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

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CEPHALON, INC., EAGLE PHARMACEUTICALS, INC.,  
TEVA PHARMACEUTICALS INTERNATIONAL GMBH,  
*Plaintiffs-Appellees,*

– v. –

SLAYBACK PHARMA LLC, FRESENIUS KABI USA, LLC,  
*Defendants,*  
APOTEX INC., APOTEX CORP., MYLAN LABORATORIES LIMITED,  
*Defendants-Appellants.*

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*Appeals from the United States District Court for  
the District of Delaware in Nos. 1:17-cv-01154-CFC,  
1:17-cv-01164-CFC, 1:17-cv-01201-CFC and 1:17-cv-01790-CFC,  
Honorable Colm F. Connolly, Judge*

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FILED: SEPTEMBER 13, 2021

**CERTIFICATE OF INTEREST**

Pursuant to FED. CIR. R. 47.4, counsel for Defendants-Appellants Apotex Inc., Apotex Corp. and Mylan Laboratories Limited certifies the following:

<b>1. Full Name of Party Represented by me</b>	<b>2. Name of Real Party in interest (Please only include any real party in interest NOT identified in Question 3) represented by me is:</b>	<b>3. Parent corporations and publicly held companies that own 10% or more of stock in the party</b>
Apotex Inc. and Apotex Corp.	N/A	See below
Mylan Laboratories Limited	N/A	See below

**4. All parent corporations and any publicly held companies that own 10% or more of the stock in the party:**

*Apotex Inc. and Apotex Corp.:* Aposherm, Inc. is the parent company of Apotex Corp. and Apotex Pharmaceuticals, Inc. is the parent company of Apotex Inc.

*Mylan Laboratories Limited* is a subsidiary of Mylan Inc. Mylan Inc. is wholly owned by Viartis Inc., a publicly held company. No publicly-held company owns 10% or more of Viartis Inc.’s stock.

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

*Apotex Inc. and Apotex Corp.*

*Hahn Loeser & Parks:* Steven E. Feldman, Sherry L. Rollo, Daniel R. Cherry, and John D. Cravero

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\* This person is no longer with the firm.

- 6. Organizational Victims and Bankruptcy Cases. Provide any information 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).**

None/Not Applicable

/s/ Steven E. Feldman

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**Apotex Inc. and Apotex Corp.**

/s/ Nicole W. Stafford

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**Mylan Laboratories Limited**

September 13, 2021

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**STATEMENT OF COUNSEL**

Based on my professional judgment, I believe the Panel decision is contrary to the following decisions of the Supreme Court of the United States and precedents of this Court: *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), *Bayer Pharma AG v. Watson Labs.*, 874 F.3d 1316 (Fed. Cir. 2017), *Par Pharm. v. TWi Pharm.*, 773 F.3d 1186 (Fed. Cir. 2014), *In re Mouttet*, 686 F.3d 1322 (Fed. Cir. 2012), *Medichem, S.A. v. Rolabo, S.L.*, 437 F.3d 1157 (Fed. Cir. 2006) and *In re Young*, 927 F.2d 588 (Fed. Cir. 1991).

Based on my professional judgment, I believe this appeal requires an answer to the following precedent-setting question of exceptional importance: whether a judgment of non-obviousness based on a purported lack of motivation to make a minor variation to the prior art and a misapplication of teach-away to overcome express teachings and suggestions in the art to do what is claimed in the absence of any unexpected results or other secondary indicia of non-obviousness violates *KSR* and 35 U.S.C. §103, and whether Fed. Cir. R. 36, is an appropriate vehicle for affirming such a judgment without an opinion.

/s/ Steven E. Feldman  
Attorney of Record for Petitioners

/s/ Nicole W. Stafford  
Attorney of Record for Petitioners

## ARGUMENT

Petitioners respectfully request that this Court reconsider *en banc* the Fed. Cir. R. 36 affirmance of the district court's legally flawed failure to hold the at-issue patents invalid for obviousness. The district court applied an improper teaching away analysis and an overly rigid motivation standard that rejected express teachings and suggestions to do what was claimed, including a reference that the court found made the claimed combination "obvious to try." Appx51-52, Appx57.

Left unclear is the Panel's basis for Rule 36 affirmance, particularly whether the Panel agreed with the totality or affirmed on alternative grounds. Here, for example, the district court found formulating bendamustine with PEG and PG, as required by the claims, "obvious to try" based on the prior art (Olthoff). Appx.57. But the court erased that finding by determining that a subsequent 102(e) reference (Drager) taught away from using PEG and PG, even though the claimed PEG and PG formulations worked exactly how Olthoff said they would in the absence of unexpected results. Appx57-58; Appx68-69.

During oral argument, putting aside the district court's teach-away analysis, the Panel questioned whether it could rationalize the court's decision as a lack of motivation to do what was claimed.



JUDGE TARANTO: Mr. Feldman, this is Judge Taranto. Can I ask -- I will assume for purposes of this question that there may be some question about the applicability of teaching away as a doctrine whose formulations have varied. Some of them have been strict, some of them have not so much been strict.

But why would we not read the District Court's findings to be that when the prior art as to formulation and administration is considered together rather than in isolation, a relevant skilled artisan would not have been motivated to go down the path of the two -- of the claimed paths, so that one did not need to rely on teaching away. Though obviously the District Court did use that terminology.

Hearing Recording at 1:23-2:19.

If teach-away were rejected, then the district court's other factual findings demonstrate no meaningful difference between the claims and what the prior art teaches and suggests, and with no unexpected results. Under §103 and *KSR*, this lack of differences mandates a conclusion of obviousness. *KSR*, 550 U.S. at 405.

If the Panel affirmed on the alternative grounds of lack of motivation, in the absence of teach-away and without any unexpected results, despite express prior art teachings and suggestions that the court found rendered the claimed formulations obvious to try, its holding would constitute a sea change in the law of obviousness (and an improper use of Rule 36). Appellants and any subsequent reviewing court are entitled to know the basis on which the Panel did that.

If the Panel adopted the court's decision in its entirety, particularly its teach-away analysis, that too conflicts with §103, *KSR*, and this Court's own precedent, because in the analysis the district court erroneously selected one

reference over another rather than considering the references together in the ultimate legal obviousness analysis. *Medichem*, 437 F.3d at 1165-66 (“each reference must be considered ‘for its power to suggest solutions to an artisan of ordinary skill . . .’” and that “the prior art must be considered *as a whole* for what it teaches” (citations omitted)); *In re Young*, 927 F.2d at 591 (“Even if tending to discredit Carlisle, Knudsen cannot remove Carlisle from the prior art. Patents are part of the literature of the art and are relevant for all they contain.”).

In short, as here, if the prior art already taught a POSA how to arrive at the claimed invention and there are no unexpected results, a purported teach-away should not render it non-obvious. If the Panel adopted this view of the law, Appellants and any future reviewing court are entitled to know the Panel’s reasoning.

**I. NON-OBVIOUSNESS BASED ON LACK OF MOTIVATION WHERE THE ART TAUGHT OR SUGGESTED WHAT WAS CLAIMED IS FUNDAMENTALLY INCONSISTENT WITH *KSR* AND §103.**

*KSR* rejected this Court’s teaching, suggestion or motivation (“TSM”) obviousness test as overly rigid. *KSR*, 550 U.S. at 419 (“Helpful insights, however, need not become rigid and mandatory formulas; and when it is so applied, the TSM test is incompatible with our precedents.”). Under the TSM test, the motivation prong was the weakest potential route to obviousness, and applied only in the absence of express teachings or suggestions. *Alza Corp. v.*

*Mylan Labs.*, 464 F.3d 1286, 1291 (Fed. Cir. 2006) (“There is flexibility in our obviousness jurisprudence because a motivation may be found *implicitly* in the prior art. We do not have a rigid test that requires an actual teaching to combine before concluding that one of ordinary skill in the art would know to combine references.”).

Yet, under a motivation-only test apparently contemplated by the Panel if the court’s teach-away findings are rejected, a lack of motivation can now trump express teachings and suggestions in the art to do what was claimed. This turns *KSR*’s finding of TSM as overly rigid on its head by replacing TSM with an even *more* rigid M-only test. Under the old TSM test, teaching or a suggestion without any additional motivation could still support a conclusion of obviousness. *Merck & Co. v. Teva Pharms.*, 395 F.3d 1364, 1375 (Fed. Cir. 2005) (“For the *Lunar News* articles to render claims 23 and 37 obvious, the district court need only have found a suggestion or motivation to modify the dosages from those in the articles to those in the claims...The *Lunar News* articles had clearly suggested the [claimed] once weekly dosing.”). Under *KSR* the old TSM test could still support a finding of obviousness, it just was not the *only* way to find obviousness. *KSR*, 550 U.S. at 419 (“There is no necessary inconsistency between the idea underlying the TSM test and the *Graham* analysis.”).

A monolithic, motivation-only test, which permits a perceived lack of motivation to overcome express teachings or suggestions to do what is claimed has undesirable practical implications. Minor modifications to existing formulations or treatment methods, which result in something that is no better than the prior art, become non-obvious. Treating such minor variations as non-obvious is contrary to *KSR*'s directive that "the results of ordinary innovation are not the subject of exclusive rights under the patent laws." *KSR*, 550 U.S. at 427.

This also violates this Court's precedent, that obviousness "does not require that the motivation be the *best* option, only that it be a *suitable* option from which the prior art did not teach away," *Par* 773 F.3d at 1197-98 (court's italics), and "just because better alternatives exist in the prior art does not mean that an inferior combination is inapt for obviousness purposes." *In re Mouttet*, 686 F.3d at 1334. Section 103 says nothing about motivation. It focuses on the *differences* between the prior art and what is claimed. *KSR* 550 U.S. at 406. *Graham v. John Deere Co.* also focuses the obviousness inquiry on the differences and does not include motivation as one of the factual inquiries underpinning obviousness. 383 U.S. 1, 17-18 (1966). While *KSR* discusses identifying reasons to do what was claimed, the ultimate conclusion of whether the claimed invention is obvious, taking into account those reasons, remains a legal question. *KSR*, 550 U.S. at 424-25 ("The consequent legal question, then, is

whether a pedal designer of ordinary skill starting with Asano would have found it obvious to put the sensor on a fixed pivot point.”). Labeling that ultimate obviousness weighing as “motivation,” transforms the analysis from legal to factual, with a concomitant change in the standard of review from *de novo* to clear error.

Rule 36 affirmance was not appropriate in this case if the Panel rejected the court’s teach-away and affirmed on alternative grounds, such as lack of motivation and Appellants should know what standard of review was applied. *Memorylink Corp. v. Motorola, Inc.*, 676 F.3d 1051, 1051-53 (Fed. Cir. 2012) (“While Rule 36 may provide an efficient tool through which to dispose of appeals that merely retread familiar ground, it does not relieve us of our obligation to determine whether that ground needs re-tilling.”) (O’Malley, J. dissenting from denial of rehearing *en banc*).

This echoes the concerns of the dissenters in *Apple, Inc. v. Samsung Elec.*, that this Court was using its “motivation” standard to transform the legal obviousness analysis into a factual one in violation of *KSR*. 839 F.3d 1034, 1075-76 (Fed. Cir. 2016) (*en banc*) (“First, the majority turns the legal question of obviousness into a factual issue for a jury to resolve, both as to the sufficiency of the motivation to combine and the significance to be given to secondary considerations.”) (Dyk, J. dissenting); *see also* Sohn, *Re-Thinking the*

“*Motivation-to-Combine*” in *Patent Law*, 48 AIPLA Q.J. 1, 19 (2020) (“[W]hen motivation-to-combine is treated as a question of fact, it essentially swallows up the entire obviousness analysis, leaving nothing for a court to decide as a question of law.”).

## **II. A RULE 36 AFFIRMANCE WAS INAPPROPRIATE IN VIEW OF THE DISTRICT COURT’S LEGAL ERRORS.**

The district court’s legally erroneous teaching away analysis led to its failure to hold the asserted patents obvious. The district court never identified the teach-away standard it was using, other than to find that stating a preference for A over B teaches away from B. Appx64 (finding teaching away where other methods were preferred over using an antioxidant). That ostensible teach-away served as an absolute bar to obviousness.

But “the teaching away inquiry does not focus on whether a person of ordinary skill in the art would have merely *avored* one disclosed option over another disclosed option.” *Bayer*, 874 F.3d at 1327 (court’s italics). Rather, teach-away focuses on whether the prior art as a whole teaches that the claimed approach would not work for its intended purpose. *Id.* (“unlikely to be productive of the result sought”); *Par*, 773 F.3d at 1198 (same); *In re Mouttet*, 686 F.3d at 1334 (“unlikely to work”).

**A. THE DISTRICT COURT APPLIED A FLAWED TEACH-AWAY ANALYSIS TO FIND THE FORMULATION CLAIMS NON-OBVIOUS.**

The formulation claims recite bendamustine dissolved in various ratios of the solvents propylene glycol (PG) and polyethylene glycol (PEG), including 90:10 PEG:PG. Appx40, Appx49. Besides these solvents, the claims include a stabilizing amount of antioxidant, with one claim specifying monothioglycerol. *Id.* Some claims also recite the bendamustine concentration is 25-50mg/ml or the resulting formation stability. *Id.*

Non-aqueous liquid bendamustine formulations were not new. Olthoff disclosed a non-aqueous liquid bendamustine concentrate of 25-100mg/mL bendamustine dissolved in polyols (non-aqueous solvents that have multiple -OH groups, such as PEG and PG) rather than water. Appx51-52. According to the district court, “Olthoff disclosed that bendamustine has ‘a[n] extraordinarily high chemical stability for the production of injection solutions in’ monovalent alcohols, glycols and polyols.” Appx51. The court also found that “Olthoff specifically proposed dissolving bendamustine in ‘polyols, particularly 1,2-propylene glycol [*i.e.*, PG]’”. Appx51-52. The court found that formulating bendamustine with PEG and PG was “obvious to try” in view of Olthoff. (Appx57). There was no finding of unexpected results. Appx68-69.

Drager, Teva’s patent directed to a different liquid bendamustine formulation (Appx22191-22202), taught that the use of an aprotic solvent (no

-OH groups), such as DMA, reduces the degradation of bendamustine because it reduces the number of -OH groups in the solvent mixture. Appx18399-18401 (437:8-443:12). The at-issue claims do not exclude DMA, but a POSA would have preferred to avoid it because it was known that DMA degrades plastic in injection systems. Appx59; Appx18399 (436:10-15).

However, aprotic solvents are not the only way to reduce the number of -OH groups in the solvent mixture. Adding PEG to PG also reduces this number because PEG has fewer -OH groups than PG. Appx18400 (441:8-13). Appellees' expert testified that a 90:10 PEG:PG formulation would have approximately the same low number of -OH groups as Drager's 66% DMA/34% PG. Appx18668 (1065:1-10). Drager also taught mixing PG and PEG solvents for bendamustine. Appx22198 (3:36-48).

Drager stated it could not reproduce Olthoff's results for a PG-only formulation, but Drager's data corroborates much of Olthoff. Appx25323-25328 at Appx25325, Appx18589-18590 (936:3-937:5). Nevertheless, the court found that Drager taught away from Olthoff. The court explained stating that:

After considering the two references, I find that a POSA would have credited Drager's data and conclusions over those in Olthoff.

Appx60. That was legal error because it was not a matter of picking Drager over Olthoff, but rather of reading them for what they together teach and suggest.

*Bayer*, 874 F.3d at 1328; *Medichem*, 437 F.3d at 1165-66.



The court also legally erred when it erased its finding that Olthoff made bendamustine formulations with PEG and PG “obvious to try” because Drager disclosed adding an aprotic solvent such as DMA. Appx57-61. Drager does not teach or suggest, nor did the court find, that the use of aprotic solvents is the only way of dealing with bendamustine degradation. *Bayer*, 874 F.3d at 1327 (An “inferior combination” may be used to prove obviousness.).

Similarly, the court erroneously found that the prior art taught away from using antioxidants despite finding that a POSA “would have been motivated to curb PEG oxidation: a process in which PEG accelerates the esterification reaction”. Appx63-65. Antioxidants curb oxidation. But the court relied on non-bendamustine prior art that merely *preferred* other methods of preventing oxidation. But even nonpreferred alternatives can support obviousness. *Bayer*, 874 F.3d at 1327; *In re Mouttet*, 686 F.3d at 1334. Additionally, Drager, which does involve bendamustine, discloses *and claims* the use of antioxidants in its polyol containing liquid bendamustine formulations. Appx22200 (7:7); Appx22202 (12:1-2). The court erred by dismissing these aspects of Drager. Appx65.

**B. THE DISTRICT COURT APPLIED A FLAWED TEACH-AWAY ANALYSIS TO FIND THE ADMINISTRATION CLAIMS NON-OBVIOUS.**

There are scant differences between the administration claims and what was already taught in the prior art about how to administer a concentrated

bendamustine formulation. The district court found that a POSA would be motivated to use the formulation, treatment, and dosing schedule limitations. Appx76-78.

The remaining elements—administration time (10 minutes or less), volume (50-100mL), and the resulting concentration (0.05-12.5mg/ml)—were not new either. The court found that the prior art Preiss references taught administering bendamustine in a 3-10 minute bolus to treat cancer patients with “only mild toxicity at high doses”. Appx74.

There is an undisputed correlation between volume, concentration, and time that the district court ignored. Appx18428-18429 (550:21-554:9); Appx18455 (660:14-660:24), Appx18566-18567 (844:10-845:10). Therefore, Preiss’s short infusions necessarily involved low-volume. Regardless, a low-volume of about 50 mL was one of the suitable options (Appx76, Appx22203-22207, Appx24089-24094, Appx18548 (770:22-771:6)) which is all that precedent requires. *Par*, 773 F.3d at 1197-98.

The court’s flawed teach-away standard and overly rigid motivation standard again erased the teachings and suggestions of the prior art. The court found that the Ribomustine Monograph, which specifies a 30-60 minute bendamustine administration in 500mL taught away from fast infusions based on a single statement that “[l]ocal irritations and thrombophlebitis occur

occasionally, especially after intravenous bolus injections.” Appx83; Appx23995. But Appellee’s expert explained, this statement is based on data reported earlier in the Monograph, (Appx18689 (1146:8-1147:6)) for a multi-drug treatment that included vincristine, Appx23953-23954, a drug known to cause thrombophlebitis. Appx18528 (689:22-692:12). Notably, the statement relied on by the court as a teach-away is unrelated to the claimed approach and therefore cannot teach-away. *Par*, 773 F.3d at 1199. If the Monograph were truly a teach-away, there should have been unexpected results, but here, there were none.

Using a known formulation for a known purpose, pursuant to a known dosing schedule, with a protocol taught and suggested by the prior art that obtains an expected result is not patentable. *KSR*, 550 U.S. at 402-03. But the court discounted Preiss’s express teachings, because, in its view, a POSA would not have been sufficiently motivated to use them “to determine a safe infusion time, volume, or concentration.” Appx80. This sets the motivation bar too high. Obviousness is not erased by the need to test to confirm the claimed invention would work as expected. *Hoffman-La Roche Inc. v. Apotex Inc.*, 748 F.3d 1326, 1331 (Fed. Cir. 2014) (“Conclusive proof of efficacy is not necessary to show obviousness. All that is required is a reasonable expectation of success.”). This is particularly true where, as here, the claimed invention worked exactly the way that Preiss said it would.

**C. THE ABSENCE OF ANY SECONDARY CONSIDERATIONS RAISES A RED FLAG.**

Reliance on secondary considerations of non-obviousness cannot remedy the district court's legal errors because the court found none. Appx68-69, Appx88-92. While secondary considerations are not required for validity, their absence is notable in a case where the court finds there is a teach-away. If it were true that the prior art taught away, then the absence of unexpected results cannot be explained. This is a telltale sign that the court's opinion should be given closer inspection and not left untouched by an affirmance without opinion.

At oral argument on questioning from the Panel, Appellees tried to argue that even if the Panel rejected the court's teach-away finding that it could still affirm based on lack of motivation under *Arctic Cat Inc. v. Bombardier Rec. Prods. Inc.*, 876 F.3d 1350 (Fed. Cir. 2017). However, *Arctic Cat* is inapposite because there, no ready solutions to the problems perceived by the prior art existed, which resulted in "surprise" that the claimed invention worked. 876 F.3d at 1364-1365. Here no unexpected results were even argued, much less found. Appx68.

The lack of unexpected results also refutes the supposedly demotivating concerns raised by Appellees' experts that they believed would have prevented a POSA from ever trying the claimed invention, including (1) potential for

precipitation at the claimed 90:10 PEG:PG solvent ratio, (2) supposed concerns over esterification at bendamustine's carboxylic acid end, and (3) alcoholysis at bendamustine's nitrogen mustard end. Hearing Recording at 19:32-21:31.

However as demonstrated below, the evidence at trial showed that these hypothetical concerns manufactured by Appellees' experts, far from paralyzing the POSA from acting on Olthoff's suggestions to try polyols, were unfounded and contradicted by actual prior art data and teachings.

Expert testimony and prior art demonstrated that routine experimentation would have confirmed 90:10 PEG:PG as a suitable choice. Appx18401 (442:25-443:5); Appx18409 (475:8-24); Appx22091; *see also* Appx 19188 (1562:10-17). Obviousness is not avoided by reciting a parameter that would have been determined by routine experimentation. *Merck Sharp & Dohme v. Hospira*, 874 F.3d 724, 730 (Fed. Cir. 2017); *In re Swain*, 156 F.2d 239, 243 (CCPA 1946). However, the court erred by ignoring, without comment, the role routine experimentation would have in determining suitable PEG:PG ratios. The Rule 36 affirmance offers no insight into how the Panel treated this aspect of the court's decision. Appx62-63.

Drager states that esterification, a reaction between the carboxylic acid end of the bendamustine and an -OH group in the polyol, occurs, but Appellees' expert testified that Drager's preferred formulation had approximately the same

number of -OH groups and the same rate of esterification as would be expected to be present in the 90:10 PEG:PG formulation that Appellants asserted would have been obvious. Appx18398 (431:2-13); Appx22199 (5:12-42); Appx18400 (441:8-441:13); Appx18410 (478:3-478:8); Appx18668 (1065:6-1065:10); Appx18669 (1067:18-1068:2). Left unclear by the Rule 36 affirmance is how the Panel treated this unrefuted evidence that undercut one of the court's primary rationales for not using PEG, particularly whether it was weighed as part of the *de novo* review of the court's obviousness conclusion or treated under a clearly erroneous standard.

The same is true with respect to the issue of whether bendamustine's nitrogen mustard group degrades in polyols (alcoholysis). Olthoff tested for it and found it did not occur. Appx22220. Drager's testing confirmed that polyols do not present an alcoholysis problem because, as Appellees' expert conceded, the data in Drager's Table II shows that adding PG to DMA does not significantly increase the impurities that such an alcoholysis reaction would produce. Appx22200; Appx18662 (1038:13-21); Appx18676-18677 (1096:17-1098:10). But because of the Rule 36 affirmance, no one knows how the Panel analyzed this issue on appellate review either.

**III. THE AFFIRMANCE WITHOUT OPINION IN THIS CASE DOES NOT MEET THE REQUIREMENTS OF RULE 36 AND IS UNCONSTITUTIONAL.**

The foregoing demonstrates that a Rule 36 affirmance is not appropriate here. Affirmance without an opinion is authorized only when the district court's decision is "based on findings that are not clearly erroneous" or "entered without an error of law." Fed. Cir. R. 36 (a)(1), (5). The district court's opinion suffers from errors of both fact and law.

Simple fairness, as well as Due Process, requires that the Panel reveal the basis for its affirmance here. Former Chief Judge Markey described Rule 36 as a "form of disposition where it's not necessary to explain, even to the loser, why he lost." *Proceedings of the Seventh Annual Jud. Conf. of the U.S. Ct. of App. For the Fed. Cir.*, 128 F.R.D. 409, 420 (1989). The court's internally inconsistent factual and legal findings and the important legal questions raised by the appeal warrant an explanation.

A party "seeking reversal of a decision is entitled to an explanation of why the arguments on which he relied for his appeal did not prevail." *In re Packard*, 751 F.3d 1307, 1314 (Fed. Cir. 2014) (Plager, concurring). The lack of any explanation impedes review of this Court's decision by a higher authority. *See Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811 (1986) (vacating the Federal Circuit's reversal) ("We therefore lack an adequate explanation of the

basis for the Court of Appeals' judgment: most importantly, we lack the benefit of the Federal Circuit's informed opinion on the complex issue of the degree to which the obviousness determination is one of fact."). The Supreme Court Rules provide that a writ of certiorari is "rarely granted when the asserted error consists of erroneous factual findings or the misapplication of a properly stated rule of law." S. Ct. R. 10. But an Appellant cannot meaningfully seek further appellate review if the rule of law that supports the Rule 36 affirmance is not disclosed.

This case presents the proper vehicle for the *en banc* Court to clarify the role of motivation in the obviousness calculus. Obviousness is "among the most commonly litigated issues in patent infringement cases," and the proper role of motivation in the obviousness determination is a critical issue before the Court, which has engendered much debate. Sohn, 48 AIPLA Q.J. 1 at 2-4. Yet here, the public is left to wonder how the Court's treatment of motivation squares with *KSR*, which rejected the rigid application of the TSM test. Where the law is left unclear, parties face uncertain outcomes and increased costs, as they continue to litigate the metes and bounds of obviousness. Reasoned decisions from the courts of appeal help practitioners, industry, and the public make rational decisions. Accordingly, *en banc* review of the present case serves to benefit patentees and defendants alike. As Justice Cardozo explained, the role of appellate courts is "not simply 'declaring justice between man and man, but... settling the law'".



Crouch, Wrongly Affirmed Without Opinion, 52 Wake Forest L.R., 561 (2017) (quoting Benjamin N. Cardozo, Jurisdiction of the Court of Appeals § 6 (2d ed. 1909)).

**IV. CONCLUSION AND STATEMENT OF RELIEF SOUGHT.**

For the foregoing reasons, Petitioners respectfully request rehearing *en banc*.

Respectfully Submitted,

Date: September 13, 2021

/s/ Steven E. Feldman

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**ADDENDUM**

NOTE: This disposition is nonprecedential.

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

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**CEPHALON, INC., EAGLE PHARMACEUTICALS,  
INC., TEVA PHARMACEUTICALS  
INTERNATIONAL GMBH,**  
*Plaintiffs-Appellees*

v.

**SLAYBACK PHARMA LLC, FRESENIUS KABI USA,  
LLC**  
*Defendants*

**APOTEX INC., APOTEX CORP., MYLAN  
LABORATORIES LIMITED,**  
*Defendants-Appellants*

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2020-2134, 2020-2137

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Appeals from the United States District Court for the District of Delaware in Nos. 1:17-cv-01154-CFC, 1:17-cv-01164-CFC, 1:17-cv-01201-CFC, 1:17-cv-01790-CFC, Judge Colm F. Connolly.

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**JUDGMENT**

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DAVID I. BERL, Williams & Connolly LLP, Washington, DC, argued for all plaintiffs-appellees. Plaintiffs-appellees

Cephalon, Inc., Teva Pharmaceuticals International GmbH also represented by ADAM HARBER, MATTHEW LACHMAN, SHAUN PATRICK MAHAFFY, BEN PICOZZI.

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STEVEN ERIC FELDMAN, Hahn Loeser & Parks, LLP, Chicago, IL, argued for defendants-appellants Apotex Inc., Apotex Corp. Also represented by DANIEL RONALD CHERRY, JOHN CRAVERO, SHERRY LEE ROLLO.

NICOLE W. STAFFORD, Wilson, Sonsini, Goodrich & Rosati, Austin, TX, argued for defendant-appellant Mylan Laboratories Limited. Also represented by ADEN M. ALLEN; DENNIS DONALD GREGORY, New York, NY; DAVID S. STEUER, Palo Alto, CA.

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THIS CAUSE having been heard and considered, it is

ORDERED and ADJUDGED:

PER CURIAM (NEWMAN, CLEVINGER, and TARANTO, *Circuit Judges*).

**AFFIRMED. See Fed. Cir. R. 36.**

ENTERED BY ORDER OF THE COURT

August 13, 2021  
Date

/s/ Peter R. Marksteiner  
Peter R. Marksteiner  
Clerk of Court

**UNITED STATES COURT OF APPEALS  
FOR THE FEDERAL CIRCUIT**

**CERTIFICATE OF COMPLIANCE WITH TYPE-VOLUME LIMITATIONS**

**Case Number:** 2020-2134, 2020-2137

**Short Case Caption:** Cephalon, Inc. v. Slayback Pharma Limited

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Date: 09/13/2021

Signature: /s/Steven E. Feldman

Name: Steven E. Feldman