United States Court of Appeals for the Federal Circuit

INDIVIOR INC., FKA RECKITT BENCKISER PHARMACEUTICALS INC., INDIVIOR UK LIMITED, FKA RB PHARMACEUTICALS LIMITED, AQUESTIVE THERAPEUTICS, INC., FKA MONOSOL RX, LLC,
Plaintiffs-Cross-Appellants

v.

DR. REDDY'S LABORATORIES, S.A., DR. REDDY'S LABORATORIES INC., WATSON LABORATORIES INC., ACTAVIS LABORATORIES UT, INC., TEVA PHARMACEUTICALS USA, INC.,
Defendants-Appellants

PAR PHARMACEUTICAL, INC., INTELGENX TECHNOLOGIES CORP.,
Defendants

2017-2587, 2018-1010, 2018-1058, 2018-1062, 2018-1114, 2018-1115, 2018-1176, 2018-1177

Appeals from the United States District Court for the District of Delaware in Nos. 1:13-cv-01674-RGA, 1:14-cv-00422-RGA, 1:14-cv-01451-RGA, 1:14-cv-01574-RGA, 1:16-cv-00178-RGA, Judge Richard G. Andrews.

INDIVIOR INC., FKA RECKITT BENCKISER PHARMACEUTICALS INC., INDIVIOR UK LIMITED, FKA RB PHARMACEUTICALS LIMITED, AQUESTIVE THERAPEUTICS, INC.,
Plaintiffs-Appellants

v.

ALVOGEN PINE BROOK, LLC,
Defendant-Cross-Appellant

2018-1949, 2018-2045

Appeals from the United States District Court for the District of Delaware in Nos. 1:15-cv-00477-RGA, 1:15-cv-01016-RGA, Judge Richard G. Andrews.

Decided: July 12, 2019

JEFFREY B. ELIKAN, Covington & Burling LLP, Washington, DC, argued for all plaintiffs-cross-appellants in 2017-2587 and for all plaintiffs-appellants in 2018-1949. Indivior Inc., Indivior UK Limited also represented by ERICA NICOLE ANDERSEN, BETH S. BRINKMANN, ROBERT JASON FOWLER, MATTHEW AARON KUDZIN, JEFFREY HOWARD LERNER, ASHLEY KWON; DUSTIN B. WEEKS, Troutman Sanders LLP, Atlanta, GA; DANIEL LADOW, JAMES M. BOLLINGER, MAGNUS ESSUNGER, KATHERINE HARIHAR, TIMOTHY P. HEATON, GERALD EAMES PORTER, New York, NY; CHARANJIT BRAHMA, San Francisco, CA.

JAMES FRANCIS HIBEY, Steptoe & Johnson, LLP, Washington, DC, for plaintiff-cross-appellant Aquestive

Therapeutics, Inc. in 2017-2587 and for plaintiff-appellant Aquestive Therapeutics, Inc. in 2018-1949. Also represented by JAMIE LUCIA, San Francisco, CA.

KEVIN PAUL MARTIN, Goodwin Procter LLP, Boston, MA, argued for defendants-appellants Dr. Reddy's Laboratories, S.A., Dr. Reddy's Laboratories Inc. in 2017-2587. Also represented by ELAINE BLAIS, EDWINA CLARKE, ROBERT FREDERICKSON, III, ALEXANDRA LU; ROBERT V. CERWINSKI, IRA J. LEVY, New York, NY.

STEPHEN R. SMEREK, Winston & Strawn LLP, Los Angeles, CA, argued for defendants-appellants Watson Laboratories Inc., Actavis Laboratories UT, Inc., Teva Pharmaceuticals USA, Inc. in 2017-2587. Also represented by JASON CRAIG HAMILTON; GEORGE C. LOMBARDI, MICHAEL KEENAN NUTTER, Chicago, IL; GEOFFREY P. EATON, Washington, DC.

STEVEN H. SKLAR, Leydig, Voit & Mayer, Ltd., Chicago, IL, argued for defendant-cross-appellant in 2018-1949. Also represented by DAVID AIRAN, GREGORY BAYS, NICOLE KOPINSKI, JAMES SANNER.

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

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

Dissenting opinion filed by *Circuit Judge* MAYER.

LOURIE, *Circuit Judge*.

Dr. Reddy's Laboratories, S.A. and Dr. Reddy's Laboratories Inc. (collectively, "DRL"); Watson Laboratories Inc. and Actavis Laboratories UT, Inc. (collectively, "Watson"); and Teva Pharmaceuticals USA, Inc. ("Teva") appeal from several decisions of the United States District Court for the District of Delaware pertaining to U.S. Patents 8,603,514 (the "'514 patent"), 8,900,497 (the "'497 patent"), and

8,017,150 (the "'150 patent"). Specifically, DRL appeals from two decisions holding the asserted claims of the '514, '497, and '150 patents not invalid as obvious. *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs. S.A.*, Nos. 14-1451-RGA, 14-1573-RGA, 14-1574-RGA, 2017 WL 3837312 (D. Del. Aug. 31, 2017) ("*DRL '514 Decision*"); *Reckitt Benckiser Pharm. Inc. v. Dr. Reddy's Labs. S.A.*, No. 14-1451-RGA, 2017 WL 3782782 (D. Del. Aug. 31, 2017) ("*DRL '150 Decision*"). Watson and Teva appeal from the court's judgment in a third decision that the '514 patent is not invalid as indefinite. *Reckitt Benckiser Pharm. Inc. v. Watson Labs., Inc.*, Nos. 13-1674-RGA, 14-422-RGA, 2016 WL 3186659 (D. Del. June 3, 2016) ("*Watson Decision*"); J.A. 212–14.[1] Watson also appeals from the court's finding in that decision that Watson infringes the '514 patent, as well as the court's subsequent order denying it relief from the infringement judgment under Rule 59. *Reckitt Benckiser Pharm. Inc. v. Watson Labs., Inc.*, Nos. 13-1674-RGA, 14-422-RGA, 2017 WL 3820943 (D. Del. Aug. 31, 2017) ("*Rule 59 Decision*").

Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. (collectively, "Indivior") cross-appeal from the district court's findings in the two DRL decisions that DRL does not infringe either the '514 or the '150 patent. Indivior also appeals from a fourth decision by the same court finding that Alvogen Pine Brook, LLC ("Alvogen") does not infringe the '514 patent. *Indivior Inc. v. Mylan Techs. Inc.*, 298 F. Supp. 3d 775 (D. Del. 2018) ("*Alvogen Decision*"). Finally, Indivior requests that the court's judgment in the Watson case of invalidity of claims 15–19 of U.S. Patent 8,475,832 (the "'832 patent") be vacated as moot.

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[1] Unless otherwise noted, all J.A. citations are to the joint appendix filed in the DRL appeal.

We vacate as moot the district court's decision holding claims 15–19 of the '832 patent invalid as obvious. We affirm the court on all other issues.

I. BACKGROUND

Indivior markets and holds the New Drug Application ("NDA") for Suboxone® sublingual film ("Suboxone Film"), an opioid addiction treatment that combines two active ingredients: the opioid buprenorphine and the opioid antagonist naloxone. Suboxone Film is applied below a patient's tongue, where it then rapidly dissolves to release the active ingredients. In 2010, the Food and Drug Administration ("FDA") approved Indivior's film product, the first such product to gain FDA approval. Previously, Indivior sold buprenorphine/naloxone only in a tablet form.

These appeals involve issues of infringement and invalidity of four patents covering pharmaceutical films and methods of making them. However, the parties' substantive disputes focus on only two patents, the '514 and '150 patents. Both patents claim pharmaceutical films and are listed in the Orange Book[2] as covering Suboxone Film. Representative claims of the two patents are set forth in the Appendix. The '497 patent is directed to film manufacturing methods, and the parties do not distinguish it from the '514 patent with respect to the issues on appeal. Aquestive Therapeutics, Inc. ("Aquestive") owns these three patents and exclusively licenses them to Indivior.[3]

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[2] This publication is formally entitled "Approved Drug Products with Therapeutic Equivalence Evaluations."

[3] Indivior was formerly known as Reckitt Benckiser Pharmaceuticals Inc. Aquestive was formerly known as MonoSol Rx, LLC. For simplicity, we refer to the former entities by their present names.

The fourth patent, the '832 patent, claims film formulations and is owned by Indivior.

A. The Patents in Suit

1. The '514 and '497 Patents

The '514 patent claims pharmaceutical films with a uniform distribution of active ingredient. 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. '514 patent col. 2 ll. 18–21, 42–46, 57–59. Generally, a film may be made by mixing an active compound with a solvent to form a flowable matrix, casting the mixture onto a planar surface, and then drying the film to produce a solid sheet. *Id.* col. 5 ll. 41–54, col. 6 ll. 49–60.

Multiple factors in the film-making process can affect uniformity. "By avoiding the introduction of and eliminating excessive air in the mixing process, selecting polymers and solvents to provide a controllable viscosity and by drying the film in a rapid manner from the bottom up, such [uniform] films result." *Id.* col. 23 ll. 16–20. Claim 62, the sole independent claim at issue from the '514 patent, is representative and recites "a *cast film* comprising a flowable water-soluble or water swellable film-forming matrix," "wherein the uniformity *subsequent to casting and drying* of the matrix is measured by . . . unit doses which do not vary by more than 10%" of the amount of active. *Id.* col. 73 ll. 49–50, col. 74 ll. 6–9 (emphases added). The claim identifies two parameters—viscosity and drying—that contribute to film uniformity: (1) the viscosity of the matrix must be "sufficient to aid in substantially maintaining non-self-aggregating uniformity" of the active (the "viscosity limitation"); and (2) the matrix must be "capable of being dried without loss of substantial uniformity of the active" (the "drying limitation"). *Id.* col. 73 l. 53–col. 74 l. 5. The other

asserted claims of the '514 patent all depend from claim 62.[4]

The drying limitation is central to several of the issues on appeal. 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.

To produce a uniform film, the specification discloses controlled drying processes that differ from conventional techniques. 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

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[4] Indivior asserted claims 62–65, 69, 71, and 73 against DRL, *DRL '514 Decision*, 2017 WL 3837312, at *2; claims 62, 64, 65, 69, and 73 against Watson, *Watson Decision*, 2016 WL 3186659, at *2; and claims 62, 63, 65, 69, 71, and 73 against Alvogen, *Alvogen Decision*, 298 F. Supp. 3d at 776.

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.

Claim 62 also recites that the flowable matrix has a viscosity "sufficient to aid" in maintaining film uniformity. *Id.* col. 73 ll. 53–55. The specification provides suitable ranges of matrix viscosity, which are "generally" 400–100,000 centipoise, "preferably" 800–60,000 centipoise, and "most preferably" 1,000–40,000 centipoise. *Id.* col. 11 ll. 26–29. The choice of polymer has an important role in affecting viscosity and hence film uniformity. *See id.* col. 11 ll. 15–24.

Similar to the '514 patent, the '497 patent claims processes for making pharmaceutical films. Claim 24, the sole asserted claim, depends from claim 1, which recites a drying limitation similar to claim 62 of the '514 patent: a "drying" step to form a film "having a substantially uniform distribution" of an active compound. '497 patent col. 57 ll. 8–10. The specification of the '497 patent is also substantively similar to that of the '514 patent.

2. '150 Patent

Like the '514 patent, the '150 patent is directed to uniform pharmaceutical films, but it claims them somewhat

differently. Rather than identifying process parameters relevant to film uniformity, as in the '514 patent, the asserted claims of the '150 patent claim pharmaceutical films by their components. Claim 1 is representative of the asserted claims and recites a film comprising an active ingredient and a water-soluble polymer component containing certain proportions of polyethylene oxide ("PEO"), including both low molecular weight PEO ("L-PEO") and high molecular weight PEO ("H-PEO"), and a hydrophilic cellulosic polymer. '150 patent col. 57 ll. 35–54. The specification lists various "useful water[-]soluble polymers," including PEO, hydrophilic cellulosic polymers, and a separate compound, polyvinyl pyrrolidone. *Id.* col. 15 ll. 47–52. The other asserted claims—4, 5, 8, and 9—each depend from claim 1. *DRL '150 Decision*, 2017 WL 3782782, at *1.

The '150 patent claims priority from an earlier provisional application, U.S. Patent Application 60/473,902 (the "'902 application").

B. The Decisions on Appeal

Several generic drug companies filed Abbreviated New Drug Applications ("ANDAs") to market generic versions of Suboxone Film prior to the expiration of the patents in suit. Indivior then brought several actions for patent infringement, accusing DRL of infringing the '514 and '150 patents, and both DRL and Watson of infringing the '497 patent; Watson of infringing the '514 and '832 patents; and Alvogen of infringing the '514 and '497 patents.[5]

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[5] DRL's ANDA was originally owned by Teva, which transferred its interest to DRL but maintained an interest in a related product. Teva agreed to be bound by the court's decision in the DRL '514 patent case for the related product. J.A. 30001–06; *see* J.A. 210–14 (district court's final judgments).

The district court held four bench trials and decided multiple issues of infringement and validity concerning the asserted patents. We discuss only the issues pertinent to these appeals.

1. Watson '514 Decision

The first trial over the '514 patent involved Indivior's claim that Watson infringed the '514 patent. Watson did not request construction of the drying limitation. The court found that Watson infringed the '514 patent and that Watson did not meet its burden to prove the asserted claims invalid as indefinite. *Watson Decision*, 2016 WL 3186659, at *16, *21.

Indivior also asserted the '832 patent against Watson. The district court concluded that claims 15–19 of the '832 patent are invalid as obvious. *Id.* at *11. In a parallel *inter partes* review proceeding, the Patent Trial and Appeal Board held claims 15–19 unpatentable as anticipated and obvious. *BioDelivery Scis. Int'l, Inc. v. RB Pharm. Ltd.*, No. IPR2014-00325, 2015 WL 4045328, at *16 (P.T.A.B. June 30, 2015), *aff'd*, 667 F. App'x 997 (Fed. Cir. 2016).

After trial, Watson modified its film manufacturing process and requested relief under Rule 59 from the district court's infringement judgment. The court denied relief, finding no manifest injustice in upholding its final judgment. *Rule 59 Decision*, 2017 WL 3820943, at *3.

2. DRL '514 Decision and the Related Appeal

In a second trial over the '514 patent, the district court considered Indivior's claims that DRL infringed the '514 patent and that DRL and Watson infringed the '497 patent. Unlike in the previous case, the parties (including Watson) disputed the meaning of the drying limitation. The court construed the drying limitation of the '514 patent to mean "dried without solely employing conventional convection air drying from the top," because it concluded that the specification disclaimed such conventional top drying

techniques. *DRL '514 Decision*, 2017 WL 3837312, at *4; *see Reckitt Benckiser Pharm. Inc. v. Teva Pharm. USA, Inc.*, Nos. 14-1451-RGA, 14-1573-RGA, 14-1574-RGA, 2016 WL 3621632, at *10–11 (D. Del. June 29, 2016) ("*Claim Construction Order*"). The court found that DRL's drying process uses dryers where the sole source of heat comes from the top and thus does not infringe the asserted claims of the '514 patent. *DRL '514 Decision*, 2017 WL 3837312, at *5–6. For similar reasons, the court found that neither DRL nor Watson infringed the asserted claim of the '497 patent. *DRL '514 Decision*, 2017 WL 3837312, at *5–6, *9.

The court also held that DRL failed to prove by clear and convincing evidence that the asserted claims of either the '514 or the '497 patent would have been obvious over the cited prior art. *Id.* at *20.

After the district court's judgment of noninfringement, Indivior amended claims of a pending continuation application that ultimately issued as U.S. Patent 9,931,305 (the "'305 patent"). The amendment removed the words "dried" and "drying" from the language of claim 62, instead reciting that the film be "capable of being *continuously cast* . . . without loss of substantial uniformity" and that "uniformity of the-*continuously cast film* is measured by . . . unit doses cut from the *continuously cast film* which do not vary by more than 10%" of the amount of the active. '305 patent col. 73 ll. 21–29 (emphases added). The '305 patent shares a specification with, and is terminally disclaimed to, the '514 patent.

Soon after the '305 patent issued, Indivior again sued DRL for patent infringement, this time asserting the '305 patent in the District of New Jersey. DRL had since launched its competing generic product, and Indivior moved for a temporary restraining order and preliminary injunction at the New Jersey court. DRL argued that Indivior's New Jersey action was barred as claim precluded by the Delaware court's judgment. The New Jersey court

concluded that claim preclusion likely would not apply and that Indivior would likely be able to prove infringement. *Indivior Inc. v. Dr. Reddy's Labs. S.A.*, No. 17-CV-7111, 2018 WL 3496643, at *8, *11 (D.N.J. July 20, 2018). Consequently, the court entered a temporary restraining order and then a preliminary injunction against DRL's generic product. *Id.* at *14.

DRL appealed to this court. Despite the claim amendments, the panel majority held that the cast films claimed in the '305 patent still had to be dried and were subject to the same specification disclaimer as the '514 patent. *Indivior Inc. v. Dr. Reddy's Labs., S.A.*, 752 F. App'x 1024, 1031–32 (Fed. Cir. 2018) ("*Indivior*"). Under the proper construction, we concluded that the asserted claims of the '305 patent were materially identical to those of the '514 patent already adjudicated. *Id.* at 1034–35. Accordingly, we held that Indivior's New Jersey action was likely claim precluded, vacated the court's preliminary injunction, and remanded for further proceedings. *Id.* at 1035.

3. Alvogen '514 Decision

In the third trial over the '514 patent, the district court considered Indivior's claim that Alvogen infringed the '514 patent. The court construed the drying limitation as it did in the *DRL '514 Decision*. *Alvogen Decision*, 298 F. Supp. 3d at 779. 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. *Id.* at 784–85.

4. DRL '150 Decision

In addition to the '514 patent, Indivior asserted that DRL infringed the '150 patent under the doctrine of equivalents. The district court held a separate trial on the '150 patent and found that DRL does not infringe any of the asserted claims. *DRL '150 Decision*, 2017 WL 3782782, at

*4–5. The court also held that DRL did not prove that the asserted claims of the '150 patent would have been obvious. *Id.* at *7–8.

C. The Appeals

DRL appeals from the district court's judgments that the asserted claims of the '514, '497, and '150 patents are not invalid as obvious. Watson and Teva appeal from the court's judgments that the '514 patent is not invalid as indefinite, that Watson infringes the '514 patent, and that Watson is not entitled to Rule 59 relief from the infringement judgment.

Indivior cross-appeals from the district court's determinations that DRL does not infringe either the '514 or the '150 patent and that Alvogen does not infringe the '514 patent. Indivior also requests vacatur of the court's judgment that certain claims of the '832 patent would have been obvious over the cited prior art.

We have jurisdiction over each appeal under 28 U.S.C. § 1295(a)(1). We first address the parties' disputes concerning the '514 patent and then turn to the '150 and '832 patents.

II. DISCUSSION

On appeal from a bench trial, we review a district court's conclusions of law *de novo* and its findings of fact for clear error. *Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1358 (Fed. Cir. 2014). A factual finding is clearly erroneous if, despite some supporting evidence, we are left with the definite and firm conviction that a mistake has been made. *United States v. U.S. Gypsum Co.*, 333 U.S. 364, 395 (1948). "The burden of overcoming the district court's factual findings is, as it should be, a heavy one." *Polaroid Corp. v. Eastman Kodak Co.*, 789 F.2d 1556, 1559 (Fed. Cir. 1986).

A. Infringement of the '514 Patent

Indivior challenges the district court's judgments that DRL and Alvogen do not infringe the '514 patent. Watson appeals from the court's separate judgment that it does infringe the '514 patent. We first consider Indivior's cross-appeal and appeal and then turn to Watson's appeal.

An infringement analysis has two steps. *Clare v. Chrysler Grp. LLC*, 819 F.3d 1323, 1326 (Fed. Cir. 2016). First, the court construes the asserted claims. Claim construction is a question of law that may involve underlying factual questions. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). But when, as here, the court's construction of the relevant limitation is based solely on the intrinsic evidence, we review its construction *de novo*. *HTC Corp. v. Cellular Commc'ns Equip., LLC*, 877 F.3d 1361, 1367 (Fed. Cir. 2017). Second, the court determines whether the accused product meets each limitation of the claim as construed, which is a question of fact that we review for clear error. *Wright Med. Tech., Inc. v. Osteonics Corp.*, 122 F.3d 1440, 1443 (Fed. Cir. 1997).

1. Indivior's Appeal and Cross-Appeal

Indivior's challenges to the district court's judgments of noninfringement largely turn on the proper construction of the drying limitation. In the DRL and Alvogen cases, the district court construed the drying limitation to mean "dried without solely employing conventional convection air drying from the top." *Alvogen Decision*, 298 F. Supp. 3d at 779; *DRL '514 Decision*, 2017 WL 3837312, at *4; *Claim Construction Order*, 2016 WL 3621632, at *11. That construction rested on the court's conclusion that the patentee disclaimed drying wet cast films using solely conventional convection air drying from the top. The court's disclaimer conclusion was based on the '514 patent specification's express statements of what the invention is, its repeated disparagement of conventional top drying methods, and the patent applicant's characterization of the invention during

prosecution. *Claim Construction Order*, 2016 WL 3621632, at *6, *11.

In *Indivior*, we likewise concluded that the same specification in the related '305 patent disclaimed conventional top air drying. 752 F. App'x at 1031–32. In addressing whether Indivior's assertion of the '305 patent raised the same cause of action as the '514 patent, we concluded:

> [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*.

Id. 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.

In both the DRL and Alvogen appeals, Indivior argues that the district court erred in concluding that the '514 patent specification disclaimed drying methods that use solely conventional convection air drying from the top. Instead, Indivior contends that the drying limitation should be given its plain and ordinary meaning. To the extent that the specification did disclaim certain top drying methods,

Indivior alternatively argues that the disclaimer cannot encompass zone drying.

Both DRL and Alvogen respond that the district court properly construed the drying limitation, as this court confirmed in *Indivior*.

We agree with DRL and Alvogen that the district court correctly construed the drying limitation and that the '514 patent specification disclaims conventional top air drying. The specification "is the single best guide to the meaning of a disputed term," *Phillips v. AWH Corp.*, 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (internal quotation marks omitted), and where it "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," *SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1341 (Fed. Cir. 2001); *see Chi. Bd. Options Exch., Inc. v. Int'l Sec. Exch., LLC*, 677 F.3d 1361, 1372 (Fed. Cir. 2012). 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.

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. For example, the specification teaches that "the conventional drying methods themselves are unable to provide uniform films." '514 patent col. 3 ll. 14–16. In the section focused on "Drying Wet Cast Films," the specification likewise discloses that "[c]onventional convection air drying from the top is not employed." *Id.* col. 28 ll. 51, 57–

58. And the patent explains why: conventional top air drying

> initiates drying at the top uppermost portion of the film, thereby forming a barrier against fluid flow, such as the evaporative vapors, and thermal flow, such as the thermal energy for drying. 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. col. 28 ll. 57–64.

This undesirable phenomenon is described elsewhere as the ripple effect. *Id.* col. 3 ll. 33–54. The ripple effect is "avoided by the present invention" "by applying heat to the bottom surface of the film with substantially no top air flow" or by using controlled microwaves, "again with substantially no top air flow." *Id.* col. 22 ll. 48–57, col. 28 ll. 52–55 ("The 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 . . . ."). "If top air is employed, it is balanced with the bottom air drying to avoid non-uniformity . . . ." *Id.* col. 29 ll. 1–3.

The specification also provides examples that demonstrate the failure of conventional drying methods to achieve uniformity. Examples CH and CG examined whether undesirable particle aggregations occurred during conventional drying techniques as compared to "the uniform drying process of the present invention." *Id.* col. 52 ll. 27–28. In example CH, films were placed in an oven "on trays lined with furnace filters, which uniformly distribute heat." *Id.* col. 52 ll. 57–59. The resulting dried films were homogenous with no particle aggregations. *Id.* col. 52 ll. 60–62. In contrast, when films were dried in an oven "by conventional top and bottom drying means," particle aggregations occurred. *Id.* col. 53 ll. 1–3, 8–10. Similarly, example CG reports that when films were "dried according to

conventional drying techniques, rather than via the uniform drying process of the present invention," the resulting films had particle aggregations. *Id.* col. 52 ll. 26–28, 39–40. And again, when films were instead dried "by the process of the present invention," on trays lined with furnace filters, the resulting films were homogenous and lacked particle aggregations. *Id.* col. 52 ll. 43–50. Nowhere does the specification describe making a uniform film with only conventional convection air drying from the top.

Indivior emphasizes that the specification describes other factors that affect film uniformity. Indivior Reply Br. 5–7. We agree that both the asserted claims and the specification identify other factors, such as viscosity, that may contribute to uniformity. *E.g.*, '514 patent col. 73 ll. 53–55, col. 74 ll. 3–5 (claim 62 containing both viscosity and drying limitations); *id.* col. 23 ll. 14–20 (specification indicating likewise). But the unequivocal disparagement of conventional top air drying detailed above demonstrates that other factors may not substitute for controlled drying of a wet cast film to achieve uniformity. As Indivior's expert explained, uniformity can be lost at any step of the manufacturing process, and once lost cannot be recovered. J.A. 17209.

Indivior nonetheless argues, first in its reply brief, that "polymer selection and the resulting viscosity may be used as an alternative to controlled drying." Indivior Reply Br. 7. This argument is inconsistent with Indivior's own acknowledgement that uniformity can be lost throughout the manufacturing process, and that neither the drying nor the viscosity limitation of the asserted claims renders the other superfluous. Indivior Cross-Appellant Br. 47. Likewise, the specification indicates that no individual factor can guarantee uniformity of a wet cast film after drying. '514 patent col. 3 ll. 3–9 ("The long length of drying time aids in promoting the aggregation of the active and other adjuvant, *notwithstanding the use of viscosity modifiers*." (emphasis added)), col. 23 ll. 14–20 ("The present invention

yields exceptionally uniform film products . . . . By avoiding . . . excessive air in the mixing process, selecting polymers and solvents to provide a controllable viscosity *and* by drying the film in a rapid manner from the bottom up, such films result." (emphasis added)). The lone statement purportedly to the contrary cited by Indivior, *id.* col. 4 ll. 61–64 ("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."), does not change our conclusion in light of the specification's unambiguous disparagement of conventional top air drying and its teachings as a whole.

Even if the specification did disclaim certain drying methods, Indivior contends that the disclaimer cannot extend to zone drying. Indivior Cross-Appellant Br. 43. Zone drying, according to Indivior, is a preferred embodiment that can achieve uniform films and cannot be excluded from the claims.

Indivior plainly waived this limited disclaimer argument by not raising it in the DRL case until post-trial briefing. *See, e.g.*, *Power Integrations, Inc. v. Fairchild Semiconductor Int'l, Inc.*, 904 F.3d 965, 974 (Fed. Cir. 2018). However, it did raise a claim construction argument resembling the one on appeal in a footnote in the Alvogen case, Alvogen J.A. 91990 n.20, which the district court rejected, *Alvogen Decision*, 298 F. Supp. 3d at 783.

Even if we assume waiver does not apply, the specification's discussion of zone drying does not qualify its disclaimer of conventional top air drying. Zone drying just refers to using a drying tunnel with multiple "drying zones" along the belt that may differ in various atmospheric conditions. '514 patent col. 32 ll. 38–45; *id.* figs. 35–36. Consistent with the rest of the specification, the patent nowhere suggests that zone drying achieves uniform films by using solely conventional top air drying. Rather, the patent explains that zone drying may be supplemented with

additional processes only "so long as controlled drying is maintained in accordance with the invention." *Id.* col. 33 ll. 1–4. And contrary to Indivior's argument, the district court's construction does not exclude any zone drying embodiments; it just excludes zone drying that uses solely conventional convection air drying from the top, which is never disclosed in the patent. We thus conclude that the disclosure of zone drying does not qualify the specification's repeated disparagement of solely top air drying.

Consistent with our previous *Indivior* decision, we ultimately agree with the district court that the '514 patent specification unmistakably disclaimed conventional top air drying as unable to produce the claimed uniform films.[6] Accordingly, we affirm the court's construction of the drying limitation and proceed to the second step of the infringement analysis, considering DRL's and Alvogen's distinct ANDA processes separately.

The district court found that DRL's ANDA product does not infringe the asserted claims of the '514 patent. *DRL '514 Decision*, 2017 WL 3837312, at *5–6. Although the court found that the drying process is controlled in certain ways to assure film uniformity, it determined that the sole source of heat in its drying process is hot air coming from above the film and that any bottom drying that occurred was incidental. *Id.* at *5. Consequently, the court found that DRL does not infringe the drying limitation and thus does not infringe any of the asserted claims. *Id.* at *6.

Indivior argues that the district court clearly erred in finding that DRL's ANDA product does not infringe the asserted claims of the '514 patent. Even under the court's

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[6] Because we conclude that the specification disclaims conventional top air drying, we need not decide whether the prosecution history further supports that disclaimer.

construction, Indivior contends that DRL's drying process is tightly controlled to maintain uniformity and uses balanced top air and bottom air drying.

DRL responds that the district court did not clearly err in finding noninfringement because DRL's drying process uses solely conventional top air drying.

We agree with DRL that the district court did not clearly err in finding that DRL's drying process does not meet the drying limitation and thus does not infringe the asserted claims of the '514 patent. Indivior does not seriously dispute the essential predicates of the court's noninfringement finding: that the sole source of heat in DRL's drying process is hot air from above the film, and that any bottom drying is merely incidental. *See id.* at *5 ("DRL's use of 'bottom drying' is essentially that the inside of the oven simply gets hot . . . ."). Indivior thus has not shown clear error in the court's holding that DRL employs conventional top air drying, which is insufficient to meet the drying limitation as properly construed. Accordingly, we affirm the court's finding that DRL does not infringe the asserted claims of the '514 patent.

We next address Indivior's appeal concerning Alvogen's ANDA product. The district court found that Alvogen's ANDA product does not infringe the '514 patent because it does not meet the drying limitation. *Alvogen Decision*, 298 F. Supp. 3d at 785. The court credited Alvogen's expert's testimony that nozzles above the film supply all the hot air to dry the films, *id.* at 780–81, and found that any bottom drying in Alvogen's process is insubstantial, *id.* at 784.

Indivior argues that the district court clearly erred in its noninfringement finding because even some insubstantial bottom drying brings Alvogen's process within the reach of the asserted claims. We disagree. Indivior's argument is largely repetitive of its claim construction arguments, which we have rejected. The district court found that even solely conventional top air drying can result in

some incidental drying from the bottom, but that such insubstantial bottom drying does not infringe the asserted claims as construed in light of the specification's disclaimer of conventional top air drying. *Id.* ("Plaintiffs have not demonstrated 'substantial' bottom drying such that Alvogen's dryer can be said to employ anything but 'conventional convection air drying from the top.'"); *accord DRL '514 Decision*, 2017 WL 3837312, at *5 (finding that incidental bottom drying did not infringe asserted claims). We conclude that this finding is not clearly erroneous or premised on an improper claim construction, and therefore affirm the district court's judgment that Alvogen does not infringe the asserted claims of the '514 patent.

2. Watson's Appeal

We now consider Watson's infringement appeal. Watson makes two arguments in its appeal from the district court's judgment that Watson's ANDA product infringes the asserted claims of the '514 patent. *Watson Decision*, 2016 WL 3186659, at *21. First, Watson argues that the court erred in not granting Watson Rule 59 relief after the amendment of its ANDA. Second, Watson argues that the court erred in finding that its ANDA product meets the viscosity limitation of the asserted claims. We address each argument in turn.

Unlike DRL and Alvogen, Watson never requested construction of the drying limitation when it litigated the '514 patent against Indivior, although it joined DRL in arguing for the narrower construction of the similar limitation in the '497 patent. After the district court entered judgment of infringement, Watson amended its ANDA process to remove bottom heating sources. It then moved under Rule 59 to reopen the court's judgment.

The district court denied Rule 59 relief. *Rule 59 Decision*, 2017 WL 3820943, at *3. The court found no manifest injustice in holding Watson to its decision not to request construction of the drying limitation. *Id.* at *2. According

to the court, Watson knew of and in fact proposed the narrower construction of that limitation alongside DRL in its case concerning the '497 patent, yet never requested such a construction in Watson's own '514 patent case. *Id.* The court observed that the broader construction of the drying limitation potentially gave Watson a stronger invalidity position at the expense of noninfringement. *Id.* Additionally, the court decided that Watson was a sophisticated litigant that "should be bound by the litigation decisions [it] make[s]." *Id.*

On appeal, Watson argues that the district court abused its discretion in not reopening the judgment under Rule 59. Indivior responds that the court acted well within its discretion in denying Watson such relief.

We agree with Indivior that the district court did not abuse its discretion. While Rule 59 gives a court authority to alter or amend a judgment, that authority is exercised only in limited circumstances, such as to prevent a manifest injustice. *See United States ex rel. Schumann v. Astra-Zeneca Pharm. L.P.*, 769 F.3d 837, 848–49 (3d Cir. 2014). Watson argues that it is manifestly unjust that different generic products will be treated differently depending on how their cases were litigated. But it is neither unusual nor unjust for a party to be bound by its litigation decisions, particularly here where Watson was fully aware of but did not request the claim construction it now seeks. The district court found that, while there is an interest in consistency across judgments, there is also a public interest in finality and judicial efficiency, *Rule 59 Decision*, 2017 WL 3820943, at *2, and we discern no abuse of discretion in the court's balancing of those factors in this particular case. Furthermore, Watson acknowledges that it can still seek a judgment of noninfringement based on the amended ANDA process even if it fails to secure Rule 59 relief. Under these circumstances, we conclude that the court acted within its discretion in declining to reopen its judgment based on a

claim construction argument that Watson knew of yet failed to raise.

Watson separately argues that the district court clearly erred in finding that Watson's ANDA product meets the viscosity limitation of the '514 patent claims. The court found that the viscosity range of Watson's product was within the preferred range disclosed in the '514 patent and thus was "sufficient to aid" in preventing aggregation of the active, as required by the viscosity limitation. *Watson Decision*, 2016 WL 3186659, at *20.

Watson argues that Indivior failed to show that viscosity contributes to the uniformity of Watson's films and that the district court improperly placed the burden on Watson to prove noninfringement. Further, Watson emphasizes the breadth of the preferred viscosity range and that no particular viscosity value can guarantee uniformity.

Indivior responds that the district court did not clearly err in finding that Watson's ANDA product meets the viscosity limitation because the ANDA requires a viscosity squarely within the most preferred range identified in the '514 patent.

We agree with Indivior and conclude that the district court did not clearly err in finding infringement. The viscosity limitation requires that the viscosity of the matrix be "sufficient to aid" in maintaining uniformity. '514 patent col. 73 ll. 53–55. As both parties agree, viscosity is one factor among several identified in the '514 patent that contributes to uniformity. *E.g.*, *id.* col. 23 ll. 14–20. Specifically, the patent explains that "[v]iscosity is one property of a liquid that controls the stability of the active" and that the viscosity of the matrix will "generally" be 400–100,000 centipoise, "preferably" be 800–60,000 centipoise, and "most preferably" be 1,000–40,000 centipoise. *Id.* col. 11 ll. 24–29. Watson's ANDA specifies a viscosity of 5,800–17,500 centipoise, J.A. 80020, 12578, which is, as the court correctly found, plainly encompassed by the most preferred

range disclosed in the '514 patent. Further, the court did not clearly err in finding that a film may satisfy the viscosity limitation even if other factors than viscosity contribute to film uniformity. *Watson Decision*, 2016 WL 3186659, at *20. As previously discussed, the asserted claims themselves identify drying as an additional factor affecting uniformity. Since Watson demonstrates no clear error in the court's infringement judgment, we affirm its finding that Watson's ANDA product infringes the '514 patent.

B. Validity of the '514 Patent

Watson, Teva, and DRL raise two challenges to the validity of the '514 patent. Watson and Teva appeal from the court's judgment that the asserted claims of the '514 patent are not invalid as indefinite. DRL appeals from the court's judgment that the claims have not been shown to be invalid as obvious. We consider the challenges separately.

1. Indefiniteness

A patent must "conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (2006).[7] Because of the statute's demand for particularity in claiming, "a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention." *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898, 901 (2014).

We review a district court's indefiniteness judgment as we do its claim construction, *Sonix Tech. Co. v. Publ'ns*

[7] Because the application of the '514 patent was filed before March 16, 2013, the pre-Leahy-Smith America Invents Act version of § 112 applies. *See* Pub. L. No. 112-29, 125 Stat. 284 (2011).

Int'l, Ltd., 844 F.3d 1370, 1376 (Fed. Cir. 2017), which in this case is *de novo*.

At the district court, the parties' indefiniteness dispute focused on claim 62's recitation of a "cast film comprising a flowable water-soluble or water swellable film-forming matrix." '514 patent col. 73 ll. 49–50. Watson alleged that this limitation is indefinite because a cast film in its final dosage form is not flowable, and the claim thus required a physical impossibility. While the court agreed that the final cast film could not be flowable, it reasoned that a product claim may recite elements "in the state in which they exist during manufacture, before the final product exists." *Watson Decision*, 2016 WL 3186659, at *15–16. And because the intrinsic evidence made clear that the cast film was made from a matrix that was flowable only before drying, the court concluded that the defendants failed to prove that the claims were indefinite. *Id.* at *16.

On appeal, Watson and Teva argue that the claims recite a physical impossibility—a flowable yet solid cast film—and are therefore indefinite. Indivior responds that the claims, understood in light of the specification, clearly recite a matrix that is flowable only before drying.

We agree with Indivior that the claim is not indefinite. The only sensible reading of the claim is that the cast film is made from a matrix that is flowable before drying and is not simultaneously dry and flowable. For example, the matrix as claimed has a viscosity, which is a property of fluids, not solids. And the matrix is "capable of being dried," which would be redundant if the matrix is already dried. The specification similarly explains that the wet matrix is "formed into a film . . . and then dried." '514 patent col. 25 ll. 27–28. The claims and specification thus make quite clear that the flowable matrix is first flowable and then dried.

Having no support in the patent itself, Watson and Teva essentially rest on the argument that a product claim

"comprising" certain elements must contain those elements simultaneously. But the district court properly rejected this position based on our precedent. For example, in *Gemtron Corp. v. Saint-Gobain Corp.*, 572 F.3d 1371, 1375–76 (Fed. Cir. 2009), the patentee claimed a refrigerator shelf "comprising" a lower wall having a certain resilience. Since the specification made clear that the resilience only referred to resilience *during assembly*, we held that the lower wall only required that property during assembly. *Id.* at 1378–79, 1380–81. The '514 patent likewise makes clear that the matrix is flowable only at a certain time—before drying. The word "comprising" in isolation does not sustain Watson and Teva's nonsensical interpretation of a flowable dried film that is contrary to both the specification and the claim language. We thus affirm the district court's judgment that the '514 patent has not been shown to be invalid as indefinite.

2. Obviousness

We now consider DRL's appeal from the district court's judgment of nonobviousness. Obviousness is a question of law based on underlying facts, including the scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill, and relevant evidence of secondary considerations. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17–18 (1966). A patent is presumed valid, and overcoming that presumption at the district court requires clear and convincing evidence. *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011); *Ferring B.V. v. Watson Labs., Inc.-Fla.*, 764 F.3d 1401, 1407 (Fed. Cir. 2014).

In its analysis of the *Graham* factors, the district court found that a person of ordinary skill would principally have a background in pharmaceutical science or chemistry but "would also be a member of a team, which would include an engineer or scientist with one to three years of relevant experience manufacturing and optimizing various types of

film products using coating and drying processes." *DRL '514 Decision*, 2017 WL 3837312, at *15. In reaching this determination, the court found some merit both in Indivior's argument that the pharmaceutical film field was nascent around the time of invention and in DRL's argument that a person of ordinary skill would have some knowledge relating to coating and drying films. *Id.*

Turning to the prior art, the district court generally found that there was limited use of top air convection dryers in the context of pharmaceutical films at the time of invention. *Id.* at *16. The court also observed that there were differences between pharmaceutical and non-pharmaceutical films, citing in particular the more demanding FDA requirements for drug content uniformity in pharmaceuticals. *Id.*

DRL asserted that the claims were obvious over U.S. Patents 4,849,246 ("Schmidt"), 6,552,024 ("Chen"), and 5,881,476 ("Strobush"). The district court made findings on the teachings of the prior art, which we summarize below.

Schmidt disclosed processes for making pharmaceutical films. Schmidt's films were made through a roll-coating process with temperature-controlled rollers and a drying tunnel that was controllable in sections. *DRL '514 Decision*, 2017 WL 3837312, at *16. Schmidt also disclosed that there was a regulatory requirement for drug content uniformity and that its processes yielded films with a reproducible weight that varied within 10%. *Id.* at *17. However, the district court found that Schmidt did not examine the uniformity of the film after drying, crediting Indivior's expert's testimony. *Id.*

Chen taught pharmaceutical films made by a casting process and a drying oven that included top air drying nozzles and that had controllable temperature and air speed. *Id.* Chen further discussed a human pharmacokinetic study conducted with its films. *Id.* at *18.

Strobush disclosed a method for drying photographic and other non-pharmaceutical films without introducing a surface defect called "mottle." *Id.* at *16. As Strobush was not directed to pharmaceutical films, it did not address drug content uniformity. *Id.*

The key dispute between the parties was whether the prior art's teachings would motivate a skilled artisan to make a uniform pharmaceutical film according to the claimed invention with a reasonable expectation of success. The district court found that Schmidt did not directly measure drug content uniformity and only indirectly measured uniformity before drying. *Id.* at *17. Further, the court cited a subsequent peer-reviewed article indicating that Schmidt's process did not produce uniform films. *Id.* The court thus found that Schmidt did not disclose how to achieve drug content uniformity. *Id.*

Turning to Chen, the district court found that the reference disclosed a human study using its films, which implicitly suggested that the films had uniform drug content. *Id.* at *18. However, the court noted that Chen did not disclose that its films had the requisite uniformity and that the defendants' expert failed to produce uniform films using Chen's protocol. *Id.* In light of this conflicting evidence, the court found that DRL failed to prove that Chen achieved drug content uniformity. *Id.*

Given the nascent status of pharmaceutical films at the time of invention and the limited knowledge of drying techniques, the district court additionally found that a person of ordinary skill would not have been motivated to combine the prior art to achieve uniformity. *Id.* at *18. Moreover, the court found that a skilled artisan would not have been motivated to combine Schmidt and Chen with the techniques in Strobush because Strobush did not address pharmaceutical films or film uniformity, but rather the surface defect called mottle. *Id.*

Finally, the district court found that secondary considerations supported nonobviousness. The court considered evidence that obtaining pharmaceutical film content uniformity was a long-felt need yet difficult to achieve, and the court gave some credit to Aquestive's work related to the '514 patent in solving that need. *Id.* at *19. That credit was supported by several pieces of evidence. First, it was undisputed that Aquestive was the first to receive FDA approval for a pharmaceutical film. *Id.* Second, several papers cited the inventors' work for demonstrating the value and viability of pharmaceutical films. *Id.* Third, DRL itself prepared an internal memorandum recognizing an Aquestive patent application that "yields uniform distribution of active," "the advantageous factor which was not appreciated by the prior arts." *Id.* The court considered that the praise did not specifically address the patents in suit and sometimes credited others as well, but the court nonetheless gave the evidence some weight because it referred to the claimed technology. *Id.* at *20.

Considering all the evidence, the district court held that DRL failed to prove by clear and convincing evidence that the asserted claims of the '514 patent would have been obvious. *Id.*.

On appeal, DRL challenges several of the district court's factual findings. First, DRL argues that the court clearly erred in finding the level of ordinary skill. Second, DRL alleges that the court clearly erred in finding that Schmidt and Chen do not teach drug content uniformity. Third, DRL argues that the court clearly erred in dismissing the teachings of Strobush. DRL also contends that secondary considerations do not compel nonobviousness.

Indivior responds that the district court did not clearly err in its factual findings and that secondary considerations support nonobviousness.

We agree with Indivior that the district court did not clearly err in its factual findings or in its ultimate

judgment of nonobviousness. First, we see no clear error in the court adopting a compromise measure of the level of ordinary skill. Although the court found that the field of pharmaceutical films was just emerging at the time of invention, it also found "merit to [DRL's] argument that one of ordinary skill would have a degree of access to some of the body of prior-art knowledge relating to coating and drying." *Id.* at *15. Consequently, the court found that a person of ordinary skill would be on a team with an engineer or scientist with experience in manufacturing films. *Id.* DRL argues that the court clearly erred in settling on the particular amount of experience: 1–3 years according to the court, while DRL preferred 5–10 years. For its part, Indivior's expert testified that a skilled artisan would have a lower amount of experience with films since the pharmaceutical film field was young and that, in his nearly 40 years of experience, he had never seen a team assembled with the experience suggested by DRL. On this record, we conclude that DRL's nitpicking over the experience level of the skilled artisan fails to demonstrate clear error.

Next, we conclude that the district court did not clearly err in finding that Schmidt did not disclose uniform dried films according to the claimed invention. As properly construed, claim 62 requires a specific type of drying, *i.e.*, without solely top air drying, to achieve a specific uniformity "subsequent to casting and drying." Schmidt disclosed neither limitation. Indeed, DRL does not dispute that Schmidt only disclosed a uniform wet film. The court thus did not clearly err in relying on Indivior's expert's testimony that since film uniformity could be lost at the drying step, a uniform wet film does not disclose the claimed uniform *dried* films.

We conclude likewise with respect to Chen. While the human study disclosed in Chen implicitly suggested that the films were uniform, Chen's actual discussion of uniformity involved films lacking an active compound, J.A. 70211–12, and the defendants' expert failed to produce

uniform films using Chen's method, *DRL '514 Decision*, 2017 WL 3837312, at *17–18. The district court did not clearly err in its weighing of this evidence, some of which supported DRL's position and some of which went against it.

Having found that neither Schmidt nor Chen taught the post-drying uniform films as claimed in the '514 patent, the district court also found that a skilled artisan would not have been motivated to modify either reference in light of Strobush with a reasonable expectation of success. *Id.* at *18–19. DRL argues that this was also clear error. We disagree. Strobush did not address the uniformity of either pharmaceutical films or non-pharmaceutical films, but rather a surface defect called mottle. Mottle may relate to uniformity, but they are different properties. The court credited Indivior's expert, who testified that lack of mottle would not imply that the film was uniform, *id.* at *18, and DRL points to no clear error in that finding. Further, while DRL emphasizes that Strobush taught bottom-drying, it does not point us to any recognition in Strobush that bottom-drying had any particularly advantageous features. While the motivation of the skilled artisan need not be the same as that of the patentee, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007), DRL's proffered motivation is too tenuous. We conclude that the district court did not clearly err in finding that a skilled artisan would not have been motivated to make a bottom-dried uniform pharmaceutical film based on a teaching that was not emphasized in any meaningful way from a reference in a different field addressing a different problem.

That finding is further supported by the court's determination that a skilled artisan would not have had a reasonable expectation of success. *DRL '514 Decision*, 2017 WL 3837312, at *19. In contrast to a "finite number of identified, predictable solutions," *KSR*, 550 U.S. at 421, the court found that multiple factors throughout the manufacturing process contribute to the uniformity of

pharmaceutical films, that adjusting the various factors would have been unintuitive, and that the field was still emergent at the time of invention. *DRL '514 Decision*, 2017 WL 3837312, at *19. We also see no clear error in those findings.

We last consider DRL's challenge to the district court's evaluation of the evidence of secondary considerations. "[E]vidence of secondary considerations may often be the most probative and cogent evidence in the record. It may often establish that an invention appearing to have been obvious in light of the prior art was not." *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983). Aquestive was the first to receive FDA approval for a pharmaceutical film and received praise for its work in achieving uniform films, including by DRL itself. Having considered DRL's arguments, we conclude that the court did not clearly err in giving some weight to Indivior's evidence.

Because we conclude that DRL has not shown clear error in the court's findings, we affirm the district court's judgment that the asserted claims of the '514 patent, as properly construed, would not have been obvious. As DRL has not argued the '497 patent separately, we affirm the court's nonobviousness judgment with respect to that patent as well.

C. Infringement of the '150 Patent

We turn to the parties' appeals concerning the '150 patent, beginning with Indivior's appeal from the district court's judgment that DRL does not infringe the asserted claims of the '150 patent. *DRL '150 Decision*, 2017 WL 3782782, at *1, *5. Claim 1 recites that the film includes a hydrophilic cellulosic polymer ("HCP"). DRL substituted polyvinyl pyrrolidone ("PVP") for HCP in its ANDA product. *Id.* at *3. Indivior argued that DRL's product infringed under the doctrine of equivalents.

The district court held that DRL's product does not infringe under the doctrine of equivalents because the '150 patent disclosed PVP as an alternative to HCP but did not claim it, thereby dedicating it to the public. *Id.* at *4–5.

Indivior argues that the district court erred in concluding that the disclosure-dedication rule applied. DRL disagrees and contends that the district court's analysis and judgment were correct.

We agree with DRL that the disclosure-dedication rule applies here and that the district court correctly found that DRL's product does not infringe under the doctrine of equivalents. When a patentee discloses subject matter but does not claim it, the patentee dedicates the unclaimed subject matter to the public and cannot recapture it through the doctrine of equivalents. *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc). The rule descends from the essential notice function of claims. As the Supreme Court long ago explained, "[t]he public is notified and informed, by the most solemn act on the part of the patentee, that his claim to invention is for such and such an element or combination, and for nothing more." *Mahn v. Harwood*, 112 U.S. 354, 361 (1884).

Here, the patentee claimed a film comprising a polymer component made up of PEO and HCP but disclosed "useful water[-]soluble polymers," including both HCP and other polymers such as PVP. '150 patent col. 15 ll. 44–60. The specification further describes examples of successful films using polymeric blends of PEO and PVP without HCP. *Id.* col. 51 l. 49–col. 52 l. 36 (example EA); *see also id.* col. 54 l. 51–col. 55 l. 11 (examples EI, EJ). These disclosures teach that PVP, an unclaimed embodiment, is an alternative to HCP and thus is dedicated to the public and cannot be recaptured through the doctrine of equivalents. *See Johnson & Johnston*, 285 F.3d at 1054. We affirm the district court's judgment that DRL's ANDA product, which

contains PVP but not HCP, does not infringe the asserted claims of the '150 patent.

D. Validity of '150 Patent

DRL alleges that the '150 patent is invalid as obvious. Its challenge to the district court's judgment of nonobviousness focuses solely on whether the '150 patent may properly claim priority from the earlier '902 application. The priority question turns on whether the '902 application provides an adequate written description of the claims of the '150 patent. *See Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1571–72 (Fed. Cir. 1997). Under 35 U.S.C. § 112, "[t]he specification shall contain a written description of the invention." The test for adequate written description "is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc). The disclosure must demonstrate that the patentee truly invented the subject matter encompassed by the claims. Whether a claim satisfies the written description requirement is a question of fact. *Id.*.

As relevant to this issue, claim 1 of the '150 patent recites a pharmaceutical film with: (1) "at least one water-soluble polymer component consisting of [PEO] in combination with a[n] [HCP]"; wherein (2) "the water-soluble polymer component comprises greater than 75% [PEO] and up to 25% [HCP]"; (3) the PEO comprises at least one L-PEO and at least one H-PEO; and (4) the L-PEO "comprises about 60% or more in the polymer component." '150 patent col. 57 ll. 35–54.

The district court held that the '150 patent properly claimed priority from the '902 application. In making that determination, the court relied primarily on the following passage from the '902 application:

> For instance, certain film properties, such as fast dissolution rates and high tear resistance, may be attained by combining small amounts of high molecular weight PEOs with larger amounts of lower molecular weight PE[O]s. Desirably, such compositions contain about 60% or greater levels of the lower molecular weight PEO in the PEO-blend *polymer component*.
>
> To balance the properties of adhesion prevention, fast dissolution rate, and good tear resistance, desirable film compositions may include about 50% to 75% low molecular weight PEO, optionally combined with a small amount of a high molecular weight PEO, with the remainder of the *polymer component* containing a hydrophilic cellulosic polymer (HPC or HPMC).

DRL '150 Decision, 2017 WL 3782782, at *6 (emphases added) (quoting J.A. 70035). The court interpreted the term "polymer component" to refer to all polymers in the formulation, including L-PEO, H-PEO, and any HCP. *Id.* Together with example formulations listed in the '902 application, the court found that this passage provided adequate support for the '150 patent's priority claim. *Id.* at *6.

On appeal, DRL argues that the district court clearly erred in finding that the '902 application provided written description support for the asserted claims of the '150 patent. According to DRL, the '902 application fails to describe the claimed composition with the specificity of the '150 patent claims.

Indivior responds that the '902 application reasonably conveys to a skilled artisan that the inventor invented and disclosed the claimed films as of the application's filing date.

We agree with Indivior that the district court did not clearly err in finding that the '902 application provides

adequate written description support for the asserted claims of the '150 patent. To obtain certain desirable film properties, the '902 application recommends that films should combine small amounts of H-PEO with larger amounts of L-PEO, and desirably the films should have at least 60% L-PEO "in the PEO-blend polymer component." J.A. 70035. Considering a broader set of properties, the application prescribes 50–75% L-PEO with the balance of the "polymer component" being H-PEO and HCP. *Id.* The application also discloses multiple example formulations with varying levels of L-PEO, H-PEO, and HCP. The court did not clearly err in finding that these disclosures would convey to a skilled artisan the claimed films with a polymer component containing at least 75% PEO, at least 60% L-PEO, some H-PEO, and up to 25% HCP.

Addressing only the examples, DRL argues that no embodiment disclosed in the '902 application has the precise combination of L-PEO, H-PEO, and HCP claimed in the '150 patent. It analogizes this case to *Purdue Pharma L.P. v. Faulding Inc.*, 230 F.3d 1320 (Fed. Cir. 2000). There, we considered a claim to a formulation characterized by a certain sustained release ratio. *Id.* at 1322–23. However, the specification never indicated that the ratio was "an important defining quality of the formulation, nor d[id] the disclosure even motivate one to calculate the ratio." *Id.* at 1327. By claiming a characteristic of the formulation that was "not discussed even in passing in the disclosure," the patentee ran afoul of the written description requirement, and we thus affirmed the district court's judgment of invalidity. *Id.* at 1327, 1329. Here, however, the '902 application does direct a skilled artisan to the claimed polymer component. Consistent with the '150 patent claims, the application discloses that a polymer component with 60% L-PEO has desirable properties and that the remainder of the component may include H-PEO and HCP. The district court did not clearly err in finding that these disclosures supported the '150 patent claims.

DRL suggests that the '902 application does not disclose that the polymer component comprises 60% L-PEO because the application in the relevant sentence refers only to the "*PEO-blend* polymer component" comprising 60% L-PEO. DRL Appellant Br. 56–57 (emphasis added). DRL indicates that the "PEO-blend polymer component" includes only PEO and not an HCP. But it provides no evidence or reasoning in support of that interpretation, and the application's disclosure is to the contrary. For each example formulation including an HCP, percentages for L-PEO and H-PEO are shown for the entire polymer component, and never for just the PEO part. J.A. 70085. We think "PEO-blend polymer component" simply refers to a polymer component containing a PEO blend and is not exclusive of other ingredients. Accordingly, we conclude that the district court did not clearly err in interpreting "polymer component" to consistently include all the polymers in the formulation.

In sum, the '902 application discloses films with varying amounts of L-PEO, H-PEO, and HCP, describes films with 60% L-PEO as having desirable properties, and states that the remainder of the polymer component apart from L-PEO may include H-PEO and HCP. This disclosure of the '902 application reasonably conveyed to a skilled artisan the films claimed in the '150 patent. The specification need not recite the claimed invention *in haec verba*. *Ariad*, 598 F.3d at 1352. We affirm the district court's holding that the '150 patent is entitled to the priority date of the '902 application. As DRL makes no other challenge to the court's judgment of nonobviousness, we affirm that holding as well.

E. Validity of '832 Patent

We last address Indivior's challenge to the district court's judgment that claims 15–19 are invalid as obvious. *Watson Decision*, 2016 WL 3186659, at *11. In a parallel *inter partes* review proceeding, the Patent Trial and Appeal

Board held claims 15–19 unpatentable as anticipated and obvious, *BioDelivery*, 2015 WL 4045328, at *16, which we affirmed, 667 F. App'x 997 (Fed. Cir. 2016). Indivior argues that the Board's unpatentability decision and our subsequent affirmance moot the parties' dispute over the validity of claims 15–19 and requests vacatur of the district court's judgment of invalidity. No party raises any objection to vacatur.

Indivior argues that, "in general, when a claim is cancelled, the patentee loses any cause of action based on that claim, and any pending litigation in which the claims are asserted becomes moot." Indivior Cross-Appellant Br. 89 (quoting *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013)). We agree that the Board's decision and our affirmance mooted any dispute over the district court's decision regarding claims 15–19 of the '832 patent. We also agree that vacatur is proper because mootness was not caused by Indivior's voluntary action. *See U.S. Bancorp Mortg. Co. v. Bonner Mall P'ship*, 513 U.S. 18, 24–25 (1994). Indeed, Indivior opposed the *inter partes* review, appealed the decision, and sought review *en banc*. No party contends on appeal that vacatur would be inappropriate in these circumstances.

CONCLUSION

We have considered the parties' remaining arguments but find them unpersuasive. For the foregoing reasons, we affirm the district court's judgments that DRL and Alvogen do not infringe the '514 patent, that Watson does infringe the '514 patent, and that Watson, Teva, and DRL failed to prove that the '514 patent is invalid. We likewise affirm the court's judgment that DRL does not infringe the '150 patent, and that DRL failed to prove that the '150 patent is invalid. We vacate the court's decision that claims 15–19 of the '832 patent are invalid as obvious.

AFFIRMED-IN-PART, VACATED-IN-PART

COSTS

No costs.

APPENDIX

'514 Patent Claim 62

> 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 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 (emphasis added).

'150 Patent Claim 1

> 1. A mucosally-adhesive water-soluble film product comprising:

> an analgesic opiate pharmaceutical active; and
>
> at least one water-soluble polymer component consisting of polyethylene oxide in combination with a hydrophilic cellulosic polymer;
>
> wherein:
>
> the water-soluble polymer component comprises greater than 75% polyethylene oxide and up to 25% hydrophilic cellulosic polymer;
>
> the polyethylene oxide comprises one or more low molecular weight polyethylene oxides and one or more higher molecular weight polyethylene oxides, the molecular weight of the low molecular weight polyethylene oxide being in the range 100,000 to 300,000 and the molecular weight of the higher molecular weight polyethylene oxide being in the range 600,000 to 900,000; and
>
> the polyethylene oxide of low molecular weight comprises about 60% or more in the polymer component.

'150 patent col. 57 ll. 37–54.

United States Court of Appeals for the Federal Circuit

INDIVIOR INC., FKA RECKITT BENCKISER PHARMACEUTICALS INC., INDIVIOR UK LIMITED, FKA RB PHARMACEUTICALS LIMITED, AQUESTIVE THERAPEUTICS, INC., FKA MONOSOL RX, LLC,
Plaintiffs-Cross-Appellants

v.

DR. REDDY'S LABORATORIES, S.A., DR. REDDY'S LABORATORIES INC., WATSON LABORATORIES INC., ACTAVIS LABORATORIES UT, INC., TEVA PHARMACEUTICALS USA, INC.,
Defendants-Appellants

PAR PHARMACEUTICAL, INC., INTELGENX TECHNOLOGIES CORP.,
Defendants

2017-2587, 2018-1010, 2018-1058, 2018-1062, 2018-1114, 2018-1115, 2018-1176, 2018-1177

Appeals from the United States District Court for the District of Delaware in Nos. 1:13-cv-01674-RGA, 1:14-cv-00422-RGA, 1:14-cv-01451-RGA, 1:14-cv-01574-RGA, 1:16-cv-00178-RGA, Judge Richard G. Andrews.

INDIVIOR INC., FKA RECKITT BENCKISER PHARMACEUTICALS INC., INDIVIOR UK LIMITED, FKA RB PHARMACEUTICALS LIMITED, AQUESTIVE THERAPEUTICS, INC.,
Plaintiffs-Appellants

v.

ALVOGEN PINE BROOK, LLC,
Defendant-Cross-Appellant

2018-1949, 2018-2045

Appeals from the United States District Court for the District of Delaware in Nos. 1:15-cv-00477-RGA, 1:15-cv-01016-RGA, Judge Richard G. Andrews.

MAYER, *Circuit Judge*, dissenting.

There is no need for this court to reach the issue of infringement because the three patents—U.S. Patent Nos. 8,017,150 B2 (the "'150 patent"), 8,603,514 B2 (the "'514 patent"), and 8,900,497 B2 (the "'497 patent")—asserted by Indivior Inc., Indivior UK Limited, and Aquestive Therapeutics, Inc. (collectively, "Indivior") are invalid as obvious. I therefore respectfully dissent.

I. Invalidity of the '497 and '514 Patents

Indivior's '497 and '514 patents are directed to sublingual films for delivering active ingredients. *See* J.A. 334–51, 412–25. According to Indivior, its patents provide a novel solution for attaining the active ingredient uniformity required in pharmaceutical films. Cross-Appellants' Br. 55–62. To the contrary, however, long before the priority dates of Indivior's patents, multiple prior art

references taught both methods to manufacture sublingual films and techniques for achieving film content uniformity.

The earliest possible priority date for the '497 and '514 patents is October 2001. *See* J.A. 170. For well over a decade prior to this date, others had achieved uniform distribution of active ingredients on mucosally-administered films. U.S. Patent No. 4,849,246 ("Schmidt"), for example, recognized that "hitherto known proposals" for producing drug delivery films had been unable to achieve the drug content uniformity required by regulators. J.A. 70217 (1:60). Schmidt explained that with his claimed invention, which used a roll-coating method, "[t]he reproducible constant weight [was] only +/-2.5% for 20 g/m² and approximately +/-10% for 1 g/m² over [the] entire surface." J.A. 70219 (6:1–3). Schmidt further taught that by roll-coating with a "doctor blade," it was "possible to achieve a weight tolerance per surface unit down to +/-1%." J.A. 70219 (6:37–42).

Schmidt focused on the importance of viscosity in achieving uniformity, explaining that "[c]oating materials with . . . a viscosity of approximately 30 to 10,000 cPs ha[d] proved particularly satisfactory" in ensuring "uniform active ingredient content." J.A. 70218 (4:50–59). Indeed, Schmidt specifically taught that by making the viscosity of a wet matrix sufficiently thick, one could successfully inhibit the movement of particles during the time it takes to dry the coated film. J.A. 70218 (4:20–59).

U.S. Patent No. 6,552,024 B1 ("Chen") likewise taught how to obtain uniform distribution of pharmacological active ingredients on a film. *See* J.A. 70210 (9:20–27), 70211 (11:7–15, 12:1–28). Specifically, Chen disclosed a process for making mucoadhesive oral thin films, explaining that after mixing and degassing the ingredients, "[t]he formulation [i]s then coated on the non-siliconized side of a polyester film at a wet thickness of 10 [millimeters] and dried in a hot air circulating oven at 50° [Celsius] for 9 minutes."

J.A. 70211 (12:12–15). Notably, moreover, U.S. Patent No. 5,881,476 ("Strobush") disclosed drying a film from the bottom, *see* J.A. 70241 (9:44–51), and explained that the claimed method could be used to avoid introducing "mottle" into the final film product, J.A. 70239 (6:26).

Indivior's efforts to evade the overwhelming evidence of obviousness are unavailing. Indivior first argues that Schmidt does not disclose a film having the drug content uniformity required by the '514 patent. *See* Cross-Appellants' Br. 57. In support, it contends that Schmidt only teaches creating films with uniform weight, not with uniform active drug content. This argument is wholly without merit. On its face, Schmidt asserts that the methods it discloses can be used to create films meeting the uniformity requirements for the active ingredient of a drug. *See* J.A. 70217 (1:59–2:47). Schmidt specifically explains that the prior art was not able to achieve the requisite "uniform active ingredient distribution," J.A. 70217 (1:62), but that the claimed invention does not suffer from the same "disadvantage[]," J.A. 70217 (2:14–15).

Indivior suggests that Schmidt only measured weight uniformity rather than drug content uniformity. Cross-Appellants' Br. 57; *see ante* at 29. This argument falls flat, however, given that Indivior's own patents acknowledge that weight uniformity is a proxy for active ingredient uniformity:

> The additive weights of eight randomly selected dosage forms . . . are as shown in Table 2 below. . . . The individual dosages were consistently 0.04 gm, which shows that the distribution of the components within the film was consistent and uniform. This is based on the simple princip[le] that each component has a unique density. Therefore, when the components of different densities are combined in a uniform manner in a film, as in the present invention, individual dosage[] forms from the same

> film of substantially equally dimensions[] will contain the same mass. J.A. 353 (41:50–42:33).

Indivior also complains that even if Schmidt teaches how to create a uniform wet matrix, it does not teach how to maintain uniformity during the drying process. Cross-Appellants Br. 57; *see ante* at 29–32. But Strobush teaches the precise bottom drying methods that the '497 and '514 patents rely upon to achieve uniform dried films. *See* J.A. 70239 (6:24–27) (teaching high-speed drying), 70241 (9:44–51) (describing an embodiment which uses "air foils . . . located below the coated substrate" to dry from the bottom).

According to Indivior, a skilled artisan would not have turned to Strobush's bottom drying method because Strobush addresses "mottle," which is a surface defect, rather than drug content uniformity. Cross-Appellants Br. 57; *see ante* at 32. To the contrary, however, Strobush defines "mottle" as "an irregular pattern *or non-uniform density defect*." J.A. 70237 (1:59–60) (emphasis added). Given that "mottle" is defined as a non-uniform density defect, a skilled artisan would certainly have appreciated that a drying technique that reduces mottle could also be employed to reduce non-uniformity.

All the elements recited in the challenged claims of Indivior's '497 and '514 patents are explicitly disclosed in the prior art. Even if they were not, however, obviousness and anticipation are different beasts. While anticipation requires that a single prior art reference disclose each and every element of the claimed invention, *see, e.g.*, *In re Smith Int'l, Inc.*, 871 F.3d 1375, 1381 (Fed. Cir. 2017), obviousness demands a more "expansive and flexible approach," *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 415 (2007). In evaluating obviousness, the pertinent perspective is that of an artisan endowed not only with "ordinary skill" and "ordinary creativity," but also with the capacity to recognize and deploy "predictable solutions" to well-known problems. *Id.* at 421; *see also Randall Mfg. v. Rea*,

733 F.3d 1355, 1362 (Fed. Cir. 2013) ("In *KSR*, the Supreme Court criticized a rigid approach to determining obviousness based on the disclosures of individual prior-art references, with little recourse to the knowledge, creativity, and common sense that an ordinarily skilled artisan would have brought to bear when considering combinations or modifications.").

Here, given that Schmidt teaches uniform active ingredient distribution, J.A. 70217, the only real dispute on the obviousness question is whether a skilled artisan would have been motivated to dry films from the bottom rather than from the top, as explicitly disclosed in Strobush, J.A. 70241 (9:44–51). At the time of the purported invention described in the '497 and '514 patents, it was well-recognized that conventional drying methods—which shot hot air from the top of a drying oven—resulted in films that were overly dry and rippled, i.e., "overcooked," on top and wet, i.e., "undercooked," on the bottom. *See* J.A. 334 (3:33–57), 346–47 (28:58–29:1). The district court determined that a person of ordinary skill "would possess a bachelor's degree in pharmaceutical science, chemistry, or a related field, plus two to five years of relevant experience in developing drug formulations" and "would also be a member of a team, which would include an engineer or scientist with one to three years of relevant experience manufacturing and optimizing various types of film products using coating and drying processes." J.A. 169. There can be no dispute that such a person would have readily recognized that switching the location of the heat source from the top to the bottom would likely ameliorate the problem of films that were overly dry on the top and overly wet on the bottom. Indeed, any person having basic familiarity with a kitchen oven would certainly appreciate that, since hot air rises, heating an item from the bottom rather than the top facilitates uniform baking. *See KSR*, 550 U.S. at 419 (explaining that "[g]ranting patent protection to advances that would occur in the ordinary course without real innovation

retards progress"); *id.* at 421 (stating that "[r]igid preventative rules that deny factfinders recourse to common sense" have no place in the obviousness analysis).

II. Invalidity of the '150 Patent

Indivior's '150 patent is likewise invalid as obvious. The district court erred in concluding that the '150 patent can claim priority to the 2003 filing date of its parent application, U.S. Patent Application No. 60/473,902 (the "'902 application"). *See* J.A. 198. To obtain the benefit of a parent application's filing date, "the claims of the later-filed application must be supported by the written description in the parent in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought." *Anascape, Ltd. v. Nintendo of Am., Inc.*, 601 F.3d 1333, 1335 (Fed. Cir. 2010) (internal quotation marks omitted). In this regard, "[e]ntitlement to a filing date extends only to subject matter that is disclosed; not to that which is obvious." *Research Corp. Techs., Inc. v. Microsoft Corp.*, 627 F.3d 859, 870 (Fed. Cir. 2010). Accordingly, "the parent application must actually or inherently disclose the elements of the later-filed claims." *Id.*; *see also PowerOasis, Inc. v. T–Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008).

The '150 patent is not entitled to rely on the priority date of the '902 application because that application nowhere conveys possession of the specific polymer component recited in independent claim 1. That claim requires low molecular weight polyethylene oxide ("PEO"), high molecular weight PEO, and a hydrophilic cellulosic polymer ("HCP"), and further specifies that the low molecular weight PEO must be at least 60% of the polymer component and that the HCP can be no more than 25% of the polymer component. J.A. 279 (57:36–54). The '902 application, however, does not suggest possession of a polymer component including at least 60% low molecular weight PEO and at most 25% HCP. Indeed, as the district court

correctly acknowledged, the '902 application provides over *ninety* examples, and yet not one of them satisfies the limitations of claim 1. *See* J.A. 197.

In concluding that the '902 application supplied adequate written description support for claim 1, the district court relied primarily upon the following passage:

> For instance, certain film properties, such as fast dissolution rates and high tear resistance, may be attained by combining small amounts of high molecular weight PEOs with larger amounts of lower molecular weight PEOs. Desirably, such compositions contain about 60% or greater levels of the lower molecular weight PEO in the PEO-blend polymer component.
>
> To balance the properties of adhesion prevention, fast dissolution rate, and good tear resistance, desirable film compositions may include about 50% to 75% low molecular weight PEO, optionally combined with a small amount of a higher molecular weight PEO, with the remainder of the polymer component containing a[n] [HCP]. J.A. 70035.

On its face, however, this passage contradicts the court's reading. As discussed above, claim 1 requires that the low molecular weight PEO constitute "about 60% or more [of] the polymer component," J.A. 279 (57:54), but the passage relied upon by the district court states that the low molecular weight PEO can be as low as 50% of the polymer component. J.A. 70035. This passage further states that "[d]esirably" there should be "60% or greater levels of the lower molecular weight PEO in the PEO-blend polymer component," i.e., there should be at least 60% low molecular weight PEO in the blend of high and low molecular weight PEO. J.A. 70035. Importantly, however, requiring 60% or more low molecular weight PEO in the "PEO-blend polymer component" is very different from requiring 60% or more low molecular weight PEO in the component

consisting of low molecular weight PEO, high molecular weight PEO, *and HCP* as claim 1 requires. Even more fundamentally, the passage relied upon by the district court says nothing about claim 1's mandate that the HCP can be no more than 25% of the polymer component.

"Requiring a written description of the invention limits patent protection to those who actually perform the difficult work of 'invention'—that is, conceive of the complete and final invention with all its claimed limitations—and disclose the fruits of that effort to the public." *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1353 (Fed. Cir. 2010) (en banc). Nothing in the '902 application even arguably suggests possession of a polymer component including at least 60% low molecular weight PEO and at most 25% HCP as required by claim 1. Because the district court erred in concluding that Indivior was entitled to rely on the 2003 priority date of the '902 application, the asserted claims of the '150 patent are invalid as obvious.