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

APPENDIX TO 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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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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CERTIFICATE OF SERVICE

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

INDIVIOR INC., INDIVIOR UK LIMITED, and AQUESTIVE THERAPEUTICS, INC., **Plaintiffs,** **v.** **DR. REDDY'S LABORATORIES S.A., AND DR. REDDY'S LABORATORIES, INC.,** **Defendant.**	Civ. No. 17-7111 (KM) (CLW) Civ. No. 18-1775 (KM) (CLW) Civ. No. 18-5288 (KM) (CLW) (Consolidated) **OPINION** **(Amended: see Order, ECF no. 134;** **Redacted for Public Filing**

KEVIN MCNULTY, U.S.D.J.:

In this patent infringement suit, the plaintiffs, Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. (collectively, unless otherwise specified, "Indivior"), seek a preliminary injunction against defendants, Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, unless otherwise specified, "DRL"). Indivior holds and practices a patent on Suboxone film, a "rapidly dissolving film that adheres to the underside of a patient's tongue or the inside of a patient's cheek." The film contains and is a means of administering buprenorphine and naloxone, drugs used in the treatment of opioid addiction. DRL recently received approval from the Food and Drug Administration ("FDA") for an Abbreviated New Drug Application ("ANDA") for a generic version of Suboxone and plans to launch this generic "at risk." Indivior claims that this generic will infringe a continuation patent (known as the '305 patent") granted to Aquestive by the Patent Office in April 2018, and seeks to enjoin DRL's launch of the generic. For the reasons explained below, I will grant the preliminary injunction.

ESSENTIAL FINDINGS OF FACT

1. The '514 "parent" patent contained a "dried/drying" limitation and was found not to claim a device that solely used "conventional" drying methods, *i.e.*, drying by convection from the top.
2. The '305 continuation patent now before the Court does not expressly or impliedly contain the "dried/drying" language of the '514 patent.
3. The claims and issues in the prior action and in this action are not identical.
4. The '305 patent claims the invention, and states embodiments thereof, without respect to drying methods used to manufacture it.
5. The '305 patent provides an adequate written description to a person skilled in the art of a device without respect to drying methods.
6. The record at present does not overcome the presumption of non-obviousness or validity.
7. The record adequately establishes infringement, particularly of Claim 26 of the '305 patent.
8. Entry of a generic would cause Indivior to lose market share and the suboxone film's advantageous formulary status, and would impair research and development.
9. DRL knowingly invested "at risk" and has not shown that the balance of harms/equities weighs in its favor. (*See* redacted portion of opinion.)
10. Although the suboxone film is an efficacious means of administering buprenorphine, it is not the only means, and the disadvantages of having no generic alternative does not outweigh the public benefit of maintaining Indivior's rights as a patent holder while this action is pending.

ESSENTIAL CONCLUSIONS OF LAW

1. Indivior has demonstrated a likelihood of success on the merits.
2. Indivior has demonstrated irreparable harm
3. The balance of the equities is at best neutral
4. The public interest does not weigh against entry of a preliminary injunction.

The remainder of the discussion in this Opinion expands upon and supports the foregoing findings of fact and conclusions of law.

I. FACTS[1]

The following facts were developed at a one-day hearing on June 28, 2018. Both sides declined to present live testimony. They presented their cases by means of oral argument, supplemented by PowerPoint presentations citing

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[1] For ease of reference, I will cite to the following items as:

Pl. Br. =	Memorandum of Law in Support of Plaintiffs' Motion for a Temporary Restraining Order and Preliminary Injunction (ECF no. 71)
Def. Opp. =	DRL's Opposition to Plaintiffs' Motion for a Preliminary Injunction and Temporary Restraining Order (ECF no. 88)
Pl. Reply =	Reply in Support of Plaintiffs' Motion for a Preliminary Injunction (ECF no. 96)
Simkin Decl. =	Declaration of Richard Simkin (ECF no. 70)
Patent '305 =	United States Patent No. 9,931,305, Exhibit B to Declaration of Philip S. May (ECF no. 71)
Patent '514 =	United States Patent No. 8,693,514, Exhibit E to Declaration of Philip S. May (ECF no. 71)
Hofmann Decl. =	Expert Declaration of Ivan T. Hofmann (ECF no. 88)
PI/TRO Hrg. Tr. =	Transcript of Motion for Preliminary Injunction Hearing on June 28, 2018 (ECF no. 110)
Langer Decl. =	Expert Declaration of Robert S. Langer, ScD (ECF no. 71)
Amiji Decl. =	Expert Declaration of Mansoor Amiji, PhD (ECF no. 91)
Langer Supp. =	Supplemental Expert Declaration of Robert S. Langer ScD (ECF no. 96)
Bennis Decl. =	Declaration of Melissa A. Bennis (ECF no. 72)
Crossley Decl. =	Declaration of Mark Crossley (ECF no. 71)
Navarro Decl. =	Declaration of Robert P. Navarro, Pharm.D. (ECF no. 72)
Rosenthal Decl. =	Expert Declaration of Richard Rosenthal, M.D. (ECF no. 90)
Sonig Decl. =	Declaration of Alok Sonig (ECF no. 88)

to the filed affidavits and exhibits. Many of the underlying historical facts were not in dispute.

Indivior, along with Aquestive, developed Suboxone film, a type of buprenorphine-containing transmucosal product for opioid dependence ("BTOD"). (Simkin ¶ 7.) It is essentially a rapidly dissolving film that adheres to the underside of a patient's tongue or the inside of a patient's cheek and combines two active pharmaceutical ingredients: (1) buprenorphine, a partial opioid agonist that decreases a patient's need for opioids, and (2) naloxone, an opioid antagonist that deters abuse. (*Id.*) Suboxone competes with several other drugs in the BTOD market, including tablets and buccal films. It maintains its position in that market partly because its generic competitors are not AB-rated—that is, pharmacies cannot substitute generics at the point of sale when a patient is prescribed Suboxone. (*Id.* ¶ 9.)

Indivior initially participated in the tablet market, having received approval from the FDA to market Suboxone in tablet form in 2002. (Hoffman Decl. ¶ 45.) It had "orphan drug exclusivity" for the drug in tablet form until October 2009. (*Id.*)

During this time, Indivior developed the film version of Suboxone with Aquestive. On December, 10, 2013, the Patent Office issued Patent No. 8,603,514 ("'514 Patent") for "Uniform Films for Rapid Dissolve Dosage Form Incorporating Taste-Making Compositions" to Aquestive.[2] ('514 Patent at [45], [54].) Once it received approval from the FDA, Indivior marketed the new drug with the objective of switching patients over from tablets to film. (*See id.* ¶¶ 46-53.) By the time of the launch of the first generic tablet version of Suboxone, Indivior had successfully migrated 85% of patients on the drug to the film version. (*Id.* ¶ 53.)[3]

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[2] At the time, Aquestive was known as MonoSol Rx, LLC. (Pl. Br. at 2.)

[3] That program to induce the switch to the film form of the drug landed Indivior in legal difficulty. In 2012, the Federal Trade Commission (FTC) initiated an investigation into the business practices of Invidior regarding Suboxone; the investigation remains pending. (Hofmann Decl. ¶ 61) Invidior also faces a class action antitrust lawsuit, as well as a lawsuit filed by more than 40 states, relating to the

DRL (as well as several other pharmaceutical companies, including Watson Laboratories, Par Pharmaceutical, Inc., Alvogen Pine Brook, Inc., Teva Pharmaceutical, Inc., Sandoz Inc. and Mylan Technologies, Inc.), sought to enter the film market as a generic competitor. They submitted ANDAs to the FDA for generic versions of the Suboxone film. (Hoffman Decl. ¶ 14.) In 2015, Indivior responded by filing actions against these companies under the Hatch-Waxman Act in the United States District Court for the District of Delaware. (*Id.*) In August 2017, Judge Richard Andrews held that Indivior failed to meet its burden of showing that DRL's generic version infringed the claims of the '514 Patent for Suboxone film. *See infra.* Judge Andrews had earlier construed the one of the claims in the '514 Patent to mean "dried without solely employing conventional convection air drying from the top" and found that there was not enough evidence to show that DRL's procedures "amount[ed] to an unconventional process" for drying. *See infra.*

Indivior responded to that decision by returning to the Patent Office. On April 3, 2018, the Patent Office issued Patent No. 9,931,305 ("'305 Patent") to Aquestive. (Patent '305 at [45].) According to the '305 patent:

> The present invention relates to rapid dissolve thin film drug delivery compositions for the oral administration of active components. The active components are provided as taste-masked or controlled-release particles uniformly distributed throughout the film composition. The composition may be formed by wet casting methods, where the film is cast and controllably dried, or alternatively by an extrusion method. (*Id.* at [57] (Abstract).)

This '305 continuation patent is a "child" of the '514 patent, the one that was the subject of the previous Delaware litigation between DRL and Indivior.

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marketing and sales of Suboxone. (*Id.* ¶¶ 62–63.) These allegations generally involve deals with Aquestive to create the Suboxone film in order to extend Indivior's market exclusivity with the drug, Indivior's marketing of the film to physicians, payers, and pharmacists as safer and superior to the tablet version, and the lowering of the price for the film to incentivize sales. (*See id.* ¶¶ 64–65.) On top of that, the Department of Justice has initiated a grand jury investigation relating to these practices, including claims about pediatric safety and the overprescribing of Suboxone tablets and film. (*Id.* ¶ 66.) Several states have also initiated civil investigations against Indivior over the marketing and promotion of Suboxone. (*Id.* ¶ 67.)

The two largely overlap, except as to the language of Claim 26 of the '305 Patent and Claim 62 of the '514 Patent. The two pertinent revisions are as follows. First, the '514 Patent claims "(i) a cast film," but the '305 Patent claims "(i) a continuously cast film produced on a manufacturing line." Second, the '514 Patent makes claims that "said flowable water-soluble or water swellable film-forming matrix is capable of being *dried* without loss of substantial uniformity in the stationing of said particulate active therein; and wherein the uniformity *subsequent to casting and drying of the matrix* is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said at least on active." The '305 patent contains the same language, except that the italicized language became "continuously cast on the manufacturing line" and "continuously cast film," respectively.[4]

[4] Below is a reproduction of a red-line of the language of Claims 26 and 62 of the '305 and '514 patents. (Pl. Br. at 5–6.)

Limitation	Claim 26 of the '305 Patent (Ex. B)	Claim 62 of the '514 Patent (Ex. E)
	A drug delivery composition comprising:	A drug delivery composition comprising:
1	(i) a ***continuously*** cast film ***produced on a manufacturing line***	(i) a cast film
2	comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water soluble or water swellable polymers; and	comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water soluble or water swellable polymers; and
3	at least one active;	a desired amount of at least one active;
4	wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix;	wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix;
5	(ii) a particulate active substantially uniformly stationed in the matrix; and	(ii) a particulate active substantially uniformly stationed in the matrix; and
6	(iii) a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide taste-masking of the active;	(iii) a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide taste-masking of the active;

In the District of Delaware, Plaintiffs and DRL had earlier litigated the validity and potential infringement of the '514 Patent (as well as similar patents held by plaintiffs) by DRL's ANDA product. *See Reckitt Benckiser Pharm. Inc. v. Teva Pharm. USA Inc.*, ("*Reckitt I*") Nos. 14-1451, 14-1573, 14-1574, 2016 WL 3621632 (D. Del. June 29, 2016) (construing the claims of multiple terms of several patents, including the '514 patent pursuant to *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (1996)); *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs. S.A.*, ("*Reckitt II*") Nos. 14-1451, 14-1573, 14-1574, 2017 WL 3837312 (D. Del. Aug. 31, 2017), *appeal docketed*, No. 18-1115 (Fed. Cir. Oct. 27, 2017) (addressing the allegations of infringement and invalidity with respect to the '514 Patent after a four-day bench trial).

In *Reckitt II*, Judge Richard Andrews, after a four-day bench trial, found that the defendants had failed to demonstrate by clear and convincing evidence that the asserted claims in the '514 patents were invalid as obvious. He also found, however, that Indivior failed to meet its burden to show that DRL's product infringed certain claims of the '514 patent. 2017 WL 3837312, at *20. In an earlier opinion, Judge Andrews had construed the claim in the '514 patent, "dried," to mean "dried without solely employing conventional

7	wherein the particulate active has a particle size of 200 microns or less and	wherein the particulate active has a particle size of 200 microns or less and
8	said flowable water-soluble or water swellable film-forming matrix is capable of being ***continuously cast on the manufacturing line*** without loss of substantial uniformity in the stationing of said particulate active therein; and wherein said uniformity of the ***continuously cast film*** is measured by substantially equally sized individual unit doses cut from the continuously cast film which do not vary by more than 10% of a desired amount of said at least one active.	said flowable water-soluble or water swellable film-forming matrix is capable of being ***dried*** without loss of substantial uniformity in the stationing of said particulate active therein; and wherein the uniformity ***subsequent to casting and drying of the matrix*** is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said at least one active.

convection air drying from the top."[5] *Reckitt I*, 2016 WL 3621632, at *10–*11. He found that Indivior had disclaimed "conventional convection air drying from the top," both through express statements and repeated disavowal in the '514 Patent specifications. *Id.* at *8, *11 (noting that the '514 patent contained identical language from process patents that were construed earlier in the opinion and applying that same reasoning to the claims in the '514 patent). After reviewing the evidence presented at trial, Judge Andrews concluded that Indivior did not prove that DRL's process of drying was unconventional, and hence infringing. He was not persuaded "that evidence of a controlled process that [did] not result in rippling and that achieve[d] drug content uniformity automatically amount[ed] to an unconventional process." *Reckitt II*, 2017 WL 3837312, at *6. Indivior initially appealed those decisions by Judge Andrews but later dismissed the appeal. *Indivior Inc. v. Watson Laboratories Inc.*, 2018 WL 3139436 (Fed. Cir. June 8, 2018).

Instead, Indivior obtained the continuation '305 patent, in which it sought to claim around the "drying" problem. The "dried/drying language" was dropped from the continuation patent, which was intended to have a broader scope in that it would no longer disclaim "conventional" drying methods. Indivior then brought this action against DRL here in the District of New Jersey, this time claiming infringement of the new '305 patent. (*See* ECF no. 1 ("Complaint for Patent Infringement").) Upon learning of DRL's plans to launch the ANDA product "at risk," Indivior moved for temporary restraints and a preliminary injunction to prevent DRL from launching its generic product. (ECF no. 70.) (This application was made on an emergent basis, because the 30-month stay granted by Hatch-Waxman had already been exhausted.)

I granted a temporary restraining order enjoining DRL from launching in order to preserve the status quo during the resolution of this motion. (ECF no.

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[5] That decision was focused on arguments made by Teva Pharmaceuticals USA, Inc., DRL's predecessor in interest.

78.) On June 28, 2018, I conducted a hearing on the preliminary injunction application.[6]

II. Discussion

a. Standard of Review

A preliminary injunction has been called "a drastic and extraordinary remedy." *Bayer CropScience AG v. Dow AgroSciences LLC*, 851 F.3d 1302, 1308 (Fed. Cir. 2017) (quoting *Nat'l Steel Car, Ltd. v. Canadian Pacific Railway*, 357 F.3d 1319, 1324–25 (Fed. Cir. 2004)) "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.*, 55 U.S. 7, 20 (2008) (numbering added); *accord Am. Express Travel Related Servs. v. Sidamon-Eristoff*, 669 F.3d 359, 366 (3d Cir. 2012); *Kos Pharm., Inc. v. Andrx. Corp.*, 369 F.3d 700, 708 (3d Cir. 2004); *see Adams v. Freedom Forge Corp.*, 204 F.3d 475, 486 (3d Cir. 2000) (movant bears the burden of establishing these elements).

A patentee need not address invalidity, an affirmative defense, as an initial matter in filing for a preliminary injunction. *Gaymar Industries, Inc. v. Cincinnati Sub-Zero Products, Inc.*, 790 F.3d 1369, 1375 n.7 (Fed. Cir. 2015). However, when the alleged infringer "raise[s] substantive issues respecting the validity and enforceability of the [patent-in-suit]," then the patentee carries the burden of showing likelihood of success on the merits with respect to the patent's validity, enforceability, and infringement. *Id.* (quoting and distinguishing *Nutrition 21 v. United States*, 930 F.2d 867, 869 (Fed. Cir. 1991)).

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[6] The hearing largely consisted of oral argument by counsel for both parties as to whether plaintiffs met the elements for the issuance of preliminary injunction. No oral testimony was proffered. Instead, the parties have cited declarations and exhibits in support of their arguments.

b. Likelihood of Success on the Merits

1. Claim Preclusion

DRL believes that the path to defeating this application for a preliminary injunction has been smoothed by rulings in prior proceedings. It contends that Indivior is barred from asserting these patent claims by the doctrines of claim preclusion and issue preclusion.[7] Indeed, that is the thrust of its presentation.

According to DRL, Indivior is barred by claim preclusion from asserting in this District the "same cause of action" it earlier asserted against DRL under the '514 patent, and lost, in the U.S. District Court for the District of Delaware. (Def. Opp. at 8.) Further, DRL argues, Indivior is estopped by the Delaware proceedings from relitigating the issue of whether DRL's methods for drying its film are "conventional" and, by extension, whether those methods infringe Indivior's '305 patent. (*Id.* at 14.)

I will address the question of claim preclusion first. In general, the Federal Circuit applies the claim preclusion law of the regional circuit in which the district court sits. *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1165 (Fed. Cir. 2018). Claim preclusion bars a suit where there has been: "(1) a final judgment on the merits in a prior suit involving (2) the same parties or their privies and (3) a subsequent suit based on the same cause of action." *Walthour v. Herron*, 720 F. App'x 130, 132 (3d Cir. 2017) (quoting *Lubrizol Corp. v. Exxon Corp.*, 929 F.2d 960, 963 (3d Cir. 1991)). The first two requirements are met, in that I have before me a final judgment on the merits from the District of Delaware between the same two parties. *See Reckitt II*, 2017 WL 3837312. The third requirement—that the prior judgment concern the "same cause of action" as the one now before this court—is peculiar to patent law and is therefore governed by Federal Circuit precedent. *Acumed LLC v. Stryker Corp.*, 525 F.3d

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[7] Though they are related, the two concepts are distinct. Claim preclusion (sometimes known as *res judicata*) bars the relitigating of claims between parties and their privies, while issue preclusion (sometimes known as collateral estoppel) prevents a party from relitigating a specific issue or question in a subsequent lawsuit where it had the opportunity to fully argue that issue before a fact-finder in a previous lawsuit. Confusingly, both terms are sometimes referred to by the umbrella term "*res judicata*."

1319, 1323 (Fed. Cir. 2008) ("Whether two claims for patent infringement are identical" is governed by the law of the Federal Circuit, because this question is "particular to patent law.")

In *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160 (Fed. Cir. 2018), the Federal Circuit Court of Appeals addressed the issue of what constitutes the "same cause of action" with respect to actions involving separate patents. SimpleAir initiated a series of patent infringement lawsuits against Google and its cloud messaging services. *SimpleAir*, 894 F.3d at 1163. The patents held by SimpleAir consisted of a parent patent and several child patents which all shared a common specification. *Id.* Google succeeded in obtaining three separate judgments in its favor. *Id.* Its fourth complaint, however, was dismissed by the district court on grounds of claim preclusion. *Id.* at 1164. The district court reasoned that "because the [patents] shared the same title and specification with the previously adjudicated continuation patents, and the filing of a terminal disclaimer to overcome the PTO's obviousness-type double patenting rejections indicated that the PTO believed the content of the patents in suit to be patentably indistinct from the earlier patents." *Id.*

The Federal Circuit vacated the decision of the district court and remanded. *Id.* at 1171. The district court, it reasoned, never actually compared the claims of the patents involved in the fourth complaint to those of the previously adjudicated patents. *Id.* at 1164. It was necessary to perform such a comparison to determine whether the causes of action in current and prior actions were identical. *Id.* at 1166. What defined a cause of action, held *SimpleAir*, were the transactional facts from which the cause of action arose *Id.* at 1165 (citing Restatement (Second) of Judgments (1982); *Senju Pharm. Co., Ltd. v. Apotex Inc.*, 746 F.3d 1344, 1349 (Fed. Cir. 2014)). The facts that make up a "transaction" in a given case, it acknowledged, are not capable of a mathematically precise definition. *Id.* (citing Restatement § 24 cmt. b.).

SimpleAir propounded a standard and method of analysis of claim preclusion in connection with continuation patents:

> As the accused activity between two cases must be "essentially the same" for claim preclusion to apply, we adopt that standard for comparison of the claims between asserted patents as well. Thus, where different patents are asserted in a first and second suit, a judgment in the first suit will trigger claim preclusion only if the scope of the asserted patent claims in the two suits is essentially the same. In applying that standard to the particular context here, we conclude that claims which are *patentably indistinct* are essentially the same. *Id.* (citations omitted and emphasis added).

The filing of a terminal disclaimer poses particular issues in connection with continuation patents. *Id.* at 1167. Terminally disclaimed continuation patents, the Court reasoned, could actually "provide larger claim scope to a patentee than the patentee had under" the parent patent. *Id.* (citing *Senju*, 746 F.3d at 1353). A terminal disclaimer, said the *SimpleAir* Court, did not wholly foreclose the question of claim preclusion, and could not be treated as rising to the level of a presumption. *SimpleAir* held that such a disclaimer is nevertheless relevant, however, and provides a "strong clue" that the claims are essentially the same, or patentably indistinct. *Id.* at 1168.[8]

SimpleAir further held that the claims were not barred by the doctrine of *Kessler v. Eldred*, 206 U.S. 285 (1907). *Id.* at 1170. Under *Kessler*, assertions of a patent against post-judgment activity are precluded if the earlier judgment held that "essentially the same" accused activity did not infringe the patent. *SimpleAir*, 884 F.3d at 1170 (citing *Brian Life, LLC v. Elekta Inc.*, 746 F.3d 1045, 1057–58 (Fed. Cir. 2014), and noting that this doctrine was meant to prevent repeated post-judgment harassment of the judgment winner). This issue, too, *Simple Air* remanded to the district court, with the following

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[8] The Federal Circuit limited its opinion to the error made by the district court—that is, *presuming* without further inquiry that a terminally-disclaimed continuation patent presents the same cause of action as a parent patent. *SimpleAir*, 884 F.3d at 1169. It noted that while the policy considerations—like whether SimpleAir made a strategic delay in bringing its fourth suit against Google and SimpleAir's assurance to the jury in the previous case that it would not engage in duplicative and burdensome litigation—were important, the presumption made by the district court was inconsistent with precedent. *Id.*

instruction: "[I]f, on remand, the district court determines that the claims . . . are patentably indistinct from those previously adjudicated, and are therefore claim-precluded . . . , then the *Kessler* doctrine would also bar SimpleAir's assertions of those patents against Google's provision of essentially the same . . . services post-judgment." *Id.* at 1170. Thus the claim preclusion and *Kessler* issues tended to merge, at least under the circumstances of that case.

The underlying inventions in *SimpleAir* (cloud technology) and in this case (vehicles for opioid addiction medication) could not be any more different. The procedural histories of that action and this case, however, are similar.[9] Invidior (like SimpleAir) holds a parent patent and a child patent with a terminal disclaimer. As in *Simple Air*, a prior judgment has held that a device did not infringe the parent patent. Like the plaintiff in *SimpleAir*, Invidior now brings suit accusing the same allegedly infringing product, this time asserting its rights under a child patent that contains language differing from that of the parent. Like the Court in *SimpleAir*, then, I will look at the claims of both the child and the parent patent, as well as the patent prosecution history, to see if the claims are patentably indistinct, and thus "essentially the same." *See also Acumed*, 525 F.3d at 1324 ("Accused devices are 'essentially the same' where the differences between them are merely 'colorable' or 'unrelated to the limitations in the claim of the patent.'"). "If the overlap between the transactional facts of the suits is substantial," plaintiffs' action in this case "should . . . be precluded." *SimpleAir*, 884 F.3d at 1165.

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9 In *SimpleAir*, the substantive dispute in the fourth complaint by SimpleAir concerned the construction of the patent claim, "whether the selected remote computing devices are online or offline *to the information providers of the received data*," compared with the claim, "whether said computing devices are online or offline *from a data channel associated with each device*," (the subject of the previous litigation). *SimpleAir*, 884 F.3d at 1168. Though the Federal Circuit noted the similarity of those claims, it left it to the district court on remand to resolve whether the claims are essentially the same—in other words, patentably indistinct. *Id.* at 1168–69. As of the date of this opinion, the district court in the Eastern District of Texas has not published an opinion determining whether those claims are "patentably indistinct" and resolving the issue of claim preclusion in that case.

A terminal disclaimer was filed with the '305 patent. ('305 Patent at [*].) Under *SimpleAir*, I must take this into account, but it is not in itself dispositive. A terminal disclaimer is not an automatic, implied concession that the two patents are the same; it is, however, a "strong clue that a patent examiner and, by concession, the applicant, thought the claims in the continuation lacked a patentable distinction over the patent." *SimpleAir*, 884 F.3d at 1168. The existence of the terminal disclaimer, then, tilts in favor of DRL, but I must consider it in light of the claims of the relevant patents.

The '305 and '514 patents make many claims, which for the most part overlap, and I do not consider them in detail. This case centers around a single point of distinction: the meaning of the removal of the terms "drying/dried" from the '514 parent patent and their replacement with the term "continuously cast on the manufacturing line" in the '305 child patent. Indivior says that the claim language in the '305 patent is clear, and that it does include a limitation of "unconventional" drying. Such a limitation, says Indivior, if it was ever present in the '514 patent, has now been removed, and should not be read back into the text of the claims of the '305 patent. (PI/TRO Hrg. Tr. at 40:25–41:15.) DRL argues that this was a change of wording, but not of substance; the process by which Suboxone film is manufactured under the '305 patent, and particularly the drying process, remains unchanged. (Def. Opp. at 9.)

"Courts are required . . . to 'look at the words of the claims themselves . . . to define the scope of the patented invention.'" *Aventis Pharm. Inc. v. Amino Chemicals Ltd.*, 715 F.3d 1362, 1373 (Fed. Cir. 2013) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). Here, the '305 patent clearly does not contain the terms "dried" or "drying." Can Judge Andrews's construction of those terms as "dried without solely employing conventional convection drying from the top," *Reckitt II*, 2017 WL 3837312, at *4, nevertheless be deemed to be present in the term "continuously cast" in the '305 patent? I must answer that question in the negative. I find that I cannot automatically carry over this construction from the earlier '514 patent. Such a

limitation on a claim must be anchored in some textual reference in the '305 patent claims to the method by which the film is dried. *See MBO Labs., Inc. v. Becton, Dickinson & Co.*, 474 F.3d 1323, 1330–31 ("However, we cannot endorse a construction analysis that does not identify a 'textual reference in the actual language of the claim with which to associate a proffered claim construction. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 990 (Fed Cir. 1999) . . ."). Within the relevant claim of the '305 patent, there is no such textual reference, and no express limitation of how the film is dried, whether conventionally or unconventionally.

I observe parenthetically that "conventional" vs. "unconventional," while employed as a useful shorthand, is not precisely the distinction drawn by Judge Andrews. He referred, rather, to "conventional convection drying from the top," and found that it had been disavowed, leaving other claimed methods intact.

DRL stresses that "drying is incorporated within the concept of continuously cast film or continuously cast film on a manufacturing line" and that "if drying is occurring, . . . all the disavowals on which Judge Andrews relied would apply to the drying which is available in this process." (PI/TRO Hrg. Tr. 66:1–11.) In other words, drying is still necessary to the process of the '305 patent, and Indivior therefore has not really changed its claims. (*See id.* at 66:12–20.) To find a limitation, however, it is not enough to find that certain methods or characteristics are functionally required. *See Markem-Imaje Corp. v. Zipher Ltd.*, 657 F.3d 1293, 1301 (Fed. Cir. 2011) ("That a device will only operate if certain elements are included is not grounds to incorporate those elements into the construction of those claims."). Similarly, patent specifications do not automatically translate to limitations within the claims, though they may be useful in understanding them. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed Cir. 2005). The court's focus must be "on understanding how a person of ordinary skill in the art would understand the claim terms. For instance, although the specification often describes very

specific embodiments of the invention, we have repeatedly warned against confining the claims to those embodiments." *Id.* (citations omitted).

The parties have submitted competing expert declarations on that subject. According to DRL's expert, "a person of ordinary skill in the art would understand that drying and rheology (including viscosity) are essential aspects of the invention [and that] that the invention provides for *unconventional* drying and viscosity" (*see, e.g.*, Amiji ¶ 85); according to Indivior's expert, the specifications merely describe a number of ways to making uniform films using conventional and unconventional methods and "do not recite a particular drying method." (*See, e.g.*, Langer Supp. ¶¶ 17–21.)

The parties did not offer up their experts for live testimony or an assessment of credibility. On a cold record, for purposes of this preliminary prediction of likelihood of success, I am persuaded by Indivior's interpretation. Indivior is likely to prevail on its contention that neither the practicalities of production nor the '305 patent language import such an implied "drying" limitation into the "continuously cast" claim.

The cause of action here involves a continuation patent with a terminal disclaimer. Nevertheless, the terms of that '305 patent do not include "dried/drying." That was the at the core of the claim decided by the *Reckitt* decisions, which was distinct from the claim presented here. Therefore, I believe that it is likely that plaintiffs will be able to show that the claims of the '305 patent are not "patentably indistinct" from the '514 patent and that this cause of action is not barred by the doctrine of claim preclusion.

2. Issue Preclusion

"Collateral estoppel, also known as issue preclusion, prohibits relitigation of an issue that has been fully and fairly litigated previously." *Kams v. Shanahan*, 879 F.3d 504, 514 n.3 (3d Cir. 2018). The elements of issue preclusion are that (1) the issue to be precluded is the same as that involved in the prior action; (2) the issue was actually litigated; (3) the issue was determined by a final and valid judgment; and (4) the determination was

essential to the prior judgment. *Id.* (quoting *Nat'l R.R. Passenger Corp. v. Pa. Pub. Util. Comm'n*, 342 F.3d 242, 252 (3d Cir. 2003)).[10] DRL's issue preclusion argument has much in common with its claim preclusion argument, and I resolve it similarly

In *Reckitt I* and *Reckitt II*, Judge Andrews defined the term "dried/drying" as "dried without solely employing conventional convection air drying from the top" and found after a bench trial that the drying methods employed by DRL were non-infringing as to the '514 patent. *Reckitt I*, 2016 WL 3621632, at *10–*11; *Reckitt II*, 2017 WL 3837312, at *6. This finding, DRL believes, estops Indivior from relitigating in connection with the '305 patent the issue of whether Indivior disclaimed films dried using conventional methods. The problem is that the previous litigation construed the "dried/drying" language of the '514 patent, language which is not present in the '305 patent. That earlier language was critical to Judge Andrews's decision to find that DRL did not infringe the '514 patent.

DRL attempts to get around this problem by arguing, through evidence in the declarations, that drying is still part of the process of "mak[ing] a continuously cast film" and that the specification in the patent "repeatedly states that drying is part of 'the present invention.'" (Def. Opp. at 15.) Because of this, DRL argues, Judge Andrews's determination binds Indivior in this case as well, and DRL's ANDA product should be deemed non-infringing.

I am unpersuaded. An apparatus claim need not recite every method of manufacturing the device, *see Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 873 (Fed. Cir. 2010), and I am wary of "reading specific process limitations into an apparatus claim" unless they are truly present, *Baldwin Graphic Sys., Inc. v. Siebert, Inc.*, 512 F.3d 1338, 1344 (Fed. Cir. 2008). The

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[10] DRL is attempting to invoke defensive mutual collateral estoppel against the same adversary it faced in the earlier litigation. Thus DRL does not seek to push the boundaries of "the modern doctrine of non-mutual issue preclusion, [under which] a litigant may also be estopped from advancing a position that he or she has presented and lost in a prior proceeding against a different adversary." *Peloro v. United States*, 488 F.3d 163, 175 (3d Cir. 2007).

'305 patent does not contain the terms "drying/dried" in the relevant part of the claim language. This fails the first element of the issue preclusion test: that the issue to be precluded in this case be the same as the issue in the previous case. The precise words of the claim are paramount; the inquiry into claim construction "begins and ends in all cases with the actual words of the claim." *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998). The '305 patent and its claims contain different language and that language requires its own distinct construction. For many of the same reasons discussed above in relation to claim preclusion, the '305 patent language presents a different issue from the one that was litigated under the '514 patent.

Because DRL fails to establish that the issue to be decided in this case is the same as the one in the previous action, plaintiffs are likely to succeed in showing that they are not precluded/estopped from litigating whether DRL's product infringes on the '315 patent.

3. Written Description

DRL next argues that Indivior, through this litigation, is attempting to broaden what the specification says the inventors invented, in a manner prohibited by the "written description" requirement.

Under 35 U.S.C. § 112, "[t]he specification [of a patent] shall contain a written description of the invention, and the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art . . . to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention." This is known as the "written description requirement." *See, e.g.*, *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1136, 1351 (Fed. Cir. 2010) ("Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement, and we have articulated a 'fairly uniform standard,' which we no affirm."). The test for sufficiency of this provision is "whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that

the inventor had possession of the claimed subject matter as of the filing date." *Id.* (citing *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562–63 (Fed. Cir. 1991)).

DRL argues that the '305 patent does not describe the use of conventional drying to retain the claimed levels of uniformity in a cast film. (Def. Opp. at 17.) In fact, DRL says, the examples discussed in the patent's specification "reveal that when the inventors tried to achieve drug content uniformity using 'conventional' drying, they failed." (*Id.*) It claims that plaintiffs, through this litigation, are attempting to broaden what the specification says the inventors invented; the '305 patent, they say, lacks a written description of an invention that would encompass production by conventional means of drying. (*Id.*)[11]

Indivior, on the other hand, observes that its '305 patent makes extensive disclosures about the films formed *without regard* to how they were dried, and discloses embodiments and ways of making films that possess the necessary uniformity. (Langer Supp. ¶¶ 7–12, 21) A person of ordinary skill in the art would understand that Indivior possessed the resulting invention. (Pl. Reply at 7.)

Indivior points to two examples in the '305 patent (CG and CH) which do not specify a drying process. (Pl. Reply at 7 (citing '305 Patent, 53:39–55:8)) Indivior's expert, Dr. Robert Langer, states that "the ['305] Patent is clear that using any one particular drying method is only one option that can be used to create the desired uniform films" and that "[a] person of ordinary skill in the art would therefore understand that a particular type of controlled drying is *not* required to create the drug content uniformity in the Patent." (Pl. Reply. at 7; Langer. Supp. ¶ 14).[12] Dr. Langer also cites the '305 Patent's description of a

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11 Once again, it is important to remember that "conventional" drying is a term used by the parties, not one construed as part of the patent. Judge Andrews used the word to mean "convection air drying from the top," and ruled that it had been disavowed in the '514 patent.

12 "Thus, the '305 Patent discloses not only a number of uniform film embodiments, but also a number of ways of making uniform films. A person of ordinary skill in the art would therefore understand that the inventors possessed the

"zone drying procedure" as suitable to make the films, and notes that this is in fact the very type of drying employed by DRL. (Langer Supp. ¶ 19 (referencing '305 Patent, 33:23–35; 33:36–56).)

DRL, in contrast, cites to particular sections of the specifications of the '305 patent which state that "conventional" methods of drying would not be able to retain uniformity (Def. Opp. at 17 (citing '305 Patent 3:29–30; 29:38–39)). DRL's expert, Dr. Mansoor Amiji, opines that, based on the evidence of the '305 patent, plaintiffs were not in possession of the invention, *i.e.*, a uniform film produced by means of conventional drying. (Def. Opp. at 17 (*e.g.*, Amiji Decl. ¶ 90 ("As these passages make clear, a person of ordinary skill in the art reviewing the specification would not understand the inventors to have invented uniform films that were manufactured using 'conventional' drying.")[13].)

Two experts have advanced contradictory interpretations, but once again their live testimony has not been offered and I am not equipped to assess their credibility. Thrown back on the inherent plausibility of those opinions, 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 primary basis for my conclusion, however, is the face of the '305 patent itself, which, I find, has disclosed films without regard to how they were dried. While a full trial record could demonstrate otherwise, I find that plaintiffs have put forward sufficient preliminary evidence to show that they are likely to prove that they were in possession of the invention described in the patent and have thus satisfied the written description requirement.

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claimed uniform cast films. Accordingly, it is my opinion that the written description requirement is satisfied." (Langer Supp. ¶ 21.)

13 "Instead, a person of ordinary skill in the art would understand that the inventors had reached the opposite conclusion: that conventional drying techniques could not result in the claimed uniform films. Nowhere in the '305 patent is there any description of how to achieve particulate ingredient uniformity in a final, dried film using conventional drying techniques." (Amiji Decl. ¶ 90.)

4. Validity and Infringement of '305 Patent

DRL argues that, should Indivior be correct that the claims of the '305 patent do not require unconventional drying (or rule out conventional drying) as part of the process of making the film, DRL would have "strong anticipation, non-infringement, and written description defenses." (Def. Opp. at 19.) That, of course, is the other side of the continuation-patent coin; by claiming more broadly, Indivior may have exposed its claims to further challenges.

The parties have touched only lightly on the issue of obviousness. (PI/TRO Hrg. Tr. at 82:11–15 ("[DRL:] We didn't raise an obviousness argument because we think this claim, if it's as broad as they say it is, [it's] anticipated by the Schmidt reference.").) Relying on *Reckitt II* and the declaration of Dr. Amiji, DRL argues that a previous patent ("Schmidt") "disclose[d] most other limitations of the '305 Patent's independent claims," and that the only way past this prior art would be to read a "solid" limitation into the claims, and that assuming "solid" simply means "dried," then the patent was anticipated. (*Id.* (citing Amiji ¶¶ 93–133); PI/TRO Hrg. Tr. 82:24–83:3.) Plaintiffs dispute this and say that DRL, by not challenging novelty or nonobviousness, has not sufficiently questioned the patent's validity: "Because the cast films of the '305 Patent are solid films, not a wet matrix, DRL's contingent arguments about alleged anticipation of the claims *if* directed to wet matrices is inapposite." (*Id.* Pl. Reply at 7 & n.3.)

Patents enjoy a presumption of validity at every stage of litigation and the burden rests on the party asserting invalidity, *Canon Computer Sys., Inc. v. Nu-Kote Int'l, Inc.*, 134 F.3d 1085, 1088 (Fed Cir. 1998). Even assuming that DRL's spare arguments were enough to shift the burden, I find on the current record that Indivior is likely to show that the '305 patent is not anticipated or obvious.

As to non-infringement, Indivior puts forward a detailed explanation of how DRL's ANDA product infringes each of eight limitations set out in Claim 26 of the '305 patent. (Pl. Br. at 10–13 (citing evidence from the litigation over the '514 patent and noting that "dried" is no longer a limitation). *See also* Langer

Decl. ¶¶ 66–105 (matching features of ANDA product to Claim 26 of '305 patent).) DRL offers little in response. It merely states that it "does not 'cut' undried 'continuously cast films.'" (Def. Opp. at 19 (citing Amiji ¶ 136.).) At this point in the litigation, the patent claim and the description of the allegedly infringing product sufficiently match; I find it likely on this record that Indivior will be able to show that the DRL's ANDA product would infringe the '305 patent.

The likelihood of success factor, then, tips in favor of Indivior.

c. Irreparable Harm

Should DRL be permitted to launch its ANDA product, Indivior says it would be harmed irreparably in four ways: (1) Indivior would lose the market share currently held by Suboxone film in the BTOD market; (2) Suboxone film would irretrievably lose favorable formulary status among insurance plans; (3) Indivior would suffer from delays in research and development and lose talent; and (4) Indivior would suffer reputational harm and a loss of goodwill. (Pl. Br. at 21–26.) Plaintiffs also argue that Aquestive in particular would suffer irreparable harm by losing an "important part of [its] business." (*Id.* at 27.)

Suboxone film leads the market in BTODs. From January 2013 to December 2017, Suboxone film maintained a 55.8% to nearly 70% share of the BROD market, despite the existence of generic non-film BTOD products in that market. (Bennis Decl. ¶ 15.) That position is maintained, in part, because generic BTOD tablets[14] are not "AB-rated" to the film. (Simkin ¶ 9.) This means that pharmacies are not allowed to substitute generic tablets at the point of sale when a patient is specifically prescribed Suboxone film. (*Id.*)

[redacted]

[14] "Tablets," by the way, are not ordinary pills to be swallowed with water. Counsel clarified at the hearing that these tablets, like the film, are placed beneath the tongue and left to dissolve.

[redacted]

Plaintiffs also claim that the launch threatens Suboxone film's advantageous formulary status. Formularies are lists of covered drugs prepared by insurance plans and third-party payers that divide drugs into "tiers." These tiers dictate that how the drug is reimbursed for the patient and correlate with the type of drug covered within a tier (e.g., low cost generic drugs, preferred brand name drugs, non-preferred brand name drugs). (Navarro ¶ 4.) As of May 2018, more than 64% of individuals covered by insurance plans have access to Suboxone film as a Tier 1 (low cost generic) or Tier 2 (preferred brand name drug). (Simkin ¶ 16.) Plaintiffs credit this status to (what they say) are the film's superior features and their willingness to extend financial incentives when strategically helpful. (*Id.*) They predict, however, that Suboxone film would likely be relegated to a lower tier status or omitted from the tiers altogether. (*Id.*) They also claim that even if Suboxone film were able to maintain this status, the existence of an AB-rated generic BTOD film would make pharmacies more likely to dispense only the generic form of the drugs, as those pharmacies could lose money by dispensing the brand form because of reimbursement incentives from the insurance plans and third-party payers. (*Id.* ¶ 17.) Indivior also claims that if DRL's ANDA product is launched but later removed from the market, confusion and frustration among patients, physicians, pharmacies, and the insurance plans would ensue, and the market would be conditioned to favor the cheaper generic alternatives to Suboxone film. (Navarro Decl. ¶ 28.)

[redacted]

[redacted] Indivior has obligations exceeding $487 million under certain

lending covenants [redacted] Despite this, in 2017, Indivior spent $89 million on development of their product pipeline. (Simkin ¶ 6.) This includes developing drugs for the treatment of alcohol use disorders and schizophrenia. (*Id.*)

[redacted]

Finally, Indivior fears that its reputation as a pharmaceutical company would suffer and it could lose the goodwill it has developed over the years. (Pl. Br. at 26.) Indivior has dedicated clinical liaisons who promote awareness of opioid dependency and educate healthcare providers about treatment options (not specific to Indivior's products) and methods for obtaining the certifications to prescribe BTODs, something which Indivior says that generic competitors do not do. (Simkin ¶¶ 28, 34.) Indivior has also donated millions of dollars to foundations which provide opioid addiction medication to those who cannot afford it and to programs oriented around awareness to addiction and prevention, treatment, recovery, and criminal justice reform. (*Id.* ¶¶ 31–32.) Indivior expects it will have to make substantial cuts to these programs upon DRL's ANDA product launch. (*Id.* ¶ 35.)

DRL believes that these claims of harm are exaggerated. (Def. Opp. at 20.) First, DRL argues that Indivior took on its debt obligations knowing that generic competition was "looming." (*Id.* at 20–21.) They point to the fact that Suboxone film was initially sold by a larger company, Reckitt Benickser, which

had a much more diversified portfolio, and that Reckitt opted to spin off Indivior as a one-product company once the initial lawsuits over Suboxone began. (Hofmann ¶¶ 92–93.) [redacted] DRL also cites to Indivior's recent launch of its "next generation" BTOD product, Sublocade, a once-monthly injectable product, which is part of Indivior's "robust contingency plan" for an anticipated generic entry. (*Id.* ¶ 70.) DRL says that Indivior expects peak net revenues of at least $1 billion from this product and expects Sublocade to become "a new standard of care" for the treatment of moderate to severe opioid use disorder.[15] (*Id.* ¶¶ 71–72.)

DRL also argues that Indivior's claims of irreparable harm are quantifiable and not imminent. DRL says that "while there may be some uncertainty *today* as to the exact actions that will be taken by various parties," the impact on the BTOD market and its financial consequences for Indivior, given the passage of time, will allow damages to be quantified and assessed with a reasonable degree of certainty. (*Id.* at 96.) In fact, it says that Indivior has already quantified the potential impact of a generic entry. (*See* Crossley ¶ 8.) [redacted]

DRL insists that Indivior's claims of loss of goodwill and reputation are merely speculative and not irreparable, (Def. Opp. at 25.) [redacted] (*Id.*) Indivior will still have the money, DRL says, to continue these programs. (*Id.*)

[redacted]

Finally, DRL argues that Aquestive's claims of irreparable harm are purely financial, as it merely receives a payment from Indivior tied to the sale of Suboxone, and that any loss in licensing revenue is clearly calculable and compensable. (Hofmann ¶ 104.)

I find that Indivior will likely suffer irreparable harm from the launch of DRL's ANDA product. Loss of market share "constitutes irreparable injury because market share is so difficult to recover." *Henkel Corp. v. Coral, Inc.*, 754 F. Supp. 1280, 1322 (N.D. Ill. 1991), *aff'd*, 945 F.2d 416 (Fed. Cir. 1991). Moreover, "[t]he right to exclude direct competition in a limited sphere, a right inherent in the grant of a patent, is irreparably harmed by the loss of sales and the competitive foothold that the infringer will gain." *Fresenius Kabi USA, LLC v. Fera Pharm., LLC*, No. 15-3654, 2016 WL 5348866, at *13 (D.N.J. Sept. 23, 2016) (citing *Systemation, Inc. v. Engel Indus., Inc.*, 194 F.3d 1331 (Fed Cir. 1999)). It comports with common sense, and Indivior has shown, that Indivior will likely lose market share to DRL's ANDA product once it is launched and will be unlikely to recover that share, even if that product is pulled from the market. Courts have found that a reduction of market share due to the loss of formulary status and a change in tier pricing, constitutes irreparable harm. *See, e.g., Antares Pharma, Inc. v. Medac Pharma, Inc.*, 55 F. Supp. 3d 526, 536–537 (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).

I am less moved by the other claims of harm. Claim of lost revenue requiring cutbacks in, e.g., research, would not necessarily move the Court if it found the likelihood of success to be weak. *See Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568. 1578 (Fed. Cir. 1996). At least as a makeweight, however, Indivior's potential cuts to research and development, in conjunction with its large potential loss of market share, further support a finding of irreparable harm. This factor favors Indivior.

d. Balance of the Equities

Indivior argues that, while it faces "devastating" harm if relief is denied, DRL has a large portfolio of generic products and that the only harm facing DRL would be deferred potential revenue. (Pl. Br. at 27.) DRL counters that its ANDA product is not just "another generic product" in its portfolio. (Def. Opp. at 28.)

DRL acquired the Suboxone ANDA from Teva Pharmaceuticals in 2016 for $70 million. (Sonig Decl. ¶ 13.) This (along with seven other products from Teva) was a large acquisition made by DRL (e.g., it was two-thirds as large as DRL's 2006 purchase of an *entire* pharmaceutical company to enter the European market). (*See id.*) Suboxone was one of the key drivers of the Teva purchase. (*Id.* ¶ 14.) DRL purchased in the belief "that there was a possibility that DRL would be the first in the market with a generic version of Suboxone," particularly after the product was deemed non-infringing as to the '514 Patent in the District of Delaware. (*Id.* ¶ 17.) After that decision, DRL prepared for a commercial launch and engaged in a "time- and resource- intensive" ramp-up, which included the purchasing of buprenorphine, naloxone, and foil packaging for the films and the spending of [redacted] to prepare for the manufacture of commercial batches of the generic films. (*Id.* ¶¶ 21–22.) This represented about [redacted] of DRL over the past three years. (*Id.* ¶ 20.)

DRL also takes issue with Indivior's attempts to move patients in the BTOD market off of film and onto Sublocade. (Def. Opp. at 29; Hofmann ¶ 111.) It says that DRL's product will not be a substitutable generic equivalent to Sublocade and that generic products generally rely on substitution for the reference listed drug. (Hofmann ¶ 111.) [redacted]

I find that the balance of equities nevertheless tips in favor of Indivior. There is no doubt that DRL may lose months of potential revenue from the sale

of its ANDA product should it be enjoined from entering the BTOD market during this litigation. Still, it is not a current market player and it has no market share to lose; its losses would more easily be calculated in damages, and Indivior will be required to bond the injunction. Indivior, on the other hand, faces substantial and irreparable harms in the form of erosion of its position as the leader in the BTOD market, a potential loss of formulary status, and damage to its goodwill and reputation among patients, physicians, pharmacies, and insurance plans. These losses would be difficult to recoup even if DRL's ANDA product were eventually found to infringe the '305 Patent. *See supra* Section II.c.

DRL's losses stem from a market it seeks to enter, not one that it is already in. DRL chose to enter the market "at risk" and took the chance it could face a potential injunction against its product. The balance of harms and equities appears to favor Indivior, and is at best neutral.

e. Public Interest

The country faces a recognized opioid addiction epidemic. (Rosenthal ¶ 21.) Buprenorphine, the active ingredient in Suboxone film, is an effective treatment for opioid addiction which does not have some of the disadvantages associated with other opioid treatment medications, such as naltrexone and methadone. (*Id.* ¶¶ 31–32.) Of the over 2.5 million people who suffer from opioid use disorder, only 30% receive medication. (Hofmann, ex. 28 at 4.) DRL ascribes the under-utilization of medication to Suboxone's high cost and certain insurance plans' unwillingness to cover such costs. (*See* Rosenthal ¶ 41–42.) A generic version of Suboxone, says DRL, would change those numbers. Prices would go down and more insurance plans would be willing to cover a lower-cost generic. (Hofmann ¶¶ 121–22.)

Indivior replies that the public interest would be disserved by the lack of an injunction in two ways. First, they argue that the public interest generally weighs in favor of protecting property rights in the absence of countervailing factors. It is always true, of course, that a generic would likely be cheaper. But

the patent owner's right to exclusivity encourages innovation and provides incentives for drug companies to continue costly development efforts. (Pl. Br. at 28 (citing *Apple, Inc. v. Samsung Elecs. Co.*, 809 F.3d 663, 647 (Fed. Cir. 2015); *Syntex (U.S.A.) v. Apotex, Inc.*, 407 F.3d 1371, 1383–84 (Fed. Cir. 2005).) Second, Indivior states that a reduction in revenue will cause Indivior to scale back its outreach, educational, and charitable programs in the field of opioid addiction and would, in turn, reduce access to opioid addiction treatment. (*See* Pl. Br. at 28–30.) It also warns that research and development by Indivior in that field would be reduced. (*Id.* at 30.)

I find that the public interest will be served by the issuance of a preliminary injunction in this case. True, the relief requested by plaintiffs would prevent the entry of DRL's generic film—a means of delivery of medication—into the market. It will not, however, deny access to the active ingredient, which may be administered by other means. There still remain other non-film generics on the market, and neither side has stated that the issuance of injunctive relief (or the lack thereof) would prevent access to these alternatives. DRL offers only that the ease of use of the film, as opposed to, e.g., the under-tongue tablet, would naturally result in better compliance. That is not a negligible consideration, but it is not enough to tilt the balance.

Under these circumstances, the public interest tilts in favor of protecting the exclusive rights held by the patent holder, *see Apple*, 809 F.3d at 647. This factor, too, favors Indivior.

III. Conclusion

I have assessed the four injunctive factors, and also weighed them. For the reasons set forth above, I will grant Indivior's motion for a preliminary injunction. For the immediate present, the restraints contained in the temporary restraining order shall continue. On or before Monday, July 16, 2018, the parties shall submit an agreed form of preliminary injunction, with required security, or shall individually submit competing forms of order for the Court to consider.

An appropriate order follows.

Dated: July 13, 2018

Kevin McNulty
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

INDIVIOR INC., INDIVIOR UK LIMITED, and AQUESTIVE THERAPEUTICS, INC., Plaintiffs, v. DR. REDDY'S LABORATORIES S.A. and DR. REDDY'S LABORATORIES, INC., Defendants.	Civil Action No. 17-7111 (KM)(CLW) Civil Action No. 18-1775 (KM)(CLW) Civil Action No. 18-5288 (KM)(CLW) (Consolidated) **PRELIMINARY INJUNCTION**

THIS MATTER having been brought before the Court upon the motion of plaintiffs, Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc., for a Temporary Restraining Order and Preliminary Injunction pursuant to Federal Rule of Civil Procedure 65 (ECF no. 70); and

WHEREAS the Court has considered the parties' submissions and argument and has concluded that Plaintiffs have carried their burden to demonstrate the prerequisites for a preliminary injunction (*see* Order and Opinion, ECF nos. 121, 122);

IT IS THIS 18th day of July, 2018,

ORDERED as follows:

1. Defendants Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc., their officers, agents, servants, representatives, and employees and any and all person or entities acting by, through, under, or in active concert with any or all of them, are hereby enjoined until further order of this Court from using engaging in the use, offering to sell, or selling within the United States, or importing into the United States, generic buprenorphine-

and-naloxone-containing transmucosal film products, including, but not limited to, the products described in defendants' Abbreviated New Drug Application nos. 205299 and 205806.

2. Defendants shall notify any customers to which such products have been shipped, including, but not limited to, drug wholesalers, warehousing chains, and mail-order pharmacies, of this Order. Defendants shall file written confirmation within five business days after entry of this Order that they have complied with this provision.
3. Plaintiffs shall post a bond of $72 million (that total figure being inclusive of any security already posted) in connection with this Preliminary Injunction on or before July 23, 2018.
4. Filing of this Order on the ECF system shall be deemed sufficient service as to the parties.
5. The Court will entertain an application on short notice to dissolve or modify the terms of this injunction should circumstances warrant.

Hon. Kevin McNulty
United States District Judge

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

INDIVIOR INC., INDIVIOR UK LTD., AQUESTIVE THERAPEUTICS, INC.,
Plaintiffs-Appellees

v.

DR. REDDY'S LABORATORIES, S.A., DR. REDDY'S LABORATORIES, INC.,
Defendants-Appellants

2018-2167, 2018-2169

Appeals from the United States District Court for the District of New Jersey in Nos. 2:17-cv-07111-KM-CLW, 2:18-cv-01775-KM-CLW, 2:18-cv-05288-KM-CLW, Judge Kevin McNulty.

Decided: November 20, 2018

JEFFREY B. ELIKAN, Covington & Burling LLP, Washington, DC, argued for all plaintiffs-appellees. Plaintiffs-appellees Indivior Inc., Indivior UK Limited also represented by ERICA NICOLE ANDERSEN, BETH S. BRINKMANN, MATTHEW AARON KUDZIN, JEFFREY HOWARD LERNER; JAMES M. BOLLINGER, MAGNUS ESSUNGER, KATHERINE HARIHAR, TIMOTHY P. HEATON, DANIEL LADOW, GERALD

EAMES PORTER, SUJATHA VATHYAM, Troutman Sanders LLP, New York, NY; CHARANJIT BRAHMA, San Francisco, CA; WILLIAM CHARLES BATON, CHARLES M. LIZZA, Saul Ewing Arnstein & Lehr LLP, Newark, NJ.

JAMES FRANCIS HIBEY, Steptoe & Johnson, LLP, Washington, DC, for plaintiff-appellee Aquestive Therapeutics, Inc. Also represented by JAMIE LUCIA, San Francisco, CA; WILLIAM CHARLES BATON, CHARLES M. LIZZA, Saul Ewing Arnstein & Lehr LLP, Newark, NJ.

KEVIN PAUL MARTIN, Goodwin Procter LLP, Boston, MA, argued for defendants-appellants. Also represented by ELAINE BLAIS, EDWINA CLARKE, ROBERT FREDERICKSON, III, ALEXANDRA LU; ROBERT V. CERWINSKI, IRA J. LEVY, ALEXANDRA D. VALENTI, New York, NY.

Before NEWMAN, LOURIE, and STOLL, *Circuit Judges*.

Opinion for the court filed by *Circuit Judge* STOLL.

Dissenting Opinion filed by *Circuit Judge* NEWMAN

STOLL, *Circuit Judge*.

Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL") appeal from the district court's order granting Indivior Inc., Indivior UK Ltd., and Aquestive Therapeutics Inc.'s (collectively, "Indivior") preliminary injunction in this patent infringement case. Because the district court's conclusion that Indivior was likely to succeed on the merits was based on an erroneous interpretation of claim scope, we vacate the preliminary injunction.

BACKGROUND

Indivior developed and now markets Suboxone Film, a leading treatment for opioid dependency. Suboxone Film contains two active ingredients: buprenorphine, which

decreases a patient's need for opioids, and naloxone, which deters abuse. Suboxone Film is a rapidly dissolving film formulation that adheres to the underside of a patient's tongue. One of the challenges in developing pharmaceutical films is maintaining drug content uniformity. These films are initially produced as large sheets that are then cut into individual dosage units. It is critical to ensure that the sheets have content uniformity so that the individual doses contain equal amounts of drug. Content uniformity is therefore essential to the safety of a pharmaceutical film and is a prerequisite to regulatory approval.

Indivior's Suboxone Film is covered by U.S. Patent Nos. 9,931,305 and 8,603,514. The '305 patent is the only patent at issue in this case. It is related to the '514 patent, sharing the same specification. The patents' shared specification discloses various methods of producing films that have drug content uniformity. '305 patent col. 1 ll. 55–59. These methods generally involve mixing a pharmaceutically active ingredient with a polymer in a solvent, casting the mixture onto a planar carrier surface to form a wet film, and then controllably drying the film to produce a solid sheet having less than ten percent variance in active ingredient throughout any given area. *Id.* at col. 7 ll. 1–11. The resulting sheet of thin film can then be cut into individual dosage units. *Id.* at col. 4 ll. 50–52.

The specification teaches that conventional drying methods—which only apply warm air to the top of the wet film—produce films that do not have the claimed content uniformity. *Id.* at col. 9 ll. 13–18. The specification explains that conventional methods that apply heat only to the top of the film cause the water on the surface to evaporate. *Id.* at col. 3 l. 48–col. 4 l. 3. This creates a polymer skin barrier on the surface of the film. *Id.* As the temperature outside the film continues to increase, water vapor pressure builds up underneath the barrier,

ultimately ripping the surface open allowing the water vapor to escape. *Id.* The polymer skin then reforms and the process repeats until the film is completely dry. *Id.* This repeated destruction and reformation of the film surface produces uneven, non-uniform films and is known as "rippling." *Id.* at col. 23 ll. 10–14.

The specification discloses controlled drying techniques that avoid the "rippling" problems produced by conventional drying methods. *Id.* at col. 23 ll. 10–21. The specification explains that "[t]he objective of the drying process is to provide a method of drying films that avoids complications, such as the noted 'rippling' effect, that are associated with conventional drying methods." *Id.* at col. 23 ll. 10–14. The invention's controlled drying techniques include applying heat to the bottom of the film, introducing controlled microwaves, controlling the air flow above and beneath the film, and employing furnace filters. *Id.* at col. 23 ll. 22–39, col. 54 ll. 20–21. These techniques control heat distribution during the drying process and produce content-uniform films. *Id.*

The Delaware Case

DRL's predecessor in interest had previously submitted two Abbreviated New Drug Applications ("ANDA") to market a generic version of Suboxone Film. In response, Indivior filed suit under the Hatch-Waxman Act in the District Court for the District of Delaware ("Delaware Court") (the "Delaware Case"), alleging infringement of several patents, including the '514 patent. Claim 62 of the '514 patent reads:

> 62. A drug delivery composition comprising:
>
> (i) a cast film comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more so substantially water soluble or water swellable polymers; and a desired amount of at least one active;

> wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix;
>
> (ii) a particulate active substantially uniformly stationed in the matrix; and
>
> (iii) a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide taste-masking of the active;
>
> wherein the particulate active has a particle size of 200 microns or less and said flowable water-soluble or water swellable film-forming matrix is *capable of being dried without loss of substantial uniformity* in the stationing of said particulate active therein; and
>
> wherein the uniformity *subsequent to casting and drying* of the matrix is measured by substantially equally sized individual unit doses which do not vary by more than 10% of said desired amount of said at least one active.

'514 patent col. 73 l. 48–col. 74 l. 9 (emphases added).

The Delaware Court determined that the patentee disavowed solely using conventional air drying from the top to produce the claimed films. *See Reckitt Benckiser Pharm. Inc. v. Teva Pharm. USA, Inc.*, No. 14-CV-1451-RGA, 2016 WL 3621632, at *6, *11 (D. Del. June 29, 2016). It noted that the '514 patent's specification expressly disclaimed and disparaged these methods, and that Indivior was "unable to point to a single portion of the specification contemplating the use of top air drying alone." *Id.* at *6–7, *11. The Delaware Court therefore construed "dried" to mean "dried without solely employing conventional convection air drying from the top." *Id.* at *10–11.

The Delaware Court conducted a four-day bench trial and determined that DRL's ANDA process does not infringe the asserted '514 patent claims. *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs. S.A.*, No. 14-CV-1451-RGA, 2017 WL 3837312, at *6 (D. Del. Aug. 31, 2017) ("Delaware Decision"). The Delaware Court found that DRL's process employs "dryers where the sole source of heat is hot air coming from air nozzles over the liner." *Id.* at *5. It was unpersuaded that this process was unconventional. *Id.* at *6. Based on this, the Delaware Court concluded that Indivior failed to meet its burden of showing that DRL infringes the asserted '514 patent claims. *Id.* at *20. The Delaware case is currently on appeal to this court. *See Indivior Inc. v. Dr. Reddy's Labs., S.A.*, No. 17-2587 (Fed. Cir. filed Oct. 13, 2017).

The Current Case

After the Delaware Court entered its judgment of non-infringement, Indivior amended certain claims of a then-pending application that ultimately issued as the '305 patent. Indivior amended the claims to remove the words "dried" and "drying," and to add "continuously" and "continuously cast" in their place. It also filed a terminal disclaimer to overcome obviousness-type double patenting rejections based on the claims of the '514 patent. J.A. 6551–52. The application issued as the '305 patent on April 3, 2018. Claim 26 reads:

> 26. A drug delivery composition comprising:
>
> (i) a *continuously cast film* produced on a manufacturing line comprising a flowable water-soluble or water swellable film-forming matrix comprising one or more substantially water soluble or water swellable polymers; and at least one active;
>
> wherein said matrix has a viscosity sufficient to aid in substantially maintaining non-self-aggregating uniformity of the active in the matrix;

> (ii) a particulate active substantially uniformly stationed in the matrix; and
>
> (iii) a taste-masking agent selected from the group consisting of flavors, sweeteners, flavor enhancers, and combinations thereof to provide taste-masking of the active;
>
> wherein the particulate active has a particle size of 200 microns or less and said flowable water-soluble or water swellable film-forming matrix is *capable of being continuously cast* on the manufacturing line without loss of substantial uniformity in the stationing of said particulate active therein; and
>
> wherein said uniformity of the *continuously cast film* is measured by substantially equally sized individual unit doses cut from the continuously cast film which do not vary by more than 10% of a desired amount of said at least one active.

'305 patent col. 73 ll. 4–29 (emphases added).

That same day, Indivior accused DRL's same ANDA process of infringing the '305 patent in the District Court for the District of New Jersey. A few months later, the FDA approved DRL's ANDAs for its generic Suboxone Film and DRL launched the same day. J.A. 11068. Indivior immediately moved for a temporary restraining order and a preliminary injunction, seeking to enjoin DRL from selling its product. J.A. 516. The TRO was granted on the same day after a telephone conference. The district court then conducted a hearing on the preliminary injunction motion. *Indivior Inc. v. Dr. Reddy's Labs. S.A.*, No. 17-CV-7111, 2018 WL 3496643, at *2 (D.N.J. July 20, 2018) ("Decision"). It granted the preliminary injunction shortly after. *Id.* at *14.

In granting the preliminary injunction, the district court concluded that Indivior was likely to succeed on the merits of its infringement claim. *Id.* at *11. The district court's decision was largely based on its interpretation of the '305 patent's claim scope. It considered the Delaware Court's determination of specification disclaimer and declined to apply it to the '305 claims. It concluded that the claims, which lack an express "drying" limitation, do not exclude any particular drying method. *Id.* at *7. The district court credited Indivior's expert over DRL's and declined to import a drying step into the "continuously cast" limitation—the limitation that Indivior added during prosecution to replace the terms "drying" and "dried." *Id.* at *8. According to the district court, the '305 claims do not include a drying limitation. *Id.*

Based largely on this reasoning, it determined that Indivior's suit was not barred by claim preclusion in light of the Delaware Case. *Id.* The district court considered it likely that Indivior would be able to show that the '305 claims are not "patentably indistinct" from the '514 claims, and thus would likely show that the suit was not barred by claim preclusion under *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160 (Fed. Cir. 2018). It further determined that Indivior would likely be able to show that DRL's ANDA would infringe the '305 patent. *Id.* at *9–11. It then weighed the remaining preliminary injunction factors in favor of Indivior and granted the preliminary injunction. *Id.* at *11–14.

DRL appeals the district court's grant of the preliminary injunction. We have jurisdiction pursuant to 28 U.S.C. § 1292.

DISCUSSION

"To obtain a preliminary injunction, a party must show 'that [it] is likely to succeed on the merits, that [it] is likely to suffer irreparable harm in the absence of preliminary relief, that the balance of equities tips in [its] favor,

and that an injunction is in the public interest.'" *Lumina-ra Worldwide, LLC v. Liown Elecs. Co.*, 814 F.3d 1343, 1352 (Fed. Cir. 2016) (quoting *Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008)).

We review a district court's grant of a preliminary injunction for an abuse of discretion. *Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1345 (Fed. Cir. 2008). In reviewing a district court's reasoning justifying a preliminary injunction, "we review factual findings for clear error, conclusions of law de novo, and the exercise of a district court's discretion for a clear error of judgment in weighing relevant factors." *Nat'l Steel Car, Ltd. v. Canadian Pac. Ry., Ltd.*, 357 F.3d 1319, 1325 (Fed. Cir. 2004).

Likelihood of Success: Specification Disclaimer

We conclude that the district court abused its discretion in granting the preliminary injunction. The '305 patent specification disclaims solely using conventional top air drying to produce films with the claimed content uniformity. Because the '305 claims thus do not cover such films, Indivior has not shown that it is likely to succeed on the merits of its infringement claim.

The inventors of the '305 patent expressly disclaimed, through remarks in the specification, solely using conventional top air drying to produce films with the claimed content uniformity. The patent distinguishes these conventional methods from the present invention and disparages their use, stating that these methods result in films that do not have content uniformity—a key feature of the invention. Under our case law on specification disclaimer, such statements exclude from the scope of the '305 claims films formed using these drying methods.

When construing claims, the specification "is the single best guide to the meaning of a disputed term" and is usually "dispositive." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc). In particular, "the

specification may reveal an intentional disclaimer, or disavowal, of claim scope by the inventor. In that instance as well, the inventor has dictated the correct claim scope, and the inventor's intention, as expressed in the specification, is regarded as dispositive." *Id.* at 1316 (citing *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343–44 (Fed. Cir. 2001)).

"Disavowal requires that 'the specification make[ ] clear that the invention does not include a particular feature.'" *Openwave Sys., Inc. v. Apple Inc.*, 808 F.3d 509, 513 (Fed. Cir. 2015) (quoting *SciMed*, 242 F.3d at 1341). "To find disavowal of claim scope through disparagement of a particular feature, we ask whether 'the specification goes well beyond expressing the patentee's preference . . . [such that] its repeated derogatory statements about [a particular embodiment] reasonably may be viewed as a disavowal.'" *Id.* (quoting *Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1372 (Fed. Cir. 2012)).

In *SciMed*, we instructed that

> [w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.

SciMed, 242 F.3d at 1341. There, we determined that the patent claims covered balloon dilation catheters with co-axial lumens and excluded catheters with dual lumens, even though no language in the claims expressly provided for such an exclusion. *Id.* at 1340. The specification cited the disadvantages of prior art dual lumens and pointed out the advantages of the co-axial lumens that were the subject of the SciMed patents. *Id.* at 1342–43. The patent's characterization of the "present invention" also

included several references to an annular, i.e. coaxial lumen. *Id.* at 1343. Further, the specification disclosed that an annular sleeve structure "is the basic sleeve structure for all embodiments of the present invention contemplated and disclosed herein." *Id.* We held that the specification language "defines SciMed's invention in a way that excludes the dual, or side-by-side, lumen arrangement." *Id.*

In *Openwave*, we affirmed the district court's construction of "mobile device" to exclude devices containing computer modules. 808 F.3d at 517. The patent specification was "rife with remarks that disparage and, therefore, disclaim mobile devices that incorporate computer modules." *Id.* at 514. The patent detailed the many problems of incorporating a computer module into a mobile device, and distinguished the present invention from prior art devices that did just that. *Id.* at 515–16. We concluded that "it is difficult to envisage how, in light of the repeated disparagement of mobile devices with 'computer modules' discussed above, one could read the claims of the patents-in-suit to cover such devices." *Id.* at 517.

Similar to *SciMed* and *Openwave*, the '305 patent is "rife with remarks that disparage, and therefore, disclaim" solely using conventional top air drying to form films. *Id.* at 514. The specification instructs that using such methods produces films without content uniformity—a claim limitation and a key feature of the invention.

The patent specification states that "conventional drying methods themselves are unable to provide uniform films." '305 patent col. 3 ll. 29–31. Conventional drying methods that dry only the top of the film produce a "ripple effect" that results in "an uneven, and therefore non-uniform film." *Id.* at col. 3 l. 57–col. 4 l. 3. The specification teaches that the rippling effect produced by conventional drying methods can be "avoided by the present

invention," by "applying heat to the bottom surface of the film with substantially no top air flow," or by introducing "controlled microwaves." *Id.* at col. 23 ll. 18–29. In its discussion of drying wet cast films, the patent discloses that a "wet film may be dried using controlled bottom drying . . . desirably in the absence of external air currents or heat on the top." *Id.* at col. 29 ll. 30–33. Notably, an embodiment in the specification discloses that "*[c]onventional convection air drying from the top is not employed* because it initiates drying at the top uppermost portion of the film . . . Such dried upper portions serve as a barrier to further vapor release as the portions beneath are dried, which results in non-uniform films." *Id.* at col. 29 ll. 36–43 (emphasis added). The specification further explains that "[i]f top air is employed, it is balanced with the bottom air drying to avoid non-uniformity and prevent film lift-up on the carrier belt." *Id.* at col. 29 ll. 48–50.

The '305 patent also discloses two examples that further disparage the use of conventional drying. In Example CG, the films were dried "according to conventional drying techniques, rather than via the uniform drying process of the present invention." *Id.* at col. 53 l. 67–col. 54 l. 2. The resulting films showed imprints of the wire rack after drying, indicating aggregations at the points of contact with the wires and non-uniformity. *Id.* at col. 54 ll. 6–14. In contrast, employing a furnace filter to uniformly distribute heat produced a uniform film. *Id.* at col. 54 ll. 19–24. In Example CH, the films were dried in an air oven "by conventional top and bottom drying means," which resulted in aggregations and non-uniformity similar to that in Example CG. *Id.* at col. 54 ll. 42–54.

Like *SciMed* and *Openwave*, the specification distinguishes conventional methods from the present invention:

> In a further aspect of the present invention, methods of forming the films of this invention are provided, by wet casting methods and hot melt extrusion methods. In a wet casting method, the film product is formed by combining a polymer and a polar solvent, forming the combination into a film, and drying the film in a controlled manner. *Preferably, the film is dried initially only applying heat to the bottom side of the film*, in order to maintain a non-self-aggregating uniform heterogeneity.

Id. at col. 4 ll. 59–67 (emphasis added).

> In still other embodiments, there is provided a method of preparing a thin film drug delivery vehicle having a substantially uniform distribution of components including . . . (e) forming a wet film from the matrix; (f) rapidly forming a visco-elastic film *by applying hot air currents to the bottom side of the wet film with substantially no top air flow* . . .

Id. at col. 7 ll. 11–29 (emphasis added).

> For the purposes of the present invention the term non-self-aggregating uniform heterogeneity refers to the ability of the films of the present invention to provide a substantially reduced occurrence of, i.e. little or no, aggregation or conglomeration of components within the film *as is normally experienced when films are formed by conventional drying methods* such as a high-temperature air-bath using a drying oven, drying tunnel, vacuum drier, or other such drying equipment.

Id. at col. 9 ll. 10–18 (emphasis added).

The above passages show that the patentee expressly disclaimed the sole use of conventional top air drying to produce the claimed films. Such disavowal places films

formed by these methods outside the scope of the '305 claims.

Indivior argues that the '305 claims are not limited to any particular drying method because "dried/drying has no textual basis" in the claims. Appellee Br. 25. According to Indivior, the specification disclaimer found by the Delaware Court in its analysis of the '514 patent was "rooted in the meaning of the claim language 'dried' and 'drying,'" and does not apply to the '305 claims because those terms are absent. *Id.* at 24–26. Indivior further argues that removal of the drying terms during prosecution removes any limitation on how the film is dried. *Id.* at 30–31.

We disagree with Indivior and conclude that the '305 claims exclude conventional top air drying. First of all, the drying limitation has a textual basis in the term "continuously cast film," which appears in claims 1 and 26 of the '305 patent. '305 patent col. 68 l. 53, col. 69 l. 14, col. 73 l. 5, 25. These claims recite films formed by wet casting, one of the two film forming methods disclosed by the patent. *See id.* at Abstract. They state that the film is initially produced as a "flowable" matrix and that the content uniformity of the film is measured by "individual unit doses *cut from* the continuously cast film." *Id.* at col. 68 ll. 53–56, col. 69 ll. 11–14, col. 73 ll. 5–7, 25–27 (emphasis added). The patent instructs that "[i]n a wet casting method, the film product is formed by combining a polymer and a polar solvent, forming the combination into a film, *and drying the film* in a controlled manner." *Id.* at col. 4 ll. 61–64 (emphasis added). The parties submitted expert declarations with their briefing on the preliminary injunction motion before the district court. Indivior's expert, Dr. Langer, explained in his declaration that:

> [t]o make a continuously cast film, the flowable coating matrix is then continuously deposited, or coated, onto a substrate . . . . The coating matrix

> is deposited on the moving substrate and is carried through an oven *where the solvent is largely removed, resulting in a continuously cast film* on the substrate that is rolled for further processing (i.e., cutting into individual dosage units and packaging).

J.A. 1313 ¶ 47 (emphasis added). The "continuously cast film" in claims 1 and 26 thus requires drying as the film starts out as a liquid and ends up as a solid that can be cut into individual dosages.

In any event, even if the claims did lack a textual hook for drying, we do not read our precedent as requiring such a hook under the circumstances in this case. As we have explained,

> [w]here the specification makes clear that the invention does not include a particular feature, that feature is deemed to be outside the reach of the claims of the patent, even though the language of the claims, read without reference to the specification, might be considered broad enough to encompass the feature in question.

SciMed, 242 F.3d at 1341. Here, the specification makes clear that the invention does not include films that were dried using conventional top air drying.

Indivior agrees that the claimed films are solid and have been dried, however, it disagrees that a dried film limits the '305 claims by *how* the film is dried. Appellee Br. 34. We disagree. The specification makes clear that a film produced using only conventional top air drying cannot satisfy the claim limitations. In particular, the specification warns that one cannot obtain the claimed level of drug content uniformity in the final cast film by using only conventional top air drying. *See* '305 patent col. 3 ll. 29–31, col. 29 ll. 36–43, 48–50. As such, the express disclaimer of conventional top air drying in the

specification disavows not just a process step from process claims, but also films produced by these drying methods from the scope of the '305 composition claims.

Indivior nonetheless argues that it is improper to import drying, a process limitation, into the '305 patent's composition claims because there is an absence of "specific process language." Appellee Br. 33–34. As a general rule, product claims are not limited to the method of manufacture disclosed in the specification. "The method of manufacture, even when cited as advantageous, does not of itself convert product claims into claims limited to a particular process." *Vanguard Prod. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000). However, "process steps can be treated as part of a product claim if the patentee has made clear that the process steps are an essential part of the claimed invention." *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361, 1375 (Fed. Cir. 2007).

In *Andersen*, we held that claims in a group of patents directed to a "composite structural member" included a pelletizing process, even though the claims themselves did not "contain an explicit process-based limitation." *Id.* at 1371–74. The patents' specification disclosed that the manufacture of the composite members "requires two important steps. A first blending step and a second pelletizing step." *Id.* at 1372. It also disclosed that these steps are necessary to obtain the "intimate mixing" that the "specification identifies as critical to the strength of the composite and ultimately, the claimed structural members." *Id.* We noted that "the specifications thus make clear that the inventors regarded the pelletization process as an essential step in producing the ultimate products—the structural members that were claimed in the Group II patents." *Id.* at 1375. After considering the specification and the prosecution history, we construed the asserted claims to be limited to composite structural

members produced with "an intermediate step of pelletization or linear extrusion." *Id.*

In *Medicines Co. v. Mylan, Inc.*, we construed a claim term "batches" to require that the product be made by an "efficient mixing" process. 853 F.3d 1296, 1302 (Fed. Cir. 2017). The specification defined "batches" as either "all batches prepared by *a same compounding process*" or "a single batch . . . wherein the levels of [Asp[9] -bivalirudin] represent levels for all potential batches *made by said processes*." *Id.* at 1303. The parties agreed that the "batches" must be made by a particular compounding process. *Id.* at 1303–04. The patentee argued, however, that "the claims do not require the use of a particular process that achieves batch consistency." *Id.* at 1303. We rejected that argument and held that the prosecution history and the specification of the patents "demonstrate that the invention disclosed by the . . . patents is a compounding process that achieves batch consistency," which the specification taught could only be achieved using "efficient mixing." *Id.* at 1304. We noted that "our decision does not impermissibly add a process limitation to a product claim that does not require a process because the specification's definition of 'batches' by itself injects a compounding process as a limitation in the asserted claims." *Id.*

As in *Medicines*, we are not "impermissibly add[ing] a process limitation to a product claim that does not require a process" because here, the claim term "continuously cast film" does require a process—the film is made through continuous casting. *Id.* The '305 patent discloses only two methods of forming the films: wet casting and extrusion. Claims 1 and 26 clearly describe films that are formed by a wet casting method, which the specification describes as "combining a polymer and a polar solvent, forming the combination into a film, and drying the film in a controlled manner." '305 patent col. 4 ll. 61–64. The claims themselves describe "continuously cast film" in

terms of processes as well. The "continuously cast film" is "produced on a manufacturing line comprising a flowable . . . film-forming matrix," which is "capable of *being continuously cast* on the manufacturing line without loss of substantial uniformity." *Id.* at col. 73 ll. 5–23 (emphasis added). The uniformity of the "continuously cast film" is measured by "individual unit doses cut from the continuously cast film which do not vary by more than 10%" of a desired amount of active ingredient. *Id.* at col. 73 ll. 25–29. The "continuously cast film" thus describes a film formed by the wet casting method described in the specification, which necessarily requires drying.

Further, similar to *Andersen*, Indivior's patent specification makes clear that the drying process is an essential part of the '305 claimed invention. *See Andersen*, 474 F.3d at 1375. The claims require content uniformity such that the desired amount of active ingredient does "not vary by more than 10%" in the individual unit doses. '305 patent col. 73 ll. 25–29. As we discussed above, Indivior expressly disavowed the sole use of conventional top air drying, warning that these methods cannot form content uniform films. *See e.g.*, *id.* at col. 3 ll. 29–31 ("[T]he conventional drying methods themselves are unable to provide uniform films."), col. 29 ll. 36–43 ("Conventional convection air drying from the top is not employed because it initiates drying at the top uppermost portion of the film, thereby forming a barrier against fluid flow. . . which results in non-uniform films."), col. 29 ll. 48–50 ("If top air is employed, it is balanced with the bottom air drying to avoid non-uniformity and prevent film lift-up on the carrier belt."). Content uniformity is an express claim limitation and is described as a problem in the prior art that the '305 patent aims to solve. *Id.* at col. 4 ll. 23–39, col. 69 ll. 14–15, col. 73 ll. 28–29. If, as the specification explains, content uniformity cannot be achieved using conventional drying methods, then using non-conventional drying methods is necessarily a part of

the claimed invention—it is essential. A drying process limitation is therefore properly read into the claims through the operation of specification disclaimer.

We hold that the '305 claims exclude films produced solely by conventional top air drying methods. We conclude that Indivior has not shown that it is likely to succeed on the merits of its infringement claim under this construction.

Likelihood of Success: Claim Preclusion

We further hold that claim preclusion likely bars Indivior's suit as the '514 claims and the '305 claims are patentably indistinct.

In determining whether claim preclusion applies, "we apply the law of the regional circuit in which the district court sits," here the Third Circuit. *SimpleAir*, 884 F.3d at 1165. Claim preclusion requires "(1) a final judgment on the merits in a prior suit involving; (2) the same parties or their privities; and (3) a subsequent suit based on the same cause of action." *CoreStates Bank, N.A. v. Huls Am., Inc.*, 176 F.3d 187, 194 (3d Cir. 1999). We compare the claims to determine whether there is "the same cause of action." *SimpleAir*, 884 F.3d at 1165.

> [W]here different patents are asserted in a first and second suit, a judgment in the first suit will trigger claim preclusion only if the scope of the asserted patent claims in the two suits is essentially the same. In applying that standard to the particular context here, we conclude that claims which are patentably indistinct are essentially the same.

Id. at 1167. Regarding continuation patents, we instructed that a terminal disclaimer does not conclusively show that the claim scope of a parent patent and a child patent is the same. *Id.* at 1168. But, "a terminal disclaimer is a strong clue that a patent examiner and, by concession, the

applicant, thought the claims in the continuation lacked a patentable distinction over the parent." *Id.*

The parties and the accused products are the same here as in the Delaware Case, where there was a final judgment on the merits. *See Delaware Decision*, 2017 WL 3837312 at *1 n.1, *20. The only claim preclusion element at issue here is whether this case is "based on the same cause of action" as the Delaware Case. *CoreStates*, 176 F.3d at 194. We thus examine whether the '514 patent claims are "patentably indistinct" from the '305 patent claims. *See SimpleAir*, 884 F.3d at 1167. We conclude that they are and that claim preclusion likely applies.

The '305 patent has the same specification as the '514 patent. The only difference between the '305 claims asserted here and the '514 claims asserted in the Delaware Case is that the '305 claims contain the term "continuously cast" in place of "dried" and "drying." *Compare* '514 patent col. 73 l. 48–col. 74 l. 9, *with* '305 patent col. 73 ll. 4–29. There is no dispute that there are no other material differences between the claims. As we discussed above, the specification limits the scope of the "continuously cast" limitation in the '305 claims as it limited the scope of the "drying" limitation in the '514 claims. Specifically, films formed with conventional top air drying methods are excluded from the scope of both claim terms. While the language of the claim terms changed, the scope of the claims did not materially change. The claims of the '305 patent are thus "patentably indistinct" from those of the '514 patent.

Our conclusion is furthered by Indivior's filing of a terminal disclaimer. During prosecution of the '305 patent, Indivior received obviousness-type double patenting rejections over the claims of the '514 patent. J.A. 4360–61. In response, Indivior amended its claims to replace the "drying" and "dried" limitations with "contin-

uously cast." J.A. 4344–45, 4354–55. It also filed a terminal disclaimer at the same time. J.A. 4360–61, 6556. While not dispositive, the filing of a terminal disclaimer here is a "strong clue" that the claims of the '305 patent are patentably indistinct from those of the '514 patent. *SimpleAir*, 884 F.3d at 1168.

We hold that the '305 claims are patentably indistinct from the '514 claims and that claim preclusion is likely to apply. As a result, Indivior has not shown that it is likely to succeed on the merits of its infringement claim against DRL.

IV

Based on the record with the proper interpretation of claim scope, we conclude that Indivior has not shown that it is likely to succeed on the merits of its infringement claim. The district court thus abused its discretion in granting the preliminary injunction. 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. Accordingly, we vacate the preliminary injunction and remand to the district court for further proceedings.

VACATED AND REMANDED

COSTS

Costs to Appellants.

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

INDIVIOR INC., INDIVIOR UK LIMITED, AQUESTIVE THERAPEUTICS, INC.,
Plaintiffs-Appellees

v.

DR. REDDY'S LABORATORIES, S.A., DR. REDDY'S LABORATORIES, INC.,
Defendants-Appellants

2018-2167, 2018-2169

Appeals from the United States District Court for the District of New Jersey in Nos. 2:17-cv-07111-KM-CLW, 2:18-cv-01775-KM-CLW, 2:18-cv-05288-KM-CLW, Judge Kevin McNulty.

NEWMAN, *Circuit Judge*, dissenting.

The district court, on full and careful analysis of law and equity, imposed a preliminary injunction pending trial.[1] The court held that the enjoined party, Dr. Reddy's Laboratories, could readily be made whole by monetary payment if the injunction was imposed in error, whereas

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[1] *Indivior Inc. v. Dr. Reddy's Labs. S.A.*, No. 17–7111, 2018 WL 3496643 (July 19, 2018) ("D.N.J. Op.").

Indivior could not recover its reputation and market share if the injunction was erroneously denied. D.N.J. Op. at *1, *12–13. The court required an injunction bond of $72 million, which the record states has been posted. My colleagues ignore this reasoning, disregard the requisite appellate standard of review, lift the injunction, and authorize Dr. Reddy's to make an "at risk" launch of its counterpart of Indivior's Suboxone®. I respectfully dissent, for on the applicable standards of law and procedure, the district court's ruling should be sustained.

The preliminary injunction is an act of equity and is reviewed accordingly

"The purpose of a preliminary injunction is to preserve the relative positions of the parties until a trial on the merits can be held." *Univ. of Tex. v. Camenisch*, 451 U.S. 390, 395 (1981); *see also Smith Int'l, Inc. v. Hughes Tool Co.*, 718 F.2d 1573, 1578 (Fed. Cir. 1983) ("A preliminary injunction will normally issue only for the purpose of preserving the status quo and protecting the respective rights of the parties pending final disposition of the litigation."). The district court's injunction was for this purpose; it is a discretionary act, and is required to be reviewed accordingly.

The district court reviewed the equities and recognized the irreparable harm that would befall Indivior in the absence of an injunction, noting that Dr. Reddy's knowingly risked the district court's grant of such interim relief. The district court found that Dr. Reddy's "chose to enter the market 'at risk' and took the chance it could face a potential injunction against its product." D.N.J. Op. at *13. The district court concluded that the balance of harms "appears to favor Indivior." *Id.* at *1.

My colleagues do not consider the district court's equitable discretion, and instead make appellate findings of the merits of infringement, although there has been no trial of infringement. My colleagues erroneously apply a

decision of the district court in Delaware on a different patent with different claims, although that decision is pending on appeal. While that appeal has not yet been heard, my colleagues rely on the Delaware court's ruling to overturn the New Jersey district court's equitable action, an injunction *pendente lite*. With all respect to my colleagues, they err in fundamental ways.

As the Court has related, "the 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.*

The New Jersey district court considered the preliminary arguments related to patent validity, for the only noteworthy invalidity argument related to the written description; there was no prior art of significance. D.N.J. Op. at *9–11. This aspect, together with other preliminary injunction factors, supports the district court's discretionary ruling to preserve the status quo pending trial. *Id.* at *11–14. The only issue before us is whether the district court had discretionary authority to preserve the status quo during the litigation.

The majority errs in its finding of "specification disclaimer"

The panel majority "read[s]" a "drying process limitation" from the specification of the '305 patent into the claims "through the operation of specification disclaimer." Maj. Op. at 19. However, the invention claimed in the '305 patent is not a drying method: it is a film for transmucosal administration of an active ingredient. *See, e.g.*, '305 patent, claim 26 (claiming a "drug delivery composition" as defined); Maj. Op. 6–7 (setting forth claim 26 in full). As the courts have repeatedly stated: "It is the claims that define the metes and bounds of the patentee's

invention." *Thorner v. Sony Comput. Entm't Am. LLC,* 669 F.3d 1362, 1367 (Fed. Cir. 2012).

The '305 specification states that the drying should avoid agglomeration of the solid ingredients, and that bottom-up drying is preferred over solely top-down drying; however, the '305 patent also states that bottom-up drying is not the only method of drying and that it can be combined with top-down drying, or replaced with viscosity control by polymer composition and other film-forming methods:

> The films may be formed with a polar solvent which may be water, a polar organic solvent, or a combination thereof. An active ingredient may be added to the polymer and water combination prior to the drying step. Alternatively, or in addition to controlling the drying the film, the polymer may be selected in order to provide a viscosity that maintains the non-self-aggregating uniform heterogeneity.

'305 patent, col. 5 ll. 7–13.

The claims are for the films, not the drying method. The Supreme Court and this court have consistently reaffirmed the primacy of the claims in defining the patent right. *See Cimiotti Unhairing Co. v. Am. Fur Ref. Co.*, 198 U.S. 399, 410 (1905) ("In making his claim the inventor is at liberty to choose his own form of expression, and while the courts may construe the same in view of the specifications and the state of the art, they may not add to or detract from the claim."); *Kara Tech. Inc. v. Stamps.com Inc.*, 582 F.3d 1341, 1348 (Fed. Cir. 2009) ("The claims, not specification embodiments, define the scope of patent protection. The patentee is entitled to the full scope of his claims, and we will not limit him to his preferred embodiment or import a limitation from the specification into the claims."); *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) ("[T]he Su-

preme Court made clear that the claims are 'of primary importance, in the effort to ascertain precisely what it is that is patented.'" (quoting *Merrill v. Yeomans*, 94 U.S. 568, 570 (1876))); *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 957 (Fed. Cir. 1983) ("In arguing that claims must be read in light of the specification, that prevention of backflow is the 'essence' of Torrey's invention, and that *all* claims must therefore be read as including the quoted limitation of claim 1, Raytheon confuses the respective roles of the specification and claims.").

My colleagues select the drying method claimed in a different patent (the '514 parent patent) and place that limitation in the claims of the '305 patent, although the patentee expressly amended the '305 claims to remove the drying method. *See* J.A. 4343–62 (Amendment and Response to Office Action of July 21, 2017 (Nov. 30, 2017)). My colleagues give the amended '305 claims identical scope to the claims of the '514 patent, the patent previously litigated in Delaware. My colleagues then conclude that the '305 claims would have the same infringement position as the '514 claims were found to have in Delaware. 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. *See Raytheon*, 724 F.2d at 957. "[I]f we once begin to include elements not mentioned in the claim, in order to limit such claim . . . , we should never know where to stop." *Phillips*, 415 F.3d at 1312 (omission in original) (quoting *McCarty v. Lehigh Valley R.R. Co.*, 160 U.S. 110, 116 (1895)).

Precedent is replete with such warning: "It is the claims that define the metes and bounds of the patentee's invention. The claims, not specification embodiments, define the scope of patent protection." *Kara Tech. Inc.*, 582 F.3d at 1341; *see also Thorner*, 669 F.3d at 1366 ("It is [ ] not enough that the only embodiments, or all of the

embodiments, contain a particular limitation. We do not read limitations from the specification into claims; we do not redefine words."); *E.I. du Pont de Nemours & Co. v. Phillips Petroleum Co.,* 849 F.2d 1430, 1433 (Fed. Cir. 1988) (it is improper to impose "a limitation read into a claim from the specification wholly apart from any need to interpret what the patentee meant by particular words or phrases in the claim").

The panel majority errs in requiring that the claims of the '305 patent be read as including the "drying process limitation" that was cancelled from the claims. Maj. Op. at 19. "In examining the specification for proper context, however, this court will not at any time import limitations from the specification into the claims." *CollegeNet, Inc. v. ApplyYourself, Inc.*, 418 F.3d 1225, 1231 (Fed. Cir. 2005). The majority blurs the "distinction between using the specification to interpret the meaning of a claim and importing limitations from the specification into the claim." *Phillips*, 415 F.3d at 1323.

The majority uses the term "specification disclaimer." Specification disclaimer requires the clear and explicit intent by the patentee to limit the claims. *See Thorner*, 669 F.3d at 1366–67 ("To constitute disclaimer, there must be a clear and unmistakable disclaimer."); *In re Am. Acad. Of Sci. Tech Ctr.*, 367 F.3d 1359, 1369 (Fed. Cir. 2004) ("We have cautioned against reading limitations into a claim from the preferred embodiment described in the specification, even if it is the only embodiment described, absent clear disclaimer in the specification." (citing *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 906 (Fed. Cir. 2004))); *see also Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003) ("We 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." (internal citation omitted) (quoting *CCS*

Fitness, Inc. v. Brunswick Corp., 288 F.3d 1359, 1366 (Fed. Cir. 2002)); *Epistar Corp. v. Int'l Trade Comm'n*, 566 F.3d 1321, 1334 (Fed. Cir. 2009).

Here the contrary intent is explicit: the '305 patent was amended to present claims that are not limited to any drying method. The patentee eliminated "drying/dried" limitations from the '305 claims, unlike the '514 claims. *See* J.A. 4343–62 (Amendment and Response to Office Action of July 21, 2017 (Nov. 30, 2017)) (removing "drying" and "dried" limitations from the claims). Reading these terms back into the claims is contrary to the patentee's clear intent.

This action is dispositive of patentee intent to remove such claim limitations. *See Laryngeal Mask Co. Ltd. v. Ambu*, 618 F.3d 1367, 1372–73 (Fed. Cir. 2010) ("The applicant deleted this requirement from the claims. . . . Regardless of why LMA amended its claims, we agree with LMA that it would be improper to read [that requirement] back into the [claim]."); *id.* at 1373 ("[D]efendant's insistence upon this court's reading back into the claims limitations which were originally there and were removed during prosecution of the application through the Patent Office cannot be permitted." (internal quotation marks omitted) (alteration in original) (quoting *Kistler Instrumente AG v. United States*, 628 F.2d 1303, 1308 (Ct. Cl. 1980))).

Specification disclaimer requires the opposite of what the majority presents, for the intrinsic evidence negates any intent to include in the claims any drying limitation from the specification. *See Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002) (requiring "expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope"). My colleagues contravene precedent.

The majority's theory of disclaimer is not supported by the cases to which they cite. In *SciMed Life Systems, Inc.*

v. Advanced Cardiovascular Systems, Inc., the specification described two types of known catheter configuration—dual lumen catheters and coaxial lumen catheters—and then explicitly excluded dual lumen catheters from the claim scope, whereby the court stated: "It is difficult to imagine how the patents could have been clearer in making the point that the coaxial lumen configuration was a necessary element of every variant of the claimed invention." 242 F.3d 1337, 1343 (Fed. Cir. 2001). The specification in *SciMed* stated: "The intermediate sleeve structure defined above [coaxial design] is the basic sleeve structure for *all embodiments of the present invention contemplated and disclosed herein* . . . ." *Id.* The '305 patent, in contrast, does not contain such unequivocal language of exclusion.

The majority points to *Medicines Co. v. Mylan, Inc.*, 853 F.3d 1296 (Fed. Cir. 2017) as an example where this court added a process limitation to a product claim based on the specification. Maj. Op. at 17. But as the panel majority notes, "[t]he specification defined 'batches' as either 'all batches prepared by *a same compounding process*' or 'a single batch . . . wherein the levels of [Asp^9-bivalirudin] represent levels for all potential batches *made by said processes*.'" *Id.* (omission in original) (quoting *Medicines Co.*, 853 F.3d at 1303).

In contrast to the '305 patent, the patents at issue in *Medicines Co.* provided an express process definition for the term "batches." *See* 853 F.3d at 1300 ("As used here, 'batch' or 'pharmaceutical batch' refers to material produced by a single execution of a compounding process of various embodiments of the present invention. 'Batches' or 'pharmaceutical batches' as defined herein may include . . . ." (quoting U.S. Patent No. 7,582,727, col. 5 ll. 24–36; U.S. Patent No. 7,598,343, col. 5 ll. 24–36)). Such an express definition is not present in the '305 specification.

The panel majority also cites *Openwave Sys., Inc. v. Apple Inc.*, although the standard for specification disclaimer, reiterated therein, is: "To find disavowal we must find that the specification is 'both so clear as to show reasonable clarity and deliberateness, and so unmistakable as to be unambiguous evidence of disclaimer.'" 808 F.3d 509, 513 (Fed. Cir. 2015) (quoting *DealerTrack, Inc. v. Huber*, 674 F.3d 1315, 1322 (Fed. Cir. 2012)). The requisite "unmistakable evidence" is not met by the usage of "preferably," "substantially," "normally," or "desirably," in the relevant portions of the '305 specification. *See* Maj. Op. at 12–14 (quoting, for example, '305 patent, col. 4 ll. 64–67 ("Preferably, the film is dried initially only applying heat to the bottom side of the film, in order to maintain a non-self-aggregating uniform heterogeneity.")).

The panel majority lastly relies on *Andersen Corp. v. Fiber Composites, LLC*, 474 F.3d 1361 (Fed. Cir. 2007) as an example of disclaimer of claim scope based on language in the specification and prosecution history. Maj. Op. at 16–17. The court read a "pelletizing" process limitation into product claims, based on both the specification and patentee statements during prosecution to distinguish the claims over prior art. 474 F.3d at 1371–75 ("[W]e conclude that the prosecution history of the Group II patents definitively resolves the question with a clear disavowal and confirms the role of pelletization in the production of the claimed structural members."). In contrast, during prosecution of the '305 patent, the applicant amended the claims to eliminate any drying method.

The panel majority's theory of specification disclaimer is devoid of support in law or precedent.

The majority erroneously treats the Delaware decision on the '514 parent patent as barring this infringement suit on the different claims of the '305 continuation patent

The panel majority further errs in its ruling that "claim preclusion likely bars Indivior's suit as the '514 claims and the '305 claims are patentably indistinct." Maj. Op. at 19. The majority writes that under *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160 (Fed. Cir. 2018), and in view of regional circuit law, the claims at issue in this New Jersey action, and those in the Delaware case, are "patentably indistinct" and that "claim preclusion likely applies." *Id.* at 19–20. The majority presents two reasons: (1) the importation of the "drying/dried" limitation into the '305 claims; and (2) the "strong clue" that "claim preclusion is likely to apply" in view of Indivior's filing a terminal disclaimer for the '305 patent. *Id.* at 20–21. Again, law and precedent do not support the majority.

"In legal principle, the 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 of the rejection. It is improper to convert this simple expedient of 'obviation' into an admission or acquiescence or estoppel on the merits." *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874–75 (Fed. Cir. 1991). Moreover, in *Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc.*, this court rejected the argument that "the filing of the terminal disclaimer represents an admission by the inventors 'equating all claims of the [second application] to all claims of the [first patent].'" 473 F.3d 1173, 1184 n.4 (Fed. Cir. 2006) (quoting argument).

This court has recognized, "Dating back at least to *Butler v. Eaton*, 141 U.S. 240, 242–44 (1891), a bedrock principle of preclusion law has been that a reversed judgment cannot support preclusion; indeed, 'a second

judgment based upon the preclusive effects of the first judgment should not stand if the first judgment is reversed.'" *Levi Strauss & Co. v. Abercrombie & Fitch Trading Co.*, 719 F.3d 1367, 1372 (Fed. Cir. 2013) (quoting 18A Charles A. Wright, *et al.*, Federal Practice and Procedure § 4433 (2d ed. 2002)). Imposing irreparable harm on Indivior looms over the panel majority's vacatur of the preliminary injunction based in part on a judgment currently pending appeal. The likelihood of such harm is supported by extensive factual findings made by the district court. D.N.J. Op. at *1, *12–13. "[A]n initial reliance on preclusion must be reversed once the underlying judgment is reversed." *Levi Strauss*, 719 F.3d at 1372. This possibility supports the district court's decision to preserve the status quo.

Other factors also support the preliminary injunction, as the district court found

The majority explicitly declines to review the traditional equitable factors, such as the balance of harms, and omits any discussion of equity and discretion. The district court found that the harm to Dr. Reddy's can be monetized and compensated and that the harm to Indivior cannot be fully remedied. D.N.J. Op. at *1, *12–13. The district court explained its reasoning at careful length.

My colleagues hold that they "need not reach" these aspects of the district court's discretionary action, based on their conclusion that Indivior "has not shown that it is likely to succeed on the merits of its infringement claim." Maj. Op. at 21. However, the balancing of all factors is the foundation of a discretionary ruling. When one side is subject to substantially greater harm, this may outweigh other factors believed to favor the opponent. "In 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.'" *Winter v. Nat.*

Res. Def. Council, 555 U.S. 7, 24 (2008) (quoting *Amoco Prod. Co. v. Gambell*, 480 U.S. 531, 545 (1987)).

The district court made extensive factual findings, detailing the likelihood of irreparable harm to Indivior in the absence of an injunction while the issues are litigated. D.N.J. Op. at *12. The district court found that "[e]ntry of a generic would cause Indivior to lose market share and the [S]uboxone film's advantageous formulary status, and would impair research and development." *Id.* at *1. The district court cited precedent that the "right to exclude direct competition in a limited sphere, a right inherent in the grant of a patent, is irreparably harmed by the loss of sales and the competitive foothold that the infringer will gain." *Id.* at *12 (internal quotation marks and citation omitted).

"Price erosion, loss of goodwill, damage to reputation, and loss of business opportunities are all valid grounds for finding irreparable harm." *Celsis in Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 930 (Fed. Cir. 2012). The district court found this case to fit these conditions:

> It comports with common sense, and Indivior has shown, that Indivior will likely lose market share to DRL's ANDA product once it is launched and will be unlikely to recover that share, even if that product is pulled from the market. Courts have found that a reduction of market share due to the loss of formulary status and a change in tier pricing, constitutes irreparable harm.

D.N.J. Op. at *12.

The district court determined that the balance of equities "appears to favor Indivior." D.N.J. Op. at *1, *13. The district court found that Dr. Reddy's "knowingly invested 'at risk,'" *id.* at *1, and its projected "losses stem from a market it seeks to enter, not one that it is already in." *Id.* at *13. As in *Sanofi-Synthelabo v. Apotex, Inc.*,

"the court did not clearly err in finding that [the accused infringer's] harms were 'almost entirely preventable' and were the result of its own calculated risk to launch its product pre-judgment." 470 F.3d 1368, 1383 (Fed. Cir. 2006).

The district court also determined that the "public interest will be served by the issuance of a preliminary injunction in this case." D.N.J. Op. at *14. The court found that "[a]lthough the Suboxone film is an efficacious means of administering buprenorphine, it is not the only means, and the disadvantages of having no generic alternative does not outweigh the public benefit of maintaining Indivior's rights as a patent holder while this action is pending." *Id.* at *1. The district court found that the injunction would not "deny access to the active ingredient, which may be administered by other means. There still remain other non-film generics on the market . . . ." *Id.* at *14. The public interest in the discovery and provision of new products is an important aspect of the court's exercise of equity.

None of these findings are reviewed by the majority. Neither law nor equity supports removal of the preliminary injunction and allowing market entry during the litigation. "It is well settled that the granting of a temporary injunction, pending final hearing, is within the sound discretion of the trial court; and that, upon appeal, an order granting such an injunction will not be disturbed unless contrary to some rule of equity, or the result of improvident exercise of judicial discretion." *Deckert v. Independence Shares Corp.*, 311 U.S. 282, 290 (1940) (internal quotation marks and citation omitted). The district court's action is fully in accord with precedent, and is within its judicial discretion.

CONCLUSION

I do not discern abuse of the district court's discretion. From my colleagues' contrary decision, I respectfully dissent.

United States Court of Appeals for the Federal Circuit

INDIVIOR INC., INDIVIOR UK LIMITED, AQUESTIVE THERAPEUTICS, INC.,
Plaintiffs - Appellees

v.

DR. REDDY'S LABORATORIES, S.A., DR. REDDY'S LABORATORIES, INC.,
Defendants - Appellants

18-2167, 18-2169

Appeals from the United States District Court for the District of New Jersey in case Nos. 2:17-cv-07111-KM-CLW, 2:18-cv-01775-KM-CLW, 2:18-cv-05288-KM-CLW, Judge Kevin McNulty

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JUDGMENT

THIS CAUSE having been considered, it is

ORDERED AND ADJUDGED:

VACATED AND REMANDED

ENTERED BY ORDER OF THE COURT

November 20, 2018

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

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

INDIVIOR INC., INDIVIOR UK LIMITED, AQUESTIVE THERAPEUTICS, INC.,
Plaintiffs-Appellees

v.

DR. REDDY'S LABORATORIES, S.A., DR. REDDY'S LABORATORIES, INC.,
Defendants-Appellants

2018-2167, 2018-2169

Appeals from the United States District Court for the District of New Jersey in Nos. 2:17-cv-07111-KM-CLW, 2:18-cv-01775-KM-CLW, 2:18-cv-05288-KM-CLW, Judge Kevin McNulty.

ON PETITION FOR PANEL REHEARING AND REHEARING EN BANC

Before PROST, *Chief Judge*, NEWMAN, LOURIE, DYK, MOORE, REYNA, WALLACH, TARANTO, CHEN, HUGHES, and STOLL, *Circuit Judges*[*].

PER CURIAM.

O R D E R

Appellees Aquestive Therapeutics, Inc., Indivior Inc. and Indivior UK Limited filed a combined petition for panel rehearing and rehearing en banc. A response to the petition was invited by the court and filed by appellants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, S.A. The petition was referred to the panel that heard the appeal, and thereafter the petition for rehearing en banc was referred to the circuit judges who are in regular active service.

Upon consideration thereof,

IT IS ORDERED THAT:

The petition for panel rehearing is denied.

The petition for rehearing en banc is denied.

The mandate of the court will issue on February 11, 2019.

FOR THE COURT

February 4, 2019
Date

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

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* Circuit Judge O'Malley did not participate.

Nos. 2018-2167, 2018-2169

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AQUESTIVE THERAPEUTICS, INC.,

Plaintiffs-Appellees,

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DR. REDDY'S LABORATORIES S.A.,
DR. REDDY'S LABORATORIES, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the District of New Jersey in
Nos. 2:17-cv-07111-KM-CLW, 2:18-cv-01775-KM-CLW,
2:18-cv-5288-KM-CLW, Judge Kevin McNulty

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TABLE OF ABBREVIATIONS

’305 Patent	U.S. Patent No. 9,931,305
’514 Patent	U.S. Patent No. 8,603,514
Actavis	Actavis Laboratories UT, Inc.
Alvogen	Alvogen Pine Brook, LLC
ANDA	Abbreviated New Drug Application
Aquestive	Plaintiff-Appellee Aquestive Therapeutics, Inc.
DRL	Defendants-Appellants Dr. Reddy’s Laboratories S.A. and Dr. Reddy’s Laboratories, Inc.
FDA	Food and Drug Administration
Indivior	Plaintiffs-Appellees Indivior Inc. and Indivior UK Limited
Plaintiffs	Plaintiffs-Appellees Aquestive Therapeutics, Inc., Indivior Inc., and Indivior UK Limited
Teva	Teva Pharmaceuticals USA, Inc.
Watson	Watson Laboratories, Inc.

Pursuant to Federal Rule of Appellate Procedure 41, Plaintiffs-Appellees Indivior and Aquestive respectfully move the Court to stay issuance of the mandate pending (1) this Court's resolution of the appeals in *Indivior Inc. v. Dr. Reddy's Laboratories, S.A.*, No. 17-2587, and *Indivior Inc. v. Alvogen Pine Brook, LLC*, No. 18-1949 ("the '514 appeals"), which concern a patent related to the one at issue in this appeal; and (2) the disposition of a petition for a writ of *certiorari* seeking review of this Court's decision in this appeal. Simultaneously with this motion, Indivior and Aquestive have moved to expedite argument in the '514 appeals.

Ample grounds are set forth below to support the Court's stay of the mandate. The mandate is currently scheduled by order of the Court to issue February 11, 2019. D.I. 122. If the Court does not stay that issuance, Indivior and Aquestive respectfully request that the mandate issue no sooner than seven days after any order denying this motion, to permit Indivior and Aquestive time to seek a stay from the Supreme Court. *See* Fed. R. App. P. 41(b) ("The court's mandate must issue . . . 7 days after entry of an order denying a timely petition for panel rehearing, petition for rehearing en banc, or motion for stay of mandate, *whichever is later*." (emphasis added)).

Indivior and Aquestive also respectfully request that the Court establish an expedited briefing schedule for this motion, with any opposition due February 8, 2019, and any reply due February 11, 2019.

INTRODUCTION

A stay of the mandate is warranted under Rule 41(b) because a reversal in the '514 appeals would eliminate the bases for the decision vacating the preliminary injunction. The district court's undisturbed findings show Indivior and Aquestive will suffer irreparable harm before those appeals are resolved. And given the posted $72 million bond, the balance of equities strongly favors maintaining the status quo.

A stay also is warranted under Rule 41(d) pending resolution of Indivior and Aquestive's forthcoming *certiorari* petition. The panel majority's decision is a strong candidate for Supreme Court review because it conflicts with rulings of other Circuits on the standard for review of preliminary injunctions. The panel majority imposed a more demanding standard than other Circuits, including the Third Circuit, whose rulings govern non-patent issues in this case. What standard governs the four-factor test for injunctive relief after *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7 (2008), has been a topic of much attention in the Circuits and it is reasonably probable the Supreme Court will grant review to clarify that standard.

There also is a reasonable probability the Supreme Court will review the panel majority's patent-disclaimer error because it is contrary to longstanding Supreme Court precedent that limitations cannot be read into a claim without a textual basis.

DRL opposes this motion and will file a response.

BACKGROUND

Indivior and Aquestive developed and now market Suboxone® Sublingual Film ("Suboxone Film"). Suboxone Film is the first FDA-approved sublingual film—a rapidly dissolving film that adheres to the underside of a patient's tongue—and a leading treatment for opioid dependency. (Other treatments on the market provide the same active ingredient in other dosage forms.) Suboxone Film is covered by a number of patents, including—most relevant here—the '514 and '305 patents.

A. The '514 Patent Infringement Litigation

1. Between 2013 and 2015, several generic drug manufacturers filed ANDAs seeking FDA approval to market generic versions of Suboxone Film. Indivior and Aquestive initiated Hatch-Waxman proceedings in the District of Delaware, alleging the proposed generics infringe multiple patents, including the '514 patent. Because the ANDAs came at different times, the litigation led to separate trials.

In the first case tried, the Delaware district court found that Watson and Actavis's proposed generics infringe the '514 patent.

In the next case, the court held that DRL and Teva's generics did not infringe the '514 patent. *See Reckitt Benckiser Pharms. Inc. v. Dr. Reddy's Labs. S.A.*, 2017 WL 3837312 (D. Del. Aug. 31, 2017) (Teva has agreed to be bound by the result in the litigation against DRL). The judgment rested on shifting claim constructions related to the "dried"/"drying" terms in the '514 claims. *Id.* at *4. The district court

gave those terms their plain meaning in the Watson/Actavis case, but then held in the DRL case that the patentees had disclaimed certain methods of drying to produce the claimed compositions. The court concluded that DRL's process did not meet the "dried/drying" limitation, as the court had narrowed it. *Id.* at *4-6.

The parties appealed and cross-appealed aspects of the Delaware district court's judgments. This Court consolidated the DRL, Teva, Watson, and Actavis appeals, which have been fully briefed since August 2018. No. 17-2587, D.I. 7, 31.

2. Indivior and Aquestive later sued another generic manufacturer, Alvogen, on the '514 patent. (Mylan was a codefendant, but later settled.) The Alvogen trial took place after the DRL case had ended. The district court concluded that Alvogen's generic did not infringe the '514 patent based again on a narrow construction of "dried." *See Indivior Inc. v. Mylan Techs. Inc*., 298 F. Supp. 3d 775 (D. Del. 2018).

Indivior and Aquestive appealed, and the Court designated that appeal as a companion to the consolidated '514 appeals. The Alovgen appeal has been fully briefed since November 2018. No. 18-1949, D.I. 2, 62.

B. The '305 Patent Infringement Litigation

1. Indivior and Aquestive believe the inventive compositions are not limited to particular drying methods. Thus, while appealing the district court's erroneous construction of the terms "dried"/"drying" in the '514 patent, Aquestive continued to prosecute another patent application. To ensure it captured the full scope of the

invention, the application included claims that removed the "dried"/"drying" terms. The PTO allowed the new claims and issued the '305 patent in April 2018.

Indivior and Aquestive brought suit for infringement of the '305 patent against DRL and Alvogen in the District of New Jersey, the appropriate venue following *TC Heartland LLC v. Kraft Food Group Brands LLC*, 137 S. Ct. 1514 (2017).[1]

2. In June 2018, FDA approved DRL's ANDAs, and DRL launched its generic at risk. Indivior and Aquestive immediately obtained a temporary restraining order from the New Jersey district court presiding over the '305 infringement litigation.

After discovery, full briefing, and a day-long hearing, the district court preliminarily enjoined DRL's launch pending trial. *See Indivior Inc. v. Dr. Reddy's Labs. S.A.* (*Indivior I*), 2018 WL 3496643 (D.N.J. July 20, 2018). The district court found that (1) Indivior and Aquestive had demonstrated a likelihood of success on the merits; (2) Indivior and Aquestive had shown irreparable harm; (3) the balance of equities appeared to favor Indivior and Aquestive; and (4) the public interest would be served by an injunction. *Id.* at *11-14. Indivior subsequently posted a $72 million bond, an amount the court determined would be adequate to compensate DRL for any damages it might incur through trial. Appx48 at D.I. 149; Appx62, ¶3.[2]

[1] Indivior and Aquestive also sued Actavis and Teva in Delaware and New Jersey, respectively. Actavis is enjoined from launching because it was found to infringe the '514 patent. Teva agreed to be bound by the result in the '305 litigation against DRL.

[2] Appx numbers refer to the original Joint Appendix in this appeal. D.I. 85, 86.

3. DRL pursued an expedited appeal and a divided panel vacated the '305 preliminary injunction. *See Indivior Inc. v. Dr. Reddy's Labs., S.A*. (*Indivior II*), — F. App'x —, 2018 WL 6069706 (Fed. Cir. Nov. 20, 2018). The panel majority did not address or disturb the district court's findings regarding irreparable harm, the balance of equities, or the public interest. *Id.* at *10.

The panel majority concluded that Indivior and Aquestive had not shown a likelihood of success. *Id.* The panel majority read into the '305 claims a "specification disclaimer" restricting the composition claims to use of certain drying processes—notwithstanding the absence in the '305 claims of the terms "dried" or "drying"—and concluded that Indivior and Aquestive had not shown that their infringement claim was likely to succeed "under this construction." *Id.* at *4-9. The panel majority held that, under this construction, Indivior and Aquestive's '305 infringement claim was likely precluded by the Delaware district court's ruling in the '514 case against DRL (which is currently on appeal), because this disclaimer rendered the '305 claims "patentably indistinct from the '514 claims," as the Delaware district court had narrowed them. *Id.* at *9-10.

4. On December 20, 2018, Indivior and Aquestive filed a petition for rehearing and rehearing *en banc*. D.I. 113. The Court denied the petition on February 4, 2019. D.I. 122. The mandate currently is scheduled by order to issue February 11, 2019. *Id.* A petition for a writ of *certiorari* is due May 6, 2019. *See* Sup. Ct. R. 13.

5. On January 24, 2019, the FDA approved Alvogen's ANDA. Indivior and Aquestive immediately obtained a temporary restraining order in the '305 infringement litigation. On February 1, 2019, the district court entered a stipulated order enjoining Alvogen from launching its generic unless this Court issues a mandate vacating the preliminary injunction against DRL.

LEGAL STANDARD

A court of appeals may "shorten or extend the time" for issuing its mandate. Fed. R. App. P. 41(b). "No exceptional circumstances need be shown to justify a stay" of the mandate and "[t]his matter is entrusted to the circuit court's sound discretion." *Bryant v. Ford Motor Co*., 886 F.2d 1526, 1528 (9th Cir. 1989).

In addition, Rule 41(d) authorizes a circuit court to stay the issuance of a mandate pending the filing of a petition for a writ of *certiorari* in the Supreme Court. The applicant must demonstrate that the petition "would present a substantial question and that there is good cause for a stay." Fed. R. App. P. 41(d)(1).

ARGUMENT

I. THE COURT SHOULD STAY ISSUANCE OF THE MANDATE PENDING RESOLUTION OF THE '514 APPEALS

A. Reversal in the '514 Appeals Would Require Reversal of the Decision Vacating the Preliminary Injunction in the '305 Litigation

The decision vacating the preliminary injunction in this case relies on the Delaware district court's erroneous judgment in the '514 litigation. Contrary to the inventors' clear intent and the claims' plain language, the panel majority read into

the ’305 claims a drying-process limitation, as the Delaware district court had read into the ’514 claims. Both decisions found a purported disclaimer in the specification shared by the ’305 and ’514 patents. *Indivior II*, 2018 WL 6069706, at *4-9. The panel majority also held that the Delaware judgment likely precludes Indivior and Aquestive’s ’305 infringement claim because the disclaimer renders the ’305 and ’514 claims patentably indistinct. *Id.* at *9-10.

If the erroneous ruling in the ’514 appeal is reversed, that holding would eliminate the foundation for the ruling here. The panel majority purported to resolve the disclaimer issue on a preliminary-injunction proceeding without any claim construction by the district court. In the ’514 appeals, this Court could, with the benefit of the full briefing and claim construction there, reverse the Delaware judgment because, among other reasons, (1) there is no disclaimer, or (2) the drying method used by DRL falls outside the scope of any disclaimer. If there is no disclaimer in the shared specification that encompasses DRL’s product, and no Delaware district court judgment, the bases for the panel majority’s decision are eliminated. Moreover, if DRL is found to infringe the ’514 patent, its ANDA approval would no longer be final, and DRL could not enter the market. *See In re Omeprazole Patent Litig.*, 536 F.3d 1361, 1367-68 (Fed. Cir. 2008).

Circuit courts stay appellate proceedings when the proper disposition of one matter depends on the resolution of another. *E.g.*, *Poyson v. Ryan*, 743 F.3d 1185,

1187 (9th Cir. 2013) (staying rehearing petition pending *en banc* review in another case posing a potentially dispositive issue). In such cases, a stay is "an easy and procedurally proper way to avoid" the unnecessary risk of injustice and harm that would flow from rendering inconsistent judgments, *Henry v. Ryan*, 766 F.3d 1059, 1067 (9th Cir. 2014) (W. Fletcher, J., concurring), especially where a posted bond protects against harm to the other side.

This practice makes particular sense here. "According preclusive effect to a judgment from which an appeal has been taken . . . risks denying relief on the basis of a judgment that is subsequently over-turned." *Martin v. Malhoyt*, 830 F.2d 237, 264 (D.C. Cir. 1987) (R. Ginsburg, J.). Courts can address "this dilemma" by "defer[ring] consideration of the preclusion question until the appellate proceedings . . . are concluded, provided they are moving forward with reasonable dispatch[.]" *Id.* at 265; *accord United States v. 5 Unlabeled Boxes*, 572 F.3d 169, 175 (3d Cir. 2009) (better to "postpon[e]" the preclusion decision "until the appeal of the first judgment has been concluded," because giving "early application of res judicata" to the first judgment "can create later problems" if it "is reversed on appeal").

This Court similarly should maintain the status quo until the '514 appeals are resolved. Indivior and Aquestive have moved to expedite those appeals, which are fully briefed. Staying issuance of the '305 mandate under these circumstances would

promote fairness and efficiency, and it would avoid irreparably harming Plaintiffs based on a judgment and underlying reasoning that might be overturned.

B. Plaintiffs Would Suffer Irreparable Harm Absent a Stay and the Balance of Equities and Public Interest Strongly Favor a Stay

In granting the preliminary injunction, the district court "made extensive factual findings, detailing the likelihood of irreparable harm to Indivior in the absence of an injunction." *Indivior II*, 2018 WL 6069706, at *15 (Newman, J., dissenting). The court found that "[e]ntry 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." *Indivior I*, 2018 WL 3496643, at *1. The court explained that "Indivior will likely lose market share to DRL's ANDA product once it is launched and will be unlikely to recover that share, even if that product is pulled from the market." *Id.* at *12. The panel majority did not question these findings.

Indivior and Aquestive will be irreparably harmed if the Court does not stay the mandate and allows DRL to enter the market. And that irreparable harm could be magnified by the domino effect of DRL's entry, which may trigger launches by other generic drug companies (including Alvogen). The result would be a severe "reduction [in Plaintiffs'] market share due to the loss of formulary status and a change in tier pricing"—a quintessential example of irreparable harm. *Id.* at *12. It would cost Indivior both substantial revenue from a product that now accounts for 98% of its U.S. business and the reputation and goodwill it has built with patients

and providers. Appx20022, Appx20025, Appx20027. Even if DRL's generic is later pulled from the market, it would be impossible to undo this harm. *See Henkel Corp. v. Coral, Inc.*, 754 F. Supp. 1280, 1322 (N.D. Ill. 1990) (damages cannot make patentee whole because lost "market share is so difficult to recover" and "never fully compensable in money" (citation omitted)), *aff'd,* 945 F.2d 416 (Fed. Cir. 1991).

DRL faces no comparable harm. DRL "knowingly invested 'at risk,'" and its projected "losses stem from a market it seeks to enter, not one that it is already in." *Indivior I*, 2018 WL 3496643, at *1, *13. Any harm to DRL is purely speculative; if DRL's product infringes either patent, it has no right to launch. Even if it is later determined that DRL's product does not infringe either patent, any losses DRL might suffer from delayed entry would be amply covered by the $72 million bond. *See* Appx48 at D.I. 149; Appx62, ¶3. With that bond in place, the balance of equities decisively favors maintaining the status quo. *See Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed. Cir. 2006) (affirming preliminary injunction where accused infringer's "harms were 'almost entirely preventable'" and "the result of its own calculated risk to launch its product pre-judgment").

The public interest also favors a stay. "Although [S]uboxone [F]ilm is an efficacious means of administering buprenorphine, it is not the only means." *Indivior I*, 2018 WL 3496643, at *1. Other treatments for opioid dependency are available on the market. *Id.* at *1-2, *14. As a result, a stay would protect Plaintiffs' patent

rights from irreparable harm without "deny[ing] [the public] access to the active ingredient [in Suboxone], which may be administered" in other forms. *Id.* at *14.

II. THE COURT SHOULD STAY ISSUANCE OF THE MANDATE PENDING PLAINTIFFS-APPELLEES' *CERTIORARI* PETITION

Rule 41(d) authorizes circuit courts "to stay [a] mandate pending the filing of a petition for a writ of certiorari" when the "petition would present a substantial question" and "there is good cause for a stay." Those conditions are met when a petition has a "reasonable probability of succeeding on the merits" and "the applicant will suffer irreparable injury" absent a stay. *Books v. City of Elkhart*, 239 F.3d 826, 827 (7th Cir. 2001) (Ripple, J., in chambers). Courts also may consider the balance of equities and the public interest. *Rostker v. Goldberg*, 448 U.S. 1306, 1308 (1980) (Brennan, J., in chambers). "The relative weight of these factors . . . var[ies] according to the facts and circumstances of each case." *CFTC v. British Am. Commodity Options Corp.*, 434 U.S. 1316, 1320 (1977) (Marshall, J., in chambers).

A. The Irreparable Harm, Equity, and Public Interest Factors Strongly Favor a Stay.

A stay is warranted where, as here, the equitable factors clearly favor the movant, even if the court believes the case for *certiorari* is not particularly strong. *See Books*, 239 F.3d at 829 (granting stay despite weak case for *certiorari* because equities favored a stay); *CFTC*, 434 U.S. at 1321 (maintaining stay after finding that

"it is not entirely inconceivable [] that four Justices of this Court will deem [the issue] worthy of review" and "the balance of equities clearly favors respondents").

As the district court's undisturbed findings show, Indivior and Aquestive would be irreparably harmed if DRL launches before the *certiorari* petition is resolved. In contrast, even if DRL prevails, any harm to it would be comparably small, readily determined, and covered by the $72 million bond. *See* pp.10-12, *supra*.

B. There Is a Reasonable Probability that Plaintiffs Will Succeed on the Merits of Their *Certiorari* Petition.

There is a reasonable probability that "at least four Justices will vote to grant certiorari *and* a reasonable *possibility* that at least five Justices will vote to reverse the judgment of this court." *Nanda v. Bd. of Trustees of Univ. of Ill.*, 312 F.3d 852, 853-54 (7th Cir. 2002) (Ripple, J., in chambers). The "reasonable probability" standard does not require proof the Supreme Court is "more likely than not" to grant review; a lesser showing will suffice. *Doe v. Miller*, 418 F.3d 950, 952 (8th Cir. 2005). In assessing whether there is a "reasonable possibility" of reversal, this Court must "dispassionately assess the merits of the case . . . and determine, as best [it] can, how the Justices will assess the judgment that [it] has rendered." *Williams v. Chrans*, 50 F.3d 1358, 1360 (7th Cir. 1995) (per curiam).

At least two issues are reasonably probable to win review and reversal: this Court's ruling on the preliminary-injunction standard and its ruling that the '305 patent disclaims certain drying processes.

1. There is a Reasonable Probability of Supreme Court Review on the Preliminary-Injunction Standard Ruling Because This Court's Ruling Widens an Important Circuit Split.

The panel majority's opinion conflicts with precedent of several circuits holding that a sliding-scale standard governs whether to grant equitable relief. That conflict presents an important issue that merits Supreme Court resolution. *See* Sup. Ct. R. 10(a). Because this case also presents a good vehicle for the Court to resolve this split, there is a reasonable probability the Court will grant *certiorari*.

The Supreme 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. *Winter* did not clarify 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.

The panel majority's decision takes a clear stand against the sliding-scale approach: "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." *Indivior II*, 2018 WL 6069706, at *10. This decision is the most recent in a line of Federal Circuit cases that treat "likelihood of success" as a threshold requirement,

rather than as one factor among four that must be balanced. Under these cases, a movant must establish a likelihood of success first, without regard for the other factors; as a result, a stronger 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. 2004) ("[A] movant is not entitled to a preliminary injunction if he fails to demonstrate a likelihood of success on the merits.").

The panel majority's standard conflicts with decisions from at least three Circuits. In *Reilly v. City of Harrisburg*, 858 F.3d 173 (3d Cir. 2017), the Third Circuit decided whether *Winter* overruled the traditional balancing-of-the-factors preliminary-injunction standard. The Third Circuit reaffirmed its sliding-scale approach: 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 Citigroup Glob. Markets, 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).

The panel majority's standard also deepens an intra-circuit split. Another line of Federal Circuit cases holds that "[a] request for a preliminary injunction is evaluated in accordance with a 'sliding scale' approach: the more the balance of irreparable harm inclines in the plaintiff's favor, the smaller the likelihood of prevailing on the merits he need show." *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).

Meanwhile, other Circuits, including the Fourth and Fifth, employ a third approach. These circuits hold that *each* factor is independent, and "satisfying one requirement 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).

The confusion surrounding the preliminary-injunction standard post-*Winter* is as important as it is pervasive. Whether that standard involves a threshold, a balancing test, or a checklist can determine whether a litigant facing irreparable harm obtains equitable relief. The outcome of such an important decision should not turn on geography. This case presents an ideal vehicle to adopt a uniform standard.

2. There is a Reasonable Possibility of Reversal of the Panel's Preliminary-Injunction Ruling.

The panel majority's ruling substitutes a rigid threshold requirement for the flexible standard traditionally applied to preliminary-injunction determinations. That ruling contravenes longstanding Supreme Court precedent recognizing the equitable nature of injunctive relief, particularly at a preliminary stage.

Long ago, the Supreme Court observed that "[f]lexibility rather than rigidity has distinguished" equitable authority. *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944). And, very recently, 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). "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*.

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 omitted) (emphasis added). As Justice Ginsburg noted, the Court "has never rejected [the balancing] formulation." *Id*. at 51 (Ginsburg, J., dissenting).

The Supreme Court's decision in *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388 (2006), provides an additional reason to believe the Court will reverse here.

The Court in *eBay* held that it was error to shortcut review of permanent injunctions in patent cases; the full four-factor test must be applied. *Id*. at 391-94. Because "[t]he standard for a preliminary injunction is essentially the same as [the standard] 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)), it is reasonably possible the Court also will hold that courts must consider and balance all four factors when reviewing a motion for a preliminary injunction.

3. There is a Reasonable Probability of Supreme Court Review on the Disclaimer Ruling Because It Conflicts with Supreme Court Precedent.

The panel majority's decision conflicts with longstanding Supreme Court precedent governing disclaimers in patent specifications. Given the Federal Circuit's exclusive jurisdiction over patent appeals, this decision threatens to sow uncertainty in an important area of patent law absent Supreme Court guidance. This conflict thus presents an important issue that merits Supreme Court review. *See* Sup. Ct. R. 10(c). Because this case presents a good vehicle to resolve this question of specification disclaimer, there is a reasonable probability the Court will grant *certiorari*.

Few principles in patent law are more settled than that the claim language controls, and a limitation may not be added to a claim without a textual basis in the claim language. The Supreme Court held as early as 1895 that "we know of no principle of law 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 Val. 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. Wasbash Appliance Corp*., 304 U.S. 364, 374 (1938); *Great Atl. & Pac. Tea Co. v. Supermarket Equip. Corp*., 340 U.S. 147, 149 (1950).

This Court's decision directly conflicts with this precedent. The panel majority declared that "we do not read our precedent as requiring . . . a [textual] hook [in the claims] under the circumstances in this case," without identifying any "circumstances" that justified this exception to the normal rules of claim construction. *Indivior II*, 2018 WL 6069706, at *7.

This ruling carries great significance. 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 Liebel-Flarsheim Co. v. Medrad, Inc*., 358 F.3d 898, 904-05 (Fed. Cir. 2004). Only by requiring some textual hook in the claim language can litigants and district courts have any idea how to construe claims consistently.

4. There is a Reasonable Possibility of Reversal of the Panel's Disclaimer Ruling.

Because the inventors removed from the '305 patent the "dried" and "drying" terms to which the Delaware district court attached a limitation in the '514 patent, the Supreme Court will likely reverse the panel majority's disclaimer ruling. Those terms do not support reading such a limitation in the '514 patent, but without them, there is not even a textual basis to attempt to read a disclaimer into the '305 patent.

The panel majority suggested that "continuously cast film" might provide a textual basis for a disclaimer in the '305 patent. *See Indivior II*, 2018 WL 6069706, at *6-7. But DRL has admitted that there is "no material difference" between "continuously cast film" and the "cast film" limitation in the '514 patent, Appx5922-5923, and conceded that its ANDA Product meets the latter limitation, which it acknowledged does not require any particular drying method, Appx1322, ¶71.

Ultimately, the panel majority eschewed the need for any textual basis for a disclaimer. *Indivior II*, 2018 WL 6069706, at *7. In its place, the panel majority built its analysis on layers of additional errors: It imported a process limitation into a composition claim, and did so based on a feature of a preferred embodiment. *Id.* at *12 (Newman, J., dissenting). And it held that the specification disclaims certain drying methods, without the unequivocal disavowal precedent requires. *Id.* at *13.

The panel majority also disregarded the district court's factual findings that supported its view that there was no disclaimer. The district court 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 to create [a film having] the drug content uniformity in the Patent." *Indivior I*, 2018 WL 3496643, at *10 (quoting Appx10102-10103, ¶14). The court's "Essential Finding of Fact #4" is clear: "The '305 patent . . . states embodiments . . . without respect to drying methods used to manufacture it." *Id.* at *1. The panel majority violated the command of *Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015), by not showing any error in these factual findings, or addressing how it could have been clear error for the district court to credit the explanations of Plaintiffs' expert.

CONCLUSION

Indivior and Aquestive respectfully request that the Court stay the mandate pending resolution of the '514 appeals and Indivior and Aquestive's forthcoming *certiorari* petition. Indivior and Aquestive also request that the Court direct that any opposition to this motion be filed by February 8, 2019, with any reply due February 11, 2019. Should the Court deny this motion, Indivior and Aquestive request that the mandate issue no sooner than seven days after the order of denial, to permit time to seek a stay from the Supreme Court.

Dated: February 5, 2019

Respectfully submitted,

/s/ Jeffrey B. Elikan

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CERTIFICATE OF INTEREST FOR
PLAINTIFFS-APPELLEES
INDIVIOR INC. AND INDIVIOR UK LIMITED

Counsel for Plaintiffs-Appellees Indivior Inc. and Indivior UK Limited certify the following:

1. The full name of every party or amicus represented by me is:

Indivior Inc. and Indivior UK Limited.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) is a Delaware corporation that is a wholly owned subsidiary of Indivior Finance LLC. Indivior Finance LLC (formerly known as RBP Finance LLC) is a Limited Liability Corporation incorporated in Delaware and resident in the United Kingdom, and it is a wholly owned subsidiary of Indivior US Holdings Inc., a Delaware corporation that is a wholly owned subsidiary of RBP Global Holdings Limited., a private company limited by shares and registered in England and Wales. RBP Global Holdings Limited is a wholly owned subsidiary of Indivior Global Holdings Limited, a private company limited by shares and registered in England and Wales. Indivior Global Holdings Limited is a wholly owned subsidiary of Indivior PLC, a public company limited by shares, registered in England and Wales and listed on the London Stock Exchange. Schroders Capital Management is a publicly traded company and holds more than 10% of the issued share capital of Indivior PLC.

Indivior UK Limited (formerly known as RB Pharmaceuticals Limited) is a wholly owned subsidiary of RBP Global Holdings Limited., a private company limited by shares and registered in England and Wales. RBP Global Holdings Limited is a wholly owned subsidiary of Indivior Global Holdings Limited, private company limited by shares and registered in England and

Wales. Indivior Global Holdings Limited is a wholly owned subsidiary of Indivior PLC, a public company limited by shares, registered in England and Wales and listed on the London Stock Exchange. Schroders Capital Management is a publicly traded company and holds more than 10% of the issued share capital of Indivior PLC.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

David L. Moses of Saul Ewing Arnstein & Lehr LLP

Daniel Sharpe of Troutman Sanders LLP

5. The title and number of any case known to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b):

Appeal No. 17-2587 (Consolidated with 18-1010, 18-1058, 18-1062, 18-1114, 18-1115, 18-1176, 18-1177): *Indivior Inc. et al. v. Dr. Reddy's Laboratories S.A. et al.*; Appeal No. 18-1405 (Consolidated with 18-1468): *Indivior Inc. v. Actavis Laboratories UT, Inc.*; Appeal No. 18-1949 (Consolidated with 18-2045): *Indivior Inc. v. Alvogen Pine Brook Inc.*

Indivior Inc. v. Actavis Laboratories UT, Inc., No. 1:18-cv-00499-RGA (D. Del); *Indivior Inc. v. Alvogen Pine Brook Inc.*, No. 2:17-cv-07106-KM-CLW (D.N.J) (lead case); *Indivior Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:17-cv-07115-KM-CLW (D.N.J.) (lead case).

CERTIFICATE OF INTEREST FOR PLAINTIFF-APPELLEE AQUESTIVE THERAPEUTICS, INC.

Counsel for Plaintiff-Appellee Aquestive Therapeutics, Inc. certify the following:

1. The full name of every party or amicus represented by me is:

Aquestive Therapeutics, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

N/A

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

David L. Moses of Saul Ewing Arnstein & Lehr

Cassandra Adams of Steptoe & Johnson LLP

5. The title and number of any case known to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b):

Appeal No. 17-2587 (Consolidated with 18-1010, 18-1058, 18-1062, 18-1114, 18-1115, 18-1176, 18-1177): *Indivior Inc. et al. v. Dr. Reddy's Laboratories S.A. et al.*; Appeal No. 18-1405 (Consolidated with 18-1468): *Indivior Inc. v. Actavis Laboratories UT, Inc.*; Appeal No. 18-1949 (Consolidated with 18-2045): *Indivior Inc. v. Alvogen Pine Brook Inc.*

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CERTIFICATE OF COMPLIANCE

I certify that this submission complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A). This submission contains 5,188 words, excluding the portions exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 27(d).

I certify that this submission complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), because it has been composed in a proportionally spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font.

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CERTIFICATE OF SERVICE

I hereby certify that on February 5, 2019, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF, thereby serving it on all counsel of record via the CM/ECF system.

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NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

INDIVIOR INC., INDIVIOR UK LIMITED, AQUESTIVE THERAPEUTICS, INC.,
Plaintiffs-Appellees

v.

DR. REDDY'S LABORATORIES, S.A., DR. REDDY'S LABORATORIES, INC.,
Defendants-Appellants

2018-2167, 2018-2169

Appeals from the United States District Court for the District of New Jersey in Nos. 2:17-cv-07111-KM-CLW, 2:18-cv-01775-KM-CLW, 2:18-cv-05288-KM-CLW, Judge Kevin McNulty.

ON MOTION

Before NEWMAN, LOURIE, and STOLL, *Circuit Judges.*

PER CURIAM.

O R D E R

Appellees Indivior Inc., Indivior UK Limited and Aquestive Therapeutics, Inc. move to stay the issuance of

the mandate. Appellants Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc. oppose the motion.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is denied.[1]

FOR THE COURT

February 11, 2019
Date

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

[1] Circuit Judge Newman would grant the motion.

Nos. 2018-2167, 2018-2169

United States Court of Appeals for the Federal Circuit

INDIVIOR INC., INDIVIOR UK LIMITED,
AQUESTIVE THERAPEUTICS, INC.,

Plaintiffs-Appellees,

v.

DR. REDDY'S LABORATORIES S.A.,
DR. REDDY'S LABORATORIES, INC.,

Defendants-Appellants.

Appeal from the United States District Court for the District of New Jersey in Nos. 2:17-cv-07111-KM-CLW, 2:18-cv-01775-KM-CLW, 2:18-cv-5288-KM-CLW, Judge Kevin McNulty

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PLAINTIFFS-APPELLEES' EMERGENCY MOTION TO STAY THE MANDATE PENDING APPLICATION TO THE SUPREME COURT OF THE UNITED STATES

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TABLE OF ABBREVIATIONS

’305 Patent	U.S. Patent No. 9,931,305
’514 Patent	U.S. Patent No. 8,603,514
Aquestive	Plaintiff-Appellee Aquestive Therapeutics, Inc.
DRL	Defendants-Appellants Dr. Reddy’s Laboratories S.A. and Dr. Reddy’s Laboratories, Inc.
Indivior	Plaintiffs-Appellees Indivior Inc. and Indivior UK Limited

Plaintiffs-Appellees Indivior and Aquestive respectfully request that the Court issue an administrative stay of the mandate in this case pending the Supreme Court's resolution of an emergency application for an administrative stay, which Indivior and Aquestive will file no later than this Friday, February 15, 2019. That stay will permit the Supreme Court time to determine promptly whether to administratively stay this Court's mandate while it considers Indivior and Aquestive's application to stay the mandate pending disposition of a petition for a writ of certiorari in this case.

Due to the emergency nature of this motion, Indivior and Aquestive ask that the Court order that any response to the motion be filed today. *See* Fed. Cir. R. 27, Practice Note Concerning Motion to Expedite Proceedings (Dec. 1, 2018).

GROUNDS FOR RELIEF AND ARGUMENT IN SUPPORT

This Court issued an opinion on November 20, 2018, vacating the district court's grant of a preliminary injunction, D.I. 96, and denied Indivior and Aquestive's petition for rehearing on February 4, 2019, D.I. 122. The Court's order denying rehearing noted that the mandate would issue February 11, 2019. *Id.* On February 5, 2019, Indivior and Aquestive filed an emergency motion to stay the mandate pending resolution of the related '514 Patent appeals pending in this Court and disposition of a petition for a writ certiorari in this case.[1] D.I. 123. Pursuant to

[1] These appeals are captioned *Indivior Inc. v. Dr. Reddy's Laboratories*, No. 17-2587, and *Indivior Inc. v. Alvogen Pine Brook, LLC*, No. 18-1949.

Federal Rule of Appellate Procedure 41(b), Indivior and Aquestive asked that the Court, should it deny the motion, set the mandate to issue no sooner than seven days after entry of the Court's order, to permit time to seek a stay from the Supreme Court. D.I. 123 at 21; D.I. 126 at 7-8. Today, the Court denied the motion to stay over Judge Newman's dissent, but did not specify when the mandate would issue. D.I. 127.

Indivior and Aquestive will file no later than this Friday, February 15, 2019, an emergency application to the Supreme Court for an administrative stay pending the Supreme Court's resolution of an application for a stay pending disposition of Indivior and Aquestive's petition for a writ of certiorari in this case.

As the Court has not indicated when the mandate will issue, Indivior and Aquestive respectfully request an administrative stay pending the Supreme Court's resolution of Indivior and Aquestive's emergency application for an administrative stay. This administrative stay from this Court will preserve the Supreme Court's ability to determine whether to maintain the status quo while it considers Indivior and Aquestive's application for a stay pending disposition of the certiorari petition. DRL has indicated that it opposes this motion.

Indivior and Aquestive will suffer severe and irreparable harm if this administrative stay is denied and the mandate issues before the Supreme Court has time to consider granting an administrative stay of its own. The district court's findings are clear:

- "Indivior will likely suffer irreparable harm" absent a preliminary injunction due to a severe loss of market share and irrevocable loss of formulary status, Appx20025;

- The loss in research and development funding, combined with the severe and irrevocable loss of market share "further support[ed] a finding of irreparable harm," Appx20025;

- Any loss to DRL if the preliminary injunction were ultimately held to have been granted improperly would be "more easily calculated in damages,"Appx20026-20027;

- "The balance of harms and equities appear[ed] to favor" Indivior and Aquestive, especially in light of DRL's decision "to enter the market 'at risk,'" Appx20027; and

- The public interest would be served by granting the preliminary injunction, because the interest in promoting innovation through patent rights outweighed the public's interest in a generic version of Suboxone Film, particularly where the public had continuing access to other generic forms of the active ingredients in Suboxone Film, including generic buprenorphine-naloxone tablets, Appx20027-20028.

These findings remain undisturbed. *See* D.I. 96, Maj. Op. at 21; Dissenting Op. at 11–13. Indivior and Aquestive will suffer irreparable harm, absent an injunction pending trial, if their market share and Suboxone Film's formulary status are irretrievably altered by DRL's premature market entry. *See, e.g.*, *Henkel Corp. v. Coral, Inc.*, 754 F. Supp. 1280, 1322 (N.D. Ill. 1991) (damages cannot make patentee whole because lost "market share is so difficult to recover" and "never fully compensable in money" (citation omitted)), *aff'd,* 945 F.2d 416 (Fed. Cir. 1991).

In contrast, DRL is protected by a $72 million bond posted by Indivior. That bond would address any loss that DRL could suffer—such as a possible loss of time

on the market or "the ability to go on the market and begin earning profits earlier," *Glaxo Grp. Ltd. v. Apotex, Inc.*, 64 F. App'x 751, 756 (Fed. Cir. 2003)—for which DRL can readily be compensated. *See* Appx48 at D.I. 149; Appx62, ¶ 3.

CONCLUSION

In view of the severe and irreparable harm that Indivior and Aquestive will immediately suffer if DRL is permitted to launch its generic version of Suboxone Film at risk, the Court should preserve the status quo long enough to permit the Supreme Court to rule on Indivior and Aquestive's emergency application for an administrative stay, which will be filed no later than this Friday, February 15, 2019.

Respectfully submitted,

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INDIVIOR INC. AND INDIVIOR UK LIMITED

Counsel for Plaintiffs-Appellees Indivior Inc. and Indivior UK Limited certify the following:

1. The full name of every party or amicus represented by me is:

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N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

Indivior Inc. (formerly known as Reckitt Benckiser Pharmaceuticals Inc.) is a Delaware corporation that is a wholly owned subsidiary of Indivior Finance LLC. Indivior Finance LLC (formerly known as RBP Finance LLC) is a Limited Liability Corporation incorporated in Delaware and resident in the United Kingdom, and it is a wholly owned subsidiary of Indivior US Holdings Inc., a Delaware corporation that is a wholly owned subsidiary of RBP Global Holdings Limited., a private company limited by shares and registered in England and Wales. RBP Global Holdings Limited is a wholly owned subsidiary of Indivior Global Holdings Limited, a private company limited by shares and registered in England and Wales. Indivior Global Holdings Limited is a wholly owned subsidiary of Indivior PLC, a public company limited by shares, registered in England and Wales and listed on the London Stock Exchange. Schroders Capital Management is a publicly traded company and holds more than 10% of the issued share capital of Indivior PLC.

Indivior UK Limited (formerly known as RB Pharmaceuticals Limited) is a wholly owned subsidiary of RBP Global Holdings Limited., a private company limited by shares and registered in England and Wales. RBP Global Holdings Limited is a wholly owned subsidiary of Indivior Global Holdings

Limited, private company limited by shares and registered in England and Wales. Indivior Global Holdings Limited is a wholly owned subsidiary of Indivior PLC, a public company limited by shares, registered in England and Wales and listed on the London Stock Exchange. Schroders Capital Management is a publicly traded company and holds more than 10% of the issued share capital of Indivior PLC.

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

David L. Moses of Saul Ewing Arnstein & Lehr LLP

Daniel Sharpe of Troutman Sanders LLP

Philip S. May of Covington & Burling LLP

5. The title and number of any case known to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b):

Appeal No. 17-2587 (Consolidated with 18-1010, 18-1058, 18-1062, 18-1114, 18-1115, 18-1176, 18-1177): *Indivior Inc. v. Dr. Reddy's Laboratories S.A.*; Appeal No. 18-1405 (Consolidated with 18-1468): *Indivior Inc. v. Actavis Laboratories UT, Inc.*; Appeal No. 18-1949 (Consolidated with 18-2045): *Indivior Inc. v. Alvogen Pine Brook Inc.*

Indivior Inc. v. Actavis Laboratories UT, Inc., No. 1:18-cv-00497-RGA (D. Del) (lead case); *Indivior Inc. v. Alvogen Pine Brook Inc.*, No. 2:17-cv-07106-KM-CLW (D.N.J) (lead case); *Indivior Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:17-cv-07115-KM-CLW (D.N.J.) (lead case).

CERTIFICATE OF INTEREST FOR
PLAINTIFF-APPELLEE
AQUESTIVE THERAPEUTICS, INC.

Counsel for Plaintiff-Appellee Aquestive Therapeutics, Inc. certify the following:

1. The full name of every party or amicus represented by me is:

Aquestive Therapeutics, Inc.

2. The name of the real party in interest (if the party named in the caption is not the real party in interest) represented by me is:

N/A

3. All parent corporations and any publicly held companies that own 10 percent or more of the stock of the party or amicus curiae represented by me are:

N/A

4. The names of all law firms and the partners or associates that appeared for the party or amicus now represented by me in the trial court or agency or are expected to appear in this Court (and who have not or will not enter an appearance in this case) are:

David L. Moses of Saul Ewing Arnstein & Lehr

Cassandra Adams of Steptoe & Johnson LLP (no longer with firm)

5. The title and number of any case known to be pending in this or any other court or agency that will directly affect or be directly affected by this court's decision in the pending appeal. *See* Fed. Cir. R. 47.4(a)(5) and 47.5(b):

Appeal No. 17-2587 (Consolidated with 18-1010, 18-1058, 18-1062, 18-1114, 18-1115, 18-1176, 18-1177): *Indivior Inc. v. Dr. Reddy's Laboratories S.A.*; Appeal No. 18-1405 (Consolidated with 18-1468): *Indivior Inc. v. Actavis Laboratories UT, Inc.*; Appeal No. 18-1949 (Consolidated with 18-2045): *Indivior Inc. v. Alvogen Pine Brook Inc.*

Indivior Inc. v. Actavis Laboratories UT, Inc., No. 1:18-cv-00497-RGA (D. Del) (lead case); *Indivior Inc. v. Alvogen Pine Brook Inc.*, No. 2:17-cv-07106-KM-CLW (D.N.J) (lead case); *Indivior Inc. v. Teva Pharmaceuticals USA, Inc.*, No. 2:17-cv-07115-KM-CLW (D.N.J.) (lead case).

CERTIFICATE OF COMPLIANCE

I certify that this submission complies with the type-volume limitation of Fed. R. App. P. 27(d)(2)(A). This submission contains 878 words, excluding the portions exempted by Fed. R. App. P. 32(f) and Fed. Cir. R. 27(d).

I certify that this submission complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and the type style requirements of Fed. R. App. P. 32(a)(6), because it has been composed in a proportionally-spaced typeface using Microsoft Word 2016 in 14-point Times New Roman font.

/s/ Jeffrey B. Elikan

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Counsel for Indivior Inc. and Indivior UK Limited

CERTIFICATE OF SERVICE

I hereby certify that on February 11, 2019, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF, thereby serving it on all counsel of record via the CM/ECF system.

/s/ Jeffrey B. Elikan

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Telephone: (202) 662-5597

Counsel for Indivior Inc. and Indivior UK Limited

NOTE: This order is nonprecedential.

United States Court of Appeals for the Federal Circuit

INDIVIOR INC., INDIVIOR UK LIMITED, AQUESTIVE THERAPEUTICS, INC.,
Plaintiffs-Appellees

v.

DR. REDDY'S LABORATORIES, S.A., DR. REDDY'S LABORATORIES, INC.,
Defendants-Appellants

2018-2167, 2018-2169

Appeals from the United States District Court for the District of New Jersey in Nos. 2:17-cv-07111-KM-CLW, 2:18-cv-01775-KM-CLW, 2:18-cv-05288-KM-CLW, Judge Kevin McNulty.

ON MOTION

Before NEWMAN, LOURIE, and STOLL, *Circuit Judges.*

PER CURIAM.

O R D E R

Appellees Indivior Inc., Indivior UK Limited and Aquestive Therapeutics, Inc. move to stay the issuance of

the mandate. Appellants Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories, Inc. oppose the motion.

Upon consideration thereof,

IT IS ORDERED THAT:

The motion is denied. Pursuant to Fed. R. App. P. 41(b), the mandate will issue 7 days from the date of this order.

FOR THE COURT

February 11, 2019
Date

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

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 Appendix to 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 Appendix has been sent to the following counsel via e-mail:

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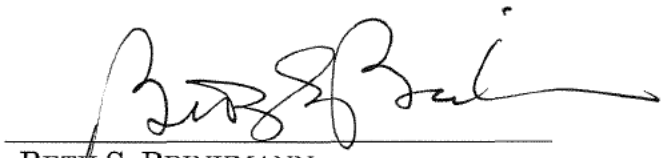

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