

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 PETITION FOR A WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF IN OPPOSITION

D. MICHAEL UNDERHILL
ERIC J. MAURER
BOIES, SCHILLER
& FLEXNER LLP
5301 Wisconsin Avenue, NW
Washington, DC 20015
(202) 237-2727

KENNETH P. GEORGE
Counsel of Record
IRA E. SILFIN
MICHAEL V. SOLOMITA
CHARLES R. MACEDO
BRIAN A. COMACK
AMSTER, ROTHSTEIN
& EBENSTEIN LLP
90 Park Avenue
New York, NY 10016
(212) 336-8000
kgeorge@arelaw.com

Counsel for Respondents

239294



COUNSEL PRESS

(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

Whether the analytical framework developed by the Court of Appeals for the Federal Circuit—and applied by the Panel in this case—to determine likelihood of success on the merits on preliminary injunction motions involving patents is consistent with this Court’s precedent?

Specifically, has a patent owner failed to establish a likelihood of success on the merits if he is unable to rebut a substantial question as to the validity of the asserted patent claims raised by an accused infringer?

**CORPORATE DISCLOSURE STATEMENT
PURSUANT TO SUPREME COURT RULE 29.6**

Respondent First Quality Baby Products, LLC has no parent corporation, and no publicly held company owns 10% or more of the stock of First Quality Baby Products, LLC.

Respondent First Quality Retail Services, LLC is a fully-owned subsidiary of First Quality Baby Products, LLC. No publicly held company owns 10% or more of the stock of First Quality Retail Services, LLC.

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INTRODUCTION

Respondents First Quality Baby Products, LLC and First Quality Retail Services, LLC (“Respondents”) submit this Brief in Opposition to the Petition for a Writ of Certiorari by Petitioners Kimberly-Clark Worldwide, Inc. and Kimberly-Clark Global Sales, LLC (“Petitioners”).

Respondents respectfully request that the Petition in this case be denied for the following reasons:

I. The analytical framework developed by the Federal Circuit and applied by the Panel here in determining likelihood of success on the merits is faithful to this Court’s jurisprudence.

A. This Court reviews preliminary injunction proceedings under a long-established four factor framework. *See, e.g., Winter v. Natural Resource Defense Counsel, Inc.*, 555 U.S. 7, 20 (2008). This framework recognizes that movants—such as Petitioners here—bear the burden of demonstrating, *inter alia*, that they are likely to succeed on the merits at trial. *Munaf v. Geren*, 553 U.S. 674, 689-90 (2008).

This Court has repeatedly recognized that “a preliminary injunction is an extraordinary and drastic remedy.” Thus, movants are required to carry—“by a clear showing”—the burden of persuasion, which is a “higher” “requirement for substantial proof” than on a movant in a motion for summary judgment. *Mazurek v. Armstrong*, 520 U.S. 968, 972 (1997) (*per curiam*).

While this Court requires that the burdens at the preliminary injunction stage “track” the burdens at

trial, it does not require either party to make the same comprehensive presentation of evidence at a preliminary injunction hearing that would be expected at trial. See *Gonzales v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 429 (2006).

This Court, last term, confirmed nearly 30 years of Federal Circuit precedent concerning the patentee and challenger’s respective burdens of proof regarding the validity of a patent claim in view of 35 U.S.C. §282. *Microsoft Corp. v. i4i LP*, 131 S.Ct. 2238, 2243 (2011).

B. In accordance with this Court’s precedent, the Federal Circuit—in *Titan Tire Corp. v. Case New Holland, Inc.*, 566 F.3d 1372, 1379 (Fed. Cir. 2009)—clarified and harmonized its jurisprudence on preliminary injunction proceedings for patent infringement actions.

Titan emphasized that the *Winter* four-factor test for preliminary injunctions applies to patent cases. *Id.* at 1375-76. *Titan* also expressly considered *Gonzales* and confirmed that the analytical framework used to analyze whether a patentee is likely to succeed on the merits in a preliminary injunction hearing in a patent case “tracks” the burdens at trial. Thus, *Titan* clarified that “the patentee seeking a preliminary injunction in a patent infringement suit must show ... that it will likely withstand challenges, if any, to the validity of the patent.” *Id.* at 1376 (discussing *Gonzales*). *Titan* further explained that a determination that “the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit” is one way of expressing that “the patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue.” 556 F.3d at 1379.

Although Petitioners seek to characterize the *Titan* framework as a *sui generis* standard that is at odds with this Court's precedent, the Federal Circuit's analytical framework, though tailored to patent infringement actions, faithfully comports with this Court's jurisprudence.

C. The Panel Decision here applied this Court's jurisprudence and the *Titan* analytical framework—which was urged by **both** parties—to find that Respondents had raised a “substantial question of validity” that “does not lack substantial merit” with respect to three of the four patents at issue. (App. 9a, 13a, 17a, *as modified by*, App. 23a-24a).

II. There is no conflict between the Panel Decision (or the Federal Circuit's law as clarified and harmonized in *Titan*) and the jurisprudence of this Court and the other circuit courts.

The alleged departures from this Court's precedent do not exist.

A. The Panel decision does not, as the Petition asserts, supplant the “likely to succeed” requirement. To the contrary, the Panel found that Respondents “asserted a defense to [three of the four patents] that raises a substantial question of validity and does not lack substantial merit.” (App. 9a, 13a, 17a, *as modified by*, App. 23a-24a). As *Titan* explained, this is simply another way of stating that Petitioners did not meet their heavy burden of establishing they are likely to succeed on the merits.

The Panel did not apply a “some” evidence or “worthy of consideration” standard. If it had, the Panel would have reversed the preliminary injunction as to the fourth

patent. (App. 18a (recognizing that Respondents had introduced evidence challenging the validity of the '316 Patent)).

B. The Petitioners' objection that the Panel did not weigh the other three *Winter* factors misses the mark. This Court has made it clear that "a party seeking a preliminary injunction **must** demonstrate, among other things, 'a likelihood of success on the merits.'" *Munaf*, 553 U.S. at 690 (emphasis added). The failure of a movant to establish likelihood of success is fatal to any request for preliminary injunctive relief, and especially one under 35 U.S.C. §283, which authorizes injunctions only "to prevent the violation of any right secured by patent."

C. Petitioners object that the Panel improperly did not require Respondents to prove invalidity by clear and convincing evidence at the preliminary injunction stage. This argument is without merit. Nothing in this Court's precedent requires Respondents, at the preliminary injunction stage, to prove that they will ultimately prevail. Respondents need only present sufficient evidence to show that it is likely the movant will not prevail.

III. Petitioners' purported fears concerning the alleged consequences of the Panel's **non-precedential** decision on the granting of preliminary injunctions are unfounded.

A. The *Titan* analytical framework does not "essentially negate[] the possibility of grant of a preliminary injunction ... during patent litigation." (*Contra* App. 68a). Indeed, the Panel's affirmance of the district court's preliminary injunction with respect to the '316 patent rebuts this argument. Other courts have similarly

continued to issue preliminary injunctions since the Panel Decision, including as recently as December 6, 2011. *See, e.g., Sciele Pharma Inc. v. Lupin Ltd.*, No. 09-0037 (D. Del. Dec. 6, 2011).

B. There is no ongoing confusion over the *Titan* framework. The alleged confusion that the Petitioners reference among district courts and practitioners (Pet. 24-26) predates *Titan* and was addressed by the Federal Circuit in that decision. Indeed, the fact that Petitioners urged the district court and the Panel to apply the *Titan* analytical framework belies their assertions.

C. Petitioners' concern over the availability of enhanced damages and attorneys' fees is baseless and is not properly addressed in the context of this Petition.

IV. In any event, this case is not an appropriate vehicle for review.

A. There is no dispute that the district court made significant errors in reaching its conclusion to enter the preliminary injunction for three of the four patents.

The district court decision was based on: (1) applying admittedly wrong claim constructions (App. 11a, 15a-16a); (2) reviewing the wrong portion of the evidence (App. 17a); and (3) misbalancing of the facts (App. 13a, 17a). These are clear errors that this Court recognizes as an abuse of discretion calling for reversal. Even Judge O'Malley's dissent recognized that "it may be that the panel ultimately reached the right result in this particular case." (App. 77a). The fact that the U.S. Patent and Trademark Office ("PTO") has found in an *inter partes* reexamination that the asserted claims of one of these patents are invalid

highlights the district court's errors. (App. 3a n.2).

B. Significantly, both Petitioners and Respondents urged the district court and the Panel to apply the *Titan* analytical framework. Because Petitioners only belatedly challenged the *Titan* framework after the preliminary injunction was vacated, this case is a poor vehicle for this Court to review that framework as applied here.

C. Given the advanced stage of the proceedings before the district court, resolution by this Court of the preliminary injunction issues raised in this interlocutory Petition is unlikely to assist the parties or the district court in resolving the underlying dispute.

For the foregoing reasons, Respondents respectfully submit the Petition should be denied.

STATEMENT OF THE CASE

I. STATUTORY PROVISION INVOLVED

35 U.S.C. §283 grants federal courts the authority to enter injunctive relief “to prevent the violation of any right secured by patent”:

The several courts having jurisdiction of cases under this title may grant injunctions in accordance with the principles of equity ***to prevent the violation of any right secured by patent***, on such terms as the court deems reasonable.

35 U.S.C. §283 (emphasis added).

II. PROCEEDINGS BELOW

Respondents manufacture baby diapers, training pants for toddlers learning to toilet train, and briefs for incontinent adults. Refastenable training pants, which include Velcro® side seams that enable the pant to be opened and reclosed by the child, are at the center of this dispute. In 2009, Respondents started manufacturing and distributing “private label” (*e.g.*, store brand) training pants to retailers. The dispute underlying the Petition involves obsolete manufacturing processes that Respondents previously used to make refastenable training pants.

A. Initial Preliminary Injunction Proceedings

On September 21, 2009, Petitioners commenced the underlying action by alleging infringement of three product patents. (App. 26a). On September 29, Petitioners moved for a preliminary injunction on two of the three patents. (ECF No. 4).

On November 16 and 17, 2009, the district court held an expedited two-day hearing, during which Respondents presented various non-infringement and invalidity defenses.

On December 11, 2009, the district court issued its decision denying Petitioners’ motion. (ECF. No. 66).

Applying the same standard and analytical framework that Petitioners now take issue with here (*id.* at ¶ 5), the district court found that no preliminary injunction should issue because Petitioners had not established a likelihood of success on the merits. Respondents raised substantial

questions concerning the validity of Petitioners' patents by presenting invalidity defenses which did not "lack[] substantial merit." (*Id.* at ¶¶32 & 35; App. 26a). Petitioners never took issue with the standard applied by the district court.

B. The Preliminary Injunction Proceeding at Issue

On March 1, 2010, Petitioners amended their Complaint to assert four additional patents against Respondents, U.S. Patent Nos. 6,514,187 ("187 patent"), 7,156,939 ("939 patent"), 6,888,143 ("143 patent"), and 6,776,316 ("316 patent"). (App. 26a-27a). These four patents—the patents at issue here—are each directed to processes for manufacturing and/or inspecting refastenable training pants. (*Id.*).

On the same day, Petitioners simultaneously made a second request for a preliminary injunction, this time for all four of the newly asserted patents. (*Id.*).

In support of their motion, and consistent with *Titan*, Petitioners acknowledged that

[t]o demonstrate a likelihood of success on the merits, K-C [Petitioners] ***must show*** that, in light of the presumptions and burdens that will inhere at trial on the merits, ... ***the infringed claim(s) will likely withstand First Quality's [Respondents'] challenge, if any, to the validity ... of the asserted claims.***

(ECF No. 114 at 9-10 (emphasis added)). Petitioners further argued that since "there is no substantial issue

as to validity of the infringed claims,” a preliminary injunction should issue. (*Id.* at 9).

Significantly, Petitioners did not:

1. Argue that they did not need to show that “there is no substantial issue as to the validity of infringed claims.” Instead they embraced that obligation. (*Id.*);

2. Object to the analytical framework the district court had previously applied in denying their initial preliminary injunction motion, despite its requirement that the movant rebut any substantial question regarding infringement or validity raised by the non-moving party. (ECF No. 66 ¶ 5); or

3. Object to the Federal Circuit’s jurisprudence on preliminary injunctions, as they now do in the Petition.

On March 15, 2010, Respondents filed their Opposition. (ECF No. 122).

One week later, on March 22, Petitioners submitted their Reply. (ECF No. 137). Adopting the *Titan* analytical framework once again, Petitioners argued that they were likely to succeed on the merits because “First Quality failed to raise a substantial question of validity of the asserted claims” (*Id.* at 15).

Thus, during the entire preliminary injunction proceedings before the district court, Petitioners consistently embraced and advocated the *Titan* analytical framework that they now challenge in this Petition. (Pet. 15-22).

The district court conducted a three-day hearing on March 25 and 26, 2010 and April 8, 2010. As pertinent here, Respondents presented evidence and expert testimony that each of the four patents at issue was likely invalid because each was either anticipated or rendered obvious by the prior art. (App. 32a-38a). The parties did not, however, dispute the analytical framework to be used in determining whether a preliminary injunction should issue. (*See* ECF Nos. 147-149, 157-158).

C. Preliminary Injunction Decision

On May 20, 2010, the district court granted Petitioners' motion in full. (App. 25a). The district court again applied the *Titan* framework—as the parties urged—to analyze likelihood of success on the merits. (Pet. 27a-28a). The district court concluded that Petitioners “ha[d] shown a strong probability that [they] will succeed on the merits of [their] claims that [Respondents] ha[ve] infringed the four process patents asserted in [their] Amended Complaint and that [their] patents are valid.” (App. 55a). Thus, the district court entered the preliminary injunction at issue here. (App. 60a).

D. Petitioners' Arguments on Appeal Embraced the *Titan* Analytical Framework

On May 26, 2010, Respondents appealed the district court's preliminary injunction order to the Federal Circuit under 28 U.S.C. §1292(c)(1). (App. 3a).

In the briefing to the Panel, both sides applied and embraced the *Titan* analytical framework. Neither side challenged it. In particular, Petitioners argued that the

district court's decision should be upheld because the court properly concluded "that FQ [Respondents] failed to **raise a substantial question of invalidity.**" (Petitioners' Red Brief at 22, 27 (emphasis added)).

E. Post-Preliminary Injunction Proceedings Pending the Appeal

While the appeal was pending, three significant events occurred.

1. The District Court Issued a Revised Claim Construction That Substantially Undermined the Basis for Its Decision Concerning the '143 and '939 Patents

On January 20, 2011, the district court issued its definitive claim construction ruling. The district court adopted claim constructions for key terms of the '143 and '939 patents that were materially different from those on which it had relied in issuing the preliminary injunction on those patents. *Kimberly-Clark Worldwide, Inc. v. First Quality Baby Prods., LLC*, No. 09-C-916, 2011 WL 196509 (E.D.Wis. Jan. 20, 2011), *cited and discussed in* App. 3a, 11a, 15a-16a. The district court's revised constructions substantially undermined its rationale for rejecting Respondents' invalidity arguments and granting the preliminary injunction as to these two patents. (App. 11a, 15a-16a). Respondents advised the Panel of this development by letter of January 24, 2011.

2. The PTO Granted Respondents' Request for *Inter Partes* Reexamination of the '187 Patent, and Confirmed the Invalidity of the Asserted Claims

On August 6, 2010, Respondents requested that the PTO conduct an *inter partes* reexamination of the '187 patent. (ECF No. 214 at 2). On December 14, 2010, the PTO granted this request, and issued an office action rejecting all asserted claims of the '187 patent as invalid. (ECF 318-1, 325 at 3). The PTO relied on some of the same prior art and arguments rejected by the district court (App. 3a n.3), including prior art that the PTO had not previously considered when it originally issued the '187 patent. Respondents advised the Panel of this development by letter of January 6, 2011.¹

3. Respondents Successfully Designed Around the '187, '143, '939 and '316 Patents, and Petitioners Dropped Their Ongoing Assertions

In response to the preliminary injunction, Respondents adopted a modified manufacturing process that even Petitioners conceded did not infringe the '187, '143, '939 and '316 patents. (ECF No. 325 at 2). Accordingly, with respect to these four patents, the parties' sole remaining dispute in the district court litigation is Respondents' liability, if any, for alleged infringement occurring before November 1, 2011.

1. The PTO recently reaffirmed its rejection of all '187 patent claims that formed the basis for the district court's preliminary injunction. *See* U.S. Patent Application Serial No. 95/001,416, 10/14/2011 Action Closing Prosecution at 1.

F. The June 1, 2011 Panel Decision

On June 1, 2011, a three-judge panel of the Federal Circuit issued a 22-page, non-precedential decision that vacated the preliminary injunction as to the '187, '939 and '143 patents because it found “that First Quality had raised ... substantial question[s] of validity ... that cannot be characterized as substantially meritless.”² (App. 9a, 13a, 17a). The Federal Circuit affirmed the preliminary injunction as to the '316 patent.

G. Petitioners' Combined Petition for Rehearing and Rehearing *En Banc*

On July 1, 2011, Petitioners filed their Combined Rehearing Petition. Eleven of the fifteen pages of the petition were directed to the Panel's statement that Respondents had presented invalidity defenses that “cannot be characterized as meritless.” Petitioners took the position that this statement applied the wrong standard of review and thus requested reconsideration and/or reconsideration *en banc* of the non-precedential panel decision. (*See, e.g.*, Combined Rehearing Petition at 5-6).

Only the last few pages of the Combined Rehearing Petition alluded to the issues addressed in the instant Petition, namely that “[t]o the extent that this Court relies on its ‘substantial question’/‘vulnerability’ articulation

2. As discussed below, on September 29, 2010, the Panel issued “Errata” correcting each appearance of the phrase “cannot be characterized as substantially meritless” to “does not lack substantial merit.” (*See* App. 23a-24a).

as a standard distinct from the established likelihood of success on the merits standard, it is in conflict with both the Supreme Court and ... the Seventh Circuit.” (*Id.* at 13-14). However, Petitioners provided no explanation of the alleged conflict. Instead, Petitioners conceded that “[a]t least some members of this Court [the Federal Circuit] regard these patent-specific tests as merely alternative verbal formulations of ‘likely to succeed on the merits’ and thus see no conflict with governing law.” (*Id.* at 13).

H. The September 29, 2011 Decisions

On September 29, 2011, the Panel issued an “Errata” deleting, in three places, its statement “First Quality has raised a substantial question of validity ... that cannot be characterized as substantially meritless,” and substituting “First Quality has asserted a defense ... that raises a substantial question of validity and does not lack substantial merit.” (App. 23a-24a).

The Federal Circuit’s corrections fully addressed the gravamen of Petitioners’ objections to the Panel Decision expressed in the Combined Rehearing Petition. Not surprisingly, the Federal Circuit denied the request for rehearing.

Although Judge Newman and Judge O’Malley each offered a dissent to the denial of rehearing *en banc*, their arguments had little if any connection to the parties’ briefing to the Panel or to the full Federal Circuit.

**I. The Present Petition for Writ of Certiorari
Raises New Issues for the First Time**

On November 10, 2011, Petitioners filed the instant Petition in which they challenge, for the first time, the *Titan* analytical framework that they previously endorsed before the district court and the Panel.

REASONS FOR DENYING THE PETITION

Respondents respectfully submit that the Petition should be denied for the reasons set forth herein.

**I. THE ANALYTICAL FRAMEWORK APPLIED
BY THE PANEL HERE (AND THE FEDERAL
CIRCUIT IN GENERAL) TO REVIEW
PRELIMINARY INJUNCTIONS IS FAITHFUL
TO THIS COURT'S PRECEDENT**

The Petition raises no issues that merit this Court's review. The Federal Circuit's analytical framework, as clarified in *Titan* and applied by the Panel, dutifully follows this Court's precedents.

**A. This Court's Jurisprudence on Preliminary
Injunctions**

This Court's jurisprudence on preliminary injunctions is clear and well-established. The same general principles that are applied by courts in equity apply in patent cases. *See, e.g., eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 391-92 (2006).

“[A] preliminary injunction is an extraordinary and drastic remedy, one that should not be granted unless the movant, **by a clear showing**, carries the burden of persuasion.” *Mazurek*, 520 U.S. at 972; *see also*, *e.g.*, *Winter*, 555 U.S. at 22 (“injunctive relief [is] an extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief”).

Thus, the proof required of a movant for a preliminary injunction is substantially higher than even the proof required to obtain summary judgment. *See, e.g., Mazurek*, 520 U.S. at 972 (“And what is at issue here is not even a defendant’s motion for summary judgment, but a plaintiff’s motion for preliminary injunctive relief, as to which the requirement for substantial proof is much higher.”).

It is well settled that “[a] plaintiff seeking a preliminary injunction **must establish**

[1] that he is **likely to succeed on the merits**,

[2] that he is likely to suffer irreparable harm in the absence of preliminary relief,

[3] that the balance of equities tips in his favor, and

[4] that an injunction is in the public interest.”

Winter, 555 U.S. at 20 (emphasis added); *see also, e.g., Munaf*, 553 U.S. at 689-90; *Amoco Prod. Co. v. Vill. of Gambell*, 480 U.S. 531, 542 (1987); *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 311-12 (1982).

In particular, “a party seeking a preliminary injunction **must demonstrate**, among other things, ‘a

likelihood of success on the merits.” *Munaf*, 533 U.S. at 690 (emphasis added); *Gonzales*, 546 U.S. at 428 (citing *Mazurek*, 520 U.S. at 972; *Doran v. Salem Inn, Inc.*, 422 U.S. 922, 931 (1975)). This requirement is especially significant in a patent case where injunctive relief is “to prevent the violation of any right secured by patent.” 35 U.S.C. §283. “[T]he burdens at the preliminary injunction stage track the burdens at trial.” *Gonzales*, 546 U.S. at 429.

This Court last term confirmed nearly 30 years of Federal Circuit jurisprudence concerning assertions that a patent claim is invalid: “[35 U.S.C. §] 282 creates a presumption that a patent is valid and imposes the burden of proving invalidity on the attacker. That burden is constant and never changes and is to convince the court of invalidity by clear evidence.” *Microsoft*, 131 S.Ct. at 2243 (quoting with approval *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1360 (Fed. Cir. 1984)). But this Court also recognized that “[w]hen new evidence touching validity of the patent not considered by the PTO is relied on, the tribunal considering it is not faced with having to disagree with the PTO or with deferring to its judgment or with taking its expertise into account. The evidence may, therefore, carry more weight and go further toward sustaining the attacker’s unchanging burden.” *Microsoft*, 131 S.Ct. at 2251 (quoting with approval *American Hoist*, 725 F.2d at 1360).

Of course, while the burden of *persuasion* on an affirmative defense like invalidity remains on the attacker throughout the trial, once the attacker has come forward with sufficient evidence to meet its burden of *production*, the burden of *production* then shifts back to the plaintiff to rebut the attacker’s evidence. *Cf. Microsoft*, 131 S.Ct. at

2245 n.4 (distinguishing between “burden of production,” “burden of persuasion,” and “standard of proof”).

Moreover, as Justice Breyer explained in his concurring opinion in *Microsoft*, “[w]here the ultimate question of patent validity turns on the correct answer to legal questions—what these subsidiary legal standards mean or how they apply to the facts as given—today’s strict standard of proof has no application.” *Microsoft*, 131 S.Ct. at 2253 (Breyer, J., concurring).

Finally, “[t]his Court, like other appellate courts, has always applied the abuse of discretion standard on review of a preliminary injunction.” *Ashcroft v. ACLU*, 542 U.S. 656, 664 (2004) (quoting *Walters v. National Assn. of Radiation Survivors*, 473 U.S. 305, 336 (1985) (O’Connor, J., concurring) (internal quotation marks omitted)). “A district court would necessarily abuse its discretion if it based its ruling on an erroneous view of the law or on a clearly erroneous assessment of the evidence.” *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 405 (1990). Similarly, when a district court “d[oes] not give sufficient weight” to the evidence or misbalances the evidence, it likewise commits an abuse of discretion. *See, e.g., Winter*, 555 U.S. at 28.

B. In *Titan*, the Federal Circuit Clarified and Harmonized Its Jurisprudence With This Court’s Precedent

In *Titan*, the Federal Circuit addressed any possible confusion regarding the analytical framework for determining whether to grant a preliminary injunction in a patent infringement action.

First, *Titan* confirmed that this Court’s most recent precedent—the four-factor test set forth in *Winter*—applies in patent infringement actions. 566 F.3d at 1375-76. *Titan* confirmed that, to the extent that there had been other formulations of the four factor test, “for our purposes the Supreme Court’s current statement of the test is the definitive one.” *Id.* (rejecting “reasonable” likelihood of success on the merits formulation in favor of *Winter*’s formulation); *see also Mazurek*, 520 U.S. at 971 (rejecting Ninth Circuit’s “fair chance of success on the merits” formulation).

Next, *Titan* relied on this Court’s decision in *Gonzales* to confirm that the parties’ respective burdens at the preliminary injunction stage track those at trial. 566 F.3d at 1376 (quoting *Gonzales*, 546 U.S. at 429). In particular, *Titan* clarified:

With regard to the first factor— establishing a likelihood of success on the merits—the patentee seeking a preliminary injunction in a patent infringement suit must show that it will likely prove infringement, and ***that it will likely withstand challenges, if any, to the validity of the patent.***

Id. (emphasis added; discussing *Gonzales*). Even *amici* concede that this articulation “adheres to the standard set forth by this Court.” (Brief for PhRMA, at 17).

Titan also clarified that a conclusion by the trial court that there is a “‘substantial question’ concerning the validity of the patent ... that the patentee has not shown lacks substantial merit” is merely another way to

express that “the patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue.” 566 F.3d at 1379.

Significantly, *Titan* demonstrated that this analytical framework is consistent with the nearly 30 years of Federal Circuit jurisprudence regarding the invalidity standard of proof, which this Court cited with approval in *Microsoft*, 131 S.Ct. at 2243. In particular, *Titan* explained how its analytical framework “is tailored to fit the preliminary injunction context”:

To begin, the patent enjoys the same presumption of validity during preliminary injunction proceedings as at other stages of litigation. Thus, if a patentee moves for a preliminary injunction and the alleged infringer does not challenge validity, the very existence of the patent with its concomitant presumption of validity satisfies the patentee’s burden of showing a likelihood of success on the validity issue.

If, instead, the alleged infringer responds to the preliminary injunction motion by launching an attack on the validity of the patent, the burden is on the challenger to come forward with evidence of invalidity, just as it would be at trial. The patentee, to avoid a conclusion that it is unable to show a likelihood of success, then has the burden of responding with contrary evidence, which of course may include analysis and argument.

* * *

... Thus the trial court first must weigh the evidence both for and against validity that is available at this preliminary stage in the proceedings. Then, ... if the trial court concludes there is a “substantial question” concerning the validity of the patent, meaning that the alleged infringer has presented an invalidity defense that the patentee has not shown lacks substantial merit, it necessarily follows that the patentee has not succeeded in showing it is likely to succeed at trial on the merits of the validity issue.

Titan, 566 F.3d at 1377-79 (citations omitted).

Thus, *Titan* explained that the Federal Circuit’s analytical framework is consistent with *Gonzales* in that it “views the matter in light of the burdens and presumptions that will inhere at trial.” *Id.* at 1376.

The Federal Circuit has subsequently followed *Titan* without criticism. *See, e.g., AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1050 (Fed. Cir. 2010), *reh’g & reh’g en banc denied*, 2011 U.S. App. LEXIS 4461 (Fed. Cir. Jan. 31, 2011).

C. The Panel Correctly Applied *Titan* and This Court’s Jurisprudence

The Panel in this case applied the same principles set forth above to determine that the district court committed reversible error in entering a preliminary injunction as to three of the four patents.

Consistent with this Court’s decision in *Ashcroft*, the Panel recognized that it “reviews a decision to grant a preliminary injunction for abuse of discretion.” (App. 3a).

The Panel then applied the same four-factor test for preliminary injunctions set forth by this Court in *Winter*:

“A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits, [2] that he is likely to suffer irreparable harm in the absence of preliminary relief, [3] that the balance of equities tips in his favor, and [4] that an injunction is in the public interest.” *Winter v. Natural Res. Def. Council, Inc.*, [555 U.S. 7, 20] (2008); *see also AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1049 (Fed. Cir. 2010).

(App. 3a-4a).

Next, consistent with *Munaf*, *Gonzales*, *Mazurek* and *Doran*, the Panel recognized that the movant “must establish” “likelihood of success on the merits” as well as “irreparable harm”:

“Although the factors are not applied mechanically, a movant must establish the existence of both of the first two factors to be entitled to a preliminary injunction.” *Altana Pharma AG v. Teva Pharm. USA, Inc.*, 566 F.3d 999, 1005 (Fed. Cir. 2009) (citing *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001)).

(App. 4a).

The Panel applied the *Titan* framework to evaluate the likelihood of success on the merits prong:

“For a patentee to establish that it is likely to succeed on the merits, it ‘must demonstrate that it will likely prove infringement of one or more claims of the patents-in-suit, and that ***at least one of those same allegedly infringed claims will also likely withstand the validity challenges presented by the accused infringer.***” *Astra-Zeneca*, 633 F.3d at 1050 (quoting *Amazon*, 239 F.3d at 1351); *see also Erico Int’l Corp. v. Vutec Corp.*, 516 F.3d 1350, 1354 (Fed. Cir. 2008).

(*Id.* (emphasis added)).

Consistent with the burdens and presumptions of the respective parties at trial, *see Gonzales*, 546 U.S. at 429, the Panel further explained the parties’ respective burdens of production:

“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.***” *AstraZeneca*, 633 F.3d at 1050. 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. *See Altana*, 566 F.3d at 1006; *Perricone v. Medicis Pharm. Corp.*, 432 F.3d 1368, 1372 (Fed. Cir. 2005).

Instead, “[v]ulnerability is the issue at the preliminary injunction stage, while validity is the issue at trial.” *Altana*, 566 F.3d at 1006 (quoting *Amazon*, 239 F.3d at 1359).

(App. 4a-5a (emphasis added)).

While *Gonzales* requires the burdens at the preliminary injunction stage to “track” those at trial, it does not require either party to show that it will win. See, e.g., *University of Texas v. Camenisch*, 451 U.S. 390, 395 (1981). Rather, at the preliminary injunction stage, the movant must prove, by a “clear showing,” *Mazurek*, 520 U.S. at 972, that it is “likely to prevail on the merits,” *Doran*, 422 U.S. at 931, i.e., that the patent is not vulnerable at the preliminary injunction stage to be found invalid by clear and convincing evidence at trial.

Applying this analytical framework, the Panel found that Respondents had raised a “substantial question of validity,” that “does not lack substantial merit” with respect to three of the four patents at issue. (App. 9a, 13a, 17a, *as modified by*, App. 23a-24a). With respect to the fourth patent, the Panel found, in pertinent part, that “the district court did not err in finding that [Respondents] failed to raise a substantial issue of patentability.” (App. 19a).

II. THE ALLEGED CONFLICTS RAISED IN THE PETITION (AND THE DISSENTS) DO NOT EXIST

The Petition incorrectly asserts that the analytical framework applied by the Panel to review preliminary injunctions in patent cases is “a stark departure from the

generally applicable standard that this Court has set forth and that all other circuits apply.” (Pet. 17). The Petitioners mischaracterize the Panel’s analytical framework. As demonstrated by a careful review of the Panel’s decision and Point I, *supra*, the Panel (and the Federal Circuit’s post-*Titan* jurisprudence) dutifully follow this Court’s jurisprudence. In addition, the Federal Circuit and the other circuit courts are not in conflict.

A. Requiring a Movant To Show That a Substantial Defense on Validity Lacks Substantial Merit Is an Inquiry Into Whether the Patentee “Is Likely To Succeed on the Merits”

In her dissent to the denial of the Petition for Rehearing *En Banc*, Judge Newman asserts that “[t]he panel’s approach is in conflict ... with every other circuit” because all other circuits “require consideration of the likely outcome on the merits” (App. 68a), and “[n]o other circuit denies a preliminary injunction merely because the non-movant has raised an argument worthy of consideration” (App. 72a).

Although Petitioners draw attention to Judge Newman’s statement (Pet. 13), they offer no argument or authority in support of this alleged circuit split. Nor can they, because no such split exists.

The cases that Judge Newman cites in support of her first point merely confirm the undisputed proposition that, in every circuit, “likelihood of success on the merits” is one of the prongs of the *Winter* test that is applied to evaluate motions for preliminary injunctions. (*See* App. 68a-71a). Neither the Panel Decision nor the Federal Circuit’s post-*Titan* jurisprudence apply a different standard. (*See* App.

3a-4a (“A plaintiff seeking a preliminary injunction must establish [1] that he is likely to succeed on the merits”). Even Petitioners reluctantly concede this point:

The [Federal Circuit] explained that the correct interpretation is that “a ‘substantial question’ of invalidity is a **substantive conclusion** by the trial court, a conclusion that the patentee is unlikely to succeed on the merits of the validity issue because the patentee is unable to establish that the alleged infringer’s invalidity defense ‘lacks substantial merit.’”

(Pet. 24 (citing *Titan*, 566 F.3d at 1378) (emphasis in original)).

With respect to Judge Newman’s second point, the Panel did not reverse the preliminary injunction “merely because the nonmovant has raised an argument worthy of consideration.” (App. 72a). Consistent with *Titan*, the Panel expressly found that “First Quality has asserted a defense to [three of the patents] that raises a substantial question of validity and does not lack substantial merit.” (App. 9a, 13a, 17a, *as modified by*, App. 23a-24a). Thus, the Panel did not find that Respondents’ arguments were merely “worthy of consideration;” rather it found that these arguments established that Petitioners were not likely to succeed on the merits. *Cf. Titan*, 566 F.3d at 1378.

Petitioners also protest that “under the Federal Circuit’s approach, if the defendant presents **some evidence** in support of its invalidity defense ... that alone is sufficient to deny the preliminary injunction.” (Pet. 19 (emphasis in original)). In support of their argument,

Petitioners rely only on two instances where the Panel decision acknowledged in passing that the district court's rejection of Respondents' invalidity defenses involved "closely contested" issues which "could change based on evidence submitted during discovery" and over the course of the litigation. (Pet. 20-21, citing App. 9a and 13a). Neither the Panel Decision nor the Federal Circuit's cases since *Titan*, however, apply a "some evidence" test. The Panel's point here was not that "some" evidence will defeat a preliminary injunction or that Respondents merely raised an argument "worthy of consideration." Rather, the Panel Decision recognized that Petitioners were not likely to succeed on the merits because they had not clearly demonstrated that Respondents would not prove their position at trial (as *Mazurek* requires).

In fact, if the Panel thought that "some evidence" or an "argument worthy of consideration" was sufficient, it would also have reversed the preliminary injunction as to the '316 patent, because Respondents presented "some" evidence that that patent was also invalid. (App. 18a).

B. Likelihood of Success on the Merits Is a Prerequisite to Relief Under This Court's Jurisprudence and the Patent Act

Petitioners also contend that the *Titan* analytical framework ignores this Court's jurisprudence because, "if the patentee cannot show that the [defendant's] invalidity defense ... 'lacks substantial merit,' the preliminary injunction must be denied—without regard to the strength or degree of the patentee's showing on the other equitable factors." (Pet. 17). In other words, Petitioners, like Judge Newman in her dissent (App. 68a), object that the

Panel did not consider “other equitable factors” once it determined that Petitioners failed to establish likelihood of success on the merits.

Petitioners’ view of the law is simply wrong. This Court has repeatedly made clear that “[a] plaintiff seeking a preliminary injunction *must* establish that he is likely to succeed on the merits, ...” *Winter*, 555 U.S. at 20 (emphasis added); *see also, e.g., Ashcroft*, 542 U.S. at 666; *Doran*, 422 U.S. at 931.

In fact, this Court has specifically rejected Petitioners’ contention in multiple cases. For example, in *Munaf*, this Court explained, “a party seeking a preliminary injunction *must* demonstrate, among other things, ‘a likelihood of success on the merits.’” 553 U.S. at 698 (emphasis added) (rejecting “fair chance of success on the merits” as insufficient); *see also, e.g., Ashcroft*, 542 U.S. at 666 (“In deciding whether to grant a preliminary injunction, a district court *must* consider whether the plaintiffs have demonstrated that they are likely to prevail on the merits.”) (emphasis added); *Doran*, 422 U.S. at 931 (“The traditional standard for granting a preliminary injunction *requires* the plaintiff to show that ... he is likely to prevail on the merits.”) (emphasis added).

Moreover, the Patent Act also emphasizes that injunctive relief is only available “to prevent *the violation of any right* secured by patent.” 35 U.S.C. §283 (emphasis added). If a plaintiff in a patent infringement action cannot establish that he is likely to succeed on the merits, *i.e.*, that his patent is likely to be found valid, enforceable, and infringed, then that plaintiff has failed to establish that he has a patent right for the court to protect.

Indeed, in his concurrence in *eBay*, Justice Kennedy noted that one reason why **permanent** injunctions should not issue under Section 283 automatically in patent infringement actions is “[t]he potential vagueness and suspect validity of some ... patents.” *eBay*, 547 U.S. at 397 (Kennedy, J., concurring). His comments are consistent with the requirement that any injunction that issues under Section 283 must be “to prevent the violation of [a valid] right secured by patent.”³

C. “Vulnerability” Is Consistent With This Court’s Precedent

Petitioners also object that the Panel purportedly applied a “less stringent substantive standard ... at the preliminary injunction stage than [would apply] in subsequent proceedings” since “[a]n accused infringer need not ‘make out a case of actual invalidity. **Vulnerability** is the issue.” Petitioners go on to argue that “[t]he showing of a substantial question as to invalidity thus requires less proof than the clear and convincing showing necessary to establish invalidity itself.” (Pet. 16-17) (emphasis in original).

Petitioners’ argument is based on a false premise. This Court does not require either party at the preliminary injunction stage to prove that they **will** prevail on the merits, only that it is **likely** they will prevail.

3. The fact the PTO granted Respondents’ request for *inter partes* reexamination subsequent to the preliminary injunction and rejected all of the asserted claims of the ’187 patent underscores Justice Kennedy’s remarks.

This Court has long recognized that, because preliminary injunction proceedings are usually time-constrained, they are customarily decided “on the basis of procedures that are less formal and evidence that is less complete than in a trial on the merits.” *University of Texas*, 451 U.S. at 395. In other words, neither party is required to come forward with **all** the evidence that would be expected at trial.

Gonzales did not alter this point in the law; it merely confirmed that the burdens at the preliminary injunction stage “track” the burdens at trial. *Gonzales* does not require that the parties present the same level of evidence to meet their trial burdens at the preliminary injunction stage—only that the burdens **track** those at trial.

The *Titan* analytical framework, as applied by the Panel—including the concept of “vulnerability”—does exactly this. While an attacker **at trial** has the burden of **persuasion** to show by “clear and convincing” evidence that a patent claim is invalid, the burden of **production** can shift. *Cf. Microsoft*, 131 S.Ct. at 2242 & 2245 n.4. Similarly, the *Titan* analytical framework likewise “tracks” this in a preliminary injunction. Although *Titan* requires the patentee to come forward with evidence that rebuts a substantial defense after it is established by the attacker, this is merely a shift in the burden of **production**. *Titan* always requires that the party attacking the patent bear the ultimate burden of persuasion. Namely, a “vulnerable” patent is one in which the attacker has presented sufficient evidence to form a “substantial defense” which has not been clearly overcome by the movant. *Cf. Titan*, 566 F.3d at 1377-78. A patent assertion that is “vulnerable” is one that is not likely to succeed at trial.

III. THE PETITION OVERSTATES THE ALLEGED CONSEQUENCES OF THE PANEL DECISION

The allegedly “stark” consequences imagined by Petitioners and Judges Newman and O’Malley in their dissents are grossly overstated and do not justify review here.

A. Although Preliminary Injunctions Are “an Extraordinary Remedy,” They Are Still Available Under the *Titan* Analytical Framework

Petitioners argue that the “difficulty of obtaining a preliminary injunction under the Federal Circuit’s improper standard reduces the likelihood that a patentee will have the full benefit of its statutory right to exclusivity....” (Pet. 27). This argument lacks merit.

This Court has repeatedly observed that “a preliminary injunction is an extraordinary and drastic remedy.” *Mazurek*, 520 U.S. at 972; *see also Winter*, 555 U.S. at 22 (2008) (“injunctive relief [is] an extraordinary remedy”). The rush and haste involved in determining preliminary injunctions, and the mistakes that are often made in complex patent cases—even without such time pressures—cautions against adopting an artificially low threshold for such an extraordinary remedy. *See, e.g., Univ. of Tex.*, 451 U.S. at 395.

As Justice Kennedy stated in his concurrence in *eBay*, “[b]oth the terms of the Patent Act and the traditional view of injunctive relief accept that the existence of a right to exclude does not dictate the remedy for a violation of that

right.” *eBay*, 547 U.S. at 396 (Kennedy, J., concurring). The majority in *eBay* held that a patent does not grant an absolute right to exclusivity even following a substantive finding that the patent is valid and infringed. *See eBay*, 547 U.S. at 391-92. If a patent which is adjudicated to be valid and infringed does not necessarily entitle a patentee to a permanent injunction, then, *ipso facto*, a patent claim that is vulnerable should not entitle the patentee to a preliminary injunction either.

Moreover, the concern expressed in Judge Newman’s dissent that the standard applied “essentially negates the possibility of grant of a preliminary injunction to preserve the status quo during patent litigation” (App. 68a)—a concern lightly echoed by Petitioners (Pet. 12, 26-27)—has not been borne out in practice.

Since the June 1, 2011 Panel decision, district courts have had no difficulty in understanding and applying the *Titan* analytical framework to issue preliminary injunctions in patent infringement actions. (*Contra* Pet. 13; App. 68a). For example, in *Sciele Pharma Inc. v. Lupin Ltd.*, No. 09-0037 (D. Del. Dec. 6, 2011) (unpublished), the district court granted a preliminary injunction prohibiting Lupin from further importation and sale of its generic version of the Fotamet[®] drug. The district court applied the same analytical framework that the Petition now questions, and rejected Defendants’ invalidity arguments as insufficient to justify denying the preliminary injunction. *See also, e.g., Momenta Pharmaceuticals, Inc. v. Amphastar Pharmaceuticals, Inc.*, No. 11-11681 (D. Mass. Oct. 28, 2011) (applying *Titan* analytical framework and entering preliminary injunction).

Even in the present case, the Panel affirmed the preliminary injunction with respect to the '316 patent, further evidence that there is no “difficulty of obtaining a preliminary injunction” under the standard applied. (*Compare* Pet. 27, *with* App. 21a).

B. *Titan* Already Addressed the Alleged Confusion

Judge O'Malley's dissent suggests that “[d]istrict courts across the country have struggled with [the Federal Circuit's] precedent in [the preliminary injunction] area.” (App. 77a). The Petition and an *amicus* brief similarly assert that there is confusion regarding the proper analytical framework. (Pet. 24; Brief for PhRMA, at 15-18).

Petitioners' support for this proposition is two pre-*Titan* district court opinions. (Pet. 24-25). The first opinion, *Erico Int'l Corp. v. Doc's Mktg., Inc.*, 2007 WL 108450 (N.D. Ohio Jan. 9, 2007), *vacated*, 516 F.3d 1350 (Fed. Cir. 2008), was decided by Judge O'Malley while still a district judge. In the other opinion, the appeal was dismissed as moot. *PrintGuard Inc. v. Anti-Marking Sys., Inc.*, 535 F.Supp.2d 189 (D. Mass. 2008), *appeal dismissed as moot*, 327 F.App'x 877 (Fed. Cir. 2008); *see also* Brief of PhRMA, at 16 (citing *Abbott Laboratories v. Sandoz, Inc.*, 544 F.3d 1341 (Fed. Cir. 2008), as purportedly exemplifying “tension in the Federal Circuit's precedent”).

To the extent any confusion existed in 2007 and 2008 when these opinions were issued, that confusion was eliminated by the Federal Circuit's *Titan* opinion, which issued in 2009.

Indeed, perhaps the best evidence that there is no confusion is that both Petitioners and Respondents in this case advocated the same analytical framework, both at the district court and appellate levels. The district court's decision here demonstrates that district courts considering preliminary injunctions are far more likely to struggle with claim construction and factual issues than with selecting the proper analytical framework.

C. Concerns Over Obtaining Enhanced Damages for Willful Infringement Do Not Justify This Court's Review

Petitioners also assert that patentees will be unable to recover enhanced damages for willful infringement as a result of the Panel Decision. (Pet. 26-27). This concern is both misplaced and inappropriate to address as a hypothetical for the first time at this stage.

In 2007, the Federal Circuit reconsidered its law on willful infringement in *In re Seagate Technology, LLC*, 497 F.3d 1360 (Fed. Cir. 2007) (*en banc*). Under *Seagate*, to establish willful infringement, a patentee must show, *inter alia*, that the defendant's actions were objectively reckless. *See Seagate*, 497 F.3d at 1371 (“[A] patentee must show by clear and convincing evidence that the infringer acted despite an objectively high likelihood that its actions constituted infringement of a valid patent.”). *Seagate* likened the test of objective recklessness to the standard that would be applied in a preliminary injunction proceeding. *Id.* at 1374.

However, as the Federal Circuit has recently made clear, a decision on a preliminary injunction that is

based on legal or factual errors, like the decision here, does not govern whether a plaintiff establishes objective recklessness and is entitled to recover enhanced damages. *See Powell v. Home Depot U.S.A., Inc.*, 2011 U.S. App. LEXIS 22838, at *30-31 (Fed. Cir. Nov. 14, 2011).

Moreover, even had the Federal Circuit not recently rejected Petitioners' position, this would hardly be the case to address jurisprudence on enhanced damages, since the issue has neither been briefed nor addressed below.

In sum, Petitioners' alleged fears are unfounded and overstated, and do not justify granting their Petition.

IV. IN ANY EVENT, THIS IS THE WRONG CASE FOR SUPREME COURT REVIEW

In any event, even if this Court were inclined to address the issues raised by the Petition, this case is not an appropriate vehicle for such review.

A. This Court Recognizes That the Kinds of Errors Identified by the Panel Justify Reversal

The district court's errors here are the kinds of errors that this Court recognizes are "clearly erroneous" and justify reversal of a district court order.

1. The district court entered the preliminary injunction based on admittedly wrong claim constructions, which are errors of law. Specifically, the district court rejected prior art presented by Respondents because the district court relied upon incorrect constructions of "pre-fastened disposable pants" in the '143 Patent and "sheer

stress” in the ’939 Patent. (App. 11a, 15a-16a). Claim construction is a question of law, *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996), and “[a] district court by definition abuses its discretion when it makes an error of law. ... The abuse-of-discretion standard includes review to determine that the discretion was not guided by erroneous legal conclusions.” *Koon v. U.S.*, 518 U.S. 81, 100 (1996); *see also, e.g., Cooter & Gell*, 496 U.S. at 405 (“A district court would necessarily abuse its discretion if it based its ruling on an erroneous view of the law...”).

2. The district court was clearly erroneous because it did not compare the correct portion of Respondents’ prior art reference to the ’187 patent claims. Specifically, the district court overlooked the explicit teaching that the rods, which Respondents claimed constituted “separation members,” lay between the leading and trailing half of the training pant during folding. (App. 8a-9a). Here, again, this Court has made it clear that “[a] district court would necessarily abuse its discretion if it based its ruling ... on a clearly erroneous assessment of the evidence.” *Cooter & Gell*, 496 U.S. at 405.

3. The district court also misbalanced the facts and thus made a clear error in judgment. In particular, the district court did not sufficiently consider that a prior art machine “has an inspection system very similar to the inspection methods taught by the ’143 patent.” (App. 13a). The district court also “failed to accord proper weight” to an explicit statement contained in prior art that Respondents argued rendered the ’939 patent invalid. (App. 17a). This court has found that the failure to “give sufficient weight” to evidence is clear error and constitutes

an abuse of discretion in the context of a preliminary injunction. *See, e.g., Winter*, 555 U.S. at 28 (holding that the district court abused its discretion in entering a preliminary injunction because it “did not give sufficient weight to the views of several top Navy officers.”).

B. The Issues Raised in the Petition Were Not Briefed to the District Court or the Panel, and Were Not Adequately Briefed to the Court of Appeals

As the above Statement of Case demonstrates, Petitioners did not raise their current contentions to the district court or the Panel. To the extent that they raised some of these issues in their Combined Rehearing Petition, it was not with sufficient clarity to establish their objections to the application of what Judge O’Malley recognized was a proper analytical framework for granting and reviewing a preliminary injunction “given [Federal Circuit] precedent.” (App. 76a).

Petitioners’ failure to raise (let alone articulate) their current arguments below renders this an inappropriate case to address the Federal Circuit’s preliminary injunction framework. *See, e.g., Grupo Mexicano De Desarrollo v. Alliance Bond Fund*, 527 U.S. 308, 319 n.3 (1999) (“Because this argument was neither raised nor considered below, we decline to consider it.”); *Adickes v. S. H. Kress & Co.*, 398 U.S. 144, 148 (1970) (“Where issues are neither raised before nor considered by the Court of Appeals, this Court will not ordinarily consider them.”).

C. Resolving This Interlocutory Petition Will Not Resolve the Dispute Between the Parties

Review by this Court will have little if any effect on the dispute between the parties. The preliminary injunction at issue was granted 19 months ago. (App. 25a). In compliance with the preliminary injunction, Respondents have already implemented new manufacturing processes that Petitioners do not accuse of infringing any of the three patents as to which the preliminary injunction was vacated. (*See* ECF No. 325 at 2). Moreover, the PTO has issued an office action finding the asserted '187 patent claims invalid. (*See* note 1, *supra*). Finally, the lower court proceedings have already reached the summary judgment stage.

Thus, even if this Court were to grant certiorari and either affirm or reverse the Panel Decision, this Court's decision is unlikely to impact the parties or the district court litigation in a meaningful way. In either event, the district court will still be required to address the validity issues in a dispositive manner, and it will, more likely than not, do so before this Court resolves the parties' interlocutory disputes if certiorari is granted.

In sum, this is simply not an appropriate case to consider the issues Petitioners seek to raise.

CONCLUSION

Respondents respectfully submit that the Petition should be denied.

Respectfully submitted,

D. MICHAEL UNDERHILL
ERIC J. MAURER
BOIES, SCHILLER
& FLEXNER LLP
5301 Wisconsin Avenue, NW
Washington, DC 20015
(202) 237-2727

KENNETH P. GEORGE
Counsel of Record
IRA E. SILFIN
MICHAEL V. SOLOMITA
CHARLES R. MACEDO
BRIAN A. COMACK
AMSTER, ROTHSTEIN
& EBENSTEIN LLP
90 Park Avenue
New York, NY 10016
(212) 336-8000
kgeorge@arelaw.com

Counsel for Respondents

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