

Nos. 2018-2414, 2019-1086

**United States Court of Appeals
for the Federal Circuit**

AMGEN INC.

Plaintiff-Appellant

v.

AMNEAL PHARMACEUTICALS LLC, AMNEAL PHARMACEUTICALS OF NEW
YORK, LLC, PIRAMAL HEALTHCARE UK LIMITED,
Defendants-Appellees,

ZYDUS PHARMACEUTICALS (USA) INC., CADILA HEALTHCARE LTD., dba
Zydus Cadila,
Defendants-Cross-Appellants

Appeal from the United States District Court for the District of Delaware,
Case No. 1:16-cv-00853-MSG

**RESPONSE OF PIRAMAL HEALTHCARE UK LIMITED TO THE
PETITION OF AMGEN INC. FOR REHEARING AND REHEARING EN BANC**

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March 30, 2020

CERTIFICATE OF INTEREST

1. Full name of Party Represented by us:	2. Name of Real Party in interest not identified in response to Question 3:	3. Parent corporations and publicly held companies that own 10% or more of stock in the party:
Piramal Healthcare UK Limited	N/A	Sri Krishna Trust

4. The names of all law firms and the partners and associates that have appeared for the party now represented by us in the agency or are expected to appear for the party in this court are (and who have not or will not enter an appearance in this case):

Phillips Goldman McLaughlin & Hall, PA: John C. Phillips, Jr., David A. Bilson; McAndrews, Held & Malloy, Ltd.: Rajendra A. Chiplunkar.

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 appeals.

Other than the cases already consolidated here for appeal purposes, the following pending case may be directly affected by the Court's decision here: *Amgen Inc. v. Watson Laboratories, Inc.*, No. 2019-1650 (Fed. Cir.), docketed March 14, 2019.

March 30, 2020

/s/ Aaron F. Barkoff
AARON F. BARKOFF

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INTRODUCTION

From the very beginning of this case, Amgen insisted that the amendment adding Markush groups of binders and disintegrants to the claims (the “Markush amendment”) was merely a “clarifying amendment,” and was not made for reasons of patentability. Now, having lost that argument twice (first in the district court, then on appeal), Amgen has finally abandoned it.

Instead, in its petition for rehearing and rehearing en banc, Amgen relies solely on the “tangential relation” (or “tangentiality”) exception to prosecution history estoppel, and argues, *for the first time*, that the “scope of surrender” is limited to non-hardening binders. Amgen argues, for example, that it “did not relinquish all binders as equivalents, just those that lacked a hardening nature.” Pet. at 3.

Until now, Amgen treated the tangentiality exception as an afterthought. As explained in detail below, Amgen’s arguments on the exception were never fully developed—either in the district court or on appeal. Amgen *never argued* that only non-hardening binders were surrendered. Moreover, on appeal, Amgen *never contested or even addressed* the district court’s rationale for its holding: that because the alleged equivalent binder in Piramal’s product, pregelatinized starch, appears in the prior art over which the claims were rejected, the tangentiality

exception does not apply. Accordingly, Amgen waived those arguments, and it is therefore improper to raise them now in a rehearing petition.

Beyond waiver, Amgen fails to meet the high standards for panel rehearing or rehearing en banc. First, with respect to panel rehearing, it is impossible for the panel to have “overlooked or misapprehended” arguments that were never properly presented to it. Second, with respect to rehearing en banc, Amgen’s petition fails to show that the panel decision is inconsistent with precedent or that this case involves a question of “exceptional importance.” Amgen’s petition should therefore be denied.

ARGUMENT

I. Amgen Waived Any Argument Regarding the “Tangential Relation” Exception or “Scope of Surrender”

A. In its appeal briefs, Amgen included only a single paragraph regarding the “tangential relation” exception or “scope of surrender”

Throughout this appeal, Amgen focused its prosecution history estoppel arguments almost exclusively on its contention that the Markush amendment was not made for reasons of patentability and therefore prosecution history estoppel did not arise at all. In fact, all of Amgen’s prosecution history estoppel arguments in its opening brief were presented under a heading entitled, “There was no prosecution history estoppel because the Markush groups were not added for patentability.” *See* ECF 54 at 45-55. The entire brief contained only a *single paragraph* regarding the

tangentiality exception, and even that paragraph appeared under a subheading entitled, “Any presumption regarding patentability is overcome by the record showing that the Markush groups were not the reasons for patentability.” *Id.* at 49.

Piramal quoted that single paragraph, in full, in its response brief, ECF 67 at 57, and it is reproduced again here:

In all events, even if defendants argue that the inclusion of Markush groups was for purposes of patentability (it was not), estoppel still does not bar an equivalents finding because the amendment bears “only a tangential relation, if that, to the equivalent in question.” *Insituform [Techs., Inc. v. Cat Contracting, Inc.]*, 385 F.3d [1360] at 1370 [Fed. Cir. 2004]; *see also Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010). Ignoring the Creekmore example, Defendants argued that the Markush groups were added for patentability because they articulated fewer combinations of binders and disintegrants than the cited art had disclosed. Appx33. But the number of excipient combinations has nothing to do with the shared properties of the Markush groups—namely, as hardening binders and superdisintegrants. Those properties were therefore at most tangential to defendants’ alleged fewer-combinations rationale for the amendment, and so Amgen did not surrender the ability to claim as equivalents other hardening binders or superdisintegrants with substantially similar functions.

ECF 54 at 52. Notwithstanding Amgen’s attempts, in its petition, to recast other portions of its briefs as arguments for a limited “scope of surrender,” the paragraph quoted above is the **only** portion of Amgen’s appeal briefs that included such an argument. Everywhere else, Amgen argued that the Markush amendment was not made for reasons of patentability. *See, e.g.*, ECF 54 at 51.

Amgen's argument in that single paragraph was not even consistent with the law, which requires a comparison of "the rationale underlying the amendment" to "the equivalent in question." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 740 (2002) ("*Festo VIII*"). Instead, Amgen argued that the "properties of the Markush groups" were "tangential to defendants' alleged fewer-combinations rationale for the amendment." This was nonsensical. Amgen did not argue, as it does now, that the rationale for the Markush amendment was to distinguish hardening binders from non-hardening binders (presumably because such an argument would have undermined Amgen's argument that the Markush amendment was unrelated to patentability in the first place), and Amgen's argument did not even mention Piramal's alleged equivalent, pregelatinized starch.

Even more fundamentally, Amgen did not address the district court's holding on tangentiality: that is, pregelatinized starch was disclosed as a binder in the prior art over which the claims had been rejected, and therefore the tangentiality exception does not apply. Appx37 (citing *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010) ("an amendment made to avoid prior art that contains the equivalent in question is not tangential.")). Prior to its petition, Amgen *never* contested this holding.¹

¹ Amgen's tangentiality argument in the district court was similarly fleeting. Amgen did not even cite it on appeal or include it in the Appendix.

Thus, Amgen waived any tangentiality argument. *See SmithKline Beecham Corp. v. Apotex Corp.*, 439 F.3d 1312, 1320 (Fed. Cir. 2006) (undeveloped arguments are waived) (collecting cases). *See also Game & Tech. Co., Ltd. v. Wargaming Grp. Ltd.*, 942 F.3d 1343, 1350 (Fed. Cir. 2019) (“GAT’s opening brief devotes only one paragraph to its substantive argument that the UK service occurred more than a year before Wargaming filed the petition. . . . This level of detail is insufficient to properly preserve GAT’s arguments on appeal.”); *Trading Techs. Int’l, Inc. v. IBG LLC*, 921 F.3d 1378, 1385 (Fed. Cir. 2019) (“In a total of four sentences in its opening brief, TT raises challenges based on a right to a jury under the Seventh Amendment, separation of powers under Article III, the Due Process Clause, and the Taking Clause. Such a conclusory assertion with no analysis is insufficient to preserve the issue for appeal.”).

Indeed, to characterize Amgen’s tangentiality argument in this case as “undeveloped” would be generous—particularly because it was *Amgen’s burden* to show that the tangentiality exception should apply. *Festo VIII*, 535 U.S. at 740 (“[W]e hold here that the patentee should bear the burden of showing that the amendment does not surrender the particular equivalent in question.”). Amgen argues that it was “the court’s responsibility to ‘identify what was not within the scope disclaimed.’” Pet. at 10 (citing *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1355-56 (Fed. Cir. 2019)). But that was not the *court’s* responsibility; it was Amgen’s.

In its response brief, Piramal pointed out that the single paragraph quoted above was the only mention of the tangentiality exception in Amgen's entire opening brief. ECF 67 at 57. In addition, Piramal noted that Amgen had failed to address the district court's rationale on the tangentiality exception. *Id.* at 58. Accordingly, Piramal argued that Amgen had waived any reliance on the tangentiality exception. *Id.* (quoting *SmithKline Beecham*, 439 F.3d at 1319 ("Our law is well established that arguments not raised in the opening brief are waived.")).

Despite this, in its reply brief, Amgen did not even *mention* the tangentiality exception, much less address Piramal's arguments, the district court's reasoning, or the rule stated in *Intervet*. Instead, Amgen argued again—this time *exclusively*—that the Markush amendment was not made for reasons of patentability. ECF 76 at 19-24 (Section B, entitled, "There was no prosecution history estoppel"). This was yet another waiver of the tangentiality exception. *See Cardsoft, LLC v. VeriFone, Inc.*, 807 F.3d 1346, 1353 (Fed. Cir. 2015) ("By failing to respond to VeriFone's argument in the briefing, CardSoft has effectively conceded [non-infringement]"). In this case, the *very first time* Amgen took issue with the district court's reasoning on the tangentiality exception or addressed the rule of *Intervet* was in its petition for rehearing and rehearing en banc. The Court should not permit such tactics.

B. At oral argument, Amgen’s counsel made only throwaway statements about the “tangential relation” exception, without any mention whatsoever of any limited “scope of surrender”

At oral argument, Amgen continued to focus, almost completely, on its contention that the Markush amendment was not made for reasons of patentability.

In Amgen’s opening argument (which went on for nearly 17 minutes), the *only portion* that related to prosecution history estoppel at all was as follows:

All I want to say is that the, uh, the one thing that made a difference, and the one claim, uh, uh element that was, that was, that um, uh made the difference in the allowance, was the narrowing of the range of the active. Uh, if you look at the excipient, uh, elements, they were never changed. All that happened was that the, uh, uh claims 6 and 8, which were the Markush groups, were moved into the independent claim. But there was no, no narrowing in response to the prior art. The only thing that was narrowed was the range of the active, and that’s why the claims were allowed. So we don’t even get to the issue of—there may have been narrowing, but it certainly wasn’t—with respect to the binder Markush group, it was not for the purposes of patentability. *And in any event, it’s, it’s, uh, uh, the narrowing of the binder was tangential, which is similar to the Lilly case.*

Oral Arg. at 15:57-16:52² (emphasis added).

Even more remarkably, in the rebuttal argument, Amgen’s counsel *expressly disclaimed* reliance on the tangentiality exception:

And so there’s, there’s, um, no narrowing due to patentability. And at a minimum, at a minimum, it was tangentially related, uh, to the equivalent, any amendment. *But, we’re not even saying that.* We’re

²Available at <http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2018-2414.MP3>.

saying that, that, uh, this, this was not narrowed for the purposes of patentability, with respect to that particular element.

Oral Arg. at 50:36-50:56 (emphasis added).

Thus, until the rehearing petition, Amgen presented only an undeveloped argument on the tangentiality exception (in a single paragraph in its opening brief), and *no argument* that the “scope of surrender” was limited to non-hardening binders. Amgen therefore waived these arguments, and Amgen’s petition should be denied for this reason alone. *See, e.g., Pentax Corp. v. Robison*, 135 F.3d 760, 762 (Fed. Cir. 1998) (“Just as this court will not address issues raised for the first time on appeal or issues not presented on appeal, we decline to address the government’s new theory raised for the first time in its petition for rehearing.”).

II. Panel Rehearing Is Not Warranted

Panel rehearing is appropriate only when the Court has “overlooked or misapprehended” a point of law or fact. Fed. R. App. P. 40(a)(2) (a rehearing petition must “state with particularity each point of law or fact that the petitioner believes the court has overlooked or misapprehended.”); Fed. Cir. R. 40(a)(4) (requiring a section of the petition setting forth “the points of law or fact overlooked or misapprehended by the panel of the court”); *U.S. v. Mageno*, 786 F.3d 768, 774 (9th Cir. 2015) (“A properly drawn petition for rehearing serves a very limited purpose Our authority under Rule 40, therefore, extends only to

those situations in which we have overlooked or misapprehended a point of law or fact.”) (internal quotation marks omitted).

Obviously, it is impossible for the Court to have “overlooked or misapprehended” arguments that Amgen never presented. *See Easley v. Reuss*, 532 F.3d 592, 593-94 (7th Cir. 2008) (“It goes without saying that the panel cannot have ‘overlooked or misapprehended’ an issue that was not presented to it. Panel rehearing is not a vehicle for presenting new arguments, and, absent extraordinary circumstances, we shall not entertain arguments raised for the first time in a petition for rehearing.”). As shown in Section I, above, Amgen’s arguments regarding the tangentiality exception were undeveloped at best, and Amgen *never* argued that the scope of estoppel was limited to non-hardening binders. *Id.* Panel rehearing is therefore unwarranted here.

Moreover, contrary to Amgen’s suggestion in its petition, it is not necessary to reissue the Court’s opinion to “clarify that the statement ‘Amgen surrendered equivalent but unclaimed binders and disintegrants’ was merely a recitation of the *Festo VIII* presumption and not a broader holding about the scope of surrender.” Pet. at 12 (quoting Slip. Op. 24). First, the context in which the statement appears, including the preceding sentence and the citation to *Warner-Jenkinson*, makes clear that the panel merely affirmed the district court’s decision that prosecution history estoppel arose, and was not a ruling about the scope of estoppel. The panel

addressed the scope of estoppel in the following paragraph of the opinion. Slip. Op. at 24-25. Second, the district court expressly held that the scope of estoppel was limited to pregelatinized starch. *See* Appx37-38. The panel opinion, therefore, did not make a broader ruling.

III. Rehearing En Banc Is Not Warranted

En banc review is discretionary and rare, granted only when necessary to secure or maintain uniformity of the Court's decisions or to address a question of exceptional importance. Fed. R. App. P. 35(a); *Missouri v. Jenkins*, 495 U.S. 33, 46 n.14 (1990). The Court tries to ensure compliance with this high standard by establishing rules stating that a frivolous petition may be subject to sanctions, Fed. Cir. R. 35(a)(2), and requiring a petition for rehearing en banc to include a Statement of Counsel attesting to the appropriateness of en banc review, Fed. Cir. R. 35(b)(2). In this case, Amgen has not come close to meeting the high standard for en banc review.

A. Amgen fails to show any inconsistency between the panel decision and Supreme Court or Federal Circuit precedent

Amgen argues that the panel decision is contrary to the following Supreme Court and Federal Circuit cases: *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722 (2002) ("*Festo VIII*"), *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359 (Fed. Cir. 2003) (en banc) ("*Festo IX*"), *Ajinomoto Co. v. ITC*, 932 F.3d 1342, 1355 (Fed. Cir. 2019), *Eli Lilly & Co. v. Hospira, Inc.*,

933 F.3d 1320, 1331 (Fed. Cir. 2019), and *Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282 (Fed. Cir. 2010). Pet. at 1, 12-14.

First, with respect to *Festo VIII* and *Festo IX*, Amgen argues that the panel did not address the scope of the subject matter surrendered, “and its failure to address the rationale for the amendment left the analysis incomplete.” Pet. at 12. But the panel obviously addressed the scope of the subject matter surrendered when it found, like the district court, that pregelatinized starch was surrendered: “Piramal uses pregelatinized starch as a binder, a use taught by Creekmore and Hsu. ‘An amendment made to avoid prior art that contains the equivalent in question is not tangential.’” Slip. Op. at 24-25 (quoting *Intervet*, 617 F.3d at 1291). Therefore, the panel’s analysis was brief (matching the treatment Amgen gave it), but it was certainly not “incomplete.” No further analysis was required to conclude that Amgen surrendered pregelatinized starch.

In fact, the rule stated in *Intervet* was previously stated by the *entire* Court in *Festo IX*: “Although we cannot anticipate the instances of mere tangentialness that may arise, we can say that an amendment made to avoid prior art that contains the equivalent in question is not tangential; it is central to allowance of the claim.” 344 F.3d at 1369 (en banc). In this regard, it is difficult to imagine how the panel’s holding in this case could have been more consistent with *Festo IX*.

With respect to *Ajinomoto*, *Lilly*, and *Intervet*, none of those cases involved a fact pattern in which the relevant claim amendment was made to avoid prior art that contained the equivalent in question. *See Ajinomoto*, 932 F.3d at 1353-56; *Lilly*, 933 F.3d at 1330-34; *Intervet*, 617 F.3d at 1291-92. Those cases, therefore, are simply inapposite.

Accordingly, the panel's decision in this case is not inconsistent with Supreme Court or Federal Circuit precedent.

B. Amgen fails to show that this case involves “a question of exceptional importance”

Amgen argues that “[t]he panel’s flawed equivalents analysis also has the unsettling risk of creating a categorical rule that conflicts with *Festo VIII* and is particularly harsh when applied to formulation patents like Amgen’s.” Pet. at 14. According to Amgen, “[t]he panel’s decision threatens to resurrect the test rejected in *Festo VIII* and risks turning the presumption [of surrender] into a complete bar [to equivalents] by another name.” *Id.* at 15. More specifically, Amgen argues that unless the Court grants rehearing en banc, “any time an equivalent appears in a cited prior art reference—a regular occurrence for formulation patents and excipients—a narrowing amendment will be assumed to have been made to avoid that equivalent, and the ‘presumption’ becomes ‘a complete bar.’” *Id.*

Amgen’s arguments are hyperbolic, as the facts of this case show. Here, as the district court found, the Markush amendment was made to avoid two prior art

references, Creekmore and Hsu, that disclosed the use of pregelatinized starch as a binder. Appx37³. In other words, the alleged equivalent did not merely “appear in a cited prior art reference”—*its use for the claimed function was taught by the prior art references that the claim amendment overcame*. Accordingly, the result here is not draconian. Amgen is fairly estopped from recapturing an equivalent that it gave up in order to secure allowance of the claims.

In this context, the purpose of the rule stated in *Intervet* and *Festo IX*, and relied on by the district court and the panel in this case, makes perfect sense: it is unnecessary to undertake a complex “tangentiality” analysis in cases where the alleged equivalent is “so central to allowance of the claim.” *Festo IX*, 344 F.3d at 1369. Moreover, when the equivalent is in the prior art cited in a rejection of the claims, the applicant can “reasonably be expected to have described the [alleged] insubstantial substitute in question.” *See Festo VIII*, 535 U.S. at 741. Choosing not to do so, thereby avoiding patent office review of the alleged equivalent, properly leads to surrender. In addition, the *Intervet/Festo IX* rule is consistent with “the principle [(repeatedly applied by this Court)] that the tangential relation criterion for overcoming the *Festo* presumption is very narrow.” *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007). *See also*

³ Again, to the extent Amgen now believes the district court’s analysis was insufficient, Amgen was obligated to raise that issue on appeal. It did not.

Integrated Tech. Corp. v. Rudolph Techs., Inc., 734 F.3d 1352, 1358 (Fed. Cir. 2013).

Finally, as shown by the cases Amgen itself cites, although narrow, the “tangential relation” exception remains viable today. *Ajinomoto*, 932 F.3d at 1355-56; *Lilly*, 933 F.3d at 1334. Further, the *Intervet/Festo IX* rule has no effect whatsoever on the other two exceptions to prosecution history estoppel: “unforeseeability” or “some other reason.” *Festo VIII*, 535 U.S. at 740-41. Therefore, Amgen’s argument that “[t]he panel’s decision threatens to resurrect the test rejected in *Festo VIII* and risks turning the presumption into a complete bar by another name” simply has no merit.

CONCLUSION

For the foregoing reasons, Amgen’s Petition for Rehearing and Rehearing En Banc should be denied.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on March 30, 2020, a true and correct copy of the foregoing was timely filed with the Clerk of Court using the appellate CM/ECF system, which will send notifications to all counsel registered to receive electronic notices.

/s/Aaron F. Barkoff
AARON F. BARKOFF

CERTIFICATE OF COMPLIANCE

This paper complies with the type-volume limitations of Federal Circuit Rules 35(e)(4) and 40(d) because it contains 3,293 words as determined by Microsoft Word.

This paper 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 it has been prepared in 14-point Times New Roman font, a proportionally spaced typeface, using Microsoft Word.

/s/Aaron F. Barkoff
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