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.,** **Defendants.**	Civ. No. 17-7111 (KM) (CLW) Civ. No. 18-1775 (KM) (CLW) Civ. No. 18-5288 (KM) (CLW)
INDIVIOR INC., INDIVIOR UK LIMITED, and AQUESTIVE THERAPEUTICS, INC., **Plaintiffs,** **v.** **ALVOGEN PINE BROOK, INC., AND ALVOGEN PINE BROOK LLC,** **Defendants.**	Civ. No. 17-7106 (KM) (CLW) Civ. No. 18-8285 (KM) (CLW) **OPINION**

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

This opinion contains the Court's construction of key patent terms following a *Markman* hearing. (Dkt. No. 7106 at DE 211; Dkt. No. 7111 at DE 290) The final section constitutes the Court's opinion on the motion by Alvogen Pine Brook, Inc. and Alvogen Pine Brook LLC (collectively, unless otherwise specified, "Alvogen") to recover on bonds posted in connection with my grant of a temporary restraining order in the 17-cv-7106 consolidated action. (*See* DE 148).

These consolidated patent infringement cases are brought by Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. (collectively, unless otherwise specified, "Indivior"), against Dr. Reddy's Laboratories S.A. and Dr. Reddy's Laboratories, Inc. (collectively, unless otherwise specified, "DRL") and Alvogen.

The patents-in-suit are Patent Nos. 9,931,305 ("the '305 Patent"), issued to Aquestive on April 3, 2018, and 9,687,454 ("the '454 Patent"), issued to Indivior on June 27, 2017. Indivior's Suboxone film is also covered by Patent No. 8,603,514 ("the '514 Patent"). The '514 Patent shares the same specification with the '305 Patent. As a result, the '305 Patent was filed with a terminal disclaimer to synchronize its expiration with that of the '514 Patent. This '514 Patent is not directly at issue here, but was at issue in a related litigation involving these same parties filed in the United States District Court for the District of Delaware ("the Delaware Litigation").

Collectively, these patents describe formulations of Suboxone film, a "rapidly dissolving film that adheres to the underside of a patient's tongue" or cheek. Indivior's Suboxone film is used to treat opioid dependency; it works to decrease a patient's need for opioids while also deterring abuse. Its two active ingredients are buprenorphine and naloxone. The films are created by 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 thin sheet that can be cut into individual dosages.

I. Procedural History[1]

I first briefly review the relevant opinions issued both in this action and in the related Delaware Litigation.

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[1] Citations to the record will be abbreviated as follows. Citations to page numbers refer to the page numbers assigned through the Electronic Court Filing system, unless otherwise indicated:

"**DE**" = Docket entry number in this case.

In broad strokes, Indivior previously moved in this action to enjoin DRL from bringing its generic Suboxone film to market. In a prior decision, I granted the motion. (Dkt. No. 7111 at DE 121). DRL subsequently appealed to the Federal Circuit, which reversed and remanded. *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 752 F. App'x 1024 (Fed. Cir. 2018) ("*Indivior I*"). The parties also appealed a number of decisions in the related Delaware Litigation. After the parties filed their *Markman* briefs here, the Federal Circuit issued its opinion concerning the Delaware Litigation appeal. *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 930 F.3d 1325, 1339 (Fed. Cir. 2019) ("*Indivior II*").

"**Dkt. No. 7106**" = Civil Action No. 2:17-cv-7106-KM-CLW.

"**Dkt. No. 7111**" = Civil Action No. 2:17-cv-7111-KM-CLW.

"**Dkt. No. 5285**" = Civil Action No. 2:18-cv-5285-KM-CLW.

"**Dkt. No. 5288**" = Civil Action No. 2:18-cv-5288-KM-CLW.

"**Pl. Opening**" = Plaintiff's Opening Markman Brief (Dkt. No. 7106 at DE 135; Dkt. No. 7111 at DE 250).

"**Pl. Ex.**" = Plaintiff's Exhibits (Dkt. No. 7106 at DE 135-1; Dkt. No. 7111 at DE 250-1), attached to the Declaration of Philip S. May (*Id.*).

"**Pl. Response**" = Plaintiff's Responsive Markman Brief (Dkt. No. 7106 at DE 146; Dkt. No. 7111 at DE 259).

"**Def. Opening**" = Defendants' Opening Markman Brief (Dkt. No. 7106 at DE 136; Dkt. No. 7111 at 249).

"**Def. Ex.**" = Defendants' Exhibits (Dkt. No. 7106 at DE 137 to 137-4; Dkt. No. 7111 at 249-1 to 249-5).

"**Def. Response**" = Defendants' Responsive Markman Brief (Dkt. No. 7106 at DE 144; Dkt. No. 7111 at 256).

"**Fassihi Declaration**" = Declaration of Reza Fassihi, Ph.D. (Dkt. No. 7106 at DE 136-1; Dkt. No. 7111 at 249-6).

"**Fuller Declaration**" = Declaration of Gerald G. Fuller, Ph.D. (Dkt. No. 7106 at DE 135-2; Dkt. No. 7111 at 250-2).

"**'305 Patent**" = United States Patent No. 9,931,305, Pl. Ex. A (Dkt. No. 7106 at DE 135-1; Dkt. No. 7111 at DE 250-1).

"**'454 Patent**" = United States Patent No. 9,687,454, Pl. Ex. B (Dkt. No. 7106 at DE 135-1; Dkt. No. 7111 at DE 250-1).

"**'514 Patent**" = United States Patent No. 8,603,514, Pl. Ex. C (Dkt. No. 7106 at DE 135-1; Dkt. No. 7111 at DE 250-1).

A. The '514 Patent

Indivior initially entered the Suboxone market by introducing a tablet in 2002. It then began developing a film version with Aquestive. The patent for that film, the '514 Patent, was issued on December 10, 2013.[2] ('514 Patent at [45], [54].).

DRL and others, including Alvogen, sought to enter the film market as generic competitors and filed ANDAs with the FDA for generic versions of the Suboxone film. Indivior responded by filing suit against a number of parties, including DRL and Alvogen, in the Delaware Litigation. Ultimately, the Delaware district court held that Indivior had failed to meet its burden of showing that DRL's and Alvogen's generic versions infringed the claims of the '514 Patent for Suboxone film. *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs. S.A.*, Nos. 14-1451, 14-1573, 14-1574, 2017 WL 3837312 (D. Del. Aug. 31, 2017); *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs. S.A.*, No. CV 14-1451-RGA, 2017 WL 3782782 (D. Del. Aug. 31, 2017); *Indivior Inc. v. Mylan Techs. Inc.*, 298 F. Supp. 3d 775 (D. Del. 2018).

With respect to DRL, District Judge Andrews had earlier construed 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 Reckitt Benckiser Pharm. Inc. v. Teva Pharm. USA Inc.*, Nos. 14-1451, 14-1573, 14-1574, 2016 WL 3621632, at *10–*11 (D. Del. June 29, 2016). He found that Indivior had disclaimed "conventional convection air drying from the top," both through express statements and repeated disavowal in the '514 Patent specification. *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

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[2] At the time, Aquestive was known as MonoSol Rx, LLC. (*See, e.g.*, Dkt. No. 5285 at DE 1).

presented at trial, Judge Andrews concluded that Indivior did not prove that DRL's process of drying was unconventional, and hence infringing. Judge Andrews later made similar findings with respect to Alvogen. *See Mylan Techs. Inc.*, 298 F. Supp. 3d at 785. ("Plaintiffs' comparison between Alvogen's exhibit batch and commercial processes fails to demonstrate that Alvogen's commercial process does not 'solely' employ drying from the top. It does not change my conclusion that Plaintiffs have not demonstrated 'substantial' bottom drying.").

Indivior then appealed to the Federal Circuit. *See* Section I.E, *infra*, discussing *Indivior II*.

B. The '305 Patent

Aquestive responded to the Delaware ruling by applying for the '305 Patent, which was issued on April 3, 2018. The '514 Patent and the '305 Patent largely overlap, except as to the language of one claim—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." The '305 Patent, however, claims "(i) a continuously cast film produced on a manufacturing line."

Second, the '514 Patent 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 similar language, except that the italicized "drying" language was dropped and references to "continuous casting" are substituted. Thus '305's Claim 26 now reads:

> 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.

(Pl. Ex. A at 85; *italicized* emphasis added).

Indivior then brought these actions against DRL and Alvogen here in the District of New Jersey, now claiming infringement of the new '305 Patent. (*See* Dkt. No. 5288 at DE 1; Dkt. No. 5285 at DE 1). 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. (Dkt. No. 7111 at DE 70). I granted a temporary restraining order enjoining DRL from launching in order to preserve the status quo during the resolution of the motions. (*Id.* at DE 78). After a hearing, on July 13, 2018, I granted Indivior's motion for a preliminary injunction. (*Id.* at DE 121). In essence, I concluded that Indivior, in the '305 Patent, had succeeded in "claiming around" the problem with the '514 Patent that was identified in the Delaware decision.

DRL then appealed that decision to the Federal Circuit, which disagreed.

C. *Indivior I*

On November 20, 2018, a divided Federal Circuit vacated the preliminary injunction issued in this action and remanded. *See Indivior I*, 752 F. App'x 1024.

The Federal Circuit first examined the '305 Patent's specification. The court particularly noted the specification's focus on drying processes:

> 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 . . .
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> 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.*

Id. at 1026.

In light of that discussion, the Federal Circuit considered whether Indivior was likely to succeed on the merits of its infringement claims, ultimately answering that question in the negative. In the '305 specification, the court found, Indivior expressly disclaimed "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." *Id.* at 1029. The Federal Circuit relied heavily on *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343–44 (Fed. Cir. 2001) and *Openwave Sys., Inc. v. Apple Inc.*, 808 F.3d 509, 513 (Fed. Cir. 2015), which instruct that disavowal of a feature in the specification results in the exclusion of that feature from the claim scope:

> "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.* at (quoting *Chicago Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1372 (Fed. Cir. 2012)).
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> 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.
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> *SciMed*, 242 F.3d at 1341. There, we determined that the patent claims covered balloon dilation catheters with coaxial 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 *1030 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.*
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> 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.

Indivior I, 752 F. App'x at 1029–30.

Thus, based on *SciMed* and *Openwave*, the Federal Circuit found a textual basis for continuing to impute a drying limitation to the '305 Patent's claims: "[T]he '305 patent is 'rife with remarks that disparage, and therefore, disclaim' solely using conventional top air drying to form films. The specification instructs that using such methods produces films without content uniformity—a claim limitation and a key feature of the invention." *Id.* at 1030. The Court was persuaded that "continuously cast film" has an inherent drying

limitation because the film, which starts as a liquid, has to be dried to ultimately become a solid film. *Id.* at 1031–32. Moreover, "[t]he specification makes clear that a film produced using only conventional top air drying cannot satisfy the claim limitations . . . 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." *Id.* at 1032.

In sum, the Federal Circuit found that Indivior was unlikely to succeed on the merits of infringement because the disavowals in the specification placed DRL's conventional, top air drying films outside the scope of the '305 Patent. *Id.* at 1031–34.

The Federal Circuit also examined the cases litigated between Indivior's predecessor (Reckitt Benckiser) and DRL in the Delaware Litigation. There, "The Delaware Court determined that the patentee disavowed solely using conventional air drying from the top to produce the claimed films" in the '514 Patent. *Id.* at 1027. In reviewing the '305 Patent and the '514 Patent, the Federal Circuit found that the only difference between the two patents was that the "'305 claims contain the term 'continuously cast' in place of 'dried' and 'drying.' There is no dispute that there are no other material differences between the claims . . . While the language of the claim terms changed, the scope of the claims did not materially change." *Id.* at 1034–35 (citations omitted). Thus, the Federal Circuit also held that claim preclusion likely barred Indivior's suit as the '305 Patent was patentably indistinct from the '514 Patent. *Id.* at 1035.

Judge Newman issued a dissenting opinion in which she first criticized the majority for failing to credit the district court's "equitable discretion, and instead mak[ing] appellate findings of the merits of infringement, although there has been no trial of infringement." *Id.* at 1036–37 (Newman, J., dissenting). Judge Newman also disagreed with the majority's efforts to read a drying limitation into the '305 Patent claims when that process limitation,

present in the '514 Patent, had been dropped for purposes of the '305 Patent. *Id.* at 1037–38. Thus, in her view, it was improper for the majority "to rewrite a product claim to contain a process limitation from the specification — here contained in a preferred but not sole embodiment— for it confounds the roles of the specification and the claims." *Id.* at 1037. The majority committed further error, wrote Judge Newman, because it treated the Delaware court's decisions on a different patent, the '514 Patent, as barring suit in this action on the '305 Patent. *Id.* at 1040.

Indivior then filed a petition for en banc rehearing, essentially espousing the position of the dissent.

D. Alvogen

Meanwhile, on January 22, 2019, Indivior moved in this Court for temporary restraints and a preliminary injunction to prevent Alvogen from launching its generic product prior to the Federal Circuit's issuance of its mandate in *Indivior I.* (Dkt. No. 7106 at DE 83). I granted a temporary restraining order ("TRO") enjoining Alvogen from launching in order to preserve the status quo pending the issuance of the mandate. (*Id.* at DE 88). I also granted Alvogen the opportunity to apply by telephone for the posting of a reasonable bond should it receive FDA approval for its Suboxone film. (*Id.*). After a hearing on the preliminary injunction application, on January 24, 2019, I entered an amended order to show cause that temporarily restrained and enjoined Alvogen and ordered Indivior to post a bond or other security in the amount of $18 million. (*Id.* at DE 102). On February 1, 2019, the parties agreed and stipulated, and I so ordered, that Alvogen would be enjoined from "engaging in the use, offer to sell, or sale within the United States, or importing into the United States its generic buprenorphine-and naloxone-containing transmucosal film products." (*Id.* at DE 105). The temporary restraints were dependent on the final outcome of the *Indivior I* appeal. (*Id.*). Indivior later agreed to post a second bond that increased the total value of the bonds posted to $36 million. (*Id.*).

On February 4, 2019, the Federal Circuit denied rehearing. On February 19, 2019, the Federal Circuit issued its mandate vacating the DRL preliminary injunction. The same day, I vacated the injunctive restraints. (*Id.* at DE 119). Alvogen then proceeded to bring to market its Suboxone film.

Alvogen now moves for an order granting it an immediate recovery on the bonds. (Dkt. No. 7106 at DE 148, 149, 171). Indivior opposes that motion. (*Id.* at DE 156).

E. *Indivior II*

Following the *Indivior I* decision, and after the parties submitted their *Markman* briefing here, on July 12, 2019, the Federal Circuit, this time with Judge Newman in the majority, issued its opinion on the appeals taken in the Delaware Litigation. In this opinion, here deemed *Indivior II*, the Federal Circuit largely upheld the Delaware district court's findings. 930 F.3d 1325. My *Markman* findings here are guided, if not strictly compelled in every particular, by the Federal Circuit's decision in *Indivior II*.

As in its prior *Indivior I* decision, the Federal Circuit here looked to the manufacturing process and the role of drying: "As described in the specification, drug content uniformity is required by regulatory authorities yet difficult to achieve in practice because of problems in manufacturing the films." *Indivior II*, 930 F.3d at 1331. One way the specification achieves uniformity, the court observed, is "by drying the film in a rapid manner from the bottom up." *Id.* The court went on to discuss the drying limitations in the specification, which, it found, disclaimed conventional drying methods. *See id.* at 1332.

On this appeal, Indivior challenged the Delaware district court's findings that DRL and Alvogen had not infringed the '514 Patent. In response, both DRL and Alvogen argued that they employ (so-called "conventional") drying processes that use "dryers where the sole source of heat comes from the top and thus does not infringe the asserted claims of the '514 Patent." *Id.* at 1334–35; *see also id.* at 1335 ("And as in the DRL case, the court found that Alvogen's film manufacturing process dries the films primarily from the top and

thus does not meet the drying limitation and does not infringe the asserted claims.").

Mirroring the reasoning of *Indivior I*, the Federal Circuit in *Indivior II* held "that the [Delaware] district court correctly construed the drying limitation and that the '514 Patent specification disclaims conventional top air drying." *Id.* at 1336. The Court incorporated the reasoning of *Indivior I* to conclude that the change of language as between the claims of the '514 and '305 patents was not sufficient to change the result. Both patents, the Court found, excluded conventional top air drying methods:

> In addressing whether Indivior's assertion of the '305 patent raised the same cause of action as the '514 patent, we concluded:
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> > [T]he 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.*
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> [*Indivior I*] at 1034–35 (emphasis added). We explained that "[w]hile the language of the claim terms changed, the scope of the claims did not materially change." *Id.* at 1035 (emphasis added). Even where different patents are asserted between two suits, claim preclusion bars a patentee from bringing successive suits accusing the defendant's same product of infringing essentially the same patent claims. *SimpleAir, Inc. v. Google LLC*, 884 F.3d 1160, 1167 (Fed. Cir. 2018); *see Acumed LLC v. Stryker Corp.*, 525 F.3d 1319, 1324 (Fed. Cir. 2008). Because—and only because—the asserted claims of the '305 Patent were materially the same as those that were or could have been asserted in the '514 Patent, we held that Indivior's action on the '305 Patent was likely claim precluded and that the district court abused its discretion in entering a preliminary injunction. Indivior, 752 F. App'x at 1035.
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> . . .
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> We agree with DRL and Alvogen that the [Delaware] district court correctly construed the drying limitation and that the '514 patent specification disclaims conventional top air drying . . . The asserted claims recite a film that is "capable of being dried without loss of substantial uniformity," but, as we already concluded in Indivior, and as we again explain below, the specification repeatedly makes

> clear that conventional top air drying does not yield uniform films. '514 Patent col. 74 ll. 3–5. Such drying is thus outside the reach of the claims.
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> A specification may disclaim an embodiment by repeatedly disparaging it. *See Openwave Sys., Inc. v. Apple Inc.*, 808 F.3d 509, 513–14 (Fed. Cir. 2015); *Chi. Bd.*, 677 F.3d at 1372. Here, the specification repeatedly disparages conventional top air drying because such drying does not produce uniform films, the central object of the claimed invention

Id. at 1336–37; *see also Id.* at 1340. Thus, in analyzing the '514 Patent in *Indivior II,* the Federal Circuit drew on its reasoning in *Indivior I,* making it clear that for these purposes, the claims of the '305 Patent are indistinct, or at least not meaningfully distinct, from those of the '514 Patent.

II. CLAIM CONSTRUCTION

A. Standards

"The purpose of claim construction is to 'determin[e] the meaning and scope of the patent claims asserted to be infringed.'" *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008) (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir.1995) (en banc), *aff'd,* 517 U.S. 370, 116 S. Ct. 1384 (1996)). "[T]he words of a claim are generally given their ordinary and customary meaning." *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (internal quotation marks and citations omitted). Courts interpret claim terms according to an objective standard: "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. To make this determination, courts may consider evidence intrinsic to the patent, *i.e.*, "the words of the claims themselves, the remainder of the specification, [and] the prosecution history," as well as "extrinsic evidence, which consists of all evidence external to the patent and prosecution history, including expert and inventor testimony,

dictionaries, and learned treatises." *Id.* at 1314, 1317 (internal quotation marks and citations omitted).

In *Phillips*, the United States Court of Appeals for the Federal Circuit, sitting en banc, explained that its prior case law had "attempted to explain why, in general, certain types of evidence are more valuable than others." *Id.* at 1324 (citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed.Cir.1996)). *Phillips* assigned significant value to intrinsic evidence and less weight to extrinsic evidence, holding extrinsic evidence useful only to the extent that "those sources are not used to contradict claim meaning that is unambiguous in light of the intrinsic evidence." *Id. at*

Thus, a court "first look[s] to the actual words of the claims and then read[s] them in view of the specification." *Profectus Tech. LLC v. Huawei Techs. Co.*, 823 F.3d 1375, 1380 (Fed. Cir. 2016). "[C]laims must be read in view of the specification, of which they are a part" because the specification "is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315. "[I]f the specification reveals a special definition given to a claim term by the inventor, then the inventor's lexicography governs, even if it differs from the term's ordinary meaning." *David Netzer Consulting Eng'r LLC v. Shell Oil Co.*, 824 F.3d 989, 994 (Fed. Cir. 2016) (citing *Phillips*, 415 F.3d at 1316). The court may also consider, where relevant, the patent's prosecution history, "which consists of the complete record of the proceedings before the PTO and [] the prior art cited during the examination of the patent." *Phillips*, 415 F.3d at 1317. Extrinsic evidence, considered in the context of the intrinsic evidence, may "help educate the court regarding the field of the invention and [] help the court determine what a person of ordinary skill in the art would understand claim terms to mean." *Phillips*, 415 F.3d at 1319.

B. Disputed Claims

1. "Continuously Cast Film" and "Continuously Cast Film Produced on a Manufacturing Line"

Term	Plaintiff	Defendant
"continuously cast film" ('305 Patent: 1)	plain and ordinary meaning, but if construction is necessary, "continuous sheet of cast film"	"a film formed by combining components to form a wet matrix, depositing the wet matrix onto a substrate, and drying the matrix without solely employing conventional convection air drying from the top"
"continuously cast film produced on a manufacturing line" ('305 Patent: 26)	plain and ordinary meaning, but if construction is necessary, "continuous sheet of cast film produced on a manufacturing line"	"a film formed by combining components to form a wet matrix, depositing the wet matrix onto a substrate, and drying the matrix without solely employing conventional convection air drying from the top"

(Pl. Opening at 11; Def. Opening at 10).[3]

The parties' primary dispute is whether, with respect to the '305 Patent, the claim "continuously cast film" has a drying limitation. No, says Indivior, for several reasons. (Pl. Opening at 11).

First, according to Indivior, "cast film" has a plain meaning — individual doses are cast in one sheet. The word "continuous" does not alter this meaning; it just refers to the fact that a sheet has not yet been cut into dosage-sized pieces. (*Id.* at 12–13). Therefore, "continuously cast film" should be given the same plain meaning that "cast film" was given in the related '514 Patent. (*Id.*).

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[3] These jointly submitted charts, summarizing the parties' positions as to the four disputed claims, are reproduced as relevant in connection with the discussion of each claim.

Second, Indivior contends that during the patent prosecution, it specifically amended the claim to remove drying limitations. Any construction of the claim, it says, must account for this history. (*Id.* at 14–15).

Third, the patent specification does not disclaim "conventional convection air drying from the top." This is demonstrated by the specification's inclusion of examples illustrating that conventional drying ovens can be used to make uniform films. (*Id.* at 15–20). Indivior points to the Fuller Declaration, which highlights that "[t]he '305 Patent guides the practitioner in the selection of the optimal choice of polymer and the use of viscosity to create uniform films when conventional drying operations are used" and notes that polymer selection, rather than the technique of drying, is the major determinant in the viscosity of the solution. (Fuller Declaration ¶¶ 62–63; *see also* Pl. Response at 13–19).

Fourth, Indivior alleges that defendants' proposed construction is improper because it imposes a process limitation onto a composition claim. (Pl. Opening at 21–22).

Fifth, Indivior contends that *Indivior I,* reversing the preliminary injunction, is not binding on this court. (*Id.* at 23–29). Indivior claims that the *Indivior I* opinion was based on a "cold record" and did not have the benefit of, *e.g.,* the Fuller Declaration. (*Id.* at 24–25; *see also* Pl. Response at 10–11).

Finally, Indivior contends that the '514 Patent is a different patent with a different prosecution history and different claims, so that the findings from the Delaware Litigation are not binding here. (Pl. Response at 11–12).

DRL and Alvogen counter that claim construction in this case must account for the findings in the Delaware Litigation and the Federal Circuit's opinions in *Indivior I* (and, now, *Indivior II*). (Def. Opening at 10).[4] Defendants

[4] As noted above, the Federal Circuit's opinion in *Indivior II* was decided after the parties submitted their *Markman* briefing. Nevertheless, DRL and Alvogen likewise argued at the *Markman* hearing that *Indivior II* also bears on these issues and requires a finding in its favor. (*Markman* Hearing Transcript (Dkt. No. 7106 at DE 213, pp. 60–61; Dkt. No. 7111 at DE 292, pp. 60–61)).

contend that these opinions already and unequivocally establish that "continuously cast film" has a drying limitation because the specification disclaimed films made using conventional, top air drying. Thus, regardless of Indivior deleting the word "dried" during the patent prosecution of the '305 Patent, Indivior is precluded by the doctrine of issue preclusion from arguing otherwise here. (*Id.* at 13–15; Def. Response at 19–20). Defendants also point to numerous examples in the specification that disparage conventional, top air drying. (Pl. Opening. 15–18). Finally, defendants contend that the *Indivior I* decision was not based on a "cold record"; the Federal Circuit had the benefit of the Delaware Litigation over the '514 Patent, briefing containing all of Indivior's arguments here, expert declarations addressing the merits of the current claims, the preliminary injunction hearing transcript, and oral argument. (Def. Response at 13–14). In any event, say the defendants, Indivior has failed to supply any new evidence here, not available before, that would change the result. (*Id.* at 16–17). As noted above, I held a *Markman* hearing in which both sides were permitted to proffer whatever evidence they deemed appropriate.

To construe the claim here I must endeavor to give the claim terms their "ordinary and customary meaning" in light of the words chosen, primarily based on the specification, which "is the single best guide to the meaning of a disputed term." *Phillips*, 415 F.3d at 1315. I also am guided by both Federal Circuit opinions in *Indivior I* and *Indivior II*, which together suggest that the '305 Patent must be construed consistent with the '514 Patent.

Turning to the '305 Patent's specification, I am constrained to find, as did the Federal Circuit, that the specification discloses creation of uniform films *via* certain controlled drying processes that differ from conventional top-down techniques:

> The specification teaches that using conventional drying methods, which apply hot air to the top of the film, produces nonuniform films. *E.g.*, *id.* col. 8 ll. 56–64, col. 22 ll. 41–60. As hot air strikes the surface of the film, water at the surface evaporates, forming a polymer skin that seals the aqueous composition below. *Id.* col. 3 ll. 37–42. But as heating continues, the vapor pressure of the

> underlying aqueous composition builds, causing the film surface to stretch and ultimately break to allow the vapor to escape. *Id.* col. 3 ll. 45–49. The polymer skin then reforms, and the cycle of surface destruction and reformation continues until drying is complete. *Id.* col. 3 ll. 49–52. Undesirably, this cycle produces a dried film that is uneven and nonuniform, which the patent refers to as the "ripple effect." *Id.* col. 3 ll. 51–54.
>
> . . .
>
> In a section titled "Drying Wet Cast Films," *Id.* col. 28 l. 51, the specification states that "[t]he wet film may be dried using controlled bottom drying or controlled microwave drying, desirably in the absence of external air currents or heat on the top (exposed) surface of the film," *Id.* col. 28 ll. 52–55 (emphasis added). Such methods allow for vapor release without the disadvantages described above. *Id.* col. 28 ll. 55–57. In contrast, "[c]onventional convection air drying from the top is not employed" because it produces the ripple effect. *Id.* col. 28 ll. 57–64 (emphasis added). If some top air is used, "it is balanced with the bottom air drying to avoid non-uniformity." *Id.* col. 29 ll. 1–3.
>
> In addition to controlling the location of the source of air, the specification teaches a "zone drying procedure" in which the film is dried along a belt with different drying zones that may vary in temperature, humidity, or other atmospheric conditions. *Id.* col. 32 ll. 38–67. The specification does not specify whether the air comes from the top or bottom during zone drying but does indicate that zone drying "dries the film without surface skinning." *Id.* col. 32 ll. 49–50. Zone drying may be supplemented with additional processes such as lamination "so long as controlled drying is maintained in accordance with the invention." *Id.* col. 33 ll. 1–4.

Indivior II, 930 F.3d at 1332. In light of the patent's specification, and giving due regard to the reasoning of the Federal Circuit, I must reject Indivior's proposed claim construction. Rather, defendants' proposed construction, which construes "continuously cast film" to include "drying the matrix without solely employing conventional convection air drying from the top" is consistent with the claim language and the overall specification. I therefore find that "continuously cast film" means a continuous sheet of cast film that has been dried without solely employing conventional convection air drying from the top.

2. "Particle Size of 200 Microns or Less" and "Particle Size of 100 Microns or Less"[5]

Term	Plaintiff	Defendant
"particle size of 200 microns or less" ('305 Patent: 1, 26)	No construction necessary (i.e., particle size of 200 microns or less)	Indefinite
"particle size of 200 microns or less" ('305 Patent: 27)	No construction necessary (i.e., particle size of 100 microns or less)	Indefinite

(Pl. Opening at 29; Def. Opening at 22).

Here, Alvogen challenges the term "particle size," stating that it is indefinite because there are many ways to measure it. (Def. Opening at 22). According to Alvogen, "particle size" is "highly dependent upon the particular method used to make the measurement." The patent, it says, is indefinite because it does not specify what method should be used. (*Id.* at 23). In support, Alvogen proffers the report of its expert, Dr. Reza Fassihi, who notes that there are numerous methods for measuring particle size and that the specification does not recognize or require a specific method of measurement. (Fassihi Declaration ¶¶ 50–66; Def. Opening at 21–23). Although sieving is one such method, Alvogen points to examples in the '305 Patent that it claims do not support the use of a sieve: "[The '305 Patent] also includes an example of an active agent having a 'mean sphere diameter' of 12 microns (40:50-51) and an example of an active agent having an 'approximated [sic]150 micron' particle size (40:38-40). Thus the specification, according to Alvogen, is at best inconsistent in its description of particle size, and in many examples does not describe how a reported particle size was determined at all." (Def. Opening at 24). Alvogen maintains that its failure to challenge the meaning of "particle

5 DRL does not join Alvogen in this argument.

size" in prior litigation involving the related '514 Patent does not preclude it from raising the issue here. (Def. Response at 32).

Indivior maintains that no construction of these terms is necessary and that, in any event, Alvogen is precluded from re-raising this issue here. (Pl. Opening at 29–31). I agree.

As to construction of the term "particle size," unless a patentee unequivocally imparts a novel meaning to terms in a claim, courts "indulge a 'heavy presumption' that claim terms carry their full ordinary and customary meaning." *Omega Eng'g, Inc, v. Raytek Corp.*, 334 F.3d 1314, 1323 (Fed. Cir. 2003). Here, I find no such novel meaning in the specification. Instead, the patent explains that particle size is to be given its plain and ordinary meaning — as construed by a person of ordinary skill in the art — such that it means where particles are able to pass through a sieve of a specified mesh size, the particles are understood to be smaller than that size.

As to collateral estoppel, my analysis is shaped by the Federal Circuit's opinion that the claims of the two patents are patentably indistinct—and indeed, virtually identical except for the "continuously cast" language:

> 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 "continuously 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.

Indivior I, 752 F. App'x 1034–1035; *see also Indivior II*, 930 F.3d at 1336 ("Even where different patents are asserted between two suits, claim preclusion bars a patentee from bringing successive suits accusing the defendant's same product of infringing essentially the same patent claims." (citation omitted)).

Apart from the "continuously cast" terminology, the '305 Patent has the same specification as the '514 Patent. The absence of any other material distinction between the two patents is underscored by the very examples Alvogen points to in support of its "particle size" indefiniteness argument. As noted above, Alvogen cites examples in the '305 Patent specification to argue indefiniteness. (Def. Opening at 24). Those very examples, however, appear verbatim in the '514 Patent. (*See* Pl. Ex. C at 162). Moreover, the claims containing the term "particle size" in the '305 Patent are identical to the '514 Patent. (*Compare* Pl. Ex. A at 83 *with* Pl. Ex. C at 179 (for example, the '514 Patent, like the '305 Patent, claims: "A drug delivery composition comprising . . . wherein the particulate active has a particle size of 200 microns or less . . ."). Whatever this language gives in terms of an argument for indefiniteness, it takes away from any argument for claim preclusion.

Alvogen ultimately stipulated in the Delaware Litigation that particle size in the '514 Patent had its plain and ordinary meaning, and a final judgment was issued. (*See* Pl. Ex. H; Ex. I). That judgment binds the parties in the subsequent '305 litigation. Alvogen cannot revive the particle size argument simply by filing a patentably indistinct second patent.

I therefore find likewise that "particle size" with respect to the '305 Patent is not indefinite and has its plain and ordinary meaning.

3. "About 2 mg to About 16 mg of Buprenorphine or a Pharmaceutically Acceptable Salt Thereof"

Term	Plaintiff	Defendant
"about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof" (Exemplary of terms concerning the quantity of buprenorphine or naloxone) ('454 Patent: 1)	plain and ordinary meaning, but if construction is necessary, for example, "approximately 2 mg to approximately 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof"	"a dosage containing buprenorphine that provides buprenorphine absorption levels bioequivalent to a comparable on dose Suboxone® tablet, i.e., a film containing 8 mg buprenorphine compared to a tablet containing 8 mg buprenorphine"
"buprenorphine Cmax from about 0.624 ng/ml to about 5.638 ng/ml" (Exemplary of terms concerning Cmax or AUC values) ('454 Patent: 1)	plain and ordinary meaning, but if construction is necessary, for example "buprenorphine Cmax from approximately 0.624 ng/ml to approximately 5.638 ng/ml"	"buprenorphine Cmax values that are bioequivalent to a comparable one dose Suboxone® tablet, i.e., a film containing 8 mg buprenorphine compared to a tablet containing 8 mg buprenorphine"

(Pl. Opening at 32; Def. Opening at 26–27).

The parties agree that the term "about" means "approximately." (*See* the parties' Joint Claims Construction and Preliminary Statement (Dkt. No. 7106 at DE 73; Dkt. No. 7111 at DE 182)). This dispute, then, is not about the

actual meaning of the term "about." Rather, the parties disagree as to whether the Suboxone film must provide buprenorphine and naloxone absorption levels that are bioequivalent to a comparable dose of Suboxone tablets. (Pl. Opening at 32–35; Def. Opening at 27–29).

DRL contends that the specification for the '454 patent supports the bioequivalence interpretations because it makes repeated reference to the purpose of the invention: the production of a Suboxone film that is bioequivalent to Suboxone tablets. (Def. Opening at 28–30). Indivior responds that the term does not require construction because all of its words have a clear and established meaning. (Pl. Opening at 32–33). DRL's "bioequivalence" construction, says Indivior, is not sustainable, if only because it would exclude disclosed embodiments. (*Id.* at 33–34; Pl. Resp. 27–29).

I agree with Indivior. "[A]bsent contravening evidence from the specification or prosecution history, plain and unambiguous claim language controls the construction analysis." *DSW, Inc. v. Shoe Pavilion, Inc.*, 537 F.3d 1342, 1347 (Fed. Cir. 2008). Here, I find that the claim language is clear and unambiguous. Moreover, DRL and Alvogen's proposed construction cannot be adopted here as it improperly limits the claim scope by excluding embodiments referenced in the specification. (*See* Pl. Ex. B, col. 14:59–63 ("In one embodiment, the film composition provides an in vivo plasma profile having a Cmax of less than about 6.4 ng/ml for the agonist and an in vivo plasma profile having a Cmax of less than about 400 pg/ml for the antagonist."); *see also Indivior Inc. v. Actavis Labs. UT, Inc.*, No. CV 18-497-RGA, 2019 WL 2098841 (D. Del. May 14, 2019) (construing the same claim in the '454 Patent and finding that "many of the sections that Defendant points to in the specification do not support its claim construction. (*Id.* col. 3:32-39 ('The 'optimum' absorption may be, for example, a level that provides a bioequivalent absorption.... An 'optimum' Cmax of buprenorphine is about 0.67 to about 5.36 ng/ml') (emphasis added); *Id.* col. 14:37-39 ('[T]he inventive film composition preferably provides an AUC value so as to provide a bioequivalent result....')").

The claim language is clear and unambiguous; it identifies a chemical substance and states the range of permissible weights in milligrams. I construe the term "about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof" to have its plain and ordinary meaning and do not find the term to be limited by bioequivalent dosages.

4. "A Polyethylene Oxide Alone"[6]

Term	Plaintiff	Defendant
"a polyethylene oxide alone or in combination with a hydrophilic cellulosic polymer" ('454 Patent: 9, 10, 11)	plain and ordinary meaning, but if construction is necessary, for example, "a polyethylene oxide or a polyethylene oxide in combination with a hydrophilic cellulosic polymer"	plain and ordinary meaning, or if a construction is necessary, "a polyethylene oxide alone or in combination with a hydrophilic cellulosic polymer"

(Pl. Opening at 35; Def. Opening at 32).

The dispute with respect to this final claim is subtle. It concerns whether DRL infringes the '454 Patent if its water-soluble matrix contains polyethylene oxide ("PO") combined with a polymer other than a hydrophilic cellulosic polymer ("HCP").

The parties ask the court to the meaning of two alternatives: a water-soluble matrix comprised of either:

(1) PO "alone"; or

(2) PO + HCP.

Everyone seems to agree that alternative **(2)** encompasses PO plus HCP. The rub is alternative **(1)**: Does it include PO in combination with polymers other than HCP? Or does it include only 100% PO, *not* PO combined with any other polymer?

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6 Alvogen does not join DRL in this argument.

DRL takes the latter view. Thus, DRL says, its polymer matrix, which includes a PO plus a polymer that is not HCP, does not infringe the claim. (*Id.* at 33). Indivior takes the former view. It points to the word "comprises," which, it contends, permits a more expansive interpretation of PO "alone." (Pl. Response at 31–32). Thus, because DRL's water-soluble matrix contains PO in conjunction with a polymer (even though the polymer is not HCP), it would infringe under alternative **(1)**.

In drafting its claim, Indivior chose the word "alone," and "alone" is a lonely word. In ordinary English, given a choice of "tea alone or tea with milk," we would not assume we were being offered tea with honey, or even tea with cream. And in general, this seems like farfetched and convoluted drafting if what the writer meant to convey was just "PO in combination with a polymer." Because Indivior chose to use the word "alone," it cannot then restore disclaimed features by relying on the word "comprising." *Spectrum Int'l, Inc. v. Sterilite Corp.*, 164 F.3d 1372 (Fed. Cir. 1998) acknowledges that "a transitional term such as 'comprising' . . . does not exclude additional unrecited elements, or steps (in the case of a method claim).'" *Id.* 1379–80 (quoting *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1271 (Fed. Cir. 1986)). As *Spectrum* points out, "in the very same sentence, however, the [*Moleculon*] court limited this broad view of 'comprising' to avoid altering the scope of the particular claim step at issue. . . . 'Comprising' is not a weasel word with which to abrogate claim limitations." *Id.* (citations omitted).

Absent some indication that the commonsense meaning of "alone" was not intended, I am "powerless to rewrite the claims and must construe the language of the claim at issue based on the words used." *SRAM Corp. v. AD-II Eng'g, Inc.*, 465 F.3d 1351, 1359 (Fed. Cir. 2006) (citation omitted). Of course, a drafter may act as its own lexicographer and define terms any way it wishes. But nothing in the record here supports Indivior's counterintuitive construction whereby DRL's film infringes because it contains a matrix consisting of PO and

a polymer that is not HCP. Here, PO "alone" plainly and unambiguously limits the alternative **(1)** water-soluble matrix to those that contain only PO.

III. Recovery on the Bonds

Finally, Alvogen moves separately for an order granting immediate recovery on the bonds posted in connection with the court's injunction pending the Court of Appeals' mandate in *Indivior I.* (Dkt. No. 7106 at DE 148).

Rule 65(c) requires an injunction bond "in an amount that the court considers proper to pay the costs and damages sustained by any party found to have been wrongfully enjoined or restrained." "The purpose of the bond requirement is to protect the enjoined party in the event the injunction should not have been imposed." *Howmedica Osteonics v. Zimmer Inc.*, 461 F. App'x 192, 198 (3d Cir. 2012). However, "[i]t is settled that one can recover on an injunction bond only after a trial and final judgment on the merits." *Clark v. K-Mart Corp.*, 979 F.2d 965, 969 (3d Cir. 1992). Only an adverse final judgment establishes that a party was wrongfully enjoined in the interim.

The Third Circuit has recently held that this rule applies to TRO bonds, like the one here. *See Nat'l Collegiate Athletic Ass'n v. Governor of New Jersey*, 939 F.3d 597, 605 (3d Cir. 2019) (confirming in the context of TROs that "whether a party was wrongfully enjoined depends upon the final judgment on the merits"). "[T]he rule increases predictability of the law, 'discourag[es] parties from requesting injunctions based on tenuous legal grounds,' and conserves judicial resources." *Id.* at 607 (citations omitted). Our system is not one in which, during the litigation, each party has to write the other a check every time it falls behind on points.

Alvogen argues that Indivior made a strategic decision to seek an injunction despite the Federal Circuit panel's having previously ordered that an injunction against DRL must be lifted. Because of this choice, says Alvogen, it was wrongfully kept from proceeding to market. (Dkt. No. 7106 at DE 149). Indivior responds, correctly in my view, that under settled Third Circuit law

Alvogen may not recover on the bonds before there is a final judgment on the merits. (*Id.* at DE 156).

A determination as to whether Alvogen was unlawfully enjoined cannot be made until "there is final judgment." *American Bible Soc.*, 446 F. 2d at 594. Such a final judgment must take into account many factors that the Court cannot properly adjudicate at this stage—for example, the likelihood of Alvogen's having been, as it now claims, the first generic to market but for this litigation or this injunction. For this reason, too, even if not barred by Third Circuit precedent, the equities would weigh against the grant of Alvogen's motion.

Alvogen's motion to recover on the bond is denied without prejudice to a later application, if and when appropriate, in connection with the final resolution of this case. (Dkt. No. 7106 at DE 148).

IV. Conclusion

I construct the disputed terms, for the reasons and in the manner detailed above, as follows:

1. "continuously cast film" means a continuous sheet of cast film that has been dried without solely employing conventional convection air drying from the top.
2. "particle size" requires no construction.
3. "about 2 mg to about 16 mg of buprenorphine or a pharmaceutically acceptable salt thereof" and its equivalent claims have their plain and ordinary meaning.
4. "a polyethylene oxide alone" means a water-soluble matrix comprised solely of PO.

Alvogen's motion to recover on the bond pursuant to Rule 65 (Dkt. No. 7106 at DE 148) is denied without prejudice.

An appropriate order follows.

Dated: November 5, 2019

Kevin McNulty
United States District Judge