2021–1729

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

ASTRAZENECA AB, ASTRAZENECA PHARMACEUTICALS LP,

Plaintiffs-Appellees

v.

MYLAN PHARMACEUTICALS INC., KINDEVA DRUG DELIVERY L.P.,

Defendants-Appellants

Appeal from the United States District Court for the Northern District of West Virginia, Case Nos. 1:18-cv-00193, 1:19-cv-00203, Judge Irene M. Keeley

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NON-CONFIDENTIAL RESPONSE TO ASTRAZENECA'S PETITION FOR PANEL REHEARING AND REHEARING EN BANC

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February 11, 2022

UNITED STATES COURT OF APPEALS
FOR THE FEDERAL CIRCUIT

CERTIFICATE OF INTEREST

Case Number 2021-1729

Short Case Caption AstraZeneca AB v. Mylan Pharmaceuticals Inc.

Filing Party/Entity Mylan Pharmaceuticals Inc.; Kindeva Drug Delivery L.P.

Instructions: Complete each section of the form. In answering items 2 and 3, be specific as to which represented entities the answers apply; lack of specificity may result in non-compliance. **Please enter only one item per box; attach additional pages as needed and check the relevant box**. Counsel must immediately file an amended Certificate of Interest if information changes. Fed. Cir. R. 47.4(b).

I certify the following information and any attached sheets are accurate and complete to the best of my knowledge.

Date: 02/11/2022

Signature: /s/Shannon M. Bloodworth

Name: Shannon M. Bloodworth

1. Represented Entities. Fed. Cir. R. 47.4(a)(1).	**2. Real Party in Interest.** Fed. Cir. R. 47.4(a)(2).	**3. Parent Corporations and Stockholders.** Fed. Cir. R. 47.4(a)(3).
Provide the full names of all entities represented by undersigned counsel in this case.	Provide the full names of all real parties in interest for the entities. Do not list the real parties if they are the same as the entities. ☑ None/Not Applicable	Provide the full names of all parent corporations for the entities and all publicly held companies that own 10% or more stock in the entities. ☐ None/Not Applicable
Mylan Pharmaceuticals Inc.		Mylan Inc.; Viatris Inc.*
Kindeva Drug Delivery L.P.		Kindeva Midco L.P.; Kindeva GP II LLC; 3M Company
		*Mylan Pharmaceuticals Inc. is wholly owned by Mylan Inc. Mylan Inc. is wholly owned by Viatris Inc., a publicly held company
		No publicly held company owns 10% or more of Viatris Inc.'s stock

☐ Additional pages attached

4. Legal Representatives. List all law firms, partners, and associates that (a) appeared for the entities in the originating court or agency or (b) are expected to appear in this court for the entities. Do not include those who have already entered an appearance in this court. Fed. Cir. R. 47.4(a)(4).

☐ None/Not Applicable ☐ Additional pages attached

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6. Organizational Victims and Bankruptcy Cases. Provide any information required under Fed. R. App. P. 26.1(b) (organizational victims in criminal cases) and 26.1(c) (bankruptcy case debtors and trustees). Fed. Cir. R. 47.4(a)(6).

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Confidential Material Omitted

The material omitted on page 7 indicates the concentration of PVP in Appellants' ANDA product.

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TABLE OF ABBREVIATIONS AND CONVENTIONS

AmicusBr.	brief for *Amicus Curiae* Pharmaceutical Research and Manufacturers of America (PhRMA)
ANDA	Abbreviated New Drug Application
AstraZeneca	Appellees AstraZeneca AB and AstraZeneca Pharmaceuticals LP, collectively
Mylan	Appellants Mylan Pharmaceuticals Inc. and Kindeva Drug Delivery L.P., collectively
patents-in-suit	U.S. Patent Nos. 7,759,328; 8,143,239; and 8,575,137
PEG	polyethylene glycol
Pet.	AstraZeneca's combined petition for panel rehearing and rehearing en banc
POSA	person of ordinary skill in the art
PVP	polyvinylpyrrolidone K25
(*xx*:*yy*-*zz*)	column or page *xx*, lines *yy*-*zz*

INTRODUCTION

AstraZeneca's petition rests on a false premise. It asserts that the panel majority "extirpated, root to branch, the settled understanding in this Court's precedent" by deviating from a supposed rule that "basic principles of mathematics" control over all else when construing numerical terms. But no such rule exists. This Court's longstanding precedent has instead consistently and sensibly rooted claim construction in the *intrinsic* record, not extrinsic mathematical concepts. That framework applies to *all* claim terms, whether or not they include numbers, and the majority faithfully adhered to established claim-construction principles in resolving this appeal. AstraZeneca's request for further review is unwarranted and should be denied.

Mylan expedited its response because time is of the essence in this case. Mylan's ANDA product has been tentatively approved by the FDA and will be eligible for final approval upon issuance of the mandate. And the district judge who has handled this case from the beginning is retiring in September and has expressed her desire to conduct any remand proceedings before then.

BACKGROUND

The patents-in-suit share the same specification, and they claim compositions containing two well-known drugs formulated with the same set of excipients. The specification and prosecution history focus on how different concentrations of one excipient, polyvinylpyrrolidone K25 (PVP), affect formulation stability, and the

asserted claims all recite formulations containing a specific amount of PVP described as yielding the "most stable" formulations: "0.001%."

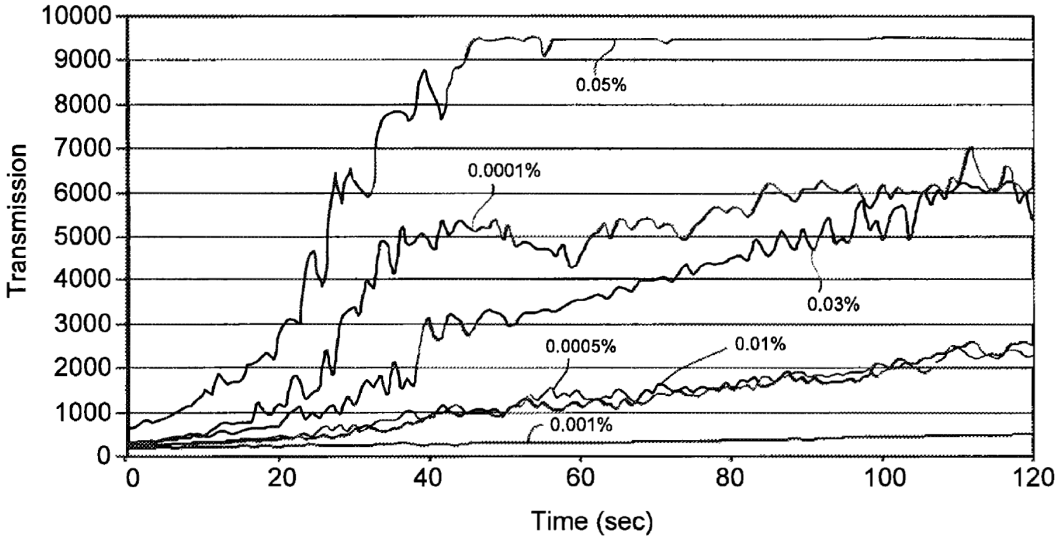
A. The patents-in-suit

AstraZeneca's patents describe formulations "comprising formoterol and budesonide for use in the treatment of respiratory diseases." Appx126(Abstract). Formoterol and budesonide had already been co-formulated for inhalers used to treat asthma and other respiratory conditions. Appx143(1:25-28). The inventors thus focused on combining those drugs with other well-known excipients, stressing that they had derived formulations comprising PVP and polyethylene glycol (PEG) that "exhibit excellent physical suspension stability." Appx143(1:32-35). Every claim at issue recites the same set of ingredients, and all require PVP at a concentration of "0.001% w/w." The following claim is representative:

> 13. A pharmaceutical composition comprising formoterol fumarate dihydrate, budesonide, HFA227, PVP K25, and PEG-1000, wherein
>
> the formoterol fumarate dihydrate is present at a concentration of 0.09 mg/ml,
>
> the budesonide is present at a concentration of 2 mg/ml,
>
> the PVP K25 is present at a concentration of 0.001% w/w, and
>
> the PEG-1000 is present at a concentration of 0.3% w/w.

Appx146; Pet. 3-4.

Throughout their specification, the inventors identified formulation stability as a key feature of the invention and touted the optimal stability achieved specifically with 0.001% PVP. *E.g.*, Appx143(1:21-24, 2:17-21). They also presented data showing superior stability with 0.001% PVP based on testing alternative PVP concentrations across a 500-fold range extending to the fourth decimal place (0.05%, 0.03%, 0.01%, 0.001%, 0.0005%, and 0.0001% PVP) in otherwise identical formulations. For example, Figure 3 shows a test in which differences in PVP concentration of a few thousandths of a percent meaningfully affected formulation stability:



Appx129. The inventors observed that the "bottom line … clearly shows that the formulation containing 0.001% PVP is the most stable." Appx145(6:40-42). Figure 5, reflecting a different test, revealed the same result:

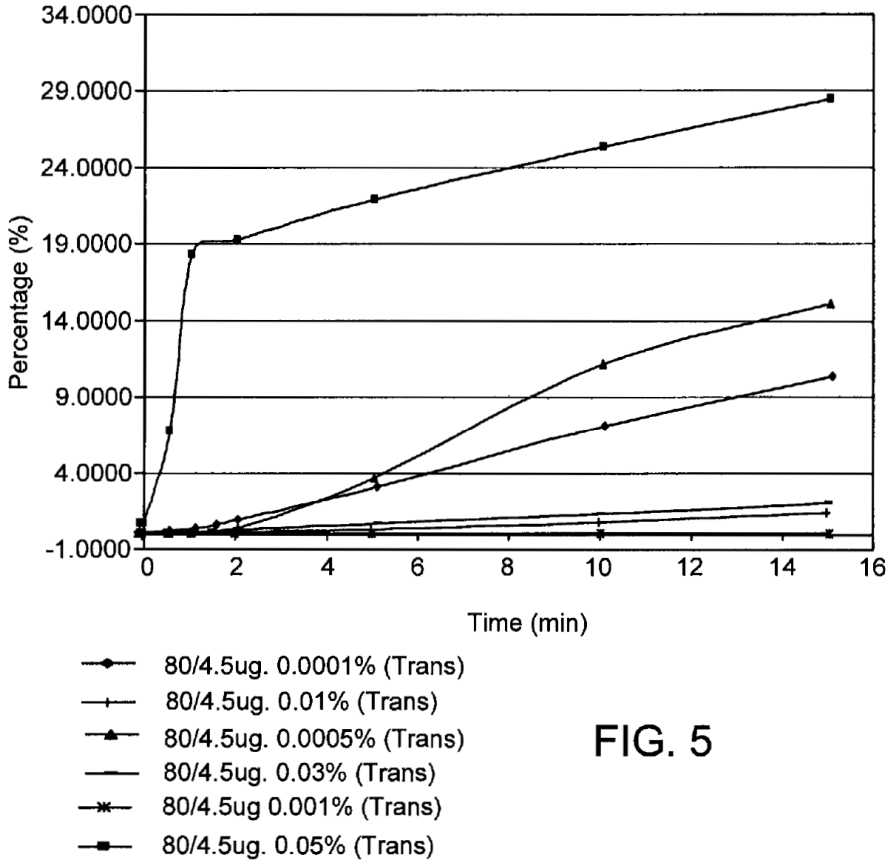


FIG. 5

Appx131. Again, "the suspension with 0.001% w/w PVP [was] the most stable (bottom bold line)." Appx145(6:52-54). In every analysis, the inventors reported that 0.001% PVP yielded the "best" and "most stable" formulations compared to other PVP concentrations. Appx145(6:30-54), Appx128-132(Figs. 2-6). In contrast, varying the PEG concentration made "little difference" in formulation stability. Appx146(7:28-31).

During prosecution, the inventors invoked the superior stability achieved with 0.001% PVP and amended their claims to recite that value specifically. Original independent claim 1 permitted an unbounded amount of PVP, and claim 2 recited PVP concentrations from "about 0.0005 to about 0.05% w/w":

> 1. (Original) A pharmaceutical composition comprising formoterol, budesonide, HFA 227, PVP and PEG.
>
> 2. (Original) A formulation according to claim 1 characterised in that the PVP is present from about 0.0005 to about 0.05% w/w and the PEG is present from about 0.05 to about 0.35% w/w.

Appx15919. The examiner rejected those claims, finding that the components were known and a POSA would have been motivated to determine an optimum amount of PVP within the range in claim 2. Appx16204-16206.

The applicants then amended the claims to recite 0.001% PVP specifically:

> 1. (Currently amended) A pharmaceutical composition comprising formoterol, budesonide, HFA 227, PVP and PEG, wherein PVP is present in an amount of 0.001% w/w.

Appx16213-16214. The applicants told the examiner they had "surprisingly demonstrated that 0.001% w/w PVP gave the best suspension stability when compared to a range of PVP concentrations from 0.0001% to 0.05% w/w." Appx16222 (citing specification). Based on the "surprising discovery that the specified low concentration of PVP" yielded superior stability, the applicants requested withdrawal of the obviousness rejection. Appx16223.

The examiner maintained the rejection. He acknowledged that the cited references did not specifically disclose 0.001% PVP but invited the applicants to "show the criticality of 0.001% w/w PVP versus the invention where PVP concentration is slightly greater or less than 0.001% w/w PVP." Appx16306-16307.

The applicants then proposed claims reciting an array of PVP concentrations tied to specific budesonide concentrations. For example, the applicants argued their data showed "the criticality of 0.001% w/w PVP in a formulation containing 2 mg/ml budesonide" and that such "formulations with higher or lower concentrations of PVP were less able to maintain a good suspension." Appx16326. Other claims recited PVP concentrations such as "0.001% w/w to 0.01% w/w"; "0.0001% to 0.001% w/w"; and "0.0001%, 0.0005%, or 0.001% w/w." Appx16319-16321. The applicants contended the prior art did not suggest that PVP concentration would govern formulation stability, and they reiterated that "the best results overall were obtained using 0.001% PVP." Appx16327-16328.

Another rejection followed, the Examiner noting that the new claims were "much broader than what are being interpreted as unexpected results." Appx16447-16448. The applicants reverted to claiming 0.001% PVP alone. Appx16455-16457. The examiner then allowed the claims, explaining that the specification's data "for the stability of the instant composition" overcame obviousness concerns and noting that the "claimed invention is specific to chemical components and the amounts thereof." Appx16478-16479.

B. Procedural history

AstraZeneca accused Mylan of infringing the asserted claims by filing an ANDA for approval to market a generic version of AstraZeneca's formoterol-

budesonide inhaler. Unlike AstraZeneca's products, which contain 0.001% PVP, Mylan's ANDA products contain percentage PVP. Appx5028.

1. The district court construed "0.001%" PVP to include all concentrations from 0.0005% to 0.0014%

AstraZeneca urged that "0.001%" must be construed to cover all PVP concentrations within ±50%—from 0.0005% to 0.0014%—due to mathematical rounding using one significant digit. Appx7383-7385; Appx7892(27:4-20). Mylan argued that the specification and file history called for a narrower construction by highlighting the criticality of 0.001% PVP and describing different, undesirable results with alternative formulations that would fall within AstraZeneca's broad reading of 0.001%. Appx6804-6806. Mylan thus construed "0.001%" PVP more precisely to mean the recited number rounded to the fourth decimal place, allowing only for minor variations of ±5%. Appx6804; Appx7708.

The district court concluded that the "plain and ordinary meaning" of "0.001%" was a number rounded to one significant digit and thus included all PVP concentrations from 0.0005% to 0.0014%. Appx68, Appx63. Because that range encompassed the ANDA products' percentage PVP concentration, Mylan stipulated to infringement under the district court's construction and appealed. On appeal, a divided panel reversed and remanded.

2. The majority construed the claims more narrowly in view of the intrinsic record

The majority recognized that, as a "standard scientific convention," the number 0.001% written with one significant figure would typically be rounded to include values from 0.0005% to 0.0014%. Op. 7. But the majority rejected AstraZeneca's wholesale reliance on that "ordinary meaning" because it "would necessitate adopting an acontextual construction" and "improperly isolat[e] the numerical term" from its context in the claims, specification, and prosecution history. *Id.*

The majority explained that the specification placed "considerable emphasis" on the superior stability of formulations with 0.001% PVP compared to slightly higher or lower concentrations. Op. 8-12. The reported test results showed that formulations containing 0.001% PVP were "more stable than (and indeed, different from)" those with even "a slight difference" in PVP concentration, including 0.0005% PVP. *Id.* at 11-12. That left "little room for doubt that slight differences in the concentration of PVP—down to the ten-thousandth of a percentage (fourth decimal place)—matter[ed] for stability in the context of this invention." *Id.* The majority also noted that during prosecution, the inventors amended the claims several times to recite 0.001% PVP specifically, repeatedly emphasized that concentration's ability to produce the most stable formulations, and deliberately chose to omit qualifiers like "about" from that term. *Id.* at 12-14.

The majority thus concluded that construing "0.001%" PVP to cover formulations containing 0.0005% to 0.0014% PVP was too broad in the context of this record. Rounding to the fourth decimal place "more accurately reflect[ed] the level of exactness the inventors used" to describe their formulations in the specification and file history, while still accommodating the practical need to provide "some room for experimental error in the PVP concentration." *Id.* at 15. In addition, the majority observed that AstraZeneca's broad construction would cover "two distinct formulations described in the written description"—formulations with 0.001% and 0.0005% PVP—even though the inventors chose to claim only one. *Id.* at 16. The majority therefore construed "0.001%" as that precise number "with only minor variations, i.e., 0.00095% to 0.00104%." *Id.* at 17.

3. The dissent read "0.001%" to have "its significant-figure meaning" and extend from 0.0005% to 0.0014%

Judge Taranto dissented, concluding that 0.001% had an ordinary meaning of "0.0005% to 0.0014%" dictated by "rules of rounding and the single significant figure at the third decimal place." Dissent 9. In his view, nothing in the intrinsic record "displace[d] the ordinary, significant-figure meaning so as to exclude concentrations down to 0.0005%." Dissent 11.

ARGUMENT

I. No precedent requires AstraZeneca's blanket approach to construing numerical terms

AstraZeneca's petition boils down to one repeated complaint: the majority "contravened precedent" that requires defining numerical claim terms according to "the controlling rules of significant digits" unless lexicography or disclaimer applies. Pet. 13.[1] But no such categorical rule of law exists, and AstraZeneca misapprehends the cases it cites for that proposition.

AstraZeneca relies primarily on *U.S. Philips Corp. v. Iwasaki Electric Co.*, 505 F.3d 1371 (Fed. Cir. 2007), and *Viskase Corp. v. American National Can Co.*, 261 F.3d 1316 (Fed. Cir. 2001). Pet. 1, 18. Neither elevates "significant-figure meaning" to the rigid rule of claim construction that AstraZeneca imputes.

[1] *See also* Pet. 1 (contending majority "disregarded entirely, and then violated fragrantly, this Court's longstanding precedent regarding the meaning of numbers in claims"), 2 ("the settled understanding in this Court's precedent … that significant figures define the scope of numbers in claim terms"), 9 (suggesting "binding precedential pronouncements" about "significant-figure meaning"), 11 ("a straightforward case under this Court's significant-digit precedent"), 12 ("*sub silentio* abrogation of this Court's significant-digits precedent"), 14 ("the rules of significant digits firmly ensconced in this Court's claim construction jurisprudence"), 16 ("precedent dictates the limited circumstances that permit displacement of the significant-digit meaning"), 17 ("uprooting this Court's significant figures pronouncements"), 18 ("repeated precedents that significant digits … dictate the precision accorded to numerical claim terms"), 19-20 (majority's approach "traduces this Court's precedent … [that] significant digits govern").

In *Iwasaki*, the Court decided a claim-construction issue that turned not on the meaning of numbers in a claim, but rather *which numbers* the claim recited. The term at issue recited "between 10^{-6} and 10^{-4} μmol/mm^3," and the parties disagreed about whether "10^{-6}" and "10^{-4}" represented the numbers 1×10^{-6} and 1×10^{-4}, as the district court had held, or instead signified "orders of magnitude" on a logarithmic scale. 505 F.3d at 1376. The Court resolved that dispute by consulting the intrinsic record, concluding that context provided by the claims and specification confirmed that the inventors had used "10^{-6}" and "10^{-4}" as shorthand for 1×10^{-6} and 1×10^{-4}. *Id.*

That was the only claim-construction issue decided in *Iwasaki*. AstraZeneca nonetheless presents *Iwasaki* as a "binding precedential pronouncement[ ]" on something else: whether the mathematical principle of significant digits governs the construction of numerical claim terms. Pet. 9 (citing 505 F.3d at 1377-78). The discussion AstraZeneca cites as "precedent" was *dictum*, and in any event does not support AstraZeneca's broad contentions. The Court expressly held that the plaintiff had waived its construction premised on rounding and significant digits, so it affirmed on noninfringement without reaching the issue. *Iwasaki*, 505 F.3d at 1377 & n.2. Moreover, subsequent comments on rounding did not suggest a categorical rule—the Court cautioned that "[i]n *some* scientific contexts, '1' represents a less precise quantity than '1.0,' and '1' *may* encompass values such as 1.1 that '1.0' *may* not." *Id.* (emphases added). The Court then turned to the *claim language* and *specification*

to examine whether 1×10^{-6} and 1×10^{-4} were "intended to be more precise" before ultimately "leav[ing] for another day" whether its construction of "between 1×10^{-6} and 1×10^{-4} μmol/mm^3" was "sufficient to answer the infringement questions presented by a future record." *Id.* at 1377-78. At most, *Iwasaki* discussed rounding to significant digits as a general principle that *may* inform the construction of numerical terms but does not displace the intrinsic record as the primary determinant of claim meaning.

AstraZeneca also misreads *Viskase*, arguing that it shows this Court consistently construes numbers in patent claims "according to the 'standard scientific convention' of significant digits." Pet. 9 (quoting 261 F.3d at 1320). In actuality, the Court *reversed* such a construction in *Viskase*. The claims recited compositions containing a very-low-density polymer with a density "below about 0.91 g/cm^3," and the district court had construed "0.91" to include 0.905 to 0.914 because numbers in that range would round to 0.91. 261 F.3d at 1320. This Court noted the "convention" of rounding but rejected a strict mathematical construction in light of the contrary intrinsic record. *Id.* at 1320-22. Specifically, the Court cited the prosecution history, which showed the inventors had used three decimal places to specify the claimed density threshold, and the specification, which cited and incorporated references to the same effect and further used three decimal places when reporting other density values. *Id.* at 1322. Accordingly, the term "about 0.91" meant "about 0.910" and

could not extend as high as 0.914, even with the inventors' use of "about." *Id.* *Viskase* thus *rejected* mathematical rounding as the controlling basis for construing numerical limitations.

AstraZeneca also asserts that *Viskase* requires nothing short of disclaimer or lexicography to displace the otherwise controlling effect of significant digits when construing numerical terms. Pet. 11-13. But this Court did not conclude that a disclaimer had occurred. It never used the word "disclaimer," did not discuss the standard for finding one, and did not cite any cases on the principle. Instead, it conducted a holistic analysis of the full intrinsic record—claims, specification, and prosecution history—to arrive at the correct construction. *See Viskase*, 261 F.3d at 1322 (explaining that POSAs "reading the … specification and prosecution histories" would have concluded that "0.91" did not include 0.914 given "the specificity in the prosecution" and "the other references" of record).

AstraZeneca's premise thus falls flat. The majority here did not "disregard[ ]" and "violate[ ] flagrantly" established, mandatory precedent dictating the construction of numerical claim terms according to the number of significant digits. Pet. 1. There simply is no rigid special rule for construing numbers in patent claims based wholly on a mathematically derived, "significant-figures meaning." AstraZeneca's cases confirm that construction of numerical limitations follows standard claim-construction principles guided by the intrinsic record for each patent.

II. The majority correctly interpreted "0.001%" PVP in context with the intrinsic record rather than as an abstract mathematical figure

The law governing claim construction makes no exception that subjugates the intrinsic record when numerical limitations are at issue, and the majority correctly rejected AstraZeneca's effort to construe "0.001%" PVP based solely on dissociated mathematical concepts. The majority took the correct approach by applying *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005) (en banc), and rooted its analysis in careful consideration of the intrinsic record. Op. 7-8. The right analysis yielded the right result and foreclosed AstraZeneca's "acontextual" construction. *Id.* at 7.

Instead of accepting AstraZeneca's argument that the "ordinary meaning" of 0.001% was mathematically defined as 0.0005% to 0.0014% absent lexicography or disclaimer, the majority recognized that the ordinary meaning for claim-construction purposes "is not the meaning of the term in the abstract" but rather the "meaning to the ordinary artisan after reading the entire patent." *Id.* at 7 (quoting *Eon Corp. IP Holdings v. Silver Spring Networks*, 815 F.3d 1314, 1320 (Fed. Cir. 2016)) (cleaned up). Proper focus rests on intrinsic evidence when construing numerical terms just like any others. *See, e.g.*, *Takeda Pharm. Co. v. Zydus Pharms. USA, Inc.*, 743 F.3d 1359, 1363-65 (Fed. Cir. 2014); *Viskase*, 261 F.3d at 1322; *Jeneric/Pentron, Inc. v. Dillon Co.*, 205 F.3d 1377, 1381 (Fed. Cir. 2000).

Turning to the specification, the majority noted the inventors' consistent emphasis on formulation stability and the superiority of 0.001% PVP. Op. 8-9 (citing,

e.g., Appx143(2:17-21)). The specification described extensive testing that compared the stability of formulations with various PVP concentrations and showed that 0.001% PVP gave the best results in every analysis. Appx145(6:30-54); Appx128-132(Figs. 2-6); Op. 9-12 (discussing same). Those results also showed that formulations with 0.0005% PVP were among the most *unstable*. For example:

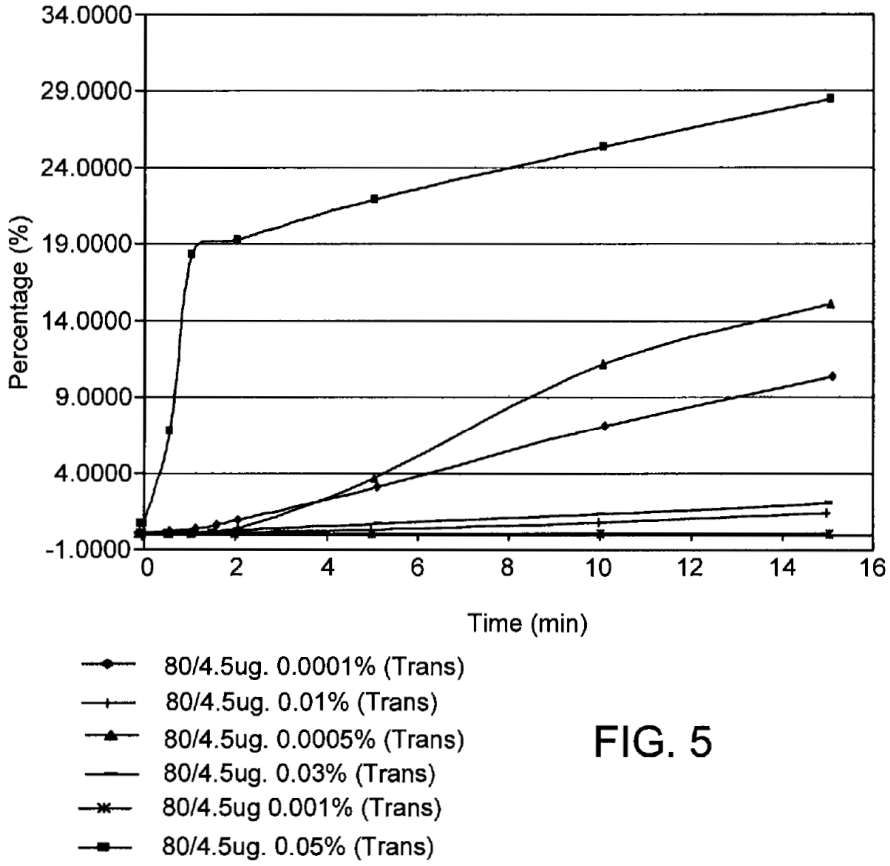


FIG. 5

Appx131; *see also* Appx128-130, Appx132(Figs. 2-4, 6). As the majority observed, "the formulation comprising 0.0005% w/w PVP (second from the top) was one of the least stable formulations tested." Op. 10-11.

The majority concluded that those disclosures made clear that the formulation with 0.001% PVP differed from the formulation with 0.0005% PVP and left "little

room for doubt" that slight differences in PVP concentration "down to the ten-thousandth of a percentage" *matter* in the particular context of this invention. Op. 11-12. While "an acontextual read of the term 0.001% might encompass amounts … between 0.0005% and 0.0014%, the written description suggests that the claimed formulations with 0.001% w/w PVP were intended to be more exact." Op. 12.

The prosecution history reinforced that understanding. The inventors narrowed the claimed PVP concentration from broader ranges to recite 0.001% specifically, "not just once but multiple times, each time emphasizing" that 0.001% PVP was critical to formulation stability. Op. 14. And the prosecution history showed the inventors "knew how to claim ranges or describe numbers with approximation" but "chose to claim exactly 0.001% w/w PVP," further supporting a narrow reading. *Id.* (citing *Takeda*, 743 F.3d at 1365).

Guided by intrinsic evidence, the majority adopted a construction narrower than the 0.0005% to 0.0014% range that AstraZeneca urged based on mathematical rounding alone, interpreting "0.001%" PVP instead to mean "that precise number, with only minor variations, i.e., 0.00095% to 0.00104%." Op. 17. The majority concluded that greater degree of precision "reflect[ed] a margin of error that is best supported by the intrinsic record." Op. 15. In contrast, AstraZeneca's proposed ±50% construction would have covered "two distinct formulations" described in the specification (0.001% and 0.0005% PVP) even though the inventors "chose to claim only

one" during prosecution. Op. 15-16. The majority's construction most closely aligned with the intrinsic evidence and was thus correct under *Phillips*.

Beyond its misreading of *Iwasaki* and *Viskase*, AstraZeneca asserts scattered secondary criticisms of the majority opinion, but none has merit. It contends that the majority "ignor[ed] the ordinary, significant digit meaning of the claim term as written." Pet. 2, *see also* Pet. 9-11. But the majority recognized the "scientific convention" of rounding based on significant digits, Op. 7; it just (correctly) disagreed with AstraZeneca's premise that general principles of significant digits took priority over consistent contrary evidence in the intrinsic record. Nor did the majority ignore significant digits when considering the specification and file history. AmicusBr 7-9. The majority addressed and rejected that argument, explaining that those sources consistently called for greater precision in the context of this invention. Op. 15-16.

AstraZeneca similarly argues that extrinsically derived concepts of plain meaning based on rounding to significant digits presumptively control unless the intrinsic record shows lexicography or disclaimer. Pet. 12-13.[2] But that argument has *Phillips* backwards—AstraZeneca would "limit[ ] the role of the specification in claim construction to serving as a check" on a proposed ordinary meaning derived from extrinsic, rather than intrinsic, sources. *Phillips*, 415 F.3d at 1320.

[2] PhRMA does not go so far, suggesting only that significant figures should control absent "compelling reasons." AmicusBr. 6.

AstraZeneca asserts that the "majority rewrote the claims" without intrinsic support. Pet. 13-15. But the majority explained the intrinsic support at length. By contrast, AstraZeneca lacks intrinsic support for its proposed construction—the specification never mentions rounding, significant digits, or AstraZeneca's proposed range of 0.0005% to 0.0014%. In the end, the panel evaluated claims reciting a specific PVP concentration, "0.001%," and a dispute over how much margin for error that value should allow. Op. 15. Under controlling claim-construction principles, the majority correctly adopted the construction most consistent with the intrinsic record over one premised entirely on extrinsic conventions of mathematical rounding.

AstraZeneca also contends that the majority's construction "limit[ed] the claims to the preferred embodiment, to the exclusion of other inventive embodiments encompassed within the term's ordinary meaning." Pet. 15-18. But the specification described formulations with 0.001% and 0.0005% PVP as *different*, with substantially different properties. And the inventors' prior claims likewise showed that they viewed formulations with 0.001% and 0.0005% PVP as distinct subject matter, Appx16321 (claiming formulations "wherein the concentration of PVP is 0.0001%, 0.0005%, or 0.001% w/w"), before electing to claim 0.001% PVP specifically.

III. AstraZeneca's petition does not warrant further review

AstraZeneca's misapprehension of *Iwasaki* and *Viskase* falls well short of demonstrating any departure from precedent requiring correction "to secure or

maintain uniformity of the court's decisions" or any "question of exceptional importance." Fed. R. App. P. 35(a). The majority addressed the parties' claim-construction dispute, consulted the available intrinsic evidence under the well-settled *Phillips* framework, and reached a construction consistent with those resources and tailored to the specific claims at issue.

AstraZeneca speculates that this case will affect "hundreds of thousands of claims," Pet. 1, 3, 13, 19, but it offers no evidence or analysis to substantiate those pronouncements.[3] Every case has its own claims and corresponding intrinsic record, and instances of a similarly glaring disconnect between a proposed construction based solely on mathematical rounding and countervailing guidance in the patent and file history will be exceedingly rare. AstraZeneca elsewhere acknowledges that these issues are "seldom-litigated," Pet. 2, and that is because most patentees take advantage of readily available tools to avoid the contradiction and ambiguity presented here, such as clearly drafted specifications and additional or alternative use of numerical limitations in range format when a particular scope of coverage is desired, *see* Op. 14.

Nor does describing the issue as a "close call" justify en banc review. *See* Pet. 1. Resolving cases is what panels must do. Some may present difficult choices, and

[3] PhRMA likewise offers only speculation about effects that "could be far-reaching." AmicusBr10.

judges may disagree on the right outcome, but such circumstances do not warrant further review unless the dispute's relevance extends well beyond a particular case. This case turned on unique facts that are highly unlikely to recur. The majority properly applied well-established law and construed the claims based on the intrinsic record, which is how claim construction works for numerical and non-numerical terms alike.

CONCLUSION

The petition should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATION

1. This brief complies with the type-volume limitation of Federal Circuit Rule 35(e)(2). The brief contains 3,897 words, excluding the portions exempted by Federal Rule of Appellate Procedure 32(f) and Federal Circuit Rule 32(b)(2).

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I certify that I have the authority of my co-counsel Shannon M. Bloodworth to file this document with her electronic signature.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

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