must, that claim 27 is an independent claim directed to a method of "preparing a mixture" of isoforms. The panel correctly rejected Hospira's attempt to read into the claim an additional method step of separately isolating the individual isoforms before the mixture is prepared. This interpretation does not read a limitation out of claim 27, nor does it conflict with any binding precedent.

BACKGROUND

Amgen markets EPOGEN® (epoetin alfa), a recombinantly produced version of the hormone erythropoietin (often called "EPO"), which stimulates the production of red blood cells and is used to treat anemia. (Panel Op. at 2.) This case is about Hospira's biosimilar version of EPO, which is currently marketed in the United States under the tradename RETACRIT®.

In 2009-2012, Hospira manufactured five commercial-scale batches of EPO drug substance to validate its commercial manufacturing process and conduct clinical trials. (Appx2312-2313.) Amgen has not sought damages for Hospira's manufacture of those first five batches.

Then, in 2013-2015, Hospira went on to manufacture another twenty-one batches of EPO drug substance for "commercial inventory." (Panel Op. at 4, 17-18; Appx2311; Appx2392-2399.) The additional twenty-one manufacturing runs produced an enormous amount of drug substance, enough to make tens of millions of doses of drug product, worth nearly a billion dollars at Hospira's forecasted prices at the time of infringement. (Appx778(609:3-10).) Amgen only sought damages for Hospira's manufacture of these additional twenty-one batches before patent expiry.

The jury found that Hospira infringed claims 24 and 27 of U.S. Patent No. 5,856,298 ("the '298 patent"). (Appx2146-2172.) Both claims 24 and 27 are

directed to methods of preparing mixtures of EPO isoforms. The panel decision affirmed the district court's judgment with respect to claim 27 without reaching claim 24. (Panel Op. at 12.)

ARGUMENT

I. The panel decision rejecting Hospira's challenge to the Safe Harbor jury instruction does not warrant rehearing en banc

Under the Safe Harbor, "It shall not be an act of infringement to make*, use,* offer to sell or sell . . . a patented invention . . . solely for uses reasonably related to the development and submission of information" to the FDA. 35 U.S.C. § 271(e)(1) (emphasis added). The statute provides immunity for the use of patented inventions "reasonably related to obtaining FDA approval." *Abtox, Inc. v. Exitron Corp.*, 122 F.3d 1019, 1030, *amended on other grounds*, 131 F.3d 1009 (Fed. Cir. 1997).

Here, Hospira's infringing acts were its uses of the methods claimed in the '298 patent to make its drug substance batches. The jury found the Safe Harbor applied to Hospira's manufacture of seven of twenty-one batches and awarded damages to Amgen based on Hospira's uses of the patented methods for making the remaining fourteen batches. (Panel Op. at 4; Appx114.)

A. The panel decision is correct and does not conflict with any binding precedent

In challenging the panel decision on the Safe Harbor jury instruction, Hospira fails to address the specific language of the instruction, why any of that

language was erroneous, or what language Hospira proposed below that would have remedied the error. *Bettcher Indus., Inc. v. Bunzl USA, Inc.*, 661 F.3d 629, 641-42 (Fed. Cir. 2011) (setting forth standard for altering judgment based on purportedly erroneous jury instructions).

The only aspect of the jury instruction that Hospira has challenged on appeal is the last sentence of the last paragraph of the instruction. (Panel Op. at 13 & Appx139.) This sentence was consistent with the statute, caselaw, and the balance of the jury instruction to which Hospira does not object.

The jury instruction properly focused the jury on Hospira's *use* of the patented invention, that is, the manufacture of drug substance, and then asked whether each act of manufacture was *for* uses reasonably related to seeking FDA approval. If so, the Safe Harbor would apply. If not, the Safe Harbor would not apply. (Appx139.)

For example, making batches for commercial inventory and then using the material for routine testing that was required only because the batches had been made would not be protected by the Safe Harbor. *Momenta Pharm., Inc. v. Teva Pharm. USA Inc.*, 809 F.3d 610, 620-21 (Fed. Cir. 2015) (concluding that "routine record retention requirements associated with testing and other aspects of the commercial production process" do not provide Safe Harbor protection). In contrast, making batches *for* testing for FDA approval would be protected.

1. The jury instruction told the jury that "underlying purposes" are *not* controlling

The district court instructed the jury that if it were to "find that an accused activity was reasonably related to the development and submission of information to the FDA for the purpose of obtaining FDA approval, then Hospira has proved its Safe Harbor defense as to that activity." (Panel Op. at 13.) Hospira does not object to this sentence, which tracks the statutory language. (*Id.*)

Hospira only objects to the final sentence of the jury instruction. (*Id.*) But this sentence did *not* tell the jury to focus on "Hospira's underlying purpose for the manufacture of its [EPO] product batches," as Hospira now contends. (Petition at 3, 12.) Rather, this sentence told the jury that "Hospira's additional *underlying purposes* for the manufacture and use of [a] batch do *not* remove that batch from the Safe Harbor defense." (Panel Op. at 13 & Appx139 (emphasis added).) Thus, the only "focus" on underlying purposes in the jury instruction was to tell the jury that underlying purposes were *not* controlling.

2. The jury instruction is consistent with this Court's and the Supreme Court's precedent

In *Abtox*, this Court said that the purpose of manufacture is irrelevant if the act of infringement was for uses reasonably related to obtaining FDA approval: "As long as the activity is reasonably related to obtaining FDA approval, [the defendant's] intent or alternative uses are irrelevant to its qualification to invoke

the section 271(e)(1) shield." *Abtox*, 122 F.3d at 1030. This is exactly how the district court instructed the jury when it told the jury that "underlying purposes" do *not* remove an otherwise infringing act from the Safe Harbor defense. (Panel Op. at 13 & Appx139.)

Nor does the Supreme Court's holding in *Merck* compel a different outcome. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005). The panel cited and quoted *Merck* for the proposition that the Safe Harbor provides broad protection regardless of the "phase of research" or the "particular submission" for which data is developed. (Panel Op. at 14.) But neither *Merck* nor *Abtox* addresses the situation where a biosimilar applicant has manufactured a billion-dollar stockpile of drug substance for "commercial inventory" before patent expiry, and neither case requires that such activities be shielded by the Safe Harbor.

3. The sentence to which Hospira objects was favorable for Hospira

Hospira does not object to the sentence of the Safe Harbor instruction that says "If you find that *an accused activity* was reasonably related" to developing information for FDA approval, the Safe Harbor applies. (Panel Op. at 13 (emphasis added).) The "accused activity" here was Hospira's use of Amgen's patented inventions to manufacture batches of drug substance. If anything, the next sentence to which Hospira objects was *favorable* for Hospira: it gave Hospira a legal hook to argue to the jury that the Safe Harbor could protect the manufacture of batches,

even if they were made for commercial inventory. During trial, Hospira asked the district court to include a sentence similar to the last sentence, saying that it was "supported by the authorities cited [by Hospira]." (Appx10818-10820.)

The message to the jury was clear: *if* Hospira proved that its accused *activities* were reasonably related to seeking FDA approval, Hospira would win on the Safe Harbor, regardless of its underlying *purposes*. The jury demonstrated its understanding of the instruction by finding that seven of the twenty-one batches were protected by the Safe Harbor despite their all having been manufactured for "commercial inventory."

B. The panel did not announce a special rule that would make the Safe Harbor "illusory" for process patents

The panel correctly rejected Hospira's contention that it was error for the jury instruction to faithfully implement the statutory language by specifically referring to the accused acts of infringement, that is, Hospira's acts of manufacture. "The jury instructions properly asked whether each act of manufacture, that is, each accused activity, was for uses reasonably related to submitting information to the FDA." (Panel Op. at 15.) In making this ruling, the panel did not announce a special Safe Harbor rule for process patents.

Neither the district court nor the panel ever ruled that how the batches were used is irrelevant, as Hospira now contends. (Petition at 4.) Rather, the panel expressly said that the Safe Harbor *would* apply if the "act of manufacture" (that is,

the infringing act) "was *for uses* reasonably related to submitting information to the FDA." (Panel Op. at 15 (emphasis added).) The jury heard contested evidence from Hospira and Amgen and found the Safe Harbor applied to the accused manufacture of seven of the twenty-one accused batches, agreeing with Hospira that despite being made for commercial inventory, those seven batches were made for uses reasonably related to developing and submitting information to the FDA for the purpose of obtaining FDA approval.

For this reason, Hospira is wrong to suggest that the panel decision "upends . . . settled precedent by asserting that '[t]he relevant inquiry, therefore, is not *how* Hospira used each batch it manufactured, but whether each act of manufacture was for uses reasonably related to submitting information to the FDA.'" (Petition at 11.) In this sentence, which Hospira takes out of context, the panel only referred to "how" because the panel was addressing Hospira's strained argument in its merits brief that the "jury instructions and verdict form improperly focused the jury on the reasons *why* each batch of EPO was manufactured, not *how* each batch was used." (Panel Op. at 13-14.) The panel rightly rejected this purported distinction, and rather than use "how" *or* "why," the panel stated the issue in the language of the statute: "whether each act of manufacture was for uses reasonably related to submitting information to the FDA." (Panel Op. at 14-15.) As the panel explained in the next sentence, the "jury instructions properly asked

whether each act of manufacture, that is, each accused activity, was for uses reasonably related to submitting information to the FDA." (*Id.* at 15.)

C. Hospira exaggerates the potential implications of the panel decision in the context of BPCIA cases and process patents

The panel decision does not "threaten[] to eviscerate" the Safe Harbor in BPCIA cases or for process patents. (Petition at 15.) This is shown by the jury's finding in Hospira's favor on the manufacture of seven of the twenty-one batches at issue in this case, and the fact that Amgen did not assert infringement against five earlier batches.

The Safe Harbor has never been limited to Hatch-Waxman cases, as the Supreme Court confirmed thirty years ago. *Eli Lilly & Co. v. Medtronic, Inc*., 496 U.S. 661 (1990) (applying the Safe Harbor to medical devices); *see also Abtox*, 122 F.3d at 1029 (applying the Safe Harbor to all classes of medical devices).

In arguing that this case is important for future BPCIA cases, Hospira repeats the same mischaracterization of the panel decision addressed above. Once again, Hospira contends that the panel announced a rule that focuses on "underlying purposes." (Petition at 15-16.) As discussed above, the district court told the jury that "underlying purposes" are not controlling. And the panel did not say that how the batches were used is irrelevant; instead, it considered the evidence about how the batches were used as part of its Safe Harbor analysis. (Panel Op. at 17-18.) The panel said the correct question is "whether each act of manufacture,

that is, each accused activity, was for *uses* reasonably related to submitting information to the FDA." (Panel Op. at 15 (emphasis added).) The panel did not read "uses" out of the statute; instead, it stated the issue using the language of the statute, just as the district court did in its jury instruction.

II. The panel decision that substantial evidence supports the jury's verdict does not warrant rehearing en banc

A. The panel relied on substantial evidence

As the panel noted, "Hospira's arguments regarding the district court's denial of JMOL are also predicated on the jury instructions being erroneous." (Panel Op. at 15.) Because the jury instruction was correct, Hospira cannot prevail on its argument that the district court should have granted JMOL.

In any event, the panel considered the evidence presented at trial and found that substantial evidence supported the jury's verdict rejecting the Safe Harbor defense on fourteen batches, an issue on which Hospira bore the burden of proof. (Panel Op. at 4, 17-18.) This does not present an issue for en banc review.

In addition to the substantial evidence cited by the panel, the jury heard evidence that specifically rebutted Hospira's arguments in its petition. Evidence presented at trial refuted Hospira's argument that all of its batches were related to seeking FDA approval due to a backdrop of "regulatory uncertainty." (Petition at 12.) Hospira's regulatory lead admitted that she did not know why Hospira made its 2015 batches, or why it made as many batches as it did, and she assumed

Hospira's supply team (not the regulatory team) made those decisions. (Appx1084(738:22-740:2).) Because this factual issue was contested, the jury was entitled to credit Amgen's evidence to reasonably conclude that Hospira did not make the asserted batches for uses reasonably related to seeking FDA approval.

In short, there was sufficient evidence for the jury to reasonably conclude that Hospira made all of its accused batches for "commercial inventory," which was at least "probative of whether Hospira's use of Amgen's patented process was reasonably related to seeking FDA approval." (Panel Op. at 17-18.) This evidence permitted the jury to reasonably conclude that Hospira only used or tested the accused batches *because it had already made them*. Hospira did not make the batches in order to put them to regulatory uses or test them. The Safe Harbor defense only applies to Hospira's manufacture of batches using the patented methods if that manufacture was for uses "reasonably related to obtaining FDA approval." *Abtox*, 122 F.3d at 1030. It does *not* apply to "routine record retention requirements associated with testing and other aspects of the commercial production process." *Momenta*, 809 F.3d at 620.

Hospira's argument that the Safe Harbor should cover the manufacture of all batches for which it submitted any data to the FDA cannot be correct. If this were the law, it would effectively extend the Safe Harbor to cover *all* commercial manufacture, so long as some data about each batch was submitted to the FDA.

Hospira's own regulatory expert conceded on cross-examination that "[s]imply submitting data [to the FDA] isn't a justification" for making batches of drug substance. (Appx1428(1098:6-10).) The panel correctly rejected "Hospira's suggestion that simply submitting information about a drug substance lot to the FDA brings the manufacture of that lot within the Safe Harbor." (Panel Op. at 17 n.3.)

B. Hospira ignores the substantial evidence presented at trial

Whether an otherwise infringing activity was for uses "reasonably related" to submitting information to the FDA necessarily presents a fact-dependent inquiry. *Integra Lifesciences I, Ltd. v. Merck KGaA*, 496 F.3d 1334, 1347 (Fed. Cir. 2007) (noting the "fact-dependency of the [Safe Harbor] inquiry"). Hospira seeks to ignore the jury's verdict, instead posing a question of purportedly exceptional importance that merely begs the question of whether substantial evidence supported the verdict. (Petition at 1.) In framing this question, Hospira makes the false factual assumption that its infringing activity was for uses reasonably related to seeking FDA approval.

As discussed above, the district court properly focused the jury on whether Hospira's "accused activit[ies] [were] reasonably related to the development and submission of information to the FDA." (Panel Op. at 13 & Appx139.) Hospira did not object to this aspect of the jury instruction. In its petition, however, Hospira

poses a question that reads "reasonably related" out of the inquiry altogether, and simply assumes that its activities were reasonably related to developing information for submission to the FDA. The jury's findings on the question of fact about whether the Safe Harbor applied to all batches, properly framed in the jury instruction, do not warrant en banc review.

III. The panel decision affirming the district court's claim construction does not warrant rehearing en banc

A. The panel decision does not read a limitation out of claim 27

Claim 27 is an independent method claim directed to preparing a mixture of two or more isoforms. It refers to, but does not depend from, claim 1, which is an independent product claim. (Panel Op. at 6.) Hospira sought to read an additional method step into claim 27 requiring that the isoforms be separately isolated prior to preparing the mixture. But neither claim 27 nor claim 1 includes a method step of isolating isoforms.

Claim 27 is directed to "preparing a mixture," not first isolating isoforms and then mixing them. As the panel found, the specification of the '298 patent teaches that a mixture of isoforms can be prepared without first isolating isoforms. (Panel Op. at 8.) The panel correctly relied on these teachings in the specification to affirm the district court's construction of claim 27 to "not require the individual isoforms of claim 1 to be separately prepared prior to making the mixture." (Panel Op. at 8.) "While the claims of a patent limit the invention, and specifications

cannot be utilized to expand the patent monopoly, it is fundamental that claims are to be construed in the light of the specifications and both are to be read with a view to ascertaining the invention." *United States v. Adams*, 383 U.S. 39, 48-49 (1966) (citations omitted). Accordingly, the panel correctly affirmed the district court's claim construction.[1]

B. The panel decision does not conflict with any binding precedent

Hospira contends that the panel's construction of claim 27 conflicts with three rules of claim construction embodied in seven precedential decisions. (Petition at 1-2, 16-17.) Yet Hospira cited only one of these cases during merits briefing, and then only in passing in its reply brief. (Hospira Reply Br. at 15 (citing *Warner-Jenkinson*).) Nevertheless, the panel's construction does not conflict with anything in any of the cases on which Hospira now relies.

Hospira admits that claim 27 is an independent method claim. (Panel Op. at 6.) None of the cases Hospira now cites addresses the interpretation of an independent claim that merely refers to another claim, much less the interpretation of an independent method claim directed to preparing a mixture of products recited

[1] Amgen proved that Hospira infringed both claims 24 and 27 of the '298 patent. The panel decision only addressed claim 27, which was sufficient to affirm the district court's judgment. (Panel Op. at 12.) If en banc review were granted, the Court should also consider whether affirmance based on claim 24 is warranted.

in an independent product claim. Accordingly, none of those cases controls here, the panel did not ignore binding precedent, and en banc review is not warranted.

CONCLUSION

The petition should be denied.

Date: February 27, 2020

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on this 27th day of February 2020, I caused the foregoing RESPONSE TO PETITION FOR REHEARING EN BANC OF PLAINTIFFS-CROSS-APPELLANTS AMGEN INC. AND AMGEN MANUFACTURING, LIMITED to be electronically filed with the Clerk of the Court for the United States Court of Appeals for the Federal Circuit by using the Court's CM/ECF system.

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Circuit Rule 35(e)(4) because it contains 3,882 words, excluding the parts of the brief exempted by the applicable rules.

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type style requirements of Federal Rule of Appellate Procedure 32(a)(6) because the brief has been prepared in a proportionally spaced typeface using Microsoft Word 2016 with 14-point Times New Roman font.

February 27, 2020

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