No. 11-605

IN THE

Supreme Court of the United States

KIMBERLY-CLARK WORLDWIDE, INC. AND KIMBERLY-CLARK GLOBAL SALES, LLC,

Petitioners,

v.

FIRST QUALITY BABY PRODUCTS, LLC AND FIRST QUALITY RETAIL SERVICES, LLC,

Respondents.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR THE PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA AND THE BIOTECHNOLOGY INDUSTRY ORGANIZATION AS AMICI CURIAE SUPPORTING PETITIONERS

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Page(s)

CASES

STATUTES

OTHER AUTHORITIES

INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America ("PhRMA") is a voluntary, nonprofit association representing the nation's leading research-based pharmaceutical and biotechnology companies.[1] PhRMA's member companies are the source of the majority of all new medicines that are discovered and marketed. In the last decade, PhRMA's members have invested over $300 billion to develop new medicines. *See* PhRMA, *Pharmaceutical Industry Profile 2011*, at 42 (2011), *available at* http://www.phrma.org/sites/default/files/159/phrma_profile_2011_final.pdf. In 2010, PhRMA members invested an estimated $49.4 billion in discovering and developing new medicines, an estimated 74% of industry spending in this area. *Id.* at inside front cover. PhRMA members have a strong interest in ensuring that the legal system provides adequate protection for valid patents on medicines discovered and developed as a result of these enormous investments.

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[1] Pursuant to Supreme Court Rule 37.6 *amici curiae* state that no counsel for any party authored this brief in whole or in part and that no entity or person, aside from *amici curiae* and their counsel, made any monetary contribution toward the preparation or submission of this brief. Pursuant to Rule 37.2(a), *amicus* PhRMA notified counsel of record for all parties of its intent to file this brief. Letters from counsel for the parties consenting to the filing of this brief have been lodged with the Clerk.

The Biotechnology Industry Organization ("BIO") is the principal trade association of the biotechnology industry, representing more than 1100 members. BIO members are involved in, *inter alia*, the research and development of innovative healthcare, agricultural, industrial, and environmental biotechnology products. As is the case with PhRMA members, BIO members have a strong interest in ensuring that the legal system provides adequate protection for valid patents discovered and developed as a result of their enormous investments.

Members of the *amici* associations depend on the availability of preliminary injunctions in patent cases because they often face irreparable harm from infringing products in the form of loss of goodwill, loss of market position, and reduced funds available for research and development. The Federal Circuit's decision departs from this Court's precedents concerning the standard for a preliminary injunction, and adds to persistent confusion over the standards that govern motions for a preliminary injunction in patent cases. As Judge O'Malley observed in her opinion dissenting from the denial of rehearing en banc, the Federal Circuit's precedent "virtually mandates denial of all [preliminary injunction] motions." Pet. App. 77a; *see also* Patently-O, *AstraZeneca v. Apotex: Affirmance of a Preliminary Injunction* (Nov. 4, 2010), http://www.patentlyo.com/patent/2010/11/astrazeneca-v-apotex-affirmance-of-a-preliminary-injunction.html (last visited Dec. 11, 2011) (While "it's still possible to obtain a preliminary injunction in a patent case," it is "very difficult.").

As a result of the Federal Circuit's decisions, *amici* may be denied preliminary injunctions in cases in which they are likely to prevail on the merits and will suffer irreparable harm in the absence of such an injunction. *Amici* thus have a strong interest in the question presented in this case.

STATEMENT

1. Petitioner Kimberly-Clark sued Respondent First Quality in September 2009 for infringing certain of its patents on disposable training pants with refastenable side seams. Pet. App. 26a. In March 2010, Kimberly-Clark moved for a preliminary injunction to preclude First Quality from performing manufacturing processes alleged to infringe several of the asserted patents. *Id.* at 26a–27a.

Following expedited discovery and a two-day evidentiary hearing, the district court granted Kimberly-Clark's motion for a preliminary injunction. Pet. App. 27a. The court found that Kimberly-Clark was likely to succeed on the merits of its claims that First Quality's manufacturing processes infringed Kimberly-Clark's patents. *See id.* at 32a–38a. The district court also found that First Quality was unlikely to succeed on its defense that the patents at issue are invalid. *See id.* at 38a–55a. The district court found that the balance of hardships and the public interest also favored Kimberly-Clark. *Id.* at 55a–57a. The district court conditioned the preliminary injunction on Kimberly-Clark's posting a $39 million bond, and stayed the injunction for thirty days to permit First Quality to appeal the ruling. *Id.* at 60a.

2. On appeal, the Federal Circuit vacated the preliminary injunction as to three of the four patents. *See* Pet. App. 1a. The Federal Circuit did not disagree with the district court's determinations that Kimberly-Clark is likely to prevail on the merits, that it will be irreparably harmed by First Quality's infringement, and that the other equitable factors favor issuance of an injunction. Instead, the court of appeals framed the issue as whether First Quality had raised a "substantial question" sufficient to show that the patents are "vulnerable" to invalidity:

> A preliminary injunction should not issue if an alleged infringer raises a substantial question regarding either infringement or validity, *i.e.*, the alleged infringer asserts an infringement or invalidity defense that the patentee has not shown lacks substantial merit. In attempting to prove invalidity when seeking a preliminary injunction, the accused infringer does not face the clear and convincing evidence burden of proof applicable at trial. Instead, vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial.

Id. at 4a–5a (citations omitted, punctuation modified).

Concluding that First Quality had presented invalidity arguments for three of the patents that "[could not] be characterized as substantially meritless," the Federal Circuit vacated the preliminary injunction as to those patents. *See* Pet. App. 9a; 13a; 17a; *see also id.* at 23a–24a (modifying

opinion to delete "cannot be characterized as substantially meritless" and substitute "raises a substantial question of validity and does not lack substantial merit").

3. The Federal Circuit denied Kimberly-Clark's petition for rehearing en banc, with three judges dissenting. *See* Pet. App. 61a–62a. Judge Newman, joined by Judges O'Malley and Reyna, concluded that the panel had "ignored" the correct preliminary injunction standard, instead relying on a formulation of the standard that imposes too great a burden on patentees seeking a preliminary injunction. *Id.* at 65a. Judge Newman concluded that the panel's approach exemplifies the Federal Circuit's fractured preliminary-injunction jurisprudence, which the court has repeatedly sought, but failed, to correct. *See id.* at 66a–67a; 74a–75a.

Judge O'Malley filed a separate dissenting opinion, concluding that the Federal Circuit's preliminary injunction standard is contrary to this Court's precedent. *See* Pet. App. at 76a–77a. Denying a preliminary injunction when a patent is "vulnerable" to invalidity is inconsistent with the "likelihood of success" factor. *Id.* at 77a. Moreover, the Federal Circuit's standard effectively ignores the other preliminary injunction factors, such as irreparable harm. *Id.* Finally, the Federal Circuit's standard gives no deference to district courts. *Id.*

REASONS FOR GRANTING THE WRIT

The Federal Circuit has departed from the established standard for granting preliminary injunctive relief in patent cases. Instead of looking to

whether the patentee demonstrated likelihood of success on the merits, the Federal Circuit shifted the analysis to whether the alleged infringer has proffered a defense that "does not lack substantial merit." This standard prevented the entry of a preliminary injunction even though the patentee demonstrated that it is likely to prevail and the remaining equitable factors weigh in favor of granting an injunction. As a result, patentees, face loss of market position and revenues necessary to continue investments in research and development. Without a reliable and effective injunction remedy, future investment in life-saving medicines, medical devices, and diagnostic tools is jeopardized.

I. The Federal Circuit's Standard Is Contrary to This Court's Precedents

"A plaintiff seeking a preliminary injunction must establish that he is likely to succeed on the merits, that he is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in his favor, and that an injunction is in the public interest." *Winter v. Natural Res. Def. Council*, 555 U.S. 7, 20 (2008). In assessing likelihood of success on the merits, "the burdens at the preliminary injunction stage track the burdens at trial." *Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 429 (2006). These "traditional principles of equity" apply "in patent disputes no less than in other cases." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006).

The Federal Circuit departed from these principles in two respects. *First*, the court of appeals applied a "vulnerability" standard that permits an alleged infringer to defeat a preliminary injunction

even if the patentee is likely to prevail on the merits of an invalidity defense. *Second*, the Federal Circuit effectively relieved the alleged infringer of its statutory burden of showing invalidity by clear and convincing evidence, by requiring the patentee to demonstrate that the alleged infringer's invalidity defenses "lack[] substantial merit." Both aspects of the Federal Circuit's standard are contrary to the preliminary injunction standards established by this Court.[2]

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[2] Even apart from this Court's affirmation in *eBay* that traditional injunction standards apply to patent cases no less than other cases, *see* 547 U.S. at 394, it is far from clear that the Federal Circuit is authorized to adopt special preliminary injunction principles for patent cases. The Federal Circuit decides procedural questions by applying the law of the regional circuit in which the case was brought. Despite this principle, the Federal Circuit has stated that the issuance of a preliminary injunction in a patent case, "although a procedural matter, involves substantive matters unique to patent law and, therefore, is governed by the law of this court." *Mikohn Gaming Corp. v. Acres Gaming, Inc.*, 165 F.3d 891, 894 n.3 (Fed. Cir. 1998). *But see Warner Chilcott Labs. Ir. Ltd. v. Mylan Pharms. Inc.*, No. 2011-1611, 2011 WL 6144301, at *3 (Fed. Cir. Dec. 12, 2011) ("This court applies regional circuit law . . . when reviewing a district court's decision to grant a preliminary injunction.").

A. The Federal Circuit's standard erroneously permits an alleged infringer to defeat a preliminary injunction merely by showing that the patent is "vulnerable" to an invalidity defense.

Under the standard employed by the Federal Circuit, the trial court need not find that it is more likely than not that the accused infringer will be able to prove at trial, by clear and convincing evidence, that the patent is invalid. Instead, the alleged infringer can avoid a preliminary injunction merely by demonstrating that the patent is "vulnerable" to invalidity. *See* Pet. App. 4a–5a (quoting *Altana Pharma AG v. Teva Pharms. USA, Inc.*, 566 F.3d 999, 1006 (Fed. Cir. 2009) ("Vulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial.")). In this case, the Federal Circuit acknowledged that its vulnerability standard would permit an alleged infringer to defeat a preliminary injunction even where the patentee had demonstrated that it was likely to overcome the invalidity defense at trial. In particular, while acknowledging that the district court's factual findings about the Herrmann reference—which led the district court to conclude that First Quality was not likely to succeed in invalidating the '187 patent—"may be true," Pet. App. 9a, the Federal Circuit nevertheless held that the issue was one "that the parties and district court can address during the litigation," *id.* Whether or not First Quality's argument was likely to succeed, its "substantial merit" sufficed, in the Federal Circuit's view, to defeat a preliminary injunction. *Id.* at 9a–10a. The

Federal Circuit's formulation and application of the preliminary injunction standard departs from this Court's decisions.

B. The Federal Circuit's standard disregards the statutory presumption of validity.

By statute, a duly-issued patent is presumed valid. 35 U.S.C. § 282. Consequently, an alleged infringer must present "clear and convincing evidence" at trial to carry its burden on a defense that the patent is invalid. *See Microsoft Corp. v. i4i Ltd. P'ship*, 131 S. Ct. 2238, 2242 (2011) ("We consider whether § 282 requires an invalidity defense to be proved by clear and convincing evidence. We hold that it does."); *id.* at 2248 n.7 ("[T]he language Congress selected reveals its intent not only to specify that the defendant bears the burden of proving invalidity but also that the evidence in support of the defense must be clear and convincing.").

This Court has made clear that "the burdens at the preliminary injunction stage track the burdens at trial." *O Centro*, 546 U.S. at 429. Thus, in order to avoid a preliminary injunction in a patent case on the basis of an invalidity defense, an alleged infringer must show that it is likely to establish at trial, by clear and convincing evidence, that the patent is invalid. The Federal Circuit imposed a substantially lower burden on alleged infringers:

> In attempting to prove invalidity when seeking a preliminary injunction, the accused infringer does not face the clear

> and convincing evidence burden of proof applicable at trial.

Pet. App. 4a.

The Federal Circuit's preliminary injunction standard disregards the presumption of validity by requiring the patentee to demonstrate that the defense lacks substantial merit. *See* Pet. App. 4a ("A preliminary injunction should not issue if . . . the alleged infringer asserts an infringement or invalidity defense that the patentee has not shown lacks substantial merit." (quoting *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010))). This requirement turns the statutory presumption of validity on its head. The fact that an accused infringer must prove invalidity at trial by clear and convincing evidence should *favor* the issuance of preliminary injunctions in cases where invalidity defenses are raised, not counsel against it. The Federal Circuit's departure from this Court's precedents makes it too easy for an alleged infringer to defeat a motion for a preliminary injunction in a patent case.

II. The Federal Circuit's Standard Is Causing Serious Harm, and Should Be Corrected As Soon As Possible

A. Preliminary injunctions are essential remedies in patent cases.

Preliminary injunctions are critical remedies in patent cases, because the marketing of infringing products may result in harm that cannot be remedied by an award of damages. The Federal Circuit has recognized that loss of market position,

market opportunities, revenue, goodwill, and research and development, as well as price erosion, will often support a finding of irreparable harm in a patent case. *See, e.g., Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1361–62 (Fed. Cir. 2008); *see also AstraZeneca*, 633 F.3d at 1062–63 (goodwill and layoffs); *Purdue Pharma L.P. v. Boehringer Ingelheim GmbH*, 237 F.3d 1359, 1368 (Fed. Cir. 2001) (price erosion and market position); *Bio-Tech Gen. Corp. v. Genentech, Inc.*, 80 F.3d 1553, 1566 (Fed. Cir. 1996) (loss of revenue, research and development, and goodwill); *Polymer Techs., Inc. v. Bridwell*, 103 F.3d 970, 975–76 (Fed. Cir. 1996) (loss of market opportunities). For example, when a generic pharmaceutical company launches "at risk" (before the end of litigation) "rapid loss of market share and revenue" occurs "that will be difficult, if not impossible for [the pioneer] to recover." *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 609 F. Supp. 2d 786, 811 (S.D. Ind. 2009). Despite the Federal Circuit's recognition that these harms are significant and irreparable, its preliminary-injunction standard leaves companies without an effective remedy in many cases.

For example, in the case of Sanofi's platelet-aggregation-inhibiting product Plavix®, the district court issued a preliminary injunction three weeks after the generic competitor, Apotex, launched its product. In the short time that elapsed between launch of the generic product and entry of the preliminary injunction, Apotex was able to flood the market with six months of product, and its generic product captured nearly 80% of U.S. Plavix® sales. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368,

1383 (Fed. Cir. 2006); Br. of Defs.-Appellants, *Sanofi-Synthelabo v. Apotex, Inc.*, No. 2006-1613, 2006 WL 3099619, at 13 (Fed. Cir. Oct. 4, 2006). The price erosion for Sanofi's product was so marked and rapid that, on appeal to the Federal Circuit, Apotex argued that the preliminary injunction should be vacated because it could not undo the irreparable harm to Sanofi's position. *See Sanofi*, 470 F.3d at 1382. Indeed, the parties in that case agreed that the only remedy likely to make the pioneer company completely whole was a preliminary injunction entered before launch of the generic product. *See id.* ("According to Sanofi, it is nearly impossible to restore Plavix® to its pre-launch price . . . ."); *id.* ("Apotex asserts that price erosion has already occurred, and thus an injunction is not necessary because it cannot ameliorate Sanofi's position."). The Federal Circuit ultimately concluded that a preliminary injunction was necessary to prevent further irreparable harm. *Id.* at 1385.

The Federal Circuit accepted the district court's findings that price erosion in the pharmaceutical industry is irreparable in part because of the "complex pricing scheme that is directly affected by the presence of [a] generic product in the market." *Sanofi*, 470 F.3d at 1382. The immediate and critical nature of the harm in such cases highlights the need for injunctive relief.

The Plavix® situation is far from unique. For example, the Southern District of Indiana agreed that a proposed generic for Evista® (for osteoporosis) would likely capture 80% of the market within two months, observing that both Pravacol® (for reduction of cholesterol) and Zoloft® (for depression) lost 80%

market share within three weeks of generic launch. *See Lilly*, 609 F. Supp. 2d at 811 nn. 22 & 23. In the case of Wyeth and Altana's drug Protonix®, a proton-pump inhibitor prescribed to treat gastrointestinal disorders, the district court denied a preliminary injunction that would have barred sales of Teva's and Sun's generic products. *See Altana Pharma AG v. Teva Pharms. USA, Inc.*, 532 F. Supp. 2d 666 (D.N.J. 2007). Wyeth and Altana presented significant evidence of irreparable harm: Protonix® constituted 50–60% of Altana's profits and 8.8% of Wyeth's; Wyeth argued it would need to cut not only pediatric development of Protonix®, but also other research and development activities; and Altana indicated it would not be able to service its debts and would need to lay off employees. *Id.* at 682. Nonetheless, the district court denied the injunction, and the Federal Circuit affirmed the denial, agreeing that Teva and Sun had raised a substantial question concerning validity. *See Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999 (Fed. Cir. 2009). Ultimately, Altana and Wyeth prevailed on the merits of the validity case. *See Altana Pharma AG v. Teva Pharms. USA, Inc.*, Civ. A. No. 04-2355 (JLL) (D.N.J. Apr. 23, 2010) (Dkt. No. 821) (jury verdict); *id.* (D.N.J. July 16, 2010) (Dkt. No. 872) (order denying Defendants' motion for judgment as a matter of law); *id.* (D.N.J. July 15, 2010) (Dkt. No. 878) (opinion denying Defendants' judgment as a matter of law).

More generally, in 2010, PhRMA members invested an estimated $49.4 billion in discovering and developing new medicines. *See* PhRMA, *Pharmaceutical Industry Profile 2011*, at inside front cover (2011), *available at* http://www.phrma.org/

sites/default/files/159/phrma_profile_2011_final.pdf. The Federal Circuit has recognized "the significant 'public interest in encouraging investment in drug development and protecting the exclusionary rights conveyed in valid pharmaceutical patents.'" *Abbott Labs. v. Sandoz*, 544 F.3d 1341, 1362–63 (Fed. Cir. 2008). Likewise, this Court has stated that the "patent laws promote . . . progress by offering a right of exclusion for a limited period as an incentive to inventors to risk the often enormous costs in terms of time, research, and development." *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 480 (1974). As shown above, the entry of an allegedly infringing product can have huge financial impact, thereby inhibiting a company's capacity to invest in research and development. While "less promising projects" may be cut first in these situations, that "is not a desirable result because sometimes the less promising projects turn out to be very successful." *See AstraZeneca LP v. Apotex, Inc.*, 623 F. Supp. 2d 579, 612–13 (D.N.J. 2009), *aff'd*, 633 F.3d 1042 (Fed. Cir. 2010). Injunctions can be a critical tool in preserving funding for research and development, and an overly stringent preliminary injunction standard can threaten the ability of companies to develop new drugs, medical devices, and diagnostic tools.

The recently enacted Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), relies heavily on preliminary injunctions as an available remedy. Under the BPCIA, an applicant seeking to market a biosimilar product is subject to a complex, two-part statutory litigation scheme with the reference product sponsor. The parties can litigate some patents quickly, in a first litigation

phase, and other patents in a second litigation phase 180 days before the biosimilar applicant intends to market its product. *See* 42 U.S.C. §§ 262(k), (l). In the second phase, the statute provides that "the reference product sponsor may seek a preliminary injunction prohibiting [the biosimilar applicant] from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement" of the second-phase patents. *Id.* at § 262(l)(8)(B). The statute also provides that the reference product sponsor and the biosimilar applicant must "reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion," in an effort to ensure timely injunctive relief in appropriate cases. *Id.* at § 262(l)(8)(C). An improper preliminary injunction standard will create inefficiencies and uncertainties in biosimilars litigation, effectively limiting a remedy specifically contemplated by this recent statute.

B. The Federal Circuit has been unable to eliminate the tension in its precedents and the resulting confusion.

As noted by Judge Newman in her dissent from the denial of rehearing en banc, the Federal Circuit has at times been faithful to this Court's preliminary-injunction standards, as articulated in *eBay*, *Winter*, and *O Centro*. *See* Pet. App. 65a–66a. In other cases, however, the Federal Circuit has departed from this Court's standards. The resulting tension in Federal Circuit precedent has persisted despite the Federal Circuit's attempts at self-

correction. This Court's review is needed to resolve a continuing problem that the Federal Circuit has been unable to correct on its own.

The tension in the Federal Circuit's precedent is exemplified by the two opinions in *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008). The majority opinion, after analyzing the four factors set out in *Winter*, added a discussion entitled "The Issue of Conflicting Precedent." *Id.* at 1363–1371. The opinion, written by Judge Newman, stressed that

> [t]he correct standard is not whether a substantial question has been raised, but whether the patentee is likely to succeed on the merits, upon application of the standards of proof that will prevail at trial. The question is not whether the patent is vulnerable; the question is who is likely to prevail in the end, considered with equitable factors . . . .

Id. at 1364. The opinion concluded that the "criterion of whether the defendant raised a 'substantial question' that may render the patent 'vulnerable' . . . conflicts with precedent of the Supreme Court and all of the regional circuits." *Id.* at 1369; *see id.* at 1365–69.

In dissent, Judge Gajarsa stated that "[v]ulnerability is the issue at the preliminary injunction stages, while validity is the issue at trial. The showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity

itself." *Abbott*, 544 F.3d at 1371–72. Judge Gajarsa concluded that "under [the Federal Circuit's] clearly established precedent, when the alleged infringer raises a substantial question regarding validity, a preliminary injunction cannot issue because the patentee has failed to demonstrate a likelihood of success on the merits." *Id.* at 1373.

The Federal Circuit attempted to "clarify the requirements" to obtain a preliminary injunction in *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1374 (Fed. Cir. 2009). The court of appeals acknowledged that, based on its prior decisions, the standard "is less than entirely clear, and leaves room for different interpretations." *Id.* at 1377.

The panel began with an articulation of the likelihood-of-success prong that adheres to the standard set forth by this Court: "the patentee . . . must show that it will likely prove infringement and that it will likely withstand challenges, if any, to the validity of the patent." *Id.* at 1376. The Federal Circuit noted that the burdens and presumptions at the preliminary injunction stage track those at trial, and that the patent "enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation." *Id.* at 1377.

In explaining the "substantial question" of validity inquiry, the Federal Circuit explained that "when analyzing the likelihood of success factor, the trial court . . . must determine whether it is more likely than not that the challenger will be able to prove at trial, by clear and convincing evidence, that the patent is invalid." *Titan Tire*, 566 F.3d at 1379–80. The panel clarified that a finding of a "substantial question" of validity is a "substantive

conclusion" indicating that the patentee is unlikely to succeed on the merits." *Id.* at 1378.

Despite the Federal Circuit's opinion in *Titan Tire*, cases such as *Kimberly-Clark* demonstrate that at times the Federal Circuit continues to use the "substantial question test" as a "substitute or replacement for the established test for injunctions." *Titan Tire*, 566 F.3d at 1378. As Judge Newman noted, "the attempted reconciliation in *Titan Tire* appears to have failed, for [the *Kimberly-Clark*] panel provides no qualification for its position that if validity is reasonably questioned, the injunction will be denied." Pet. App. 74a. As one district court observed, an invalidity defense that "has a 49% likelihood of success on the merits" is "plainly 'substantial,' yet it is not 'likely to succeed.'" *PrintGuard, Inc. v. Anti-Marking Sys., Inc.*, 535 F. Supp. 2d 189, 196 (D. Mass. 2008).

Notwithstanding its efforts, the Federal Circuit has been unable to eliminate the confusion surrounding its precedent. The Federal Circuit's conflicting opinions have caused "[d]istrict courts across the country" to "struggle[] with [the] precedent in this area." Pet. App. 77a (O'Malley, J., dissenting from rehearing en banc). In these circumstances, it is appropriate for this Court to resolve the confusion. Although the Federal Circuit's opinion in this case is non-precedential, it exemplifies a pervasive problem in the court of appeals' application of the preliminary-injunction criteria, and thus is an appropriate vehicle for

correcting the standard.[3] For these reasons, the Supreme Court should grant review in this case.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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[3] This Court has granted certiorari in prior cases despite the non-precedential nature of the opinion of the court of appeals. *See, e.g.*, *Teleflex, Inc. v. KSR Int'l Co.*, 119 F. App'x 282 (Fed. Cir. 2005) (non-precedential), *rev'd and remanded* 550 U.S. 398 (2007); *KSR Int'l Co. v. Teleflex, Inc.*, 548 U.S. 902 (2006) (granting certiorari); *Mims v. Arrow Fin. Servs., LLC*, 131 S. Ct. 3063 (2011) (granting certiorari in *Mims v. Arrow Fin. Servs., LLC*, 421 F. App'x 920 (11th Cir. 2010)); *Wood v. Milyard*, 132 S. Ct. 70 (2011) (granting certiorari in *Wood v. Milyard*, 403 F. App'x 335 (10th Cir. 2010)).