NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

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

v.

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

2018-2167, 2018-2169

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

Decided: November 20, 2018

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

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

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

Dissenting Opinion filed by *Circuit Judge* NEWMAN

STOLL, *Circuit Judge*.

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

BACKGROUND

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

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

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

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

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

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

The Delaware Case

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

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

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

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

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

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

The Current Case

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

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

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

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

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

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

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

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

DISCUSSION

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

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

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

Likelihood of Success: Specification Disclaimer

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

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

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

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

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

In *SciMed*, we instructed that

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Likelihood of Success: Claim Preclusion

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

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

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

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

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

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

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

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

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

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

IV

Based on the record with the proper interpretation of claim scope, we conclude that Indivior has not shown that it is likely to succeed on the merits of its infringement claim. The district court thus abused its discretion in granting the preliminary injunction. Having held that the district court's likelihood of success analysis was an abuse of discretion, we need not reach the other preliminary injunction factors. Accordingly, we vacate the preliminary injunction and remand to the district court for further proceedings.

VACATED AND REMANDED

COSTS

Costs to Appellants.

NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

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

v.

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

2018-2167, 2018-2169

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

NEWMAN, *Circuit Judge*, dissenting.

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

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

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

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

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

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

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

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

As the Court has related, "the decision whether to grant or deny injunctive relief rests within the equitable discretion of the district courts." *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 394 (2006). "[S]uch discretion must be exercised consistent with traditional principles of equity, in patent disputes no less than in other cases governed by such standards." *Id.*

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

The majority errs in its finding of "specification disclaimer"

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

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

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

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

'305 patent, col. 5 ll. 7–13.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

"In legal principle, the filing of a terminal disclaimer simply serves the statutory function of removing the rejection of double patenting, and raises neither presumption nor estoppel on the merits of the rejection. It is improper to convert this simple expedient of 'obviation' into an admission or acquiescence or estoppel on the merits." *Quad Envtl. Techs. Corp. v. Union Sanitary Dist.*, 946 F.2d 870, 874–75 (Fed. Cir. 1991). Moreover, in *Ventana Medical Systems, Inc. v. Biogenex Laboratories, Inc.*, this court rejected the argument that "the filing of the terminal disclaimer represents an admission by the inventors 'equating all claims of the [second application] to all claims of the [first patent].'" 473 F.3d 1173, 1184 n.4 (Fed. Cir. 2006) (quoting argument).

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

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

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

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

My colleagues hold that they "need not reach" these aspects of the district court's discretionary action, based on their conclusion that Indivior "has not shown that it is likely to succeed on the merits of its infringement claim." Maj. Op. at 21. However, the balancing of all factors is the foundation of a discretionary ruling. When one side is subject to substantially greater harm, this may outweigh other factors believed to favor the opponent. "In each case, courts 'must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief.'" *Winter v. Nat.*

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

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

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

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

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

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

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

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

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

CONCLUSION

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