No. A-_____

In the Supreme Court of the United States

INDIVIOR, INC., ET AL.,

Applicants,

v.

DR. REDDY'S LABORATORIES S.A., ET AL.,

Respondents.

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

APPLICATION TO STAY MANDATE OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT PENDING CERTIORARI

To the Honorable John G. Roberts, Jr., Chief Justice of the
United States and Circuit Justice for the Federal Circuit

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PARTIES TO THE PROCEEDING

Applicants are Indivior, Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. All were plaintiffs in the district court and appellees in the court of appeals.

Respondents are Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. All were defendants in the district court and appellants in the court of appeals.

RULE 29.6 DISCLOSURE STATEMENT

Indivior Inc. is a wholly owned subsidiary of Indivior Finance LLC. Indivior Finance LLC is a wholly owned subsidiary of Indivior US Holdings, Inc., which is in turn a wholly owned subsidiary of RBP Global Holdings Limited. RBP Global Holdings Limited is a wholly owned subsidiary of Indivior Global Holdings Limited, which is in turn a wholly owned subsidiary of Indivior PLC, a public company limited by shares. Standard Life Aberdeen and Scopia Capital Management both hold more than 10% of the issued share capital of Indivior PLC.

Indivior UK Limited is a wholly owned subsidiary of RBP Global Holdings Limited. RBP Global Holdings Limited is a wholly owned subsidiary of Indivior Global Holdings Limited, which is in turn a wholly owned subsidiary of Indivior PLC, a public company limited by shares. Standard Life Aberdeen and Scopia Capital Management both hold more than 10% of the issued share capital of Indivior PLC.

Aquestive Therapeutics, Inc. has no parent company, and no publicly traded company owns 10% or more of Aquestive Therapeutics, Inc.

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TO THE HONORABLE JOHN G. ROBERTS, JR., CHIEF JUSTICE OF THE UNITED STATES AND CIRCUIT JUSTICE FOR THE FEDERAL CIRCUIT:

Pursuant to 28 U.S.C. § 1651(a) and Supreme Court Rules 22 and 23, Applicants Indivior, Inc. and Indivior UK Limited (collectively, "Indivior"), and Applicant Aquestive Therapeutics, Inc. ("Aquestive"), respectfully request an order staying issuance of the mandate of the United States Court of Appeals for the Federal Circuit in *Indivior, Inc. v. Dr. Reddy's Laboratories, S.A.*, Appeal Nos. 18-2167, 18-2169, pending the filing of and final action by this Court on a petition for a writ of certiorari seeking review of that judgment, which Applicants will file in time for the petition

and any opposition to be considered by the Court before the end of this Term. Applicants expect that the mandate will issue Tuesday, February 19, 2019.[1] The district court has indicated its intent to vacate the preliminary injunction immediately after it receives the Federal Circuit's mandate.

Should the Court determine that it needs additional time to consider this application before the mandate issues, Applicants respectfully request that the Court enter an administrative stay pending disposition of this application.

INTRODUCTION

In a divided ruling, the Federal Circuit has ordered the dissolution of a preliminary injunction granted to Applicants by the district court in this Hatch-Waxman action. The Federal Circuit's ruling clears the way for drug companies to prematurely launch generic versions of Applicants' patent-protected Suboxone Film, a pharmaceutical product for treatment of opioid dependency. If the mandate issues, Respondents will launch their generic, others will follow, and Applicants' business will be immediately and irreparably harmed. All of this will come to pass because of a divided ruling below that makes two fundamental errors of law worthy of this Court's review.

[1] The Federal Circuit's order of February 11, 2019 denying an administrative stay provided that the mandate will issue "7 days from the date" of that order. App.124a. However Monday, February 18, 2019, is designated as a "Legal Holiday" in honor of Washington's Birthday, 5 U.S.C. § 6103(a), Fed. R. App. P. 26(a)(6)(A). Rule 26 provides that, in computing any time period specified in a "court order," if the last day of the period is a legal holiday, "the period continues to run until the end of the next day that is not a Saturday, Sunday, or legal holiday." Fed. R. App. P. 26(a)(1)(C).

First, the panel majority expressly disregarded all equitable considerations in reviewing the district court's preliminary injunction because it believed, on the limited preliminary-injunction record before it, that Applicants' infringement claim is unlikely to succeed. How to apply the four-factor test for preliminary injunctions has divided courts across the country since this Court's decision in *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7 (2008). Some circuits continue to use the longstanding sliding-scale standard. Other circuits view a minimum likelihood of success as a threshold requirement, or consider the four factors as requirements that must be separately satisfied rather than factors that a court must balance. Such an important question should not depend on geography. This case, where the district court's undisturbed findings establish that the risk of harm, balance of equities, and public interest all strongly favor an injunction, presents an ideal opportunity to resolve the disagreement and adopt a uniform standard.

Second, the majority opinion below takes the novel position that a supposed disclaimer in a patent specification can narrow the scope of a patent claim even in the absence of any corresponding language in the claim. That ruling defies this Court's long-standing instruction that no court may read a limitation, let alone one removed during prosecution, into a claim without a textual basis in the claim itself. It casts doubt on the scope of patent claims, undermines the value of patents, and will promote frequent litigation. And it reflects the Federal Circuit's varied, panel-

dependent approach to identifying claim-scope limiting disclaimers in a patent specification. This case is an ideal vehicle for this Court to offer authoritative guidance that will improve the reliability and consistency of claim construction.

If the mandate issues and Respondents launch their generic at risk, the harm to Applicants will be immediate, severe, and irreversible. The district court's undisturbed findings make that clear. Even a later order finding infringement and directing Respondents to pull their generic from the market will not correct the irreparable damage that will already have been done. This is not simply a matter of money. As the district court found, the harm to Applicants will extend far beyond lost sales. Respondents' launch will undermine Suboxone Film's formulary status and tier pricing, reset the market toward generic opioid treatments of all kinds, slash Suboxone Film's market share, undermine the goodwill Indivior has built with physicians, patients, and pharmacies, and jeopardize revenue from a product that now accounts for 98% of Indivior's U.S. revenue. An entire business, and the jobs and livelihoods that depend on it, will be in peril.

Respondents, meanwhile, face *no irreparable harm* from any preliminary injunction or stay. They have an entire portfolio of generic products and are protected in this case by a $72 million bond, an amount the district court determined fully protects them from any harm pending trial on the merits.

Given the risk of severe and irreparable harm to Applicants, and the substantial questions presented that warrant this Court's review, Applicants respectfully request that the Court stay issuance of the Federal Circuit's mandate and maintain the

status quo pending disposition of Applicants' petition for a writ of certiorari, which Applicants will file in time for the petition and any opposition to be considered by the Court before the end of this Term.

Applicants have exhausted all possibilities of securing a stay of the mandate from the Federal Circuit, and the district court has indicated its intent to vacate the preliminary injunction immediately after it receives the Federal Circuit's mandate. Applicants sought and were denied a stay by the Federal Circuit, with Judge Newman, who dissented below, indicating that she would have granted the stay.

OPINIONS BELOW

The opinion of the district court granting Applicants' motion for a preliminary injunction (App.1a–30a)[2] is unreported. *See Indivior Inc. v. Dr. Reddy's Labs. S.A.*, Civ. No. 17-7111 (KM)(CLW), 2018 WL 3496643 (D.N.J. July 20, 2018). The court's order entering the preliminary injunction (App.31a–32a) is unreported.

The Federal Circuit's majority opinion (App.33a–53a), and the dissenting opinion (App.54a–67a), are unreported. *See Indivior Inc. v. Dr. Reddy's Labs., S.A.*, — F. App'x —, Nos. 18-2167, 18-2169, 2018 WL 6069706 (Fed. Cir. Nov. 20, 2018). The Federal Circuit's judgment (App.68a–69a), and its orders denying Applicants' petition for rehearing (App.70a–71a), motion to stay issuance of the mandate (App.107a–108a), and motion for an administrative stay (App.123a–124a), are all unreported.

[2] "App." citations are to the Appendix filed contemporaneously with this application.

JURISDICTION

The district court had jurisdiction over this patent-infringement action pursuant to 28 U.S.C. §§ 1331 and 1338. The Federal Circuit had jurisdiction over the appeal from the district court's order granting the preliminary injunction pursuant to 28 U.S.C. § 1292(a)(1). The Federal Circuit issued its opinion and judgment vacating the preliminary injunction on November 20, 2018. The Federal Circuit denied Applicants' petition for panel rehearing and rehearing en banc on February 4, 2019.

On February 5, 2019, Indivior and Aquestive filed with the Federal Circuit a request to stay issuance of the court's mandate. The Federal Circuit denied that request over Judge Newman's dissent. That same day, Indivior and Aquestive moved for an administrative stay pending this Court's resolution of this application. The Federal Circuit denied the administrative stay on February 11, 2019, and entered an order stating that the mandate will issue "7 days from the date of th[at] order," so that the mandate is now expected to issue on Tuesday, February 19, 2019, (*see* note 1, *supra*). This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1254, and may stay the Federal Circuit's mandate pursuant to 28 U.S.C. § 1651(a).

STATEMENT OF THE CASE

1. Indivior and Aquestive developed and now market Suboxone® Sublingual Film ("Suboxone Film"). Suboxone Film is a leading treatment for opioid dependency and the first Food and Drug Administration ("FDA")-approved sublingual film, a rapidly dissolving film that adheres to the underside of a patient's tongue. Suboxone Film is protected by a number of patents listed in *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"), including U.S. Patent No. 8,603,514

(the "'514 Patent") and U.S. Patent No. 9,931,305 (the "'305 Patent"). Sales of Suboxone Film, which Aquestive manufactures and supplies to Indivior, now comprise 98% of Indivior's U.S. revenue.

The active ingredient in Suboxone Film, buprenorphine, has been shown to have advantages over other opioid treatments. But Suboxone Film is not the only buprenorphine-based treatment for opioid dependency. Other products, including non-film generics like buprenorphine-naloxone tablets, are on the market.

The inventors of Suboxone Film achieved what the prior art had tried but failed to accomplish: a final film in which the amount of particulate active ingredient is uniform from one dosage unit to another. This invention, captured in patent claims that recite a film composition having this specific content uniformity, was critical to developing a dissolvable film that could deliver consistent dosages of an active pharmaceutical ingredient to the patients who use it.

2. Between 2013 and 2015, several generic drug manufacturers filed Abbreviated New Drug Applications ("ANDAs") seeking FDA approval to market generic versions of Suboxone Film. Applicants initiated Hatch-Waxman proceedings against each of the manufacturers in the U.S. District Court for the District of Delaware, asserting that the proposed generics infringe, among others, the '514 Patent.

Because the ANDAs were filed at different times, the '514 Patent-infringement litigation resulted in separate trials. In the first trial, the Delaware district court found that the '514 Patent was infringed by the proposed generics manufactured by Watson Laboratories, Inc. ("Watson"), Actavis Laboratories UT, Inc. ("Actavis"), Par

Pharmaceutical, Inc. ("Par"), and Intelgenx Technologies Corp. ("Intelgenx"). *See Reckitt Benckiser Pharms. Inc. v. Watson Labs., Inc.*, C.A. Nos. 13-1674-RGA, 14-422-RGA, 2016 WL 3186659 (D. Del. June 3, 2016).[3] Par and Intelgenx later settled.

In the next case, the district court ruled that Respondents' proposed generics did not infringe the '514 Patent. *See Reckitt Benckiser Pharms. Inc. v. Dr. Reddy's Labs. S.A.*, C.A. Nos. 14-1451-RGA, 14-1573-RGA, 14-1574-RGA, 2017 WL 3837312 (D. Del. Aug. 31, 2017). The judgment rested on a number of shifting claim constructions related to the words "dried" and "drying" in the claims of the '514 Patent. *See id.* at *4–6. The district court gave those terms their plain meaning in *Watson*, but then concluded in *Dr. Reddy's* that the patentees disclaimed certain methods of drying to produce the claimed compositions with the specified content uniformity. *Id.* at *4. Specifically, the court concluded that the '514 Patent did not encompass films dried "solely employing conventional convection air drying from the top," and then determined that Respondents' drying process did not meet the purported "dried/drying" limitation, as the court had construed it. *Id.* at *6.[4]

In a third Delaware case, the district court concluded that a generic version of Suboxone Film manufactured by Alvogen Pine Brook, LLC ("Alvogen") did not infringe the '514 Patent. The court purported to again rely on a narrowing construction

[3] Applicant Indivior, Inc. was formerly known as Reckitt Benckiser Pharmaceuticals Inc. Applicant Indivior UK Limited formerly went by RB Pharmaceuticals Limited.

[4] Another generic manufacturer, Teva Pharmaceuticals USA, Inc., agreed to be bound by the result of the '514 Patent-infringement litigation against Respondents.

of the "dried/drying" claim terms, but introduced further changes to that construction. *See Indivior Inc. v. Mylan Techs. Inc.*, 298 F. Supp. 3d 775 (D. Del. 2018).[5]

3. The parties appealed and cross-appealed various aspects of the Delaware district court's judgments in the '514 Patent-infringement actions. Those appeals remain pending at the Federal Circuit. *See Indivior Inc. v. Dr. Reddy's Labs. S.A.*, No. 17-2587 (Fed. Cir.) (consolidated '514 appeals); *Indivior Inc. v. Alvogen Pine Brook, LLC*, No. 18-1949 (Fed. Cir.) (companion Alvogen appeal).

On February 12, 2019, the Federal Circuit issued an order granting Indivior and Aquestive's motion to expedite oral argument in the '514 appeals to the next available oral argument calendar. *See* Order, *Indivior Inc. v. Dr. Reddy's Labs. S.A.*, No. 17-2587 (Fed. Cir. Feb. 12, 2019) (ECF No. 56); Order, *Indivior Inc. v. Alvogen Pine Brook, LLC*, No. 18-1949 (Fed. Cir. Feb. 12, 2019) (ECF No. 79).

4. Indivior and Aquestive have, at every stage of every dispute, maintained that their inventive compositions are not limited to any particular drying method. They won their initial patent infringement case on that basis. And they continue to seek that construction in the pending Federal Circuit appeals regarding the '514 Patent. But that patent was not the exclusive means through which Indivior and Aquestive could secure their full patent rights. So, even as they appealed the district court's erroneous construction of "dried/drying" in the '514 Patent, Aquestive continued to prosecute another patent application based on the same specification. To remove any doubt that the patent claims captured the full scope of the invention,

[5] Mylan Technologies, Inc., another generic manufacturer and co-defendant, settled.

Aquestive did not include the terms "dried" and "drying" in the patent application's claims. The Patent and Trademark Office allowed the new claims without those terms and issued the '305 Patent on April 3, 2018.

That same day, Indivior and Aquestive initiated Hatch-Waxman proceedings against Respondents and Alvogen for infringement of the '305 Patent. Indivior and Aquestive filed the actions in the District of New Jersey in light of this Court's decision in *TC Heartland LLC v. Kraft Food Group Brands LLC*, 137 S. Ct. 1514 (2017). *See id.* at 1516–17 (clarifying that a domestic corporation "resides" only in its State of incorporation for purposes of the patent venue statute).[6]

Respondents insinuated before the Federal Circuit that Indivior and Aquestive were forum shopping when they filed in New Jersey rather than pressing their new patent claims in Delaware, where the '514 actions had been litigated. *See* Defendants-Appellants' Opposition to Motion to Stay Issuance of the Mandate at 3, 9, *Indivior, Inc. v. Dr. Reddy's Labs., S.A.*, Nos. 18-2167 (Fed. Cir. Feb. 6, 2019) (ECF No. 124). But the New Jersey district court denied Respondents' motion to transfer venue to the District of Delaware. *See Indivior Inc. v. Dr. Reddy's Labs. S.A.*, Civ. Nos. 17-7106 (KM)(CLW), 17-7111 (KM(CLW), 17-7115 (KM)(CLW), 2018 WL 4089031 (D.N.J. Aug. 27, 2018). The court noted that Respondents did not dispute that venue was proper in New Jersey under *TC Heartland*. *Id.* at *2. Notably, the court also concluded

[6] Indivior and Aquestive also initiated '305 Patent-infringement actions Actavis and Teva in the Districts of Delaware and New Jersey, respectively. Those cases are ongoing. Actavis is presently enjoined from launching its generic because it was found to infringe the '514 Patent. Like in the '514 litigation, Teva has agreed to be bound by the result in the '305 infringement action against Respondents.

that Respondents had not established either that venue would have been proper in Delaware originally or that transfer was appropriate under the circumstances. *Id.* at *2–4. Indivior and Aquestive simply followed the law.

5. On June 14, 2018, FDA approved Respondents' ANDAs. Respondents immediately launched their generic product "at risk," meaning they put their generic on the market even though it is the subject of ongoing patent-infringement litigation.

The next morning, Indivior and Aquestive moved for a temporary restraining order and preliminary injunction pending trial, based on the '305 Patent. The district court convened a teleconference and issued a temporary restraining order later that afternoon. The parties then proceeded through expedited discovery and submitted extensive briefing and declarations from fact and expert witnesses. Two weeks later, the court held a full-day preliminary injunction hearing, and on July 13, 2018, it granted Aquestive and Indivior's motion for a preliminary injunction pending trial. *See* App.1a–30a (amended opinion), 31a–32a (preliminary injunction). Indivior subsequently posted a $72 million bond, an amount the district court determined would be adequate to compensate Respondents for any damages they might incur through trial, if they were to ultimately prevail. App.32a.

In granting the preliminary injunction, the district court concluded that (1) Respondents' generic version of Suboxone Film likely infringes the '305 Patent; (2) Indivior and Aquestive would suffer irreparable harm absent an injunction; (3) the balance of the equities "appears to favor Indivior"; and (4) "the public interest will be served by the issuance of a preliminary injunction in this case." App.2a, 21a–29a.

The district court supported its conclusions with extensive factual findings. With respect to the likelihood of success, the district court found that Indivior and Aquestive's expert credibly explained that a person of ordinary skill in the art would understand that "neither the practicalities of production" nor the specification require any particular drying method to produce the claimed films. App.16a, 19a–20a.

The court then addressed the equitable considerations in detail. Entry into the market of a potentially infringing generic, the court determined, would cause Indivior and Aquestive "substantial and irreparable harm[]." App.28a. Indivior and Aquestive face severe "erosion of [their] position as the leader in the . . . market, a potential loss of formulary status, and damage to its goodwill and reputation among patients, physicians, pharmacies, and insurance plans." *Id.*; *see also* App.2a ("Entry of a generic would cause Indivior to lose market share and the [S]uboxone [F]ilm's advantageous formulary status, and would impair research and development."). Moreover, the lost market share and sales "would be difficult to recoup even if [Respondents'] ANDA product were eventually found to infringe the '305 Patent," App.28a, due "to the loss of formulary status and a change in tier pricing," App.26a (citing *Antares Pharma, Inc. v. Medac Pharma, Inc.*, 55 F. Supp. 3d 526, 536–37 (D. Del. 2014) (finding the launch of a competing product that would force the renegotiating of the current tier and pricing structure to carry the burden of demonstrating irreparable harm)).

In contrast, any potential harm to Respondents from a temporary delay in launching their generic would "more easily be calculated in damages" and guarded

against by the $72 million bond posted by Indivior. App.28a. Additionally, Respondents are "not a current market player and [they] ha[ve] no market share to lose"; their "losses [if any, would] stem from a market [they] seek[] to enter, not one that [they are] already in." *Id.* In the district court's view, Respondents "chose to enter the market 'at risk' and took the chance [they] could face a potential injunction against [their] product." *Id.* Moreover, any delay in launching Respondents' generic is "wrongful" only if that product is found not to infringe the '305 Patent. *See, e.g.*, *In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367–68 (Fed. Cir. 2008) (a previously approved generic found to infringe a valid patent no longer has final FDA approval to be on the market).

The district court also explained why "the public interest will be served by the issuance of a preliminary injunction in this case." App.29a. While "[t]he country faces a recognized opioid addition epidemic," the active ingredient in Suboxone Film (buprenorphine)—"which does not have some of the disadvantages associated with other opioid treatment[s]"—remains available through "other non-film generics" (including generic buprenorphine-naloxone tablets). App.28a–29a. Respondents, meanwhile, "offer[ed] only that the ease of use of the film, as opposed to, e.g., the under-tongue tablet, would naturally result in better compliance." App.29a. That consideration was "not enough to tilt the balance." *Id.* Protection of patent rights also reflects an important public interest. And with continued access to generic buprenorphine ensured, the public interest "favor[ed] protecting the exclusive rights" held by Indivior and Aquestive, patent rights that "encourage[] innovation and provide[] incentives for drug companies to continue costly development efforts." *Id.*

6. Respondents sought an expedited appeal to the Federal Circuit. Indivior and Aquestive opposed the motion to expedite because Respondents' arguments in the '305 preliminary injunction appeal depended on the alleged preclusive effect of the Delaware district court judgment then (and now) on appeal in the '514 cases. Indivior and Aquestive explained that it was critical to proceed in the proper order and first resolve the '514 appeals.[7] The judgments in those cases were on the merits, and based on a full trial record.[8] By contrast, the appeal regarding the '305 Patent concerned a preliminary injunction, and therefore only what would *likely* happen on the merits, along with substantial equitable considerations. *See generally* Opposition, *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, No. 18-2167 (Fed. Cir. July 24, 2018) (ECF No. 58-1). The Federal Circuit nevertheless granted Respondents' motion to expedite, and ordered Indivior and Aquestive to file their responsive brief in less than two weeks. *See* Order, *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, No. 18-2167 (Fed. Cir. July 27, 2018) (ECF No. 64). The Federal Circuit held oral argument in October, and on November 20, 2018, the Federal Circuit issued a split decision vacating the preliminary injunction (App.33a–53a), over a lengthy dissent by Judge Newman (App.54a–67a).

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[7] Resolution of the '514 appeals in Indivior and Aquestive's favor would be dispositive of Respondents' non-infringement and disclaimer arguments in this case.

[8] The '514 appeals include analysis of important issues not discussed in this appeal, including whether Respondents' product infringes even under the narrow construction that the district court applied in the '514 case. For example, the patent specification extensively discusses "zone drying," the drying method used by Respondents, as a method of "controlling the drying process" to make the inventive uniform films. *See* Joint Appendix at 6156, 33:23–56, *Indivior, Inc. v. Dr. Reddy's Labs. S.A.*, No. 18-2167 (Fed. Cir. Aug. 20, 2018) (ECF Nos. 85, 86).

The panel majority did not address or disturb the district court's findings that Indivior and Aquestive would be irreparably harmed absent an injunction, that the balance of equities favored them, and that the public interest favored protecting their exclusive patent rights pending trial on the merits. *See* App.53a ("[W]e need not reach the[se] other preliminary injunction factors."). And the panel did not question that the $72 million bond that Indivior has posted protects Respondents from any harm that could arise during the pendency of the injunction.

The panel majority vacated the preliminary injunction based solely on its view, after truncated briefing and on the limited appellate record, that the "district court's likelihood of success analysis was an abuse of discretion." *Id.* Although the '305 claims lacked the terms "dried" and "drying," the panel majority read a "drying process limitation . . . into the claims through the operation of [a] specification disclaimer." App.51a. Specifically, the panel majority held that the patentee "disclaimed the sole use of conventional top air drying to produce the claimed films," App.45a, because the specification suggested that the requisite content uniformity "cannot be achieved using conventional drying methods," App.50a. The panel majority did not explain how it could have been clear error for the district court to credit the testimony of Indivior and Aquestive's expert that a person of ordinary skill in the art would not understand the '305 Patent to disclaim use of any particular drying method. *See* App.20a ("I find that, in this preliminary posture, the opinion of Indivior's expert is more persuasive in that it is tied more closely to the patent language."). The panel simply ignored the expert testimony. It likewise ignored passages in the specification explaining how top

air drying could be employed in the manufacture of the film, so long as its effect is "balanced" by "other factors." Joint Appendix, *supra* note 8, at 6154, 29:55–62.

As noted above, the '305 Patent does not even use the terms "dried" or "drying" in the patent's claims. Nonetheless, the panel majority proposed that the drying-process limitation could be read into the term "continuously cast film" in the '305 claims—because a "'continuously cast film' . . . requires drying as the film starts out as a liquid and ends up as a solid that can be cut into individual dosages." App.47a. Ultimately, though, the panel majority declared that there was no need for a "textual hook" in the claim language for the drying-process limitation: "[W]e do not read our precedent as requiring a hook under the circumstances in this case." *Id.*

The panel majority then concluded that Indivior and Aquestive had not shown that their '305 infringement claim was likely to succeed "under this construction" disclaiming use of certain drying methods. App.51a. The panel majority held that the district court judgment that Respondents did not infringe the '514 Patent—the (still pending) challenge to which the panel leap-frogged to expedite this case—likely precludes the '305 infringement claim. App.52a–53a. The court predicated its holding on the notion that the purported disclaimer rendered the '305 claims "patentably indistinct from the '514 claims" as the Delaware court had narrowed them. App.53a.

Judge Newman vigorously dissented. She emphasized how "[t]he majority explicitly decline[d] to review the traditional equitable factors, such as the balance of harms, and omits any discussion of equity and discretion." App.64a. Yet "the balancing of all factors is the foundation of a discretionary ruling," and "[w]hen one side is

subject to substantially greater harm, this may outweigh other factors believed to favor the opponent." App.64a. And here "[t]he district court made extensive factual findings, detailing the likelihood of irreparable harm to Indivior in the absence of an injunction," and determining that the balance of equities and public interest favored an injunction. App.65a–66a. Judge Newman pointed out that the majority reviewed "[n]one of these findings." App.66a. Instead, it "ma[d]e appellate findings of the merits of infringement, although there has been no trial of infringement," and "'erroneously appl[ied] a decision of the district court in Delaware on a different patent with different claims, although that decision is pending on appeal." App.55a–56a.

Whether to grant an injunction pending trial, Judge Newman explained, is committed to the district court's "sound discretion," and "will not be disturbed" on appeal "unless contrary to some rule of equity, or the result of improvident exercise of judicial discretion." App.66a (quoting *Deckert v. Independence Shares Corp.*, 311 U.S. 282, 290 (1940)) . In this case, the district court's balancing of the equitable factors was "fully in accord with precedent." App.66a. By nonetheless setting aside the preliminary injunction, the panel majority "err[ed] in fundamental ways" and failed to afford the district court the equitable discretion it was due. App.56a.

Judge Newman also explained why "[t]he panel majority's theory of specification disclaimer is devoid of support in law or precedent." App.62a. Supreme Court and Federal Circuit precedent has stressed repeatedly "the primacy of the claims" in defining the patent right. App.57a. Here, "[t]he claims are for the films, not the drying method." *Id.* Yet, the majority imported a drying-process limitation that the Delaware

district court had found in the '514 Patent into the '305 Patent, even though the patentee "expressly amended the '305 claims to remove the drying method." App.58a. "This is improper. It is improper for a court to rewrite a product claim to contain a process limitation from the specification—here contained in a preferred but not sole embodiment—for it confounds the roles of the specification and the claims." *Id.*

Moreover, the majority relied on a purported "specification disclaimer" to read back in a "'drying process limitation' that was cancelled from the claims." App.59a. But "[s]pecification disclaimer requires the clear and explicit intent by the patentee to limit the claims," and "the intrinsic evidence negates any intent to include in the claims any drying limitation from the specification." App.59a–60a. By amending "the '305 patent . . . to present claims that are not limited to any drying method," the patentee made their intent "explicit" and "clear." App.60a. "This action" should have been "dispositive of patentee intent to remove such claim limitations." *Id.*

Finally, Judge Newman noted that the mere fact that the '305 Patent contained a terminal disclaimer was not a "strong clue" that "claim preclusion is likely to apply." App.63a (internal quotation marks omitted). "[T]he filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits[.]" *Id.* (quoting *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874–75 (Fed. Cir. 1991)) (internal quotation marks omitted). Moreover, Judge Newman reasoned, the Delaware district court's '514 judgment is still on appeal; if the Federal Circuit va-

cates it, that district court decision will not have any preclusive effect. App.64a. Rather than "[i]mposing irreparable harm on Indivior" based on a judgment that might be vacated, the better course would be "to preserve the status quo." *Id.*

7. The FDA approved Alvogen's ANDA on January 24, 2019. Indivior and Aquestive immediately obtained a temporary restraining order in their '305 infringement action. On February 1, 2019, the district court entered a stipulated order enjoining Alvogen from launching its generic version of Suboxone Film unless the Federal Circuit issues a mandate vacating the injunction against Respondents.

8. Respondents subsequently moved the Federal Circuit panel to issue its mandate immediately. The Federal Circuit denied that request and on December 20, 2018, Indivior and Aquestive filed a petition for panel rehearing and rehearing en banc. The Federal Circuit called for a response from Respondents, and ultimately denied the petition on February 4, 2019. App.70a–71a. The order denying rehearing provided that the mandate would issue 7 days thereafter. App.71a.

The next day, Indivior and Aquestive filed an emergency motion (App.72a–106a) asking the Federal Circuit to stay issuance of the mandate until that court can resolve the now-expedited '514 appeals and until this Court could consider Indivior and Aquestive's forthcoming petition for a writ of certiorari in this case.

The stay motion noted that the district court's findings on irreparable harm, the balance of the equities, and the public interest remained undisturbed. App.88a–91a. Indivior and Aquestive would be irreparably harmed by the launch of a potentially infringing generic, and under the circumstances, equity and the public interest

favored guarding against that harm, especially when Respondents are protected by a $72 million bond. The motion asked the Federal Circuit to temporarily maintain the status quo, rather than issuing the mandate and risking one-sided, irreparable harm to Indivior and Aquestive—when, in the '514 appeals, the Federal Circuit could soon eliminate the basis for the panel majority's claim-preclusion ruling (*see* note 7, *supra*), and when there is a reasonable probability this Court will grant certiorari.

The panel majority denied the motion to stay on February 11, 2019, over the dissent of Judge Newman. App.107a–108a. That same day, Aquestive and Indivior filed an emergency motion asking the Federal Circuit to enter an administrative stay long enough to preserve this Court's ability to determine whether to issue an administrative stay pending its review of this application. App.109a–122a. The Federal Circuit denied the motion that same day. App.123a–124a.

The mandate is now scheduled to issue on Tuesday, February 19, 2019 (see note 1, *supra*). App.124a. The district court has indicated its intent to vacate the preliminary injunction immediately after it receives the Federal Circuit's mandate. If the mandate issues, and the preliminary injunction barring Respondents' at-risk launch is lifted, Respondents and Alvogen could launch their generics immediately. Those launches likely will soon trigger other generic launches.

REASONS FOR GRANTING THE STAY

The All Writs Act empowers the Supreme Court to issue "all writs necessary or appropriate in aid of [its] jurisdiction[] and agreeable to the usages and principles of law." 28 U.S.C. §1651(a). This includes the power to "hold an order in abeyance" by granting a stay pending appellate review. *Nken v. Holder*, 556 U.S. 418, 426 (2009). Together, the All Writs Act and Rule 23 authorize a Circuit Justice to stay issuance of a Circuit Court's mandate pending the disposition of a petition for a writ for certiorari. Stephen M. Shapiro et al., Supreme Court Practice 885 (10th ed. 2013).

A stay pending disposition of a certiorari petition is warranted if there is "(1) a reasonable probability that this Court will grant certiorari, (2) a fair prospect that the Court will then reverse the decision below, and (3) a likelihood that irreparable harm will result from the denial of a stay." *Maryland v. King*, 133 S. Ct. 1, 2 (2012) (Roberts, C.J., in chambers) (internal quotation marks and alterations omitted). The Court also may consider the "'balance of the equities'—to explore the relative harms to applicant and respondent, as well as the interests of the public at large." *Rostker v. Goldberg*, 448 U.S. 1306, 1308 (1980) (Brennan, J., in chambers). This application satisfies all four criteria.

I. There Is A Reasonable Probability That This Court Will Review And A Fair Prospect It Will Reverse The Decision Below.

The panel majority's decision is based on two erroneous rulings of law that present substantial issues worthy of this Court's review: (1) whether an appellate court can disregard all equitable considerations in reviewing an order granting a preliminary injunction because it believes, on review of a limited record developed for

preliminary injunction proceedings, that the plaintiff is not likely to succeed on the merits; and (2) whether a supposed disclaimer of patent scope in a patent specification can narrow the scope of a patent's claim where there is no corresponding language in the claim to construe. The first issue—regarding the correct standard of review of preliminary injunction rulings—presents an important and recurring issue that has divided courts across the country. The second issue—regarding the limits on specification disclaimers without a textual hook in the claims—is a subject of frequent and inconsistent rulings by the Federal Circuit, casting into doubt the scope of patent claims, undermining the value of patents, and promoting frequent litigation.

A. There Is a Reasonable Probability that this Court Will Grant Certiorari to Review the Panel's Preliminary-Injunction Ruling Because it Widens an Important Circuit Split.

The Federal Circuit's opinion conflicts with precedent of several circuits holding that a sliding scale governs whether to grant preliminary equitable relief. That conflict presents an important issue that merits resolution by this Court. *See* Sup. Ct. R. 10(a). And this case also presents an ideal vehicle for the Court to resolve this split.

This Court in *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7 (2008), stated that "[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." *Id.* at 20 (citations omitted). *Winter* did not explain whether it intended to alter the sliding-scale standard that numerous circuits had applied for decades. Since then, there has been inconsistency among the circuits

concerning the standard that governs preliminary-injunction requests. As one commentator noted:

> Preliminary injunctions are among the most broadly and frequently used remedies employed by federal courts, and courts have traditionally used a four-factor test in determining whether to grant a preliminary injunction. However, circuit courts are divided on the validity of the "sliding scale" test, in which the trial court weighs the strength of each of the factors against one another and allows serious questions going to the merits to satisfy the likelihood of success prong. In a recent decision involving the propriety of a preliminary injunction—*Winter v. Natural Resources Defense Council*—the Supreme Court failed to comment on whether the sliding scale test remains viable, thus deepening the existing circuit split.

See, e.g., Bethany M. Bates, Note, *Reconciliation After* Winter*: The Standard for Preliminary Injunctions in Federal Courts*, 111 Colum. L. Rev. 1522, 1522 (2011).[9]

The panel majority's decision takes a clear stand against the sliding-scale standard: "Having held that the district court's likelihood of success analysis was an abuse of discretion, we need not reach the other preliminary injunction factors." App.53a. This decision is not the sole Federal Circuit decision to take this view. Other cases have held that a movant must establish a sufficiently high likelihood of success first, without regard for the other three preliminary-injunction factors; as a result, a strong showing on the other factors cannot overcome a lesser likelihood of success. *E.g.*, *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1325 (Fed. Cir.

[9] *See also, e.g.*, Jean C. Love, *Teaching Preliminary Injunctions After* Winter, 57 St. Louis U. L.J. 689, 706–07 (2013) (describing confusion over whether *Winter* foreclosed access to the sliding scale); Kevin J. Lynch, *The Lock-In Effect of Preliminary Injunctions*, 66 Fla. L. Rev. 779, 799 (2014) (describing the conflict among the circuits); Rachel A. Weisshaar, Note, *Hazy Shades of* Winter*: Resolving the Circuit Split Over Preliminary Injunctions*, 65 Vand. L. Rev. 1011, 1033–48 (2012) (same).

2004) ("[A] movant is not entitled to a preliminary injunction if he fails to demonstrate a likelihood of success on the merits."). Yet the Federal Circuit has been inconsistent. In other cases, it has articulated "a sliding scale approach." *Qingdao Taifa Grp. Co. v. United States*, 581 F.3d 1375, 1378–79 (Fed. Cir. 2009); *see also, e.g.*, *Sofamor Danek Grp., Inc. v. DePuy-Motech, Inc.*, 74 F.3d 1216, 1219 (Fed. Cir. 1996).

Other circuits also have taken a stand against the sliding-scale standard. The Fourth and Fifth Circuits, for instance, hold that *each* factor is an independent "requirement" and "satisfying one . . . does not necessarily affect the analysis of the other requirements." *Def. Distributed v. U.S. Dep't of State*, 838 F.3d 451, 457 (5th Cir. 2016); *see also Real Truth About Obama, Inc. v. FEC*, 575 F.3d 342, 347 (4th Cir. 2009), *vacated on other grounds*, 559 U.S. 1089 (2010), *reissued-in-part*, 607 F.3d 355 (4th Cir. 2010) (per curiam). That is, they view not only the likelihood of success as a threshold factor, as the panel did here, but also each of *Winter*'s factors as presenting an independent threshold a party seeking a preliminary injunction must clear.

These threshold-based standards conflict with decisions from at least three other circuits. In *Reilly v. City of Harrisburg*, 858 F.3d 173 (3d Cir. 2017), the Third Circuit expressly reaffirmed its sliding-scale standard after *Winter*: whether "a claim on the merits is [strong] enough depends on the balance of the harms: the more net harm an injunction can prevent, the weaker the plaintiff's claim on the merits can be while still supporting some preliminary relief." *Id.* at 178 (citation omitted). The Second and Seventh Circuits have reached the same conclusion, explaining that a strong showing on one or more of the factors, in particular irreparable harm, can justify an

injunction despite a weaker showing on the other factors. *See, e.g.*, *Citigroup Global Mkts., Inc. v. VCG Special Opportunities Master Fund Ltd.*, 598 F.3d 30, 35–38 (2d Cir. 2010); *Hoosier Energy Rural Elec. Co-op., Inc. v. John Hancock Life Ins. Co.*, 582 F.3d 721, 725 (7th Cir. 2009).[10]

The confusion surrounding the preliminary injunction standard post-*Winter* is as important as it is pervasive. Whether that standard articulates one (or more) threshold requirements, or requires balancing or a checklist, can determine whether a litigant facing irreparable harm obtains equitable relief. And this case is ideally postured to present the issue both because the Federal Circuit was so clear that it did not weigh any equitable factors in its review, and because the district court's findings so dramatically illustrate the one-sided nature of those factors. As Judge Newman's dissent makes plain, a court that employed the sliding scale could reach but one conclusion here: affirm the district court's preliminary injunction ruling.

The outcome of such an important decision, indeed a decision upon which, as this case illustrates, whole businesses and livelihoods may hinge, should not turn on

[10] Before the Federal Circuit, Respondents described this circuit split as "illusory," offering rote recitations of the preliminary factors quoted from various cases. Opposition to Motion to Stay at 13, No. 18-2167 (Fed. Cir. Feb. 6, 2019). Respondents disregard the fact that the question presented here, which divided this panel as it has countless courts, is about the standard that governs a court's consideration of the factors relevant to a preliminary injunction determination, not the identity of those factors. *See id.* Even the cases Respondents cited grappled with that question of the standard in *Winter*'s aftermath, reaching conflicting outcomes. *Compare, e.g.*, *Reilly*, 858 F.3d at 177–78 (3d Cir.) (holding that the sliding scale standard, in which all four factors are balanced, survived *Winter*), *with Def. Distrib.*, 838 F.3d at 456–57 (5th Cir.) (suggesting failure to satisfy any factor independently was grounds to deny a preliminary injunction), *and id.* at 463 & n.5 (Jones, J., dissenting) (suggesting the "district court's balancing of harms went awry" amid confusion about which factors it must consider, and advocating for a sliding-scale standard).

geography or subject matter. This case presents an ideal vehicle to adopt a uniform standard.

B. There Is More Than a Fair Prospect that this Court Will Reverse the Federal Circuit's Preliminary Injunction Ruling.

There is more than a fair prospect that this Court would adopt the sliding-scale standard and reverse the decision below. "[T]he decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts . . . ." *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006). "[S]uch discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." *Id.* And "the balancing of all factors is the foundation of [that] discretionary ruling. When one side is subject to substantially greater harm, this may outweigh other factors believed to favor the opponent." App.64a (Newman, J., dissenting). As Judge Newman highlighted, the panel majority's rigid approach contravenes longstanding Supreme Court precedent recognizing the equitable nature of injunctive relief, particularly at a preliminary stage.

Long ago, this Court observed that "[f]lexibility rather than rigidity has distinguished" equitable authority. *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). In *Trump v. International Refugee Assistance Project*, the Court explained that "[c]rafting a preliminary injunction is an exercise of discretion and judgment, often dependent as much on the equities of a given case as the substance of the legal issues it presents." 137 S. Ct. 2080, 2087 (2017) (per curiam). "The purpose of such interim equitable relief is not to conclusively determine the rights of the parties, but to balance the equities as the litigation moves forward." *Id.* (citation omitted).

In *Winter* itself, the Court directed that, "[i]n each case, courts must *balance* the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief." 555 U.S. at 24 (citation and internal quotation marks omitted) (emphasis added). As Justice Ginsburg noted, the Court "has never rejected [the balancing] formulation, and I do not believe it does so today." *Id.* at 51 (Ginsburg, J., dissenting).

The Court's decision in *eBay* provides an additional reason to believe the Court will reverse here. *eBay* held that it was error to shortcut review of permanent injunctions in patent cases; the full four-factor test must be applied. 547 U.S. at 391–94. Because "[t]he standard for a preliminary injunction is essentially the same as for a permanent injunction with the exception that the plaintiff must show a likelihood of success on the merits rather than actual success," *Winter*, 555 U.S. at 32 (citation omitted), there is a fair prospect this Court will hold that courts must consider and balance all four factors when reviewing a motion for a preliminary injunction.

C. There Is a Reasonable Probability that this Court Will Grant Certiorari to Review the Panel's Disclaimer Ruling Because it Conflicts with Supreme Court Precedent.

The Federal Circuit's decision also conflicts with longstanding Supreme Court precedent governing disclaimers of the scope of patent claims. This decision exposes the deep inconsistency in Federal Circuit treatment of supposed disclaimers of patent scope in patent specifications. Given the Federal Circuit's exclusive jurisdiction over patent appeals, guidance from this Court is critical to promote uniformity in this important area of patent law. *See* Sup. Ct. R. 10(c). This case presents a strong vehicle

to illuminate when a patent's specification should and should not be read to disclaim a patent's scope. There is a reasonable probability the Court will grant certiorari.

To begin, the issue could not be more starkly presented. The accused infringers are claiming that the specification disclaims a method of drying to produce the required film composition *even though* the patentees removed any reference to drying from the patent's claim language. As Judge Newman noted, that should have been dispositive of the inventors' intent and, without a textual basis for narrowing the scope of the claims, should have prevented the majority from reading a drying-process limitation into the claims. App.59a–60a (Newman, J., dissenting). The panel majority flatly disagreed: "[W]e do not read our precedent as requiring . . . a [textual] hook [in the claims] under the circumstances in this case." App.47a (majority opinion).[11]

Few principles in patent law should be more settled than that a patent's claim language controls, and that a limitation may not be added to a claim without a textual basis in the claim language. This Court held as early as 1895 that "we know of no principle of which would authorize us to read into a claim an element which is not present," and "if we once begin to include elements not mentioned in the claim, in order to limit such claim, . . . we should never know where to stop." *McCarty v. Lehigh*

[11] The Federal Circuit alternatively suggested that the term "continuously cast film" in the '305 claims might provide a textual basis for a disclaimer in the '305 Patent. App.46a–47a. But Indivior and Aquestive have pointed out repeatedly that reliance on such a textual basis is error. Respondents have admitted that there is "no material difference" between "continuously cast film" and another term ("cast film") in the '514 Patent that Respondents have conceded does not require any particular drying method and is met by their generic product. *See* Joint Appendix, *supra* note 8, at 5922–23; Joint Stipulation & Order Regarding the "Cast Film Element," *Reckitt Benckiser Pharms. Inc. v. Dr. Reddy's Labs. S.A.*, C.A. No. 14-1451-RGA (D. Del. Nov. 21, 2016) (ECF No. 265).

Valley R.R. Co., 160 U.S. 110, 116 (1895). Later decisions have consistently followed the teachings of *McCarty*. *E.g.*, *Permutit Co. v. Graver Corp.*, 284 U.S. 52, 60 (1931); *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 374 (1938); *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp.*, 340 U.S. 147, 149 (1950). Claim construction is and always must be a matter of interpreting the words in the patent's claims. To say, as the panel did here, that one need not base a supposed disclaimer that narrows the patent's scope on any "textual hook" in the claims, is to deny that the act of *claim* construction is, fundamentally, about construing the patent's *claims*.

The Federal Circuit's decision is emblematic of the inconsistent analyses within the court. Just last week, a different panel of the Federal Circuit demonstrated the correct approach, analyzing an alleged disclaimer "[b]eginning with the claim language." *Continental Circuits LLC v. Intel Corp.*, — F.3d —, No. 18-1076, 2019 WL 489069, at *5 (Fed. Cir. Feb. 8, 2019). There, the Federal Circuit limited its use of the specification to informing its construction of the "plain language" of the claims, refusing to "improperly import[] limitations" untethered to claim language. *Id.* at *5–6.

Our patent system is ill served by such inconsistent treatment by the sole Court of Appeals that construes patents. The Federal Circuit's decision in this case carries great significance, deepening the division within the court. It will embolden litigants to argue disclaimer without identifying any textual basis in a claim, adding more uncertainty to an area of patent law that already requires courts to navigate the fuzzy line between properly using a specification to aid in construing a claim term and impermissibly reading into the claim a limitation from an embodiment described

in the specification. *See, e.g.*, *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 904–05 (Fed. Cir. 2004). Only by unequivocally requiring a textual basis in the claim language can litigants and courts have any idea how to construe claims consistently.

D. There Is More Than a Fair Prospect that this Court Will Reverse the Federal Circuit's Disclaimer Ruling.

The majority's disclaimer ruling would not withstand this Court's scrutiny. The majority opinion upends settled law by eschewing the need for any textual basis for a disclaimer. In its place, that opinion constructed a disclaimer on layers of additional errors: it held that the '305 Patent specification disclaims certain drying methods, and therefore read a process limitation into these product claims. And it did so without the unequivocal language of disavowal that precedent requires and by improperly relying on the features of a preferred but not sole embodiment.

"Specification disclaimer requires the clear and explicit intent by the patentee to limit the claims." App.59a (Newman, J., dissenting) (citing *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366–67 (Fed. Cir. 2012) ("To constitute disclaimer, there must be a clear and unmistakable disclaimer.")). Courts "indulge a 'heavy presumption' that claim terms carry their full ordinary and customary meaning unless the patentee unequivocally imparted a novel meaning to those terms or expressly relinquished claim scope during prosecution." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2013) (citation omitted). Here, the patentees exhibited the exact opposite intent: they "eliminated 'drying/dried' limitations from the '305 claims" during prosecution to ensure that the patent "present[s] claims that are not limited to any drying method." App.60a (Newman, J., dissenting).

The majority nevertheless constructed the requisite intent to narrow the scope of the '305 claims from three passages of a 67-column specification that it concluded "show the patentee expressly disclaimed the sole use of conventional top air drying to produce the claimed films." App.45a. The problem is that each of those passages concerned *preferred embodiments*, not disclaimers. The first states: "*Preferably*, the film is dried initially only applying heat to the bottom side of the film." *Id.* The second begins, "In still *other embodiments*," explicitly describing particular preferred embodiments." *Id.* The third refers to what "is *normally* experienced when films are formed by conventional drying methods such as a high-temperature air-bath . . . ." *Id.*

These statements are not the unequivocal language of disclaimer that precedent requires—they are antithetical to it. A statement about what is "normally" experienced in methods "such as high-temperature air-bath[s]" is no blanket prohibition on "conventional top air drying" under any temperature conditions. If particular film embodiments are "preferably" dried in particular ways, they perforce may be dried in other ways. *E.g.*, *Info-Hold, Inc. v. Applied Media Techs. Corp.*, 783 F.3d 1262, 1267 (Fed. Cir. 2015) ("[T]he patent's 'preferably operational in a receive-only manner' language illustrates that transmission can occur in either direction.").

Elsewhere the specification reinforces that the majority's select passages discuss only particular embodiments. The Summary of the Invention provides that "*[a]lternatively*, or in addition *to controlling the drying [of] the film*, the polymer may be selected in order to provide a viscosity that maintains the non-self-aggregating

uniform heterogeneity." Joint Appendix, *supra* note 8, at 6142, 5:10–13. The specification teaches that appropriately balancing parameters such as viscosity, film thickness, mixing technique, size of the particulate active, additives, humidity, air velocity, and temperature, allow a party to manufacture uniform films even with "top" air drying." *Id.* at 6141–6153, 3:35–4:22, 18:13–21, 24:5–36, 28:40–49. Even though the panel determined that the patent disclaims traditional top-drying methods, the specification extensively discusses "zone drying," the drying method used by DRL, without restriction on the source or direction of air flow, as a method of "controlling the drying process" to make the inventive uniform films. *Id.* at 6156, 33:23–56.

This Court would likely conclude that no disclaimer arises from these passages. Indeed, "[p]recedent is replete with . . . warning[s]" against limiting claim language based on specification embodiments, App.58a (Newman, J., dissenting): "The claims, not specification embodiments, define the scope of patent protection." *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009). As a result, "[i]t is improper for a court to rewrite a product claim to contain a process limitation from the specification—here contained in a preferred but not sole embodiment—for it confounds the role of the specification and the claims." App.58a (Newman, J., dissenting). Yet that confusion is a continued source of inconsistency in the Federal Circuit, as it was here.

As noted above, just days ago, another panel of the Federal Circuit cautioned expressly against casually reading a limitation from specification embodiments into the claims. In *Continental Circuits LLC v. Intel Corp.*, the Federal Circuit stressed that neither embodiments "provid[ing] a best mode to make and use an invention"—

which describe "only one method for making the invention—nor "criticism of a particular embodiment" are sufficient to establish "clear disavowal" or to meet the "exacting standard" for concluding that a process step is an "essential" element of a product claim. 2019 WL 489069, at *6–7. Unlike the majority here, the panel deciding *Continental Circuits* thus refused to convert the features of a "preferred embodiment" into a disclaimer limiting the scope of the claim language at issue. *See id.*

In constructing a disavowal from what are plainly the features of preferred embodiments, the majority's opinion committed a fundamental, if oft-repeated, error. It stepped across the "fine line between construing the claims in light of the specification and improperly importing a limitation from the specification into the claims." *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011). In doing so, the majority's decision undermines a critical tenet of the Patent Act: that it is the claim language itself, not preferred embodiments, that define the scope of patent claims.

The Federal Circuit's decision also likely will not survive this Court's review because it violated the command of *Teva Pharmaceuticals USA, Inc. v. Sandoz Inc.* that "a court of appeals 'must not . . . set aside a' district court's '[f]indings of fact' unless they are clearly erroneous,'" including findings subsidiary to claim construction. 135 S. Ct. 831, 836 (2015) (alterations and omissions in original) (quoting Fed. R. Civ. P. 52(a)(6)). This Court in *Teva* explained that sometimes a district court must "look beyond the patent's intrinsic evidence" (*i.e.*, the patent itself) and "consult extrinsic evidence" (*e.g.*, expert testimony) to understand the language of the patent.

Id. at 841. "In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence"—for example, about how "a person of ordinary skill in the art at the time of the invention" would have understood "a term of art." *Id.* Per Federal Rule of Civil Procedure 52(a)(6), those findings must be reviewed for clear error on appeal, even if the ultimate question of interpreting the patent is a legal question. *Teva*, 135 S. Ct. at 842.

Here, the district court considered expert testimony on whether a skilled artisan would have understood that a particular drying method was necessary to create a film with the content uniformity claimed in the patent. *See, e.g.*, App.16a, 19a–20a. The court ultimately credited the explanation of Indivior and Aquestive's expert that a skilled artisan would "understand that a particular type of controlled drying is *not* required." App.19a; *see also* App.16a (finding more "persua[sive]" the explanation of Indivior and Aquestive's expert that "the practicalities of production" would not lead a skilled artisan to believe that a "continuously cast" film requires a particular drying process). Based on that testimony, the court made "Essential Finding of Fact # 4": that the "embodiments" of the '305 Patent do not restrict the "drying methods used to manufacture" the films with drug content uniformity. App.2a. In turn, the district court's factual finding that a skilled artisan would know that "a particular type of controlled drying is *not* required" informed its legal conclusion that the '305 Patent does not disclaim any particular drying method. *See, e.g.*, App.16a.

Teva required the panel majority to review these underlying factual findings for clear error. *See* 135 S. Ct. at 843 (vacating Federal Circuit decision because it did

not review for clear error district court's finding, based on expert testimony, "about how a skilled artisan would understand the way in which a curve created from chromatogram data reflects molecular weights"). The majority did not do so; it did not address the district court's findings let alone explain how it could have been clear error for the district court to credit Indivior and Aquestive's expert. *See, e.g.*, App.66a (Newman, J., dissenting) ("None of these findings are reviewed by the majority.").

If the panel majority's disclaimer ruling falls, so, too, does its vacatur of the preliminary injunction—regardless of this Court's view on the majority's (lack of) balancing. The panel majority's decision to vacate the preliminary injunction rested entirely on the likelihood of success factor. And the panel majority's ruling that Indivior and Aquestive are unlikely to establish that Respondents' generic product infringes the '305 Patent rested on the purported disclaimer limiting the asserted claims to films produced using certain drying methods. Thus, even if the Federal Circuit were not obligated to consider all four equitable factors when reviewing the district court's preliminary injunction, the majority's error reading a disclaimer into the '305 claims would still require reversing the decision below and reinstating the injunction.

II. Applicants Will Suffer Irreparable Harm Absent A Stay, And The Balance Of Equities And Public Interest Strongly Favor A Stay

This Court has recognized time and again that the likelihood of irreparable harm to an applicant is one of the most important factors in evaluating a stay application. *See Rubin v. United States*, 524 U.S. 1301, 1301 (1998) (Rehnquist, C.J., in chambers) ("An applicant for stay *first* must show irreparable harm if a stay is denied." (emphasis added)); *John Doe Agency v. John Doe Corp.*, 488 U.S. 1306, 1308 (1989) (Marshall, J., in chambers) (considering the equitable considerations first); *Ruckelshaus v. Monsanto Co.*, 463 U.S. 1315, 1317 (1983) (Blackmun, J., in chambers) (considering irreparable harm before considering other factors).

1. In this case, the district court's undisturbed findings establish not only that Indivior and Aquestive would be irreparably harmed absent a stay, but that the risk of harm is entirely one-sided in light of the $72 million bond. The district court granted the preliminary injunction enjoining Respondents' launch of its generic onto the market after a full-day evidentiary hearing, careful review of declarations of fact and expert witnesses from both sides, and briefing. Considering that record, the court unequivocally concluded that Indivior and Aquestive "will likely suffer irreparable harm from the launch of [Respondents'] ANDA product." App.26a.

The district court supported that finding with "extensive factual findings, detailing the likelihood of irreparable harm to Indivior in the absence of an injunction." App.65a (Newman, J., dissenting). "[E]ntry of a generic," the court determined, "would cause Indivior [and Aquestive] to lose market share and [S]uboxone [F]ilm's advantageous formulary status, and would impair research and development."

App.2a. "Indivior will likely lose market share to [Respondents'] ANDA Product," and most importantly, "will be unlikely to recover that share, even if that product is pulled from the market." App.26a. "Indivior . . . faces substantial and irreparable harms in the form of erosion of its position as the leader in the . . . market, a potential loss of formulary status, and damage to its goodwill and reputation among patients, physicians, and insurance plans." App.28a. Formulary status and tier pricing are critical to a pharmaceutical drug's success, but as the market and insurance providers quickly adjust to the generic(s) entry, Suboxone Film's position in the market would quickly erode on all fronts. App.23a, 26a.

Those changes will ossify, erode goodwill among physicians, patients, and pharmacies, and condition the market to substitute generics of any kind (including non-film generics) as alternatives to Suboxone Film. As the market fundamentally shifts, pulling generics from the market once they are found to infringe one of Indivior and Aquestive's patents will not reset Suboxone Film's formulary status, tier pricing, or market share. App.26a, 28a.[12]

Indivior would be imperiled because it derives 98% of its U.S. revenue from Suboxone Film. App.88a. As sales inevitably fall following the generic's entry, Indivior would be required to drastically cut research and development and slash its "outreach, educational, and charitable programs in the field of opioid addiction." App.24a, 29a; *see also* App.26a (finding that "Indivior's potential cuts to research and

[12] If Respondents launch their generic version of Suboxone Film, and other generics quickly follow, Indivior will be forced to launch an authorized generic of its own—to try, however little, to mitigate the severe harm to Indivior and Aquestive's business.

development, in conjunction with its large potential loss of market share, further support a finding of irreparable harm"). Indivior will suffer all of this harm even though, Respondents products, if ultimately found to infringe a patent, should never have been on the market in the first place.

Absent a stay of the mandate pending this Court's consideration of a certiorari petition by Indivior and Aquestive, that irreparable harm will come to pass. Yet, as set forth above, there is a reasonable probability this Court will review and reverse the flawed decision of the Federal Circuit that vacated the preliminary injunction.

Respondents face *no irreparable harm* by comparison. As the district court explained, Respondents "knowingly invested 'at risk' and [have] not shown that the balance of harms/equities weighs in [their] favor." App.2a. Any risk to Respondents is purely speculative; if their product infringes a patent, they have no right to enter the market. And even if the injunction were improvidently granted, Respondents are "not a current market player and [have] no market share to lose," and their "losses would more easily be calculated in damages" and readily compensated by Indivior's $72 million bond. App.28a, 32a. The district court thus found expressly that the balance of harms and equities favored restraining Respondents' at-risk launch while the '305 litigation is ongoing. App.2a, 26a–28a.

The district court similarly determined that the public interest favored an injunction. App.28a–29a. While the active ingredient in Suboxone Film has advantages over other opioid treatment medications, there are several generic treatments already on the market that provide the same active ingredient in other dosage forms.

Id. Thus neither an injunction, nor any stay, would deny the public "access to the active ingredient, which may be administered by other means." App.29a. Under these circumstances, "the public interest tilts in favor of protecting the exclusive rights held by the patent holder," and so "[t]his factor, too, favors Indivior [and Aquestive]." *Id.*

The panel majority did not disturb any of these findings. Indeed, as discussed above, its failure to do so provides one of the strong grounds for this Court's review. *See* App.53a (majority); App.64a–66a (Newman, J., dissenting).

Because the findings remain undisturbed, they are entitled to deference here. *Cf. Block v. N. Side Lumber Co.*, 473 U.S. 1307, 1307 (1985) (Rehnquist, J., in chambers) (denying an application to vacate a stay where there was "no basis for disturbing" the district court's findings on the equities when the court of appeals stayed the mandate even after reversing an injunction).[13]

2. In opposing the stay below, Respondents flatly ignored the district court's express findings. They argued that Indivior and Aquestive's harm "all boil down to economic harms that can be remediated by money damages." Defendants-Appellants' Opposition to Motion to Stay at 18, No. 18-2167 (Fed. Cir. Feb. 6, 2019). But the district court expressly found that money could not repair the irreparable harm that

[13] In opposing the stay below, Respondents cited *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 572 U.S. 1301 (2014) (Roberts, C.J., in chambers). *See* Opposition to Motion to Stay at 8, No. 18-2167 (Fed. Cir. Feb. 6, 2019). But that case is inapposite. The Court denied Teva's application to recall and stay the Federal Circuit's mandate precisely because Teva had not shown that money damages for past infringement would be inadequate to remedy any harm it suffered before prevailing at the Supreme Court. *Teva*, 572 U.S. at 1301–02. Here, by contrast, the district court has expressly determined that the harm to Indivior and Aquestive could not be remedied adequately through ordinary damages.

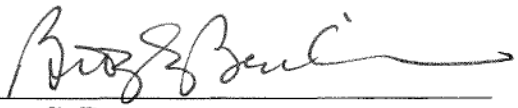
Respondents' at-risk launch would cause Indivior and Aquestive. *E.g.*, App.2a, 26a; *see also* App.64a (Newman, J., dissenting) ("The district court found that the harm to Dr. Reddy's can be monetized and compensated and that harm to Indivior cannot be fully remedied."). Respondent claimed, too, that "the balance of equities and public interest strongly favor allowing" Respondents to launch, Opposition to Motion to Stay at 19–20, No. 18-2167 (Fed. Cir. Feb. 6, 2019), even though the only factfinder to weigh the evidence expressly rejected that exact argument, App.27a–29a.

In the end, Respondents can complain of no more than the risk of lost profits from delayed entry to the market—lost profits to which they might have no right, and which (even if they do) have been secured by a $72 million bond. Equity strongly favors a stay where, as here, Respondents' speculative claim to potential harm is limited "to the difference between what [money] they would receive" if a stay is denied, but the other side faces harm far greater in scope and far harder to quantify or remedy. *NCAA v. Bd. of Regents of Univ. of Okla.*, 463 U.S. 1311, 1312–13 (1983) (White, J., in chambers).

CONCLUSION

For the foregoing reasons, Indivior and Aquestive respectfully request that the Court stay the mandate of the Federal Circuit pending the filing and disposition of a petition for a writ of certiorari, which Applicants will file in time for the petition and any opposition to be considered by the Court before the end of this Term. Should the Court determine that it needs additional time to consider this application before the mandate issues, Applicants respectfully request that the Court enter an administrative stay pending disposition of this application.

Respectfully submitted,



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No. A-_____

In the Supreme Court of the United States

INDIVIOR, INC., ET AL.,

Applicants,

v.

DR. REDDY'S LABORATORIES S.A., ET AL.,

Respondents.

CERTIFICATE OF SERVICE

I, Beth S. Brinkmann, a member of the Supreme Court Bar, hereby certify that one copy of the attached Application to Stay Mandate of the United States Court of Appeals for the Federal Circuit Pending Certiorari was served via Next-Day Service on the following parties on this 14th day of February, 2019.

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Pursuant to Supreme Court Rule 29.3, an electronic pdf copy of the Application has been sent to the following counsel via e-mail:

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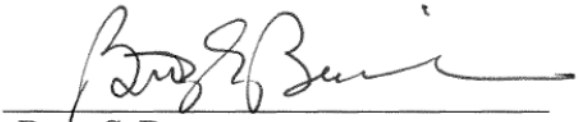

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