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.

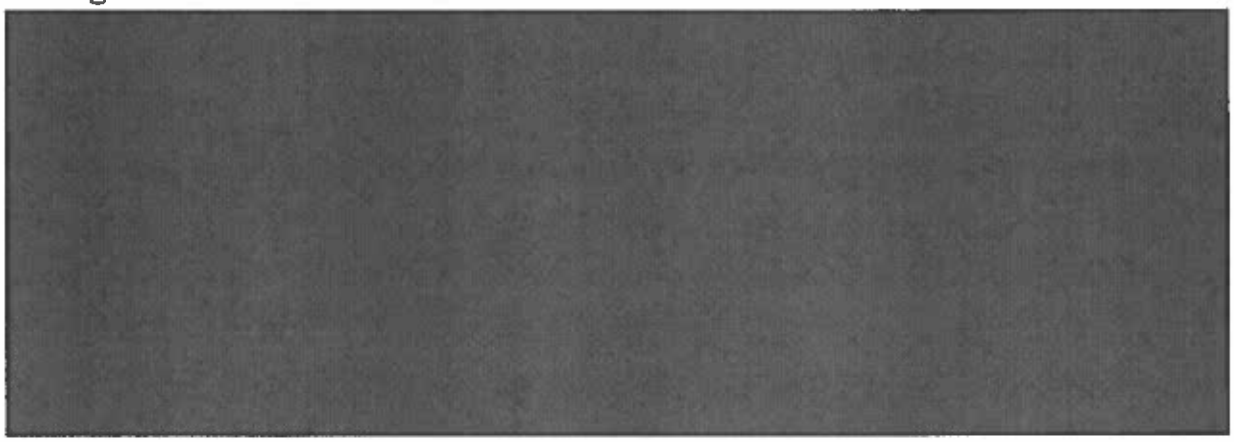
[redacted]

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.*)



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