U.S. Court of Appeals for the Federal Circuit

MTD PRODUCTS INC., Appellant v. ANDREI IANCU, UNDER SECRETARY of COMMERCE for INTELLECTUAL PROPERTY and DIRECTOR of the UNITED STATES PATENT and TRADEMARK OFFICE, Intervenor

Appeal No. 2017–2292

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2016–00194.

Decided: August 12, 2019

JOHN SALVATORE CIPOLLA, Calfee, Halter & Griswold LLP, Cleveland, OH, argued for appellant. Also represented by ANDREW ALEXANDER, TRACY SCOTT JOHNSON, MARK MCDOUGALL.

PETER JOHN SAWERT, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for intervenor. Also represented by THOMAS W. KRAUSE, PHILIP J. WARRICK.

Before REYNA, TARANTO, and STOLL, *Circuit Judges*.

STOLL, *Circuit Judge*.

The Toro Company sought inter partes review of claims 1–16 of U.S. Patent No. 8,011,458 before the U.S. Patent and Trademark Office's Patent Trial and Appeal Board. The Board instituted review and, in its final written decision, held the challenged claims obvious under 35 U.S.C. § 103. Critical to its decision, the Board determined that the claim term "mechanical control assembly . . . configured to" perform certain functions is not a means-plus-function term subject to 35 U.S.C. § 112, ¶ 6. MTD Products Inc., owner of the '458 patent, appeals the Board's decision.

We conclude that the Board erred by conflating corresponding structure in the specification with a structural definition for the term, and by misinterpreting certain statements in the prosecution history. Under the appropriate legal framework, we conclude that the term "mechanical control assembly" is a means-plus-function term governed by § 112, ¶ 6. We therefore vacate the Board's obviousness conclusion, which was predicated on its incorrect claim construction, and remand for further proceedings consistent with this opinion. Because we are persuaded by MTD's primary argument, we do not reach its alternative arguments.

BACKGROUND

I

The '458 patent discloses a steering and driving system for zero turn radius ("ZTR") vehicles, with specific reference to ZTR lawn mowers. '458 patent col. 1 ll. 17–21. The patented system is designed to provide a more intuitive steering mechanism to operators of ZTR vehicles. *Id.* at col. 1 ll. 20–38. In contrast to prior art systems that reverse in the opposite direction of a forward motion turn, the claimed invention permits ZTR vehicles to turn in the same direction both forward and backwards. *Id.* at col. 1 ll. 20–47. The claimed steering mechanism thus mimics the forward and backward movements of an automobile.

The term "mechanical control assembly" appears in both claims 1 and 9, the only independent claims of the '458 patent. Claim 1 recites:

> 1. A vehicle capable of making a small radius turn, comprising:
>
> a frame;
>
> a left drive wheel and a right drive wheel, both coupled to the frame;
>
> two independent left and right drive units, the left drive unit coupled to the left drive wheel via an axle and the right drive unit coupled to the right drive wheel via another axle;
>
> a steering device coupled to the frame;
>
> a speed control member coupled to the frame; and
>
> a *mechanical control assembly* coupled to the left and right drive units that is configured to actuate the left and right drive units based on a steering input received from the steering device and a speed input received from the speed control member;
>
> the *mechanical control assembly* being configured such that if the speed control member is shifted from (a) a forward position in which the left drive wheel is rotating in a forward direction at a first forward speed and the right drive wheel is rotating in a forward direction at a second forward speed that is less than the first forward speed as a result of the steering device being in a first right turn position to (b) a reverse position while the first right turn position of the steering device is maintained, then the left drive wheel will rotate in a reverse direction at a first reverse speed and the right drive wheel will rotate in a reverse direction at a second reverse speed that is less than the first reverse speed.

Id. at col. 7 l. 63–col. 8 l. 24 (emphasis added to highlight portion of disputed claim term). Claim 9 is identical to claim 1 in substantial part, adding only the further limitation of:

> the *mechanical control assembly* also being configured to cause the vehicle to execute a zero-radius turn when the speed control member is in a maximum forward position and the steering device is in a maximum turn position.

Id. at col. 9 ll. 13–16 (emphasis added).

While the patent specification does not expressly refer to a "mechanical control assembly," it discloses a preferred embodiment that includes a "ZTR control assembly." *Id.* at col. 3 ll. 41–42. The specification describes components of the ZTR control assembly and its inputs, outputs, and linkages. *Id.* at col. 3 l. 41–col. 4 l. 57.

II

Toro petitioned for inter partes review of the '458 patent in November 2015, arguing that the challenged claims were invalid as anticipated or obvious. MTD responded that the term "mechanical control assembly" is a means-plus-function term, and that the asserted prior art did not disclose the claim term's corresponding structure. In support of its argument, MTD introduced expert testimony indicating that "mechanical control assembly" has no reasonably well-understood meaning in the art. Specifically, MTD's expert testified that "mechanical control assembly" is a nonce term that is not used in common parlance and does not bring to mind any specific structure to a person of ordinary skill in the art. J.A. 1366. He explained that the term is used as a black box recitation for structure and, at most, amounts to a collection of various parts. J.A. 1248, 1366. He further demonstrated that the term is used in various prior patents and publications to describe a wide variety of structures with varying functions. J.A. 1367–69 (noting that "mechanical control assembly" is used generically to describe mechanisms for infusion pumps, digital firing systems, flush tanks, endoscopes, transmissions, and engine outputs).

Toro did not expressly contradict MTD's evidence that "mechanical control assembly" did not have a well-understood structural meaning. Instead, Toro responded that a person of ordinary skill in the art would understand the term to denote a specific structure in the context of the '458 patent specification. Specifically, Toro argued that the "ZTR control assembly" disclosed in the specification provides an express structural definition for the claimed "mechanical control

assembly." J.A. 2201–03. Toro also argued that MTD admitted that the term "mechanical control assembly" conveys particular structure when it distinguished the patent claims from a prior art reference during prosecution. J.A. 2203.

The Board initially agreed with MTD, stating that when viewed "in isolation, the genericness of this term bears similarities to other words or phrases that have been held to be subject to § 112, ¶ 6 . . . such as 'mechanism,' 'element,' 'device,' 'link member,' and 'control mechanism.'" *Toro Co. v. MTD Prods. Inc.*, No. IPR2016–00194, 2017 WL 1969747, at *9 (P.T.A.B. May 10, 2017) (first citing *Williamson v. Citrix Online, LLC*, 792 F.3d 1339, 1350 (Fed. Cir. 2015) (en banc); then citing *Mas-Hamilton Grp. v. LaGard, Inc.*, 156 F.3d 1206, 1215 (Fed. Cir. 1998); and then citing *Toro Co. v. Deere & Co.*, 355 F.3d 1313, 1325 (Fed. Cir. 2004)). The Board also determined that the "language reciting what the mechanical control assembly is 'configured to' do . . . fits the mold of functional language because it describes the mechanical control assembly by what it does." *Id*. The Board thus concluded that "the claim language of the disputed phrase is primarily, but not entirely, functional, which tends to favor [MTD]'s position that § 112, ¶ 6 applies." *Id.*

The Board agreed with Toro, however, that the '458 patent specification weighed against application of § 112, ¶ 6. *Id.* at *10. Citing the parties' briefs, the Board stated that "[t]he parties agree that the claimed 'mechanical control assembly' is referred to in the specification as a 'ZTR control assembly.'" *Id.* According to the Board, a person of ordinary skill in the art would understand "mechanical control assembly" to denote structure because "the specification illustrates and describes the specific structure that makes up the ZTR control assembly, and how it connects to and operates with other components." *Id.*

The most persuasive piece of evidence to the Board, however, was the prosecution history. *Id.* at *9 ("The factor that weighs most heavily in [the] determination is the prosecution history."). According to the Board, MTD admitted that the term "mechanical control assembly" connotes specific structure by asserting that the claims recite "a mechanical control assembly that is structurally different from what [the asserted prior art] discloses." *Id.* The Board emphasized MTD's statements that "the claim language at issue concerns the ***configuration*** of the claimed mechanical control assembly" and "the claimed configuration ***is*** indeed structural." *Id.*(emphases in original). The Board concluded that these statements "present[] strong evidence that the disputed phrase should be understood as a structural limitation rather than a means-plus-function limitation under § 112 ¶ 6."

Id. at *11. Relying on the specification and prosecution history, the Board ultimately determined that "mechanical control assembly" is not governed by § 112, ¶ 6. *Id.*

DISCUSSION

I

This appeal requires us to address whether a particular claim limitation is drafted in means-plus-function format. Whether claim language invokes 35 U.S.C. § 112, ¶ 6[1] is a legal question of claim construction that we review de novo. *Williamson*, 792 F.3d at 1346. We review the Board's factual findings underlying this inquiry for substantial evidence. *EnOcean, GmbH v. Face Int'l Corp.*, 742 F.3d 955, 959 (Fed. Cir. 2014).

Under this court's guidance in *Williamson*, we begin by asking whether the claim limitation employs the word "means." *Williamson*, 792 F.3d at 1348. If it does not, we apply a rebuttable presumption that the term conveys sufficiently definite structure and is not subject to § 112, ¶ 6. *Id.* A challenger can rebut the presumption by demonstrating "that the claim term fails to 'recite sufficiently definite structure' or else recites 'function without reciting sufficient structure for performing that function.'" *Id.* (quoting *Watts v. XL Sys., Inc.*, 232 F.3d 877, 880 (Fed. Cir. 2000)). The "essential inquiry is not merely the presence or absence of the word 'means' but whether the words of the claim are understood by persons of ordinary skill in the art to have a sufficiently definite meaning as the name for structure." *Id.*

One way to demonstrate that a claim limitation fails to recite sufficiently definite structure is to show that, although not employing the word "means," the claim limitation uses a similar "nonce word that can operate as a substitute for 'means' in the context of § 112, para. 6." *Id.* at 1350. Generic terms like "module," "mechanism," "element," and "device" are commonly used as verbal constructs that operate, like "means," to claim a particular function rather than describe a "sufficiently definite structure." *Id.* Our case law is replete with guidance on whether or not a particular claim term is a "nonce" term. *See, e.g.*, *Zeroclick, LLC v. Apple Inc.*, 891 F.3d 1003, 1008 (Fed. Cir. 2018) (holding that "program" and "user interface code" are not

[1] Because the issue date of the '458 patent is September 6, 2011, and neither the '458 patent nor the application from which it issued ever contained a claim with an effective filing date on or after September 16, 2012, the version of 35 U.S.C. § 112 that applies here is the one preceding the changes made by the America Invents Act. *See* Leahy-Smith America Invents Act, Pub. L. No. 112–29, 125 Stat. 284, 296, § 4(c) (2011).

nonce words because they are "used not as generic terms or black box recitations of structure or abstractions, but rather as specific references to conventional graphical user interface programs or code"); *Williamson*, 792 F.3d at 1350 (noting that "module" is a nonce term because it "sets forth the same black box recitation of structure for providing the same specified function as if the term 'means' had been used"). In each case, a critical question is whether "the claim term is used in common parlance or by persons of skill in the pertinent art to designate structure," including either a particular structure or a class of structures. *Skky, Inc. v. MindGeek, s.a.r.l.*, 859 F.3d 1014, 1019 (Fed. Cir. 2017) (citing *TecSec, Inc. v. Int'l Bus. Machs. Corp.*, 731 F.3d 1336, 1347 (Fed. Cir. 2013)) (holding that the claim term "wireless device means" does not invoke § 112, ¶ 6 because it denotes a class of structures).

In addition, even if the claims recite a nonce term followed by functional language, other language in the claim "might inform the structural character of the limitation-in-question or otherwise impart structure" to the claim term. *Williamson*, 792 F.3d at 1351. In assessing whether the claim limitation is in means-plus-function format, we do not merely consider the introductory phrase (e.g., "mechanical control assembly") in isolation, but look to the entire passage including functions performed by the introductory phrase. *See Apex Inc. v. Raritan Computer, Inc.*, 325 F.3d 1364 (Fed. Cir. 2003). The ultimate question is whether "the claim language, read in light of the specification, recites sufficiently definite structure to avoid § 112, ¶ 6." *Media Rights Techs. Inc. v. Capital One Fin. Corp.*, 800 F.3d 1366, 1372 (Fed. Cir. 2015) (citing *Robert Bosch, LLC v. Snap-On Inc.*, 769 F.3d 1094, 1099 (Fed. Cir. 2014)).

In *Apex*, for example, the court concluded that the term "circuit" recited sufficient structure in the context of the claims at issue. 325 F.3d at 1372–73 (considering the use of the term "circuit" in the claim limitation "a first interface circuit for receiving keyboard and cursor control device signals from the workstation"). Based on a dictionary definition of the word "circuit," the court reasoned that "the term 'circuit' by itself connotes some structure," and that "the term 'circuit with an appropriate identifier such as 'interface,' 'programming,' and 'logic,' certainly identifies some structural meaning to one of ordinary skill in the art." *Id.* at 1373. The court noted that the extrinsic evidence did not show that the term "circuit" was not understood to have structure, but rather "only that the term 'circuit' is under-stood . . . as a very broad term." *Id.* at 1374. As neither the specification nor the prosecution history used the term "in a manner clearly inconsistent with the ordinary meaning," the court held that the defendant

failed to rebut the presumption that § 112, ¶ 6 did not apply. *Id.* at 1373–74.

In contrast, in *Diebold Nixdorf, Inc. v. International Trade Commission*, the court held that the term "cheque standby unit" for performing certain specified functions was governed by § 112, ¶ 6. 899 F.3d 1291, 1300 (Fed. Cir. 2018). The court noted that "there is no evidence—in the form of dictionary definitions or otherwise—that 'cheque standby unit' was reasonably well understood by persons of ordinary skill in the art to refer to a structure or class of structures." *Id.* at 1302. Instead, the extrinsic evidence demonstrated only that "a skilled artisan would understand the functional term 'cheque standby unit' to be *any* structure capable of performing the claimed function." *Id.* at 1301. Further, neither the words of the claim nor the specification suggested a "structural limitation that might serve to cabin the scope of the functional term," thus supporting the conclusion that the claim limitation was written in means-plus-function format. *Id.*

Finally, we note that "[c]laims are interpreted in light of the written description supporting them, and that is true whether or not the claim construction involves interpreting a 'means' clause." *Inventio AG v. ThyssenKrupp Elevator Ams. Corp.*, 649 F.3d 1350, 1356 (Fed. Cir. 2011), *overruled on other grounds by Williamson*, 792 F.3d at 1339. For example, a patentee may avoid application of § 112, ¶ 6 by acting as a lexicographer and providing its own structural definition of a nonce term in the specification by "'clearly set[ting] forth a definition of the disputed claim term' other than its plain and ordinary meaning." *Thorner v. Sony Comput. Entm't Am. LLC*, 669 F.3d 1362, 1365 (Fed. Cir. 2012) (citing *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002)). Just as it is improper to "import[] limitations from the specification into the claims," *Phillips v. AWH Corp.*, 415 F.3d 1303, 1323 (Fed. Cir. 2005), however, a preferred embodiment disclosed in the specification cannot impart structure to a term that otherwise has none. As with all lexicography, "[i]t is not enough for a patentee to simply disclose a single embodiment." *Thorner*, 669 F.3d at 1365. Rather, "the patentee must 'clearly express an intent' to redefine the term." *Id.* (quoting *Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1381 (Fed. Cir. 2008)).

With these background principles in mind, we turn to the claim language at issue in this case.

II

The disputed claim limitation is lengthy and recites:

> a mechanical control assembly coupled to the left and right drive units that is configured to actuate the left and right drive units

> based on a steering input received from the steering device and a speed input received from the speed control member;
>
> the mechanical control assembly being configured such that if the speed control member is shifted from (a) a forward position in which the left drive wheel is rotating in a forward direction at a first forward speed and the right drive wheel is rotating in a forward direction at a second forward speed that is less than the first forward speed as a result of the steering device being in a first right turn position to (b) a reverse position while the first right turn position of the steering device is maintained, then the left drive wheel will rotate in a reverse direction at a first reverse speed and the right drive wheel will rotate in a reverse direction at a second reverse speed that is less than the first reverse speed.

'458 patent col. 8 ll. 7–24.

At the outset, we agree with the Board that the term "mechanical control assembly" is similar to other generic, black-box words that this court has held to be nonce terms similar to "means" and subject to § 112, ¶ 6 because the term does not connote sufficiently definite structure to one of ordinary skill in the art. *Toro*, 2017 WL 1969747, at *9. We also agree with the Board that the rest of the "claim language of the disputed phrase is primarily, but not entirely, functional." *Id.* While the claim language reciting that the mechanical control assembly is "coupled to the left and right drive units" connotes structure, the claim language reciting what the mechanical control assembly is "configured to" do is functional. In this respect, as the Board correctly recognized, the claim format tends to favor MTD's position that § 112, ¶ 6 applies.[2]

We also discern no error in the Board's acceptance of MTD's extrinsic evidence as showing that the term "mechanical control assembly"

[2] The Board also stated that construing the disputed phrase as a means-plus-function limitation "would seem to render the second part [of the claim's recitation of a 'me-chanical control assembly'] . . . superfluous" as it "would no longer serve to define functionally the structural features of the mechanical control assembly, as those features would be part and parcel of what [MTD] alleges is the corresponding structure." *Toro*, 2017 WL 1969747, at *9. We disagree. Both the first and second limitations following the two occurrences of the term "mechanical control assembly" recite functions associated with the "mechanical control assembly"; i.e., (1) actuate the left and right drive units and (2) rotate the wheel in a particular direction based on the position of the speed control member. As we have held, "[w]here there are multiple claimed functions, as we have here, the patentee must disclose adequate corresponding structure to perform all of the claim functions." *William-son*, 792 F.3d at 1351–52. Thus, the corresponding structure for "mechanical control assembly" in the specification must perform both of these functions.

does not have an established meaning in the art and instead merely operates as a generic label for a collection of parts. Toro did not dispute MTD's expert testimony that, in common parlance, "mechanical control assembly" does not bring to mind any specific structure to a person of ordinary skill in the art. J.A. 1366. Toro likewise did not dispute MTD's reliance on various prior patents and publications that used "mechanical control assembly" to describe a wide variety of structures with varying functions. J.A. 1367–69 (noting that "mechanical control assembly" is used generically to describe mechanisms for infusion pumps, digital firing systems, flush tanks, endoscopes, transmissions, and engine outputs).

We conclude that the Board erred, however, when it relied on the specification's description of a "ZTR control assembly" to conclude that the claim term "mechanical control assembly" has an established structural meaning. While the parties agreed that the ZTR control assembly in the specification is the structure "corresponding to" the claimed mechanical control assembly, MTD did not agree that the specification expressly defines the claim term "mechanical control assembly." That the specification discloses a structure corresponding to an asserted means-plus-function claim term does not necessarily mean that the claim term is understood by persons of ordinary skill in the art to connote a specific structure or a class of structures.

Interpretation of an asserted means-plus-function limitation involves two steps. First, we determine if the claim limitation is drafted in means-plus-function format. As part of this step, we consider whether the claim limitation connotes "sufficiently definite structure" to a person of ordinary skill in the art. If we conclude that the limitation is in means-plus-function format, the second step requires us to review the specification to identify the structure that performs the claimed function(s) and thus "corresponds to" the claimed means. While related, these two inquiries are distinct. In this case, however, the Board conflated these distinct inquiries, holding that the specification's disclosure of corresponding structure demonstrates that the alleged means-plus-function term is sufficiently definite so as to not invoke § 112, ¶ 6. The Board's analysis implies that so long as a claim term has corresponding structure in the specification, it is not a means-plus-function limitation. This is not consistent with our prior decisions. Indeed, this view would seem to leave § 112, ¶ 6 without any application: any means-plus-function limitation that met the statutory requirements, i.e., which includes having corresponding structure in the specification, would end up not being a means-plus-function limitation at all.

While we agree with the Board that the specification plays a role in assessing whether particular claim language invokes § 112, ¶ 6, we do not agree that the patent specification at issue here renders the nonce term "mechanical control assembly" sufficiently structural to a person of ordinary skill in the art. The specification does not demonstrate that the patentee intended to act as its own lexicographer and define the nonce term "mechanical control assembly" as the "ZTR control assembly" of the preferred embodiment. Indeed, the specification does not even refer to a "mechanical control assembly." Furthermore, the functional language in the claim limitation suggests a broader meaning of the generic term "mechanical control assembly," as it specifically adds to the "mechanical control assembly" limitation the ability to execute a zero radius turn. '458 patent col. 9 ll. 13–16. Interpreting the "mechanical control assembly" as the "ZTR"—or zero-turn-radius—control assembly would render this functional language superfluous.

We are also not persuaded by the Board's interpretation of the prosecution history. While it would have avoided uncertainty and argument had MTD shared its current view that the claim limitation is written in means-plus-function format during the original prosecution, MTD's statements did not clearly disclaim such an interpretation. Rather, MTD's statements indicated that the phrase "mechanical control assembly configured to" perform certain functions must be given weight because it connotes structure and thus is not merely an intended use. These statements were not made within the context of § 112, ¶ 6. Moreover, stating that the limitation connotes structure and has weight is not inconsistent with claiming in means-plus-function format since means-plus-function limitations connote structure (i.e., corresponding structure and their equivalents) and have weight. Furthermore, as MTD explained, its interpretation of the claims as being in means-plus-function format during inter partes review was based on this court's intervening law in *Williamson*. J.A. 1204. Given the lack of any clear and undisputed statement foreclosing application of § 112, ¶ 6, we conclude that the Board erred in giving dispositive weight to the equivocal statements it cited in the prosecution history.

CONCLUSION

We conclude that the Board erred by using the existence of corresponding structure in the specification to conclude that "mechanical control assembly" has a sufficiently definite structure to evade § 112, ¶ 6. The Board also erred by giving improper weight to out-of-context

statements in the prosecution history. We hold that the remaining evidence and the Board's factual findings demonstrate that the term "mechanical control assembly . . . configured to" perform certain functions in independent claims 1 and 9 of the '458 patent is governed by § 112, ¶ 6. We therefore vacate the Board's decision and remand for further proceedings consistent with this opinion.

VACATED AND REMANDED
COSTS

Costs to Appellant.

NALPROPION PHARMACEUTICALS, INC., Plaintiff-Appellee v. ACTAVIS LABORATORIES FL, INC., Defendant-Appellant

Appeal No. 2018–1221

Appeal from the United States District Court for the District of Delaware in No. 1:15-cv-00451-RGA, Judge Richard G. Andrews.

Decided: August 15, 2019

DOMINICK A. CONDE, Venable LLP, New York, NY, argued for plaintiff-appellee. Also represented by CHRISTOPHER P. BORELLO, JOSHUA DANIEL CALABRO, ZACHARY GARRETT, BRENDAN M. O'MALLEY.

JONATHAN D. BALL, Greenberg Traurig LLP, New York, NY, argued for defendant-appellant. Also represented by SCOTT JOSEPH BORNSTEIN, JUSTIN ALBANO MACLEAN, RICHARD CHARLES PETTUS.

Before PROST, *Chief Judge,* LOURIE and WALLACH, *Circuit Judges.*

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

Opinion dissenting in part filed by *Chief Judge* PROST.

LOURIE, *Circuit Judge.*

Actavis Laboratories FL, Inc. ("Actavis") appeals from the judgment of the U.S. District Court for the District of Delaware that (1) its proposed naltrexone hydrochloride and bupropion hydrochloride extended-release tablets, which are the subject of Abbreviated New Drug Application No. 208043 (the "ANDA product"), would infringe claim 1 of U.S. Patent 7,375,111 ("the '111 patent"), claims 26 and 31 of U.S. Patent 7,462,626 ("the '626 patent"), and claim 11 of U.S. Patent 8,916,195 ("the '195 patent"); (2) the asserted claims are not invalid; (3) the effective date of any FDA approval of ANDA No. 208043 shall be no earlier than the latest expiration of the '111, '626, and '195 patents; and (4) Actavis is permanently enjoined from manufacturing, using, or selling its ANDA product before the expiration of the patents in suit. *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793 (D. Del. 2017) ("*Decision*"); Final Judgment, *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, No. 1:15-cv-451 (D. Del. Oct. 26, 2017), ECF No. 186. Because we conclude that the district court did not err in finding claim 11 of the '195 patent not invalid for lack of written description, but did err in finding that claim 1 of the '111 patent and claims 26 and 31 of the '626 patent would not have been obvious in view of the prior art, we affirm-in-part and reverse-in-part.

BACKGROUND

Appellee Nalpropion Pharmaceuticals, Inc. ("Nalpropion")[1] holds New Drug Application No. 200063 for and markets Contrave® for weight management in overweight or obese adults. Relevant here are the three Orange Book-listed patents for Contrave® that Nalpropion asserted against Actavis: the '626, '195, and '111 patents.

The '626 patent is drawn to a method for treating overweight or obesity comprising (1) diagnosing an individual as suffering from overweight or obesity by body mass index, (2) administering bupropion in an amount effective to induce weight loss, and (3) administering naltrexone in an amount effective to enhance the weight loss activity of bupropion. '626 patent col. 38 l. 60–col. 39 l. 4. Nalpropion asserted claims 26 and 31. Claim 26 depends from claim 25, which recites:

> A method of treating overweight or obesity, comprising administering a weight loss effective amount of a first and second compound to an individual who has been diagnosed as suffering from overweight or obesity in order to treat said overweight or obesity, wherein said first compound is bupropion, or a pharmaceutically acceptable salt thereof, and said second compound is naltrexone, or a pharmaceutically acceptable salt thereof, and wherein the weight loss activity of said first and second compounds is enhanced compared to the administration of the same amount of either compound alone.

Id. col. 40 ll. 16–26. Claim 26 adds the additional limitation that naltrexone and bupropion "are administered together." *Id.* col. 40. ll. 27–30. Claim 30 depends from claim 25 and requires that at least one of the drugs be in a "sustained-release formulation," *id.* col. 40 ll. 41–44, while claim 31, which depends from claim 30, requires that the drugs be "administered in a single oral dosage form," *id.* col. 40 ll. 45–49.

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[1] Takeda Pharmaceutical Company Limited ("Takeda Ltd."), Takeda Pharmaceuticals International GmbH, Takeda Pharmaceuticals USA, Inc. ("Takeda USA"), and Takeda Pharmaceuticals, America, Inc. (collectively, "Takeda") and Orexigen Therapeutics, Inc. ("Orexigen") filed this suit in the District of Delaware. At the time of filing, Orexigen owned all three patents in suit, Takeda Ltd. was the exclusive licensee of the patents, and Takeda USA held approved New Drug Application No. 200063 for extended-release tablets containing 8 mg of naltrexone hydrochloride and 90 mg of bupropion hydrochloride. During the litigation, Orexigen acquired all of Takeda's rights to Contrave®, including ownership of the NDA. Stipulation and Order at 1, *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, No. 1:15-cv-451 (D. Del. Oct. 5, 2017), ECF No. 92. After this appeal was taken, however, Orexigen commenced bankruptcy proceedings under Chapter 11 of Title 11 of the United States Code in the U.S. Bankruptcy Court for the District of Delaware and transferred ownership of the patents-in-suit to Nalpropion. Unopposed Motion for Substitution of Nalpropion Pharms. Inc. for Orexigen Therapeutics, Inc. at 1, *Nalpropion Pharm. Inc. v. Actavis Labs. FL, Inc.*, No. 18–1221 (Fed. Cir. Aug. 28, 2018), ECF No. 30.

The '195 patent is also directed to methods of treating overweight or obesity, but the claims are drawn to specific dosages of sustained-release naltrexone and bupropion that achieve a specific dissolution profile. At issue here is claim 11:

> A method of treating overweight or obesity having reduced adverse effects comprising orally administering daily about 32 mg of naltrexone and about 360 mg of bupropion, or pharmaceutically acceptable salts thereof, to a person in need thereof, wherein the bupropion or pharmaceutically acceptable salt thereof is administered as a sustained release formulation, wherein the naltrexone or pharmaceutically acceptable salt thereof is administered as a sustained release formulation, and wherein said sustained release formulation of naltrexone has an in vitro naltrexone dissolution profile in a dissolution test of USP Apparatus 2 Paddle Method at 100 rpm in a dissolution medium of water at 37° C. of:
>
> a) between 39% and 70% of naltrexone released in one hour;
>
> b) between 62% and 90% of naltrexone released in two hours; and
>
> c) at least 99% in 8 hours;
>
> wherein about 16 mg of said sustained release formulation of naltrexone or a pharmaceutically acceptable salt thereof is administered twice daily, and about 180 mg of said sustained release formulation of bupropion or a pharmaceutically acceptable salt thereof is administered twice daily.

'195 patent col. 31 l. 5–col. 32 l. 3.

Finally, the '111 patent is directed to a composition of sustained-release bupropion and naltrexone for affecting weight loss. Asserted here is claim 1:

> A composition for affecting weight loss comprising:
>
> (a) a sustained release formulation of bupropion or a pharmaceutically acceptable salt thereof in an amount effective to induce weight loss in an individual; and
>
> (b) a sustained release formulation of naltrexone or a pharmaceutically acceptable salt thereof in an amount effective to enhance the weight loss effect of the bupropion or salt thereof;
>
> wherein said composition is in a single oral dosage form fixed combination.

'111 patent col. 41 ll. 26–35.

Actavis filed an ANDA seeking to enter the market with a generic version of Contrave® prior to the expiration of the patents in suit, and

Nalpropion responded by bringing an action for patent infringement, alleging that Actavis's ANDA product would infringe the '111, '626, and '195 patents. Actavis in turn brought invalidity counter claims, challenging claim 11 of the '195 patent as invalid for lack of adequate written description and challenging claim 1 of the '111 patent and claims 26 and 31 of the '626 patents as invalid as obvious. The district court held a bench trial on all of these issues and held each claim not invalid and infringed. *Decision*, 282 F. Supp. 3d at 797.

First, the district court considered Actavis's written description argument. Actavis argued that claim 11 of the '195 patent lacked adequate written description support because its claimed dissolution profile was achieved using the USP Apparatus 2 Paddle Method ("USP 2"), but the specification discloses data obtained using the different USP Apparatus 1 Basket Method ("USP 1"). The court was not persuaded that the use of a different method from what is prescribed in the claim presented a written description problem, holding that "whether the dissolution data reported in the specification was obtained using the basket method or the paddle method is not relevant to whether the inventors had possession of the invention." *Id.* at 802. Instead, the court credited Nalpropion's expert who opined that a person of ordinary skill would recognize that the inventors possessed an embodiment of the invention as described in Table 10, regardless whether USP 2 or a "'substantially equivalent' method" was used. *Id.* at 801 (citation omitted).

Next, the district court addressed the question of obviousness of claim 1 of the '111 patent and claims 26 and 31 of the '626 patent. Actavis argued that it would have been obvious for a person of skill to combine bupropion and naltrexone for treating overweight and obesity because both drugs were known to cause weight loss, but the court disagreed, finding Actavis's argument to be "a classic case of hindsight bias." *Id.* at 809.

Actavis appealed from the district court judgment, and we have jurisdiction under 28 U.S.C. § 1295(a)(1).

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 when, despite some supporting evidence, we are left with a definite and firm conviction that the district court was in error." *Alcon Research Ltd. v. Barr Labs., Inc.*,

745 F.3d 1180, 1186 (Fed. Cir. 2014) (citing *Alza Corp. v. Mylan Labs., Inc.*, 464 F.3d 1286, 1289 (Fed. Cir. 2006)). "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). "Where there are two permissible views of the evidence, the factfinder's choice between them cannot be clearly erroneous." *Anderson v. City of Bessemer City,* 470 U.S. 564, 574 (1985) (citing *United States v. Yellow Cab Co.*, 338 U.S. 338, 342 (1949)).

Whether a claim satisfies the written description requirement is a question of fact, *Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc), that we review for clear error, *Alcon*, 745 F.3d at 1190. "Whether an invention would have been obvious at the time it was made is a question of law, which we review de novo, based on underlying facts, which we review for clear error." *Tokai Corp. v. Easton Enters., Inc.*, 632 F.3d 1358, 1366 (Fed. Cir. 2011) (citing *Media Techs. Licensing, LLC v. Upper Deck Co.*, 596 F.3d 1334, 1337 (Fed. Cir. 2010)).

The district court rejected Actavis's invalidity arguments that (1) claim 11 of the '195 patent is invalid for lack of adequate written description and (2) claim 1 of the '111 patent and claims 26 and 31 of the '626 patent are invalid as obvious. We address the court's holdings in turn.

I. Written Description

Claim 11 of the '195 patent recites a method of treating overweight or obesity comprising orally administering about 16 mg of naltrexone and about 180 mg of bupropion, both in sustained-release formulations administered twice daily. This method claim also requires that the claimed naltrexone formulation have an in vitro dissolution profile

> in a dissolution test of USP Apparatus 2 Paddle Method at 100 rpm in a dissolution medium of water at 37ºC. of:
>
> a) between 39% and 70% of naltrexone released in one hour;
>
> b) between 62% and 90% of naltrexone released in two hours; and
>
> c) at least 99% in 8 hours . . . .

'195 patent col. 31 l. 14–col. 32 l. 3.

Example 1 of the specification discloses formulations of sustained-release naltrexone with varying amounts of either hydroxypropylmethyl cellulose (HPMC) or polyethylene oxide as excipients. The HPMC formulations range from 5% HPMC to 66% HPMC, and dis-

solution of these formulations was tested in Example 2 using 10-mesh baskets at 100 rpm. The 15% HPMC tablet released 39% of its naltrexone at one hour and 62% at two hours. *Id.* col. 17–18 (Table 5).

The first example in the specification to discuss a naltrexone-bupropion combination is Example 3, which describes tri-layer tablets with sustained-release naltrexone and bupropion layers on opposite sides of an inert layer. That formulation includes 10% HPMC. Dissolution of naltrexone was measured and reported in Table 10, but the specification is silent as to whether the data were obtained using USP 1 or USP 2. *Id.* at col. 20 ll. 1–11.

In finding adequate written description support for the claimed dissolution profile, the district court found that the values in Table 10—67% release in one hour and 85% release in two—fell squarely within the claimed range in claim 11. *Decision*, 282 F. Supp. 3d at 802. The court found the lower bounds were supported by the dissolution data for the 15% HPMC formulation in Table 5. *Id.*

Actavis had argued that neither table provided adequate written description support because the data listed were obtained using USP 1, but the court held that the dissolution technique used was not relevant because a person of skill would understand in the context of the patent that the inventors possessed the claimed invention. The court relied on Nalpropion's expert's testimony that a person of skill would understand that the inventors possessed the invention—whether USP 2 or a substantially equivalent method was used to measure it.

On appeal, Actavis repeats its argument that Tables 5 and 10 fail to provide adequate written description support for the claimed dissolution profile because the data in those tables were obtained using USP 1. According to Actavis, both inventor and expert testimony demonstrated that the two dissolution methods would produce different results. Actavis further argues that the data in Table 5 cannot support the claimed range because a person of ordinary skill in the art would not appreciate that the 15% HPMC data were relevant to the claims.

Nalpropion responds that there was no evidence that the data in either table were obtained using USP 1. Even if USP 1 had been used, however, Nalpropion submits that a person of skill would understand the inventors to have had possession of their invention "irrespective of whether they used USP 1 or USP 2 because those methods are 'substantially equivalent.'" Appellee's Br. 22 (citing J.A. *Decision*, 282 F. Supp. 3d at 801–02). We conclude that the district court did not

clearly err in finding that the inventors had possession of the invention consisting of treating overweight and obesity with the stated amounts of bupropion.

It is important to take note of the peculiarity of claim 11, which begins clearly enough by reciting a method of treating overweight or obesity by carrying out the specific, positive steps of administering a formulation of specific amounts of sustained-release naltrexone and bupropion in twice a day. The claim then records the dissolution data resulting from that formulation.

But that dissolution profile for naltrexone as measured by USP 2 relates only to the measurement of resultant in vitro parameters, not to the operative steps to treat overweight or obesity. And the district court concluded, on the facts, that USP 1 and USP 2 would be "substantially equivalent," *Decision*, 282 F. Supp. 3d at 801 (citation omitted). Thus, it found that, irrespective of the method of measurement used, the specification shows that the inventors possessed the invention of treating overweight or obesity with naltrexone and bupropion in particular amounts and adequately described it. We conclude that this finding does not present clear error.

As we explained in *Ariad*, the written description of an invention "must 'clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed.'" 598 F.3d at 1351 (alteration in original) (quoting *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (Rich, J.) (citing *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989))). "In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession *of the claimed subject matter* as of the filing date." *Id.* (emphasis added). It is not necessary that the exact terms of a claim be used *in haec verba* in the specification, and equivalent language may be sufficient.

To support their respective positions, both parties point to evidence regarding whether a person of skill would understand USP 1 and USP 2 to be "substantially equivalent." But the court credited Nalpropion's expert, Dr. Treacy, as more credible over what it interpreted as untrustworthy, self-serving statements by Actavis's expert, Dr. Mayersohn. *See Decision*, 282 F. Supp. 3d at 801–02 ("It seems to me that Dr. Mayersohn's theoretical opinion that the methods would yield different results is at odds with his reliance on a prior art reference using the basket method to argue that claim 11, which specifies the paddle method, was obvious."). The district court performed precisely its fact-finding function, weighing credibility of testimony. *See* Fed. R. Civ. P. 52(a)(6) ("Findings of fact, whether based on oral or other evidence, must not be set aside unless clearly erro-

neous, and the reviewing court must give due regard to the trial court's opportunity to judge the witnesses' credibility."). We do not disturb this finding.

Having found USP 1 and USP 2 substantially equivalent, the district court found Table 5 and Table 10 adequately supported the dissolution data ranges in claim 11. Particularly, the court was not convinced that relying on data from two tables presented a written description issue, noting that it found "nothing odd or invalidating about the inventors looking to different tables of dissolution data and other places in the specification to determine the ranges for the claimed dissolution profile," and finding that "multiple tests are necessarily required to establish a range." *Decision*, 282 F. Supp. 3d at 803. The court relied on the 15% HPMC data in Table 5, crediting both expert's testimony that 15% HPMC formulations were the first listed in the table in which a person of skill in the art would observe "a sustained release profile." *Id.* at 802 (quoting J.A. 11369:6–19, 11409:10–17). The court also credited Dr. Treacy's testimony that the 99% dissolution at eight-hour data point was supported by Table 10's disclosure, discounting Dr. Mayersohn's view that the dissolution profile would plateau and never reach the claimed 99% at eight hours. *Id.* While Actavis may disagree with the court's findings, these findings are supported by the record, and we do not disturb them. *See Anderson*, 470 U.S. at 573–74 ("If the district court's account of the evidence is plausible in light of the record viewed in its entirety, the court of appeals may not reverse it even though convinced that had it been sitting as the trier of fact, it would have weighed the evidence differently.").

The district court was convinced by its fact findings that Actavis had not proven by clear and convincing evidence that claim 11 of the '195 patent is invalid for lack of adequate written description. While as a general matter written description may not be satisfied by so-called equivalent disclosure, in this case, buttressed by the district court's fact-finding, and where the so-called equivalence relates only to resultant dissolution parameters rather than operative claim steps, we affirm the district court's conclusion. Rigidity should yield to flexible, sensible interpretation.

II. Obviousness

Actavis also challenges claim 1 of the '111 patent and claims 26 and 31 of the '626 patent as obvious in view of O'Malley and Jain. We begin by reviewing the relevant references.

O'Malley is U.S. Patent 6,541,478, entitled "Smoking Cessation Treatments Using Naltrexone and Related Compounds." J.A. 7912.

O'Malley teaches that weight gain is "[t]he significant problem" with smoking cessation and discloses use of opioid antagonists, including naltrexone, alone or with other withdrawal attenuating agents to minimize weight gain during treatment. O'Malley col. 1 l. 59–62. Claim 1 of O'Malley is drawn to a method of treating a person for nicotine dependency and minimizing weight gain during smoking cessation therapy comprising "administering . . . an effective amount of naltrexone and another compound selected from the group consisting of . . . bupropion. . . ." *Id.* col. 12 ll. 30–37.

Jain[2] is a research paper entitled "Bupropion SR vs. Placebo for Weight Loss in Obese Patients with Depressive Symptoms." J.A. 7171. Jain notes that "[p]reliminary studies suggest that bupropion SR is also an effective adjunct to diet for weight loss during acute and long-term therapy in nondepressed patients" and "is associated with weight loss in overweight or obese depressed patients." J.A. 7171. The authors then describe their double-blind study where sustained-release bupropion was administered in conjunction with a 500-kcal deficit diet. Sustained-release bupropion was found to be more effective than placebo at reducing weight in obese patients with depressive symptoms.

Additional references provide context for the obviousness arguments in this case: (1) Anderson for bupropion, (2) Atkinson and Bernstein for naltrexone, and (3) Dante for both naltrexone and its combination with bupropion.

Anderson[3] discloses a 48-week double-blind, placebo-controlled trial where sustained-release bupropion was administered to obese adults. J.A. 7160. Adjusted for placebo, subjects lost 2.2% and 5.5% of net bodyweight with 300 mg/d and 400 mg/d of sustained-release bupropion, respectively. *Id.*

Atkinson[4] examined the effects of long-term naltrexone administration on body weight and obesity, administering naltrexone to 60 obese subjects over 8 weeks. J.A. 8948. Atkinson found a small but significant weight loss in women but no significant effect in men. Similarly, Bernstein[5] teaches a method for curbing carbohydrate cravings and overeating through long-term administration of

[2] desh K. Jain et al., Bupropion SR vs. Placebo for Weight Loss in Obese Patients with Depressive Symptoms, 10 OBESITY RES. 1049–56 (2002), J.A. 7171–78 ("Jain").

[3] James Anderson et al., *Bupropion SR Enhances Weight Loss: A 48-Week Double-Blind, Placebo-Controlled Trial*, 10 OBESITY RES. 633–41 (2002), J.A. 7160–68 ("Anderson").

[4] Richard Atkinson et al., *Effects of Long-Term Therapy with Naltrexone on Body Weight in Obesity*, 38 CLIN. PHARMACOL. THER. 419–22 (1985), J.A. 8948–51 ("Atkinson").

[5] U.S. Patent Application 2002/0198227, J.A. 7179–85 ("Bernstein").

low-dose naltrexone. Bernstein comments that the administration of naltrexone as described "would benefit . . . obese persons." J.A. 7181 ¶ 13.

Dante, U.S. Patent 5,817,665, teaches use of an opioid antagonist like naltrexone with serotonin or norepinephrine reuptake inhibitors to treat mental and emotional disorders. Of note are Examples 2 and 3. Example 2 describes a woman in her thirties who was started on naltrexone without making any other changes. Dante col. 6 ll. 16–17. She rapidly lost her craving for sweets and lost thirty pounds in three weeks. *Id.* col. 6. l. 18–19. Example 3 describes similar results in an obese man. *Id.* col. 6. ll. 32–56. While these examples address only administration of naltrexone, the claims in Dante focus on its combination with bupropion. Claim 1 of Dante is drawn to "[a] method of treating depression comprising administering to a patient a pharmacologically effective dose of an opioid antagonist" and a "nontricyclic antidepressant[]." *Id.* col. 8 ll. 19–30. Claim 7 requires that the "nontricyclic antidepressant" be "selected from a group" including bupropion. *Id.* col. 8. ll. 47–51.

Despite these references, the district court rejected Actavis's obviousness argument. According to the district court, the weight loss effects of bupropion were known to be relatively modest at best, and prior art references reported potential risks, including a potential for seizures. Because a person of skill would not understand bupropion's mechanism of action and because of its modest effectiveness, the court concluded that a person of skill would not have found bupropion to be an obvious starting point for further study. *Decision*, 282 F. Supp. 3d at 807.

The district court was also convinced that a person of skill would not have understood naltrexone to be effective for weight loss. The court did not find Bernstein to disclose weight loss and read Atkinson's disclosure of weight loss in women to be counterbalanced by increased body weight in men. *Id.* at 808.

As for the combination of the two drugs, the district court concluded that Dante and O'Malley did not teach a person of ordinary skill that the combination was effective for weight loss. *Id.* at 809. According to the court, neither reference teaches anything about weight loss or that naltrexone enhances bupropion's weight loss effects. The court likewise discounted the disclosure in Jain because men experienced weight gain. *Id.*

Finally, persuaded that the synergistic effect of the combination was an unexpected result and that others had failed to develop safe and effective weight loss drugs, the district court held that secondary considerations supported a finding of nonobviousness. *Id.* at 810.

On appeal, the parties primarily dispute whether a person of skill would have been motivated to combine bupropion, as disclosed by Jain, and naltrexone, as disclosed in O'Malley, to arrive at the claimed composition of the '111 patent and the method of the '626 patent with a reasonable expectation of success. Actavis argues that the district court incorrectly interpreted the prior art and discounted the fact that both compounds were known to affect weight loss and had been administered together for that purpose. Appellant's Br. 56. In response, Nalpropion submits that naltrexone was not known to affect weight loss, bupropion had safety concerns and yielded only modest weight loss, and the combination had been used only to treat depression or to minimize weight gain in smoking cessation therapy. Nalpropion also argues that naltrexone was not known to enhance bupropion's effectiveness for weight loss.

Obviousness is a question of law, supported by underlying fact questions. *In re Baxter Int'l, Inc.* 678 F.3d 1357, 1361 (Fed. Cir. 2012). In evaluating obviousness, we consider the scope and content of the prior art, differences between the prior art and the claims at issue, the level of ordinary skill in the pertinent art, and any secondary considerations. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17–18 (1966); *see also Apple Inc. v. Samsung Elecs. Co.*, 839 F.3d 1034, 1048 (Fed. Cir. 2016) (en banc) ("Objective indicia of nonobviousness must be considered in every case where present.").

We agree with Actavis and conclude that the claims at issue would have been obvious to a person of skill in the art in view of O'Malley and Jain. The prior art here discloses the claimed components of the composition claims and the steps of the method claims including the use claimed by the method.

The references teach that bupropion causes weight loss. For example, Jain specifically teaches that sustained-release bupropion was "an effective adjunct to diet for weight loss" in both non-depressed and depressed patients, J.A. 7171, and was well-tolerated, J.A. 7177. This statement is confirmed by Anderson, which discloses the results from a 48-week, double-blind, placebo-controlled trial. J.A. 7160. Notably, Anderson's data indicate that administration of sustained-release bupropion yielded weight loss in non-depressed patients. J.A. 7161, 7165. Anderson's reported weight loss was dependent on bupropion SR dosage. J.A. 7165. Even Dr. Weber, a named inventor of the '626 and '111 patents, confirmed that bupropion had been considered safe and had weight loss effects. J.A. 11028–29.

Likewise, the record indicates that naltrexone can cause weight loss. Atkinson reports statistically significant weight loss in female obese patients and states that "naltrexone or similar drugs may have

a role in the clinical treatment of obesity." J.A. 8950. While Atkinson reports weight loss only in women, the claims are not limited to men, and Dante discloses weight loss in two examples—for both a man and a woman. In Example 2, an obese woman was started on 25 mg of naltrexone and rapidly "lost her craving for sweets and a weight loss effort which was stalled took off. She lost thirty pounds in three weeks." Dante col. 6 ll. 16–19. Similarly, 25–50 mg of naltrexone was administered to an obese man in Example 3, and he reported losing about 10 pounds a week and no longer craved sweets. *Id.* col. 6 ll. 32–51. Bernstein also discloses that naltrexone reduces carbohydrate cravings and administration of it would benefit "obese persons." J.A. 7181 ¶ 13.

Given that both drugs had shown weight loss effects, we conclude that a person of ordinary skill would have been motivated to combine them. In fact, such persons did so. O'Malley teaches a combination of effective amounts of sustained-release bupropion and naltrexone for minimizing weight gain. Likewise, Dante teaches use of an opioid antagonist, preferably naltrexone, and an antidepressant, including bupropion, for decreasing sugar cravings, noting that naltrexone administration alone led reduced sugar cravings and weight loss in two examples. A person of skill would have understood that a combination for reducing weight gain and decreasing carbohydrate cravings may affect weight loss as well. *See, e.g.*, J.A. 7156 (speculating that success of a weight-loss treatment could be linked to beneficial effects on "food cravings"); 7172 (explaining that patient hunger is relevant to efficacy and outcomes of a weight-loss treatment); 7181 (explaining "obese persons" would benefit from a method for reducing carbohydrate cravings).

Nalpropion suggests that, even in view of these references, a person of skill would not have been motivated to develop bupropion for weight loss (1) because bupropion yielded only a "paltry 2.8% placebo-adjusted weight loss," which was too insignificant to obtain FDA approval as a weight loss drug, Appellee's Br. 41, (2) because bupropion carried a seizure risk, and (3) because its mechanism of action was unknown.

We are not persuaded. Nalpropion argues that bupropion does not possess sufficient weight loss efficacy to obtain FDA approval by itself. But, while bupropion alone may not have been entitled to FDA approval as a weight-loss treatment, "[t]here is no requirement in patent law that the person of ordinary skill be motivated to develop the claimed invention based on a rationale that forms the basis for FDA

approval." *Allergan, Inc. v. Sandoz Inc.*, 726 F.3d 1286, 1292 (Fed. Cir. 2013). "Motivation to combine may be found in many different places and forms; it cannot be limited to those reasons the FDA sees fit to consider in approving drug applications." *Id.* Instead, "[t]he court should consider a range of real-world facts to determine 'whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue.'" *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc.*, 876 F.3d 1350, 1359 (Fed. Cir. 2017) (quoting *Intercontinental Great Brands LLC v. Kellogg N. Am. Co.*, 869 F.3d 1336, 1344 (Fed. Cir. 2017), *cert. denied*, 139 S. Ct. 143 (2018)). The inescapable, real-world fact here is that people of skill in the art *did combine* bupropion and naltrexone for reductions in weight gain and reduced cravings—goals closely relevant to weight loss. Contrary to Nalpropion's view, persons of skill *did combine* the two drugs even without understanding bupropion's mechanism of action but with an understanding that bupropion was well-tolerated and safe as an antidepressant. *See* J.A. 7165 ("The precise mechanism for bupropion SR that is responsible for effects on weight loss is unknown."); *see also* J.A. 7157 (same). Thus, we conclude that skilled artisans would have been motivated to combine the two drugs for weight loss with a reasonable expectation of success.

We next consider the specific language of the claims in relation to the prior art. Claim 1 of the '111 patent requires (1) a sustained-release formulation of bupropion or a pharmaceutically acceptable salt thereof in an amount effective to induce weight loss in an individual; and (2) a sustained-release formulation of naltrexone or a pharmaceutically acceptable salt thereof in an amount effective to enhance the weight loss effect of the bupropion or salt thereof; (3) in a single oral dosage form fixed combination.[6] Jain discloses 300 and 400 mg per day dosages of sustained-release bupropion as facilitating weight loss, meeting the first limitation. O'Malley discloses a sustained-release formulation of naltrexone administered with bupropion as a "withdrawal attenuating agent," O'Malley col. 2 ll. 59–66, that "enhance[s] the efficacy of the nicotine dependency treatment," *id.* col. 4 ll. 25–33, a treatment designed to minimize weight gain, *id.*col. 8 ll. 45–48. The naltrexone dosages in O'Malley—from 12.5 mg to 150 mg—are amounts effective to enhance the weight loss

[6] Actavis argues that the preamble, which recites "a composition for affecting weight loss," is not limiting, while Nalpropion argues that it is limiting because it recites the fundamental purpose of the invention. Appellee's Br. 49. Because neither party asked the district court to construe the preamble, these arguments are waived. *Interactive Gift Exp., Inc. v. Compuserve Inc.*, 256 F.3d 1323, 1346 (Fed. Cir. 2001).

effects of bupropion. *Id.* col. 5 ll. 46–50.[7] O'Malley also discloses a single oral dosage form of bupropion and naltrexone.

Next, we turn to claims 26 and 31 of the '626 patent. Claim 25, from which both claims 26 and 31 depend, requires administering a weight-loss effective amount of a first and a second compound to treat an individual suffering from overweight or obesity for that condition. The first and second compounds are bupropion and naltrexone, and the weight loss effects of the compounds are "enhanced" compared to the administration of either compound alone. Claim 26 adds the requirement that the two drugs be administered together, and claim 31 requires that at least one of the drugs is in a sustained-release formulation and that they are administrated in a single oral dosage form. As with the '111 patent, the combination of O'Malley and Jain meets these requirements, with Jain disclosing effective amounts of sustained-release bupropion for weight loss and O'Malley disclosing its combination with naltrexone in a single dosage form.

Having concluded that every limitation in the claims at issue was met by O'Malley and Jain, we consider objective indicia of nonobviousness. Nalpropion argues that many others tried and failed to find a combination effective for weight loss and that the claimed combination exhibited unexpected results. But the inventors only combined two drugs known to affect weight loss. Both drugs were known to affect weight loss, and combining them for this known purpose as claimed in the patents yields no unpredictable result. *See KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 416 (2007) ("The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results."). The result—a combination drug that affected weight loss—could not have been unexpected. To the extent Nalpropion maintains that the failure of others supports a finding of nonobviousness, that factor alone cannot overcome the clear record in this case that the combination of the two drugs was known and that both drugs would have been understood to be useful for this purpose.

Because we conclude that claim 1 of the '111 patent and claims 26 and 31 of the '626 patent would have been obvious to a person of skill in the art in view of O'Malley and Jain, we reverse the district court's holding that these claims are not invalid.

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[7] Claim 2 of the '111 patent depends from claim 1, and thus requires an amount of naltrexone effective to enhance the weight loss effect of bupropion. That claim is drawn to about 5 mg to about 50 mg of naltrexone. Thus, about 5 mg to 50 mg of naltrexone constitutes an amount effective to enhance the effect of bupropion. *See* 35 U.S.C. § 112 ¶ 4 (2010).

Finally, Nalpropion filed a motion to strike Actavis's reply brief. Plaintiff-Appellee Nalpropion Pharms. Inc.'s Motion to Strike, *Nalpropion Pharm. Inc. v. Actavis Labs. FL, Inc.*, No. 18–1221 (Fed. Cir. Dec. 27, 2018), ECF No. 54. We deny this motion as moot.

CONCLUSION

We have considered both parties' remaining arguments and find them unpersuasive. For the reasons detailed above, we hold that the district court did not clearly err in finding claim 11 of the '195 patent not invalid for lack of adequate written description and affirm its judgment in this respect. We reverse, however, the court's judgment that claims 26 and 31 of the '626 patent and claim 1 of the '111 patent are not invalid.

AFFIRMED-IN-PART AND REVERSED-IN-PART

COSTS

No costs.

NALPROPION PHARMACEUTICALS, INC., Plaintiff-Appellee v. ACTAVIS LABORATORIES FL, INC., Defendant-Appellant

Appeal No. 2018–1221

Appeal from the United States District Court for the District of Delaware in No. 1:15-cv-00451-RGA, Judge Richard G. Andrews.

PROST, *Chief Judge*, dissenting in part.

Today, the majority adds what appears to me to be a new rule to this court's long-standing written description jurisprudence. It holds that a "substantially equivalent" disclosure may satisfy the written description requirement when the relevant claim limitation recites only "resultant dissolution parameters rather than operative claim steps." Majority Op. 12. Respectfully, that is not the law. Premised on my understanding of this court's precedent, I would find claim 11 of the '195 patent invalid for lack of adequate written description. Consequently, I must dissent from Section I of the majority's opinion.

The disputed limitation is the wherein clause directed to the dissolution profile for sustained-release naltrexone, as measured by the USP Apparatus 2 Paddle Method ("USP 2"):

> wherein said sustained-release formulation of naltrexone has an in vitro naltrexone dissolution profile in a dissolution test of USP Apparatus 2 Paddle Method at 100 rpm in a dissolution medium of water at 37° C. of
>
> a) between 39% and 70% of naltrexone re-leased in one hour;
>
> b) between 62% and 90% of naltrexone re-leased in two hours; and
>
> c) at least 99% in 8 hours . . . .

'195 patent col. 31 ll. 11–21 (hereinafter "the USP 2 clause").

The majority and I agree that the essence of the claimed invention is "a method of treating overweight or obesity." Majority Op. 10. We also agree that claim 11 includes one operative step, which relates to orally administering, among other things, a specific amount of sustained-release naltrexone formulation. *Id.*

I part ways with the majority, however, for at least three reasons. First, the USP 2 clause is limiting. Second, the majority's "substantially equivalent" rule is inconsistent with this court's precedent. Third, the district court clearly erred in finding that the '195 patent's written description includes a disclosure "substantially equivalent" to USP 2.

As to the limiting effect of the USP 2 clause, the majority determines that the clause is nonlimiting because it relates only to the measurement of dissolution data resulting from the oral administration step. *See* Majority Op. 10. This conclusion is wrong. A clause is limiting if, as here, the clause "relate[s] back to and clarif[ies] what is required by the count." *Griffin v. Bertina*, 285 F.3d 1029, 1033 (Fed. Cir. 2002). Indeed, the USP 2 clause does not "merely state the inherent result of performing the manipulative steps." *Id.*; *compare Bristol-Myers Squibb Co. v. Ben Venue Labs., Inc.*, 246 F.3d 1368, 1375 (Fed. Cir. 2001) (concluding a statement directed to the intended result of administering express dosage amounts to be nonlimiting where the result "does not change those amounts or otherwise limit the claim"). Rather, the USP 2 clause "is part of the process itself." *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329–30 (Fed. Cir. 2005).

Specifically, the USP 2 clause clarifies what the claimed invention requires by reciting a property of the claimed naltrexone formulation necessary to "treat[] overweight or obesity." '195 patent col. 31 ll. 5–6. Claim 11 requires the sustained-release naltrexone to be formulated such that it obtains the recited dissolution profile as particularly measured by USP 2—not as generally measured by any method. The '195 patent disclosure confirms this view.

According to the '195 patent, oral dosage forms of sustained-release naltrexone "comprise naltrexone and a sustained-release carrier." *Id.* col. 13 ll. 1–2. Sustained-release carriers, such as hydroxypropylmethyl cellulose ("HPMC") or polyethylene oxide ("PolyOx"), are mixed with naltrexone to effect sustained, as opposed to immediate, release. *Id.* col. 13 ll. 1–12, col. 16 ll. 8–26. The amount of sustained-release carrier determines the in vitro release rate (dissolution) profile of the naltrexone formulation. *Id.* col. 13 ll. 35–45. Thus, the dissolution profile, as measured using USP 2, reflects the amount of sustained-release carrier included in the orally administered naltrexone formulation.

The prosecution history also evidences the material role of the USP 2 clause. In response to an obviousness rejection during prosecution, Applicant argued that, having used a different method, there was no basis to conclude that the prior art inherently disclosed a formulation that falls within the claimed dissolution profile. J.A. 7039 (Prosecution History, Applicant's Remarks). Applicant specifically emphasized the significance of the claimed dissolution profile as performed "under the specific dissolution test conditions recited in the . . . claims." *Id.* ; *see also Hoffer*, 405 F.3d at 1329–30 (stating that a clause cannot be ignored if it is material to patentability).

Applicant did not stop there. Applicant further stated that "there are sustained-release [naltrexone] formulations which fall outside the scope of the . . . claimed dissolution profiles." J.A. 7039. There is no evidence to the contrary in the record. Even during litigation, neither party identified any evidence that a 32 mg dose of any sustained-release naltrexone formulation necessarily contains an amount of sustained-release carrier that inherently generates the claimed USP 2 dissolution profile measurement.

Moreover, and most tellingly, the parties do not even dispute that the USP 2 clause is limiting. Indeed, Appellee expressly agrees that the USP 2 clause is limiting for purposes of infringement. Appellee's sole written description argument is that the '195 patent's disclosure of USP Apparatus 1 Basket Method ("USP 1") provides adequate written description for the USP 2 clause. *See* Oral Arg. at 15:09–33, No. 2018–1221, http://www.cafc.uscourts.gov/oral-argument-recordings ("[F]or purposes of infringement you need to use [USP 2]. But if you look in terms of the 112 issues, . . . the patent is clear that USP 1 and USP 2 are equivalent to one other."). By concluding that the USP 2 clause is nonlimiting, the majority has sua sponte addressed a claim construction argument never presented to the district court.

To the extent that the majority determined that construing the USP 2 clause was necessary to resolve the written description dispute, it should have adopted the district court's undisputed, implied construction, which treated the clause as limiting.[1] *Applied Med. Res. Corp. v. U.S. Surgical Corp*., 448 F.3d 1324, 1333 (Fed. Cir. 2006) (explaining that this court has "decline[d] to construe [a claim term] in the first instance and appl[ied] the undisputed claim construction adopted by the district court").

As the USP 2 clause is limiting and the original patent disclosure fails to literally or inherently disclose it, the written description inquiry should end there. *PowerOasis, Inc. v. T-Mobile USA, Inc.*, 522 F.3d 1299, 1306 (Fed. Cir. 2008) (explaining that to satisfy the written description requirement, "the written description [must] actually or inherently disclose the claim element"). But it does not. After determining that the USP 2 clause is nonlimiting, the majority adopts Appellee's view that disclosure of USP 1 can provide adequate written description support for the USP 2 clause because the two testing

[1] Although the district court did not explicitly articulate a construction of the USP 2 clause, a reading of its opinion compels the conclusion that it construed the USP 2 clause to have limiting effect. *E.g.*, *Orexigen Therapeutics, Inc. v. Actavis Labs. FL, Inc.*, 282 F. Supp. 3d 793, 801 (D. Del. 2017) ("Claim 11 includes the limitation that the naltrexone have a specific dissolution profile measured 'in a dissolution test of [USP 2] . . . .'").

methods are "substantially equivalent." Majority Op. 12; *see also id.* at 10–11.

Such a conclusion problematically articulates a new rule for written description. According to the majority, written description for nonlimiting clauses may be satisfied by disclosure that is "substantially equivalent" even though the same disclosure would not be sufficient for limiting clauses. This rule, however narrow, is at odds with this court's precedent.

Written description requires sufficient disclosure to "clearly allow persons of ordinary skill in the art to recognize that the inventor invented what is claimed." *Ariad Pharm., Inc. v. Eli Lilly and Co.*, 598 F.3d 1336, 1351 (Fed. Cir. 2010) (en banc) (brackets omitted). A substantially equivalent disclosure, even if it would render the claim limitation obvious, cannot satisfy the written description requirement. *See id.* at 1352 ("[A] description that merely renders the invention obvious does not satisfy the requirement."); *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) ("The question is not whether a claimed invention is an obvious variant of that which is disclosed in the specification.").

In any event, even if the majority's "substantially equivalent" rule was appropriate, I would still disagree with its affirmance on the written description issue. In finding that USP 1 and USP 2 are substantially equivalent, the majority overlooks the district court's clear error. Not a shred of record evidence supports this fact-finding. And other record evidence refutes it.

The record contains no evidence showing that the two methods produce the same results. Oral Arg. at 24:04–12 (Q: Do you have positive tests, confirmative testing saying [USP 1 and USP 2] are the same thing? A: No. Neither side submitted any testing data on that point.). Indeed, Appellee's expert, Dr. Treacy, testified that he had formed no opinion about any differences between USP 1 and USP 2. *See* J.A. 11410:24–11411:2.

Instead, the record includes evidence that the two methods do not produce the same results. First, Dr. Soltero, one of the inventors named on the '195 patent, testified that USP 1 and USP 2 results are not comparable. He confirmed that "just because you got a certain profile [using] a USP 1 method, you would not necessarily expect that you would get the same release profile [using] USP 2." *See* J.A. 11319:17–11321:12. The trial court's opinion does not even mention this testimony.

Second, Appellant's expert, Dr. Mayersohn, opined that a skilled artisan would not have understood the two methods to yield the same results. J.A. 11356:22–11357:3. The district court discounted Dr.

Mayersohn's testimony, finding that his "theoretical opinion that the methods would yield different results is at odds with his reliance on a prior art reference using [USP 1] to argue that claim 11, which specifies [USP 2], was obvious." *See* Majority Op. 11 (citing *Orexigen*, 282 F. Supp. 3d at 801–02).

The standard for obviousness is not, however, the same as the standard for written description. Based on our precedent, teachings related to USP 1 may render methods using USP 2 obvious, but Dr. Mayersohn's testimony that the two would not produce the same results is nonetheless relevant for written description. *See Ariad*, 598 F.3d at 1352; *Lockwood*, 107 F.3d at 1572.

In a record devoid of evidence showing that USP 1 and USP 2 are "substantially equivalent," the district court clearly erred in disregarding Dr. Soltero's testimony and in discounting Dr. Mayersohn's, which indicate that they are not substantially equivalent.

For the foregoing reasons, I respectfully dissent from Section I.

IRIDESCENT NETWORKS, INC., Plaintiff-Appellant v. AT&T MOBILITY, LLC, ERICSSON INC., Defendants-Appellees

Appeal No. 2018–1449

Appeal from the United States District Court for the Eastern District of Texas in No. 6:16-cv-01003-RWS-JDL, Judge Robert Schroeder, III.

Decided: August 12, 2019

SHAWN DANIEL BLACKBURN, Susman Godfrey LLP, Houston, TX, argued for plaintiff-appellant. Also represented by PARKER C. FOLSE, III, IAN B. CROSBY, Seattle, WA; ERIC J. ENGER, ALDEN HARRIS, LESLIE PAYNE, Heim, Payne & Chorush, LLP, Houston, TX.

MICHAEL HAWES, Baker Botts, LLP, Houston, TX, argued for defendants-appellees. Also represented by DOUGLAS M. KUBEHL, BETHANY ROSE FORD, JEFFERY SCOTT BECKER, Dallas, TX. Defendant-appellee AT&T Mobility, LLC also represented by BRYANT C. BOREN, JR., Palo Alto, CA.

Before PROST, *Chief Judge,* REYNA and TARANTO, *Circuit Judges.*

REYNA, *Circuit Judge*.

Iridescent Networks, Inc. sued AT&T Mobility, LLC and Ericsson Inc. in the U.S. District Court for the Eastern District of Texas for infringement of U.S. Patent No. 8,036,119. Following claim construction, the parties jointly stipulated to noninfringement, and the district court entered judgment in favor of AT&T Mobility, LLC and Ericsson Inc. Iridescent Networks, Inc. appeals on the ground that the district court erred in its construction of the term "high quality of service connection." Because the district court correctly construed this term, we affirm.

BACKGROUND

I. The '119 Patent

Iridescent Networks, Inc. ("Iridescent") is the assignee of U.S. Patent No. 8,036,119 ("the '119 patent"), entitled "System and Method of Providing Bandwidth on Demand." The '119 patent is directed to a system and method of network communication that provides guaranteed bandwidth on demand for applications that require high bandwidth and minimizes data delay and loss during transmission.[1] '119 patent col. 1 ll. 19–22, 58–60, col. 3 ll. 46–48, col. 6 ll. 21–23.

[1] Modern networks, including cellular networks, transfer data in small blocks called "packets." Appellant's Br. 6–7. Transmission of the packets may be affected by three factors: bandwidth, latency, and packet loss. "Band-width" refers to the maximum data transfer rate of a network. *See id.* at 14. "Latency" refers to the time required to transmit a packet across a network, with longer latency indicating a delay. *See id.* "Packet loss" refers to the loss of packets during transmission. *See id.* at 7.

The '119 patent discloses that prior art networks transmit data packets in an ad hoc manner, with each packet taking an unpredictable route to its destination. *Id.* col. 1 ll. 35–45. This is undesirable because some applications delivered on broadband "are very sensitive to any delay and . . . any variance in the delay" of packet transmission. *Id.* col. 1 l. 66–col. 2 l. 2. The '119 patent teaches that some applications "are also sensitive to any packets . . . which may be lost in the transmission (0.0001% packet loss is the preferred quality for video transmission)." *Id.* col. 2 ll. 2–5. The '119 patent also teaches that some applications require significantly more bandwidth than others to provide tolerable levels of quality. *Id.* col. 1 ll. 58–60, col. 3 ll. 31–45. The '119 patent describes video applications as examples of such applications and explains that prior art "video compression methods vary greatly in the bandwidth they require to transport the video in real-time—some solutions are as low as 64 kbps up to 300 Mbps." *Id.* col. 3 ll. 31–45. Figure 3 of the '119 patent illustrates bandwidth, packet loss, and latency requirements of several applications, including different video applications:

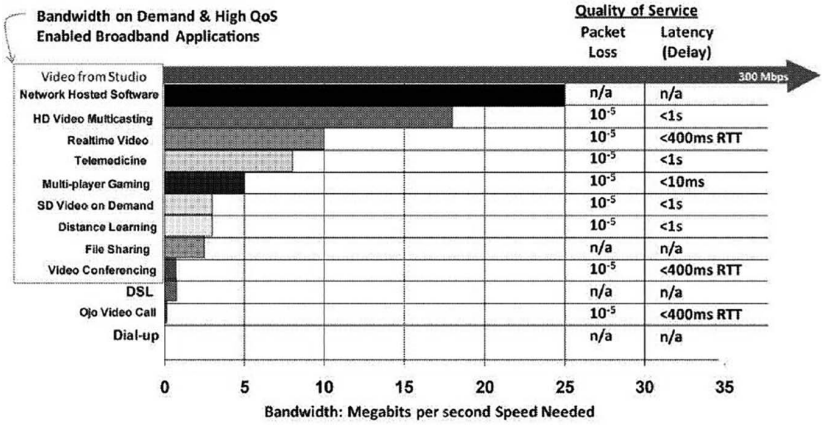

FIG. 3

Id. Fig. 3.

To deal with these parameter-sensitive applications, the '119 patent discloses a system and method for managing network traffic routes and bandwidth availability to minimize adverse network conditions and to assure that the network connection maintains a requested minimum level of one of these three parameters. *Id.* col. 5 l. 64–col. 6 l. 3. Rather than using existing ad hoc network routes, the invention creates custom routes to maximize the availability of the required bandwidth, minimize packet loss, and reduce latency. *Id.* col. 5 ll.

64–67; *id.* col. 6 ll. 57–61. According to the '119 patent, this results in a "high quality" network connection with bandwidth "on demand." *Id.* col. 5 ll. 23–29. Applications that do not have minimum network connection parameter requirements may be routed through existing "best-effort" ad hoc network connections using "existing network components." *Id.* col. 5 ll. 14–20. Claim 1 is illustrative and recites:

> 1. A method for providing bandwidth on demand comprising:
>
> receiving, by a controller positioned in a network, a request for a *high quality of service connection* supporting any one of a plurality of one-way and two-way traffic types between an originating end-point and a terminating end-point, wherein the request comes from the originating end-point and includes at least one of a requested amount of bandwidth and a codec;
>
> determining, by the controller, whether the originating end-point is authorized to use the requested amount of bandwidth or the codec and whether the terminating end-point can be reached by the controller;
>
> directing, by the controller, a portal that is positioned in the network and physically separate from the controller to allocate local port resources of the portal for the connection;
>
> negotiating, by the controller, to reserve far-end resources for the terminating end-point; and
>
> providing, by the controller to the portal, routing instructions for traffic corresponding to the connection so that the traffic is directed by the portal based only on the routing instructions provided by the controller, wherein the portal does not perform any independent routing on the traffic, and wherein the connection extending from the originating end-point to the terminating end-point is provided by a dedicated bearer path that includes a required route supported by the portal and dynamically provisioned by the controller, and wherein control paths for the connection are supported only between each of the originating and terminating end-points and the controller and between the portal and the controller.

Id. col. 7 l. 43–col. 8 l. 7 (emphasis added).

The application that led to the '119 patent is a continuation of U.S. Application No. 11/743,470 ("the parent application"), which issued as U.S. Patent No. 7,639,612, also assigned to Iridescent. Both patents share a substantially identical specification.

During prosecution of the parent application, the examiner rejected several claims containing a similar limitation: "high quality and low latency bandwidth." J.A. 271, 369. The examiner explained that this limitation was rejected as not enabled because the specification "d[id]

not adequately describe how *high quality and low latency* are determined." J.A. 368–69; *see also* J.A. 270–71. In response, the applicant amended the claims to replace the rejected term with the "high quality of service connection" limitation at issue in this appeal. J.A. 140. The applicant argued that Figure 3 and its description supported this new claim language:

> As illustrated by the boxed set of applications on the left side of Fig. 3, high QoS (quality of service) may be viewed in the present application as having speeds varying from approximately 1–300 megabits per second, packet loss requirements that are typically about 10^{-5}, and latency requirements that are typically less than one second. These are commonly used parameters and, as illustrated in Fig. 3, often vary somewhat based on the type of application. For example, video conferencing may be possible with the listed parameters, while HD video multicasting typically has more stringent requirements in order to be acceptable.
>
> . . . .
>
> Accordingly, Applicant submits that the term "high quality of service connection" is supported by the various connection parameters illustrated for high quality of service enabled bandwidth applications in Fig. 3.

J.A. 141. After considering Iridescent's arguments, the examiner withdrew the rejection and allowed the amended claims containing the "high quality of service connection" limitation to issue.

II. District Court Proceedings

On July 11, 2016, Iridescent brought suit against AT&T Mobility, LLC and Ericsson Inc. (collectively, "AT&T") for infringement of claims 1, 3–4, 7, and 11 of the '119 patent. Claim 1 was the only asserted independent claim. During claim construction proceedings, Iridescent proposed broadly construing the term "high quality of service connection" to mean "a connection in which one or more quality of service connection parameters, including bandwidth, latency, and/or packet loss, are assured from end-to-end based on the requirements of the application." *Iridescent Networks, Inc. v. AT&T Mobility, LLC*, No. 6:16-CV-01003, 2017 WL 3033400, at *3 (E.D. Tex. July 18, 2017) ("*Claim Construction Order*"). The magistrate judge, however, largely adopted AT&T's proposed construction, construing the term to mean "a connection that assures connection speed of at least approximately one megabit per second and, where applicable based on the type of application, packet loss requirements that are about 10^{-5} and latency requirements that are less than one second."

Id. at *5. The magistrate judge determined that "high quality of service connection" is a term of degree that is "not a known term of art, but rather a term coined by the patentee." *Id.* at *4. Relying on the '119 patent's intrinsic record, the magistrate judge explained that Figure 3 of the '119 patent and Iridescent's statements during prosecution of the parent application "serve to provide some standard for measuring this term of degree." *Id.* at *5 (internal quotation marks omitted).

Iridescent subsequently objected to the magistrate judge's construction, raising the same arguments it renews on appeal. *Iridescent Networks, Inc. v. AT&T Mobility, LLC*, No. 6:16-CV-01003, 2017 WL 10185852, at *1–3 (E.D. Tex. Dec. 1, 2017) ("*Order Adopting Constructions*"). The district judge overruled Iridescent's objections, determining that the magistrate judge's construction was not clearly erroneous or contrary to law. *Id.* at *3.

The parties agreed that under the district court's construction, AT&T's accused network products and services were excluded, and they jointly stipulated to noninfringement. On December 18, 2017, the court entered a final judgment against Iridescent. Iridescent timely appealed. We have jurisdiction over this appeal under 28 U.S.C. § 1295(a)(1).

DISCUSSION

Whether a district court's construction of a claim is correct presents a legal question that we review de novo. *Info-Hold, Inc. v. Applied Media Techs. Corp*., 783 F.3d 1262, 1265 (Fed. Cir. 2015). We review underlying factual findings related to extrinsic evidence for clear error. *E.I. du Pont De Nemours & Co. v. Unifrax I LLC*, 921 F.3d 1060, 1067 (Fed. Cir. 2019). When claim construction is based solely upon intrinsic evidence, as in this case, our review is de novo. *Teva Pharm. USA, Inc. v. Sandoz, Inc*., 135 S. Ct. 831, 841 (2015).

Claim construction seeks to ascribe the meaning to a claim term as understood by a person of ordinary skill in the art at the time of invention. *Phillips v. AWH Corp*., 415 F.3d 1303, 1312–14 (Fed. Cir. 2005) (en banc). The meaning of a term "must be considered in the context of all the intrinsic evidence, including the claims, specification, and prosecution history." *Biogen Idec, Inc. v. GlaxoSmithKline LLC*, 713 F.3d 1090, 1094 (Fed. Cir. 2013) (citing *Phillips*, 415 F.3d at 1314). The prosecution history, like the specification, provides evidence of how the U.S. Patent and Trademark Office and the inventor understood the patent. *Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1327 (Fed. Cir. 2009) (citing *Phillips*, 415 F.3d at 1317). Statements made during prosecution of a parent application are

relevant to construing terms in a patent resulting from a continuation application if such statements relate to the subject matter of the claims being construed. *Ormco Corp. v. Align Tech., Inc.*, 498 F.3d 1307, 1314 (Fed. Cir. 2007); *see also E.I. du Pont*, 921 F.3d at 1070 ("When a parent application includes statements involving 'common subject matter' with the terms at issue, those statements are relevant to construction of the terms in the child patent."); *Wang Labs., Inc. v. Am. Online, Inc.*, 197 F.3d 1377, 1384 (Fed. Cir. 1999) (applying statements from prosecution of a parent application where subject matter was common to the continuation-in-part application).

This appeal turns on whether the term "high quality of service connection" is a term of degree that is limited to the minimum connection parameter requirements disclosed in Figure 3 of the '119 patent. We conclude that it is.

We begin with the language of the claims. *In re Power Integrations, Inc.*, 884 F.3d 1370, 1376 (Fed. Cir. 2018) (citing *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 457 F.3d 1293, 1301 (Fed. Cir. 2006)). Here, the district court found that "high quality of service connection" is a coined term that has no ordinary meaning in the industry. *Claim Construction Order*, 2017 WL 3033400, at *4; *Order Adopting Constructions*, 2017 WL 10185852, at *3. We agree that the claim language is not sufficiently clear on its face to provide guidance to a person of ordinary skill in the art as to the meaning of the term "high quality of service connection." Although every network connection has some degree of quality of service, Reply Br. 2–3, the claims expressly require the connection to provide *high* quality of service. The claim language, however, is silent as to what amount of quality is sufficient to be "high." We therefore look first to the specification, followed by the prosecution history, to determine the meaning of the term "high quality of service connection."

As noted above, the applicant of the '119 patent relied on Figure 3 during prosecution to support an amendment that gave rise to the term "high quality of service connection." Figure 3 indicates minimum requirements for connection speed, packet loss, and latency. Figure 3 shows a box labeled "High QoS" ("Quality of Service") that is drawn around some, but not all, listed applications. '119 patent Fig. 3. The applications placed within this box have connection parameter requirements consistent with the district court's construction for the disputed term. For example, the written description explains that "[t]hese real time critical applications are very sensitive to any delay[,] . . . any variance in the delay[,]. . . . [and] any packets (or frames) which may be lost in the transmission (0.0001% packet loss is the

preferred quality for video transmission)." *Id.* at col. 1 l. 66–col. 2 l. 5. One application ("Ojo Video Call") and two network transmission line technologies ("DSL" and "Dial-up") are placed outside the "High QoS" box. *Id.* Fig. 3. The Ojo Video Call application is shown to have lower minimum connection requirements than the applications within the box. *Id.* Figure 3 and the written description, therefore, imply that a "high quality of service connection" involves minimum service parameters required by the applications within the "High QoS" box. This conclusion is consistent with the prosecution history of the '119 patent.

During prosecution of the parent application, the applicant argued that "the various connection parameters illustrated for high quality of service enabled bandwidth applications in Fig. 3" supported the term "high quality of service connection." J.A. 141. The applicant stated that the term "may be viewed in the present application as having speeds varying from approximately 1–300 megabits per second, packet loss requirements that are typically about 10^{-5}, and latency requirements that are typically less than one second," which are the illustrated parameters for the applications within the "High QoS" box in Figure 3. *Id.* Thus, the applicant relied on the minimum connection parameter requirements described in Figure 3 to overcome the examiner's § 112 enablement rejection.

Iridescent argues that the term "high quality of service connection" is a mere requirement that the connection assure the level of quality that meets the service parameter needs of a particular service or application. Appellant's Br. 14. Iridescent raises three primary arguments in support of its proposed construction. We address each in turn.

First, Iridescent contends that the term serves to distinguish a high quality of service connection from a prior art "best-effort" connection that does not guarantee any level of quality. Appellant's Br. 13–15, 22. Iridescent points to the '119 patent's disclosure that different applications have varying connection parameter requirements, and argues that "there are no hard-and-fast numerical requirements for the quality of service parameters." *Id.* at 15. This argument, however, contradicts the written description and Figure 3 of the '119 patent. If, as Iridescent contends, a "high quality of service connection" is one that provides only some assurance of required quality of connection, then a connection that meets the requirements of all the applications listed in Figure 3 would fall within that definition. Yet Figure 3 excludes the Ojo Video Call application from the box identified as "High QoS," even though that application also has specific connection parameter requirements of less than 1 megabit per second in band-

width, packet loss of 10^{-5}, and latency delay of less than 400 milliseconds—parameters that would satisfy Iridescent's proposed construction of "high quality of service connection." '119 patent Fig. 3.

Iridescent argues that Figure 3's exclusion of the Ojo Video Call application from the "High QoS" box demonstrates only that a prior art best-effort connection is sufficient to meet that application's connection requirements. Reply Br. 6. The '119 patent, however, teaches that a best-effort connection provides no assurance of any amount of quality. *See* '119 patent col. 1 ll. 23–60 (detailing the ad hoc nature of prior art network connections); *id.* col. 3 ll. 6–22, 46–48 (distinguishing "best-effort internet" from "guaranteed high bandwidth" connections); *see also* Appellant's Br. 7, 13. Thus, a best-effort connection may not always meet the connection requirements of the Ojo Video Call application. Rather, Figure 3 excludes that application from the "High QoS" box because its connection requirements are lower than what the patentee intended to be covered by the term "high quality of service connection."

The written description demonstrates that the inventor knew how to describe quality assurance. For example, the written description teaches that prior art Multi-Protocol Label Switching technology provided "packet quality assurance." '119 patent col. 2 ll. 6–8, 43–47. The written description also discloses that when the prior art "IEEE 802.1p" standard is utilized, "[s]ervices are delivered with assurance." *Id.* col. 3 ll. 16–19. By contrast, the claims here require a "high quality of service connection." When read in the context of the written description, the inventor's decision to claim a connection that provides *high* quality of service instead of a connection that provides *assured* quality of service informs a person of ordinary skill in the art that the claims require something more than mere assurance of quality.

Iridescent's statements during prosecution of the parent application also belie Iridescent's attempt to equate "high" quality of service with "assured" quality of service. In response to the examiner's § 112 rejection, Iridescent argued that "high QoS (quality of service) may be viewed in the present application as having speeds varying from approximately 1–300 megabits per second, packet loss requirements that are typically about 10^{-5}, and latency requirements that are typically less than one second. These are commonly used parameters . . . ." J.A. 141. This language focuses on the objective characteristics of the quality of the connection rather than on whether any amount of quality is assured. In view of the intrinsic record, we are not persuaded that the term "high quality of service connection" equates with assurance of quality.

Second, Iridescent contends that the prosecution history is irrelevant to the claim construction question because there is no clear and unmistakable disavowal of claim scope. Appellant's Br. 12. We disagree. We have explained that "[a]ny explanation, elaboration, or qualification presented by the inventor during patent examination is relevant, for the role of claim construction is to 'capture the scope of the actual invention' that is disclosed, described, and patented." *Fenner Invs., Ltd. v. Cellco P'ship*, 778 F.3d 1320, 1323 (Fed. Cir. 2015) (quoting *Retractable Techs., Inc. v. Becton, Dickinson & Co.*, 653 F.3d 1296, 1305 (Fed. Cir. 2011)); *see also Aptalis Pharmatech, Inc. v. Apotex Inc.*, 718 F. App'x 965, 971 (Fed. Cir. 2018) (relying on the prosecution history to inform a claim construction analysis without finding a disavowal of claim scope). Although the prosecution history may not in some cases be as clear a guide as the specification, it nonetheless "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Phillips*, 415 F.3d at 1317.

Iridescent's reliance on *3M Innovative Properties Co. v. Tredegar Corp.*, 725 F.3d 1315 (Fed. Cir. 2013), is misplaced. In *3M*, we held that where there is no clear disavowal, "the ordinary and customary meaning of the claim term will be given its full effect." 725 F.3d at 1326. The question here, however, is not whether Iridescent narrowed the scope of the disputed term during prosecution from its full ordinary and customary meaning. Rather, because the disputed term is a coined term, meaning it has no ordinary and customary meaning, the question is whether the intrinsic evidence provides objective boundaries to the scope of the term. *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1371 (Fed. Cir. 2014). In these circumstances, where there is no clear ordinary and customary meaning of a coined term of degree, we may look to the prosecution history for guidance without having to first find a clear and unmistakable disavowal.

Third, Iridescent contends that even if its statements during prosecution may be considered, they are still irrelevant to the construction of the disputed term because Iridescent made those statements in response to an enablement rejection. Appellant's Br. 27–29; Reply Br. 10–11. Iridescent argues that unlike an indefiniteness rejection, an enablement rejection is not issued "to force the applicant to define the metes and bounds of the claim." Appellant's Br. 27. This is not correct. It is long-settled that "[e]nablement serves the dual function in the patent system of ensuring adequate disclosure of the claimed invention and of preventing claims broader than the disclosed inven-

tion. This important doctrine prevents both inadequate disclosure of an invention and overbroad claiming that might otherwise attempt to cover more than was actually invented." *MagSil Corp. v. Hitachi Glob. Storage Techs., Inc.*, 687 F.3d 1377, 1380–81 (Fed. Cir. 2012) (internal citation omitted); *see also Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195–96 (Fed. Cir. 1999). Thus, Iridescent's statements made to overcome the examiner's enablement rejection inform the claim construction analysis by demonstrating how Iridescent understood the scope of the disputed term.

Iridescent raises other arguments that we find unpersuasive. For example, Iridescent argues that the district court's determination that the disputed term is a term of degree rests on an erroneous finding that the '119 patent discloses a third "quality of service" connection. Appellant's Br. 19–24. Iridescent asserts that the '119 patent discloses only two connection types—best-effort and high quality of service connections—and "[t]here is no question of degree between" the two. *Id.* at 22.

We agree that "quality of service" is not a connection type, but a characteristic of any network connection, much like "height" is a characteristic of any human being. Iridescent is mistaken, however, that the district court misread "quality of service" to be a third connection type, or that such a misreading is a necessary predicate to determining that the term "high quality of service connection" is a term of degree. That "quality of service" is a characteristic of any network connection says nothing about the *level* of quality of service that connection provides. The district court was thus correct to look to the specification and the prosecution history for disclosure of what constitutes *high* quality of service. Because Figure 3 and the applicant's prosecution history statements disclose the disputed term's scope, the district court's analysis was correct.

Iridescent also argues that this court's precedent forecloses limiting the term "high" to numerical values. We disagree. In each case on which Iridescent relies, this court concluded that importing numerical limits into the independent claim at issue would have rendered a dependent claim meaningless. *See Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982, 993–94 (Fed. Cir. 2007); *In re Cruciferous Sprout Litig.*, 301 F.3d 1343, 1348–49 (Fed. Cir. 2002); *Am. Seating Co. v. USSC Grp., Inc.*, 91 F. App'x 669, 676 (Fed. Cir. 2004). That is not a concern here. Additionally, in *American Seating*, the claim language itself defined the disputed term. 91 F. App'x at 675. By contrast, the claims here provide no clear meaning or definition of "high quality of service connection."

CONCLUSION

We have considered Iridescent's remaining arguments and find them unpersuasive. We hold that the correct construction of "high quality of service connection" means "a connection that assures connection speed of at least approximately one megabit per second and, where applicable based on the type of application, packet loss requirements that are about 10^{-5} and latency requirements that are less than one second." We therefore affirm the district court's judgment.

AFFIRMED

COSTS

No costs.

JAKE LATURNER, TREASURER of the STATE of KANSAS, ANDREA LEA, in her official capacity as AUDITOR of the STATE of ARKANSAS, Plaintiffs-Appellees v. UNITED STATES, Defendant-Appellant

Appeal No. 2018–1509, 2018–1510

Appeals from the United States Court of Federal Claims in Nos. 1:13-cv-01011-EDK, 1:16-cv-00043-EDK, Judge Elaine Kaplan.

Decided: August 13, 2019

DAVID CHARLES FREDERICK, Kellogg, Huber, Hansen, Todd, Evans & Figel, PLLC, Washington, DC, argued for all plaintiffs-appellees. Plaintiff-appellee Jake LaTurner also represented by SCOTT H. ANGSTREICH, KATHERINE COOPER, BENJAMIN SOFTNESS; JONATHAN BRETT MILBOURN, Horn Aylward & Bandy, LLC, Kansas City, MO.

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Before DYK, CHEN, and HUGHES, *Circuit Judges.*

DYK, *Circuit Judge*:

During the Great Depression, President Franklin D. Roosevelt signed legislation allowing the U.S. Department of Treasury ("Treasury") to issue savings bonds, a type of debt security designed to be affordable and attractive to even the inexperienced investor. Under longstanding federal law, savings bonds never expire and may be redeemed at any time after maturity. *See, e.g.*, 31 U.S.C. § 3105(b)(2)(A); 31 C.F.R. § 315.35(c). Federal law also limits the ability to transfer bonds. 31 C.F.R. § 315.15. Kansas and Arkansas (the "States") passed so-called "escheat" laws providing that if bond owners do not redeem their savings bonds within five years after maturity, the bonds will be considered abandoned and title will transfer (i.e., "escheat") to the state two or three years thereafter. Kan. Stat. Ann. §§ 58–3935(a)(16), 58–3979(a) (2000); Ark. Code Ann. § 18–28–231(a)–(b) (2015).

Pursuant to these escheat laws, the States sought to redeem a large but unknown number of bonds, estimated to be worth hundreds of millions of dollars. When Treasury refused, the States filed suit in the Court of Federal Claims ("Claims Court"). The Claims Court agreed

with the States, holding that Treasury must pay the proceeds of the relevant bonds—once it has identified those bonds—to the States. The cases were certified for interlocutory appeal to this court.

We reverse for two independent reasons. First, we hold that federal law preempts the States' escheat laws. That means that the bonds belong to the original bond owners, not the States, and thus the States cannot redeem the bonds. Second, even if the States owned the bonds, they could not obtain any greater rights than the original bond owners, and, under Federal law, 31 C.F.R. § 315.29(c), a bond owner must provide the serial number to redeem bonds six years or more past maturity, which includes all bonds at issue here. Because the States do not have the physical bonds or the bond serial numbers, Treasury properly denied their request for redemption.

BACKGROUND

This case concerns the ability of states to acquire U.S. savings bonds through escheat, the centuries-old right of the states to "take custody of or assume title to abandoned personal property." *Delaware v. New York*, 507 U.S. 490, 497 (1993). A savings bond is a contract between the United States and the bond owner, and Treasury regulations are incorporated into the bond contract. *See Treasurer of New Jersey v. U.S. Dep't of the Treasury*, 684 F.3d 382, 387 (3d Cir. 2012), *cert. denied*, 569 U.S. 1004 (2013).

Treasury "regulations do not impose any time limits for bond owners to redeem the[se] savings bonds." *Id.* at 388; *see also* 31 U.S.C. § 3105(b)(2)(A) (authorizing Treasury to adopt regulations providing that "owners of savings bonds may keep the bonds after maturity"). In addition, Treasury regulations provide that savings bonds are generally "not transferable and are payable only to the owners named on the bonds." 31 C.F.R. § 315.15. When the sole owner of a bond dies, "the bond becomes the property of that decedent's estate." 31 C.F.R. § 315.70(a). Federal law imposes no time limit on the redemption of savings bonds, and numerous savings bonds in the country have matured but have not yet been redeemed by their owners. Generally, in order to redeem bonds not in the physical possession of the owner—for example, bonds that have been lost or destroyed—the owner must supply the serial numbers of the bonds to Treasury. 31 C.F.R. §§ 315.25, 315.26(a), 315.29(c). The States do not have the serial numbers of the bonds in question.

This case is related to an earlier litigation that resulted in a decision by the Third Circuit. In the 2000s, several states attempted to acquire the proceeds of unredeemed savings bonds through so-called

"custody escheat" laws. *See New Jersey*, 684 F.3d at 389–90. These laws provided that if bond owners with last known addresses in the state did not redeem their bonds within a certain time after maturity (such as five years), the bonds would be deemed abandoned property. The state could then obtain legal custody of (but not title to) the bonds. When several states asked Treasury to redeem bonds obtained through these custody escheat laws, Treasury refused. Treasury explained that for the bonds to be paid, a state "must have possession of the bonds" and "obtain title to the individual bonds"—neither of which the states had. J.A. 507 (2004 letter to North Carolina); *accord* J.A. 509 (letter to Illinois); J.A. 511 (letter to D.C.); J.A. 513 (letter to Kentucky); J.A. 515 (letter to New Hampshire); J.A. 517 (letter to South Dakota); J.A. 519 (letter to Connecticut); J.A. 521 (letter to Florida).

A number of states filed suit in the District of New Jersey, seeking an order directing the government to pay the bond proceeds. The district court upheld Treasury's denial of payment, holding that the states' custody escheat laws were preempted. *See New Jersey*, 684 F.3d at 394. The Third Circuit affirmed, explaining that the states' laws "conflict[ed] with federal law regarding United States savings bonds in multiple ways." *Id.* at 407. The court reasoned that unredeemed bonds are "not 'abandoned' or 'unclaimed' under federal law because the owners of the bonds may redeem them at any time after they mature." *Id.* at 409. "The plaintiff States' unclaimed property acts, by contrast, specify that matured bonds are abandoned and their proceeds are subject to the acts if not redeemed within a [certain] time period" after maturity. *Id.* at 407–08. "There simply is no escape from the fact that the Federal Government does not regard matured but unredeemed bonds as abandoned even in situations in which [state law] would do exactly that." *Id.* at 409. However, the Third Circuit declined to address whether the outcome would be different if states obtained *title* to savings bonds, as opposed to mere custody. *Id.* at 413 n.28 ("We simply are not faced with that possibility and thus we do not address it.").

After the *New Jersey* litigation, Kansas and Arkansas acted to obtain title to the bonds using "title escheat" laws—precisely the circumstance the Third Circuit's *New Jersey* decision did not reach. Kansas's title escheat law provides that a savings bond will be considered "abandoned" if it is not redeemed within five years of maturity. Kan. Stat. Ann. § 58–3935(a)(16). If the bond remains unredeemed for three more years—that is, for a total of eight years after maturity—Kansas may obtain a state court judgment that title to the

bond has escheated to the state. *Id.* § 58–3979(a). Arkansas's law is similar, providing that savings bonds will be considered abandoned five years after maturity and that the state can obtain title to the bonds two years after that. Ark. Code Ann. § 18–28–231(a)–(b).

Kansas and Arkansas obtained state court judgments purporting to give them title to the category of bonds deemed abandoned under these title escheat laws—that is, all unredeemed bonds that were sufficiently past maturity and were registered to owners with last known addresses in Kansas or Arkansas.[1] *See* J.A. 251 (Kansas); J.A. 1244 (Arkansas). These bonds were not in the States' possession.[2] Kansas and Arkansas estimated that the allegedly abandoned bonds were worth $151.8 million and $160 million, respectively.

The States then attempted to redeem these bonds, asking Treasury to redeem bonds whose registered owners had last known addresses in the state, relying on its general authority to escheat debts owed to individuals whose last known addresses were in the state. *See generally Texas v. New Jersey*, 379 U.S. 674, 680–81 (1965) (holding that as to abandoned intangible property—there, various debts—"the right and power to escheat the debt should be accorded to the State of the creditor's last known address").[3] Treasury declined, stating that "[u]nless some exception or waiver in [its] regulations applies, Treasury is only authorized to redeem a savings bond to the registered owner," J.A. 368, who retains the right "to redeem their savings bonds at any time, even after maturity," J.A. 369.

The States sued for damages under the Tucker Act, 28 U.S.C. § 1491, alleging that the States were the owners of the absent bonds and that the government had breached the terms of the savings-bonds contracts by refusing to redeem the bonds. On cross-motions for summary judgment, the Claims Court sided with the States, holding that Treasury was liable to the States and had an obligation to identify the absent bonds. The Claims Court reasoned that there was

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[1] For Kansas, the relevant bonds are 40-year Series E bonds issued between 1941 and December 31, 1961; 30 year Series E bonds issued between 1965 and December 31,1972; and Series A–D, F, G, H, J, and K bonds issued before December 31, 1972. J.A. 245. For Arkansas, the relevant bonds are "all unredeemed series A through D, F, G, J, and K bonds, and all series E and H bonds that were issued on or before October 16, 1978." J.A. 1243.

[2] The States also escheated and asked Treasury to redeem a much smaller number of bonds that they did possess. Treasury did so, relying on its authority under 31 C.F.R. § 315.90 to waive its other regulations. *See* Regulations Governing United States Savings Bonds, 80 Fed. Reg. 37,559, 37,3560 (U.S. Dep't of Treasury July 1, 2015). The bonds in the States' possession are not at issue in this case.

[3] Below, the government challenged the States' authority to escheat based on the last known address of the registered bond owners, since some bond owners may have moved out of state. The government does not make this argument on appeal, and we assume without deciding that the States have the authority—absent preemption—to escheat savings bonds based on the last-known address of the registered owner.

no preemption because "federal law itself (i.e., 31 C.F.R. § 315.20(b)) requires Treasury to recognize claims of ownership based on title-based escheatment statutes." *Laturner v. United States*, 133 Fed. Cl. 47, 71 (2017).

The court also concluded that the States have the "right[] as an owner of the bonds to make a claim for their proceeds based on the theory that they are 'lost.'" *Id.* at 70. It determined that "Treasury breached the [bond] contract when it refused to provide [the States] with information about the bonds and demanded that [the States] produce the bond certificates as a condition of redeeming their proceeds." *Id.* at 65. Thus, the Claims Court held that the States were "entitled to receive from the government the information necessary to allow it to make a request to redeem the bonds," including the serial numbers of the absent bonds. *Id.* at 77; *see also id.* at 70; *Laturner v. United States*, 135 Fed. Cl. 501, 505 (2017).

The Claims Court certified its summary judgment orders for interlocutory appeal under 28 U.S.C. § 1292(d)(2),[4] noting that identifying the absent bonds would be time-intensive and expensive and that there are eight other pending cases in which other states are asserting similar claims. The court also stayed the proceedings pending appeal.

We granted the government's petitions for leave to appeal and consolidated the appeals. We have jurisdiction under 28 U.S.C. § 1292(d)(2).

DISCUSSION

I

We first address whether, as the government contends, the Treasury regulations governing U.S. savings bonds preempt the States' escheat laws regarding unredeemed savings bonds. The parties assume that the regulations in effect before December 24, 2015, are the relevant regulations.[5] We proceed on that assumption.

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[4] The language of section 1292(d)(2) "is virtually identical to 28 U.S.C. § 1292(b) . . . which governs interlocutory review by other courts of appeals." *United States v. Connolly*, 716 F.2d 882, 883 n.1 (Fed. Cir. 1983) (en banc).

[5] The government's position is that the relevant regulations are those "that were in effect at the time the requests were made"—that is, in May 2013 (for Kansas) and in November 2015 (for Arkansas), respectively. Gov't Open. Br. at 7 n.3. (There was no change in the regulations between these dates.) The Claims Court indicated that it was applying the regulations in effect when the States filed their complaints—that is, in December 2013 (for Kansas) and in November 2015 (for Arkansas), respectively. The States' position is somewhat unclear, though they agree that the pre-amendment regulations apply to this case. Given the parties' agreement as to the relevant regulations, we assume that the regulations in effect at the time the bonds were issued were not materially different.

A

The Constitution limits state sovereignty "by granting certain legislative powers to Congress while providing in the Supremacy Clause that federal law is the 'supreme Law of the Land . . . any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.'" *Murphy v. NCAA*, 138 S. Ct. 1461, 1476 (2018) (quoting U.S. Const. art. VI, cl. 2) (internal citation omitted). "This means that when federal and state law conflict, federal law prevails and state law is preempted." *Id.* The Supreme Court has "identified three different types of preemption—'conflict,' 'express,' and 'field,' but all of them work in the same way: Congress enacts a law that imposes restrictions or confers rights on private actors; a state law confers rights or imposes restrictions that conflict with the federal law; and therefore the federal law takes precedence and the state law is preempted." *Id.* at 1480 (internal citation omitted). For example, in *Arizona v. United States*, 567 U.S. 387 (2012), the Court held that federal statutes "provide a full set of standards governing alien registration" and therefore "foreclose any state regulation in the area." *Id.* at 401. In *Murphy*, the Court elaborated that "[w]hat this means is that the federal registration provisions not only impose federal registration obligations on aliens but also confer a federal right to be free from any other registration requirements." 138 S. Ct. at 1481. Authorized Federal regulations can preempt just as federal statutes can. *See Hillsborough Cty. v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985).

The Supreme Court's decision in *Free v. Bland*, 369 U.S. 663 (1962) illustrates how preemption applies in the context of the U.S. savings bond program. In that case, Treasury regulations provided that when one bond owner died, the surviving co-owner (there, the decedent's husband) became the *sole* owner of the bond. *Id.* at 664–65. Under Texas state community property laws, however, the principal beneficiary under the decedent's will (there, the decedent's son) was entitled to a one-half interest in the bonds—despite not being a co-owner of the bond under Treasury regulations. *Id.* The Court held that the state law was preempted because it prevented bond owners "from taking advantage of the survivorship provisions" of the Treasury regulations. *Id.* at 669–70. The Court reasoned that "Federal law of course governs the interpretation of the nature of the rights and obligations created by the Government bonds," *id.* at 669–70 (quoting *Bank of Am. Tr. & Sav. Ass'n v. Parnell*, 352 U.S. 29, 34 (1956)),and a state may not "fail[] to give effect to a term or condition under which a federal bond is issued," *id.* at 669. In other words, Treasury regulations conferred a right on bond holders which Texas state law impermissibly restricted.

Here there is a similar conflict between state and Federal law. Federal law confers on bond holders the right to keep their bonds after maturity. Congress specifically authorized Treasury to prescribe regulations providing that "owners of savings bonds may keep the bonds after maturity," 31 U.S.C. § 3105(b)(2)(A), as well as regulations setting forth "the conditions, including restrictions on transfer, to which they will be subject," *id.* § 3105(c)(3), and the "conditions governing their redemption," *id.* § 3105(c)(4). Treasury regulations impose no time limit on the redemption of savings bonds. *See, e.g.*, 31 C.F.R. § 315.35(c) ("A series E bond will be paid *at any time* after two months from issue date at the appropriate redemption value . . . ." (emphasis added)); *New Jersey*, 684 F.3d at 409 ("[U]nder federal law . . . the owners of the bonds may redeem them at any time after they mature . . . ."). And 31 C.F.R. § 315.15 provides that "[s]avings bonds are not transferable and are payable only to the owners named on the bonds, except as specifically provided in these regulations and then only in the manner and to the extent so provided." *See also id.* § 315.5(a) (providing that savings bonds "are issued only in registered form" and "must express the actual ownership of" the bond, and that "registration is conclusive of ownership" with limited exceptions).Federal law thus confers on bond holders "a federal right to engage in certain conduct"—the right to keep their bonds after maturity without the bonds expiring—"subject only to certain (federal) constraints." *See Murphy*, 138 S. Ct. at 1480.

The States' escheat laws on the other hand impermissibly restrict the bond holder's right to retain ownership of the bonds. Under the escheat laws, if bond holders do not redeem their bonds promptly enough (as decided by the States), they lose ownership and the bonds will transfer to the state. Absent Federal law authorizing such a state law restriction, the result is clear: "the federal law takes precedence and the state law is preempted." *Id.*

B

The States do not contest that Federal law would preempt their escheat laws absent Federal authorization for the state legislation. But they contend that here there is no conflict between Federal law and the States' escheat laws because Treasury regulations themselves permit the transfer of ownership under escheat laws. They rely on 31 C.F.R. § 315.20(b), which provides that "Treasury will recognize a claim [of bond ownership by a third party] . . . if established by valid, judicial proceedings, *but only as specifically provided in this subpart*" (emphasis added)—i.e., subpart E (§§ 315.20–23). The States contend that their escheat proceedings constitute "valid, judicial proceedings"

under this regulation. Although the Third Circuit in the *New Jersey* litigation did not decide the question before us, the States quote language from the Third Circuit's opinion that "as provided in the federal regulations and as recognized by the Treasury, third parties, including the States, may obtain ownership of the bonds—and consequently the right to redemption—through 'valid[] judicial proceedings,' 31 C.F.R. § 315.20(b)." 684 F.3d at 412–13 (alteration in original).

The States also argue that Treasury has made repeated statements interpreting § 315.20(b) to allow escheat-based claims so long as the state has title (which the States allegedly have here). The States rely on two sets of statements: first, statements Treasury made in denying past escheat claims by various states; and second, portions of Treasury's briefing in the *New Jersey* litigation. Treasury responds that its prior statements are entirely consistent with its present position that it "considers escheat-based redemption claims as an exercise of its discretionary waiver authority under provisions such as 31 C.F.R. § 315.90, rather than under § 315.20(b)," and that it grants such a waiver only when a state has both title *and possession*. Gov't Open. Br. at 16 & n.8.

Paradoxically, the States disclaim any reliance on *Auer* deference, but offer no other basis for deferring to Treasury's supposed interpretation of its regulations. In any event, there is no basis for *Auer* deference here. As the Supreme Court recently clarified, "a court should not afford *Auer* [*v. Robbins,* 519 U.S. 452 (1997)] deference unless the regulation is genuinely ambiguous," *Kisor v. Wilkie*, 139 S. Ct. 2400, 2415 (2019), even after applying "all the 'traditional tools' of construction," *id.* (quoting *Chevron U.S.A. Inc. v. Nat. Res. Def. Council, Inc.*, 467 U.S. 837, 843 n.9 (1984)). Even if the regulation is genuinely ambiguous, *Auer* deference is not appropriate unless "an independent inquiry into . . . the character and context of the agency interpretation" shows that the interpretation (1) constitutes the agency's "authoritative" or "official position," (2) implicates the agency's "substantive expertise," and (3) reflects the agency's "fair and considered judgment" of the issue. *Id.* at 2416–18.

Although we are dubious that the statements here (particularly those made in the *New Jersey* briefs) reflect Treasury's "fair and considered judgment" on the question of whether 31 C.F.R. § 315.20(b) requires Treasury to recognize escheat claims, *id.* at 2417 & n.6, we need not decide that question. Nor need we decide whether Treasury's earlier interpretations were overridden by its more recent interpretations of the regulations. That is so because using "the 'traditional tools' of construction," the Treasury regulations are not

"genuinely ambiguous," and thus *Auer* deference is inappropriate. *Id.* at 2415.

The regulation on which the States rely, § 315.20(b),states that Treasury will recognize the "judicial proceedings" "*only as* specifically provided in this subpart" (emphasis added). The only judicial proceedings specifically provided in the subpart are those for bankruptcy (§ 315.21), divorce (§ 315.22), and proceedings finding a person to be entitled to the bond "by reason of a gift causa mortis" (a gift made in contemplation of impending death) "from the sole owner" (§ 315.22). Escheat proceedings are not mentioned. Accordingly, the general prohibition on transfers of ownership contained in § 315.15 applies.

The States advance a contrary interpretation of the regulation, arguing that § 315.20(b)'s "only as specifically provided in this subpart" limitation refers to "the *manner* in which judicial proceedings will be recognized, not the *sorts* of proceedings that will be recognized." Kansas Resp. Br. at 31 (emphasis in original). This is not a tenable reading of the regulation. A different provision, § 315.23, already specifies how to prove the validity of a proceeding, such as by providing certified copies of the judgment. The "only as specifically provided in this subpart" language in § 315.20(b) plainly refers to the types of judicial proceedings that will be recognized.

The States also assert that § 315.20(a), not § 315.20(b),exclusively defines the transfers of ownership that Treasury will not recognize. Section 315.20(a) states that Treasury "will not recognize a judicial determination that gives effect to an attempted voluntary transfer inter vivos of a bond" or that "impairs the rights of survivorship conferred by these regulations upon a coowner or beneficiary." Contrary to the States' argument, § 315.20(a) simply lists additional transfers that Treasury will not recognize. It hardly suggests that all other transfers are valid.

In short, we reject the States' contention that Treasury regulations permit the transfer of ownership under escheat laws. To the contrary, the plain language of the regulations confers on bond holders the right to retain their bonds *without* losing ownership if they do not redeem the bonds within a time limit set by the States.

While we do not rely on it, we note that Treasury in December 2015 confirmed this interpretation of its regulation when it amended § 315.20 to specifically provide that "[e]scheat proceedings will not be recognized under this subpart." Treasury also added a new regulation, section 315.88, providing that Treasury "will not recognize an escheat judgment that purports to vest a State with title to a bond that the State does not possess"—as is the case here—"or a judgment

that purports to grant the State custody of a bond, but not title"—as was the case in the *New Jersey* litigation.[6]

II

There is an additional reason that the States cannot prevail. The States concede that even if Federal law recognized them as the rightful bond owners, they could have no greater rights than the original bond owners. *See* Oral Arg. at 35:45–36:00. In general, a bond owner must "present the bond to an authorized paying agent for redemption." 31 C.F.R. § 315.39(a). The States cannot do so here since they do not have physical possession of the bonds.[7] However, the States advance several reasons for why they need not present the physical bonds for redemption.

A

The States maintain that they need not present the physical bonds because the bonds should be considered "lost" and the States can meet the requirements for redeeming lost bonds. The Claims Court agreed. Under 31 C.F.R. § 315.25, "[r]elief, by the issue of a substitute bond or by payment, is authorized for the loss . . . of a bond after receipt by the owner." When a bond is lost, "the savings bond must be identified by serial number and the applicant must submit satisfactory evidence of the loss." *Id.* There is an exception to the serial number requirement: "If the bond serial number is not known, the claimant must provide sufficient information to enable" the government "to identify the bond by serial number." 31 C.F.R. § 315.26(b). But if an owner seeks to redeem the bond "six years or more after the final maturity of a savings bond"—which applies to all bonds at issue here—"[n]o claim . . . will be entertained, unless the claimant supplies the serial number of the bond." 31 C.F.R. § 315.29(c). In other words, the regulations foreclose the option of redeeming a bond by providing other identifying information when the bonds at issue are six years or more past maturity.

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[6] In *Estes v. U.S. Dept' of the Treasury*, the states argued that the amended regulations were arbitrary and capricious because they represented a change in policy without an explanation for that change. *See* 219 F. Supp. 3d 17, 27–28; *Encino Motorcars, LLC v. Navarro*, 136 S. Ct. 2117, 2125 (2016) ("Agencies are free to change their existing policies so long as they provide a reasoned explanation for the change.") The district court rejected this argument, holding that the amended regulation was not a policy change but rather "a clarification of prior guidance" and "simply elaborated on the standards" followed by Treasury before. *Estes,* 219 F. Supp. 3d at 27–31. The court also rejected the states' Constitutional challenges (based on the Appointments Clause and Tenth Amendment) to the amended regulations, *id.* at 37–41, and the States do not renew those arguments here.

[7] As discussed above, there is no issue here regarding bonds that the States possess. Treasury allowed the States to redeem such bonds, invoking its authority under 31 C.F.R. § 315.90 to waive the provisions that only the original bond owner may redeem the bond, *e.g.*, 31 C.F.R. § 315.15. And when a state possesses the bonds, it is of course able to present the physical bonds for payment.

The government contends that the bonds here are not "lost" within the meaning of the regulations, because here there is no evidence that the bonds have been lost by the original owners. We need not resolve this issue, because even if the bonds here are considered lost, the States do not have the bond serial numbers as required by 31 C.F.R.§ 315.29(c).

B

Kansas argues that it is entitled to relief under the regulation governing "nonreceipt of a bond," 31 C.F.R. § 315.27, which does not require the bond owner to provide the serial number. That regulation provides that "[i]f a bond issued on any transaction is not received, the issuing agent must be notified as promptly as possible and given all information available about the nonreceipt." *Id*. "If the application is approved, relief will be granted by the issuance of a bond bearing the same issue date as the bond that was not received." *Id.* This regulation does not apply here. It is directed at the situation where an individual purchases a bond but does not receive it—in other words, where Treasury fails to deliver the bond to the original owner. Indeed, Arkansas (unlike Kansas) recognizes that this provision governs "those cases where a bond 'is not received' by the original owner in the first place"—which is not the situation here. Arkansas Resp. Br. at 50.

C

Arkansas contends that if it can properly claim ownership of the bonds under 31 C.F.R. § 315.20—an argument rejected earlier in part I—it need not present the physical bonds or the bond serial numbers. There is no basis for this contention in the regulations. The provisions in 31 C.F.R.§§ 315.20–23 lay out requirements for establishing ownership when ownership transferred due to proceedings such as bankruptcy or divorce. They also establish certain circumstances in which Treasury will not recognize the transfer of ownership, such as when judicial proceedings are still pending. *See* 31 C.F.R. § 315.20(c) (stating that Treasury "will not accept a notice of an adverse claim or notice of pending judicial proceedings"). But the general requirements for redeeming a bond—such as presenting the physical bond, or, if the bond is lost, providing the serial number—still apply, and the States cannot meet them.[8]

[8] Alternatively, Arkansas argues that since Treasury has exercised its waiver authority under 31 C.F.R. § 315.90(a) to allow states to redeem bonds where the states had both title and possession, its refusal to extend such a waiver here "violates its duty of good faith and fair dealing" implicit in the bond contract. Arkansas Resp. Br. at 53–54. We disagree. When a state has possession and title, Treasury has been willing to waive the prohibition on transfers of ownership and the requirement that only the registered owner may redeem a bond. *See* 31 C.F.R. § 315.15. But Treasury does *not* waive the requirement that the owner

D

Finally, both States argue that even if they must provide the bond serial numbers, the government has the obligation under the Freedom of Information Act ("FOIA") to disclose those serial numbers to the States, or, alternatively, that the government through discovery may be compelled to ascertain the serial numbers.

The States suggest that the government is obligated to provide serial numbers in response to a FOIA request, citing 31 C.F.R. § 323.2(b). But that regulation merely restricts *who* may obtain information through a FOIA request, providing that securities records "will ordinarily be disclosed *only* to the owners of such securities." *Id.* (emphasis added). It does not specify what information maybe obtained and under which circumstances. In any event, whether the States have the right to obtain serial numbers of bonds through a FOIA request is not before us. Kansas filed such a FOIA request, which Treasury denied.[9] Kansas did not pursue further review in court, which it would have had to seek in district court. *See* 5 U.S.C. § 552(a)(4)(B). The Claims Court therefore properly declined to rely on FOIA, noting that it has no jurisdiction over denials of FOIA requests. *See Laturner*, 135 Fed. Cl. at 505 n.3.

Alternatively, the States argue that they should be entitled to obtain the bond serial numbers through the ordinary discovery process. While the Claims Court opinion is not entirely clear, it appears to have agreed. However, the court recognized in certifying its orders for interlocutory appeal that "the burdens of discovery going forward (both in terms of effort and expense) will undoubtedly be formidable given the state of Treasury's savings bond records." J.A. 5. Treasury's bond records are not digitized and therefore not computer-searchable. Nor are they organized by the state listed in the bond's registration. For that reason, locating the serial numbers of the bonds would require manually searching approximately 3.8 billion savings bonds records to identify those whose registered owners had an address in

must present the physical bond (or, if applicable, the bond serial number). *See* 31 C.F.R. §§ 315.39(a), 315.25, 315.29(c). Treasury's refusal to waive those requirements here does not violate the provisions of the bond contract, and the "implied duty of good faith and fair dealing cannot expand a party's contractual duties beyond those in the express contract or create duties inconsistent with the contract's provisions." *Dobyns v. United States*, 915 F.3d 733, 739 (Fed. Cir. 2019) (quoting *Precision Pine & Timber, Inc. v. United States*, 596 F.3d 817, 831 (Fed. Cir. 2010)).

[9] Treasury's denial of Kansas's FOIA request rested on two grounds. First, Treasury stated that it lacked responsive records because its records are not compiled or searchable by the state listed in the bond's registration. Second, it determined that disclosing bond records to someone other than the registered owner would, under the circumstances, constitute an unwarranted invasion of personal privacy pursuant to FOIA Exemption 6. *See* 5 U.S.C. § 552(b)(6).

Kansas or Arkansas. Treasury estimates that locating these bonds here would cost $100 million and take over 2,000 hours of employee time. J.A. 817.

We need not decide whether locating the bond serial numbers would be unduly burdensome such that it would be an abuse of discretion to grant the States' discovery request. That is so because requiring the government to disclose the bond serial numbers as a matter of discovery would impermissibly circumvent the requirement in 31 C.F.R. § 315.29(c) that the bond owner provide the serial number to redeem a bond six or more years past maturity. Adopting the States' position would effectively eliminate this requirement, as a bond holder could always file suit and then obtain the serial number through discovery. This would contravene the principle that the Federal Rules of Civil Procedure cannot "enlarge or modify any substantive right." 28 U.S.C. § 2072(b); *see Shady Grove Orthopedic Assocs., P.A. v. Allstate Ins. Co.*, 559 U.S. 393, 423 (2010) (Stevens, J., concurring) ("A federal rule . . . cannot govern a particular case in which the rule would displace a state law that . . . functions to define the scope of the state-created right."); *Semtek Int'l Inc. v. Lockheed Martin Corp.*, 531 U.S. 497, 503–04 (2001) (noting that if state law granted a particular right, "the federal court's extinguishment of that right" through application of a Rule of Civil Procedure "would seem to violate this limitation" contained in § 2072(b)).

The Second Circuit's decision in *Federal Treasury Enterprise Sojuzplodo import v. SPI Spirits Ltd.*, 726 F.3d 62 (2d Cir. 2013), provides an illustration. There, the plaintiff sought to sue for trademark infringement under the Lanham Act, but could not meet the Lanham Act's statutory standing requirement, which "permits only 'registrants' to bring actions for infringement of registered marks." *Id.* at 83. The plaintiff was not the registrant but argued that it could nonetheless bring suit because the real party in interest had ratified the plaintiff's suit as permitted by Federal Rule of Civil Procedure 17(a). The Second Circuit held that the corporation could not use Rule 17(a) "to bypass the standing requirement" in the Lanham Act. *Id.* at 83. The court reasoned that "[t]o enlarge standing [by applying Rule 17] would extend the entitlement to sue to a new party that is otherwise unauthorized under the" Lanham Act, and thus "amount to an improper expansion of the substantive rights provided by the Act." *Id.*; *see also Eden Toys, Inc. v. Florelee Undergarment Co.,* 697 F.2d 27, 32 n.3 (2dCir. 1982) ("While [Federal Rule of Civil Procedure 17(a)]ordinarily permits the real party in interest to ratify a suit brought by another party, the Copyright Law is quite specific in stating that only the 'owner of an exclusive right under a copyright' may bring suit."

(internal citation omitted) (quoting 17 U.S.C. § 501(b) (1980))), *superseded on other grounds by* Fed. R. Civ. P. 52(a).

Similarly, here the States cannot use the discovery rules to bypass the serial number requirement of the Treasury regulations. Allowing the States to do so would improperly expand the substantive right to payment under the Treasury regulations, since it would extend the right to receive payment to circumstances in which the claimant would otherwise *not* be entitled to payment.

This is also a situation in which the bond holders have agreed to the requirements of the Treasury regulations as part of the bond contract. It is well-established that "before suit has been filed, before any dispute has arisen," parties may waive various rights through contract—even those based in the Constitution, such as due process rights to notice and a hearing. *D. H. Overmyer Co. v. Frick Co.*, 405 U.S. 174, 184–85 (1972); *see also Herman Miller, Inc. v. Thom Rock Realty Co.*, 46 F.3d 183, 189 (2d Cir. 1995) (enforcing contract provision waiving right to a jury trial). It follows that even if bond holders might otherwise be entitled to certain discovery, they may limit that right by agreeing to the terms of the bond contract, which require them to present the physical bonds or the bond serial numbers for payment.

III

Finally, the States assert that Treasury's denial of their redemption requests was a "taking" of their property. The essence of a takings claim is that the government "takes possession of an interest in property for some public purpose" and must therefore "compensate the former owner." *Tahoe-Sierra Pres. Council, Inc. v. Tahoe Reg'l Planning Agency*, 535 U.S. 302, 322 (2002). But here the government has not taken possession of any interest in the bonds. The bonds remain the property of the original owners, who under Treasury regulations retain the right to redeem the bonds at any time. The States simply do not have a property interest in the bonds, and, even if they did, they can have no greater property interest than the original owners. *See A & D Auto Sales, Inc. v. United States*, 748 F.3d 1142, 1151 (Fed. Cir. 2014) ("[T]he existence of a valid property interest is necessary in all takings claims." (quoting *Wyatt v. United States*, 271 F.3d 1090, 1097 (Fed. Cir. 2001)). Because no property interest of the States has been impaired, there can be no taking.

CONCLUSION

Because the States' escheat laws attempt to transfer ownership of the bonds to the States in contravention of Treasury regulations, they are preempted by Federal law. In addition, because the States lack

the serial numbers or possession of the bonds at issue, they could not redeem the bonds even if they validly owned them.

We reverse the judgment below and remand with instructions to enter summary judgment for the government.

REVERSED
COSTS

No costs.

SWAGWAY, LLC, Appellant v. INTERNATIONAL TRADE COMMISSION, Appellee SEGWAY, INC., DEKA PRODUCTS LIMITED PARTNERSHIP, NINEBOT (TIANJIN) TECHNOLOGY CO., LTD., Intervenors

Appeal No. 2018–1672

Appeal from the United States International Trade Commission in Investigation Nos. 337-TA-1007, 337-TA-1021.

OPINION ISSUED: May 9, 2019

OPINION MODIFIED: August 14, 2019*

LAURENCE M. SANDELL, Mei & Mark LLP, Washington, DC, argued for appellant. Also represented by LEI MEI, ROBERT HALL, PHILIP ANDREW RILEY.

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NICHOLAS A. BROWN, Greenberg Traurig LLP, San Francisco, CA, argued for intervenors. Also represented by JONATHAN D. BALL, New York, NY.

Before DYK, MAYER, and CLEVENGER, *Circuit Judges.*

CLEVENGER, *Circuit Judge*.

This appeal was previously decided by our opinion dated May 9, 2019. *Swagway, LLC v. Int'l Trade Comm'n*, 923 F.3d 1349 (Fed. Cir. 2019). Intervenors, Segway, Inc., DEKA Products Ltd. Partnership, and Ninebot (Tianjin) Technology Co., Ltd. (collectively, "Segway") thereafter filed a combined petition for panel rehearing and rehearing en banc which questioned Part III of our original decision. In Part III of our decision, we accepted Swagway's conditional withdrawal of its argument regarding its consent order motion because we held that the International Trade Commission's ("the Commission") trademark determinations are not entitled to preclusive effect.[1] The panel invited a response from the Commission and Swagway, LLC ("Swagway").

After considering Segway's petition and the Commission's and Swagway's responses, we grant Segway's petition for panel rehearing to the extent that we vacate Part III of our original decision on the issue of the preclusive effect of the Commission's trademark decisions under 19 U.S.C. § 1337 ("§ 337"). The court's opinion is modified accordingly. The remaining portions of the opinion are unchanged.

* This opinion has been modified and reissued following a combined petition for panel rehearing and rehearing en banc filed by Intervenors.

[1] Oral Arg. at 35:04–35:09, 34:31–40 (agreeing to withdraw its argument regarding its consent order motion if this Court held that the Commission's trademark determinations are not entitled to preclusive effect).

Swagway, LLC appeals the Final Determination of the International Trade Commission, which found that Swagway violated 19 U.S.C. § 1337. Because we conclude that the Commission did not err in its determination, we affirm.

BACKGROUND

Segway filed a Complaint with the Commission on May 18, 2016, alleging violations of § 337 based on infringement of six patents not at issue in the current appeal, and two trademarks: U.S. Trademark Registration Nos. 2,727,948 ("the '948 mark") and 2,769,942 ("the '942 mark").

Segway owns both the '948 and '942 marks. The '948 mark is the non-stylized SEGWAY mark, which covers "motorized, self-propelled, wheeled personal mobility devices, namely, wheelchairs, scooters, utility carts, and chariots." J.A. 220. The '942 mark is the stylized version of the SEGWAY mark covering the same goods as its non-stylized counterpart. The Complaint filed with the Commission alleged that Swagway's self-balancing hoverboard products, marketed under the names SWAGWAY X1 and X2, as well as SWAGTRON T1 and T3, infringed Segway's marks.

On August 16, 2016, Segway filed another Complaint with the Commission alleging infringement of the same patents and trademarks, but naming additional respondents. The Commission instituted investigations based on both complaints, consolidated them, and assigned an administrative law judge ("ALJ").

On March 21, 2017, Swagway moved for partial termination of the investigation regarding the trademark infringement allegations on the basis of a consent order stipulation. Swagway amended its consent order stipulation and the corresponding proposed consent order on two separate occasions. The proposed consent order stipulated, among other things, that Swagway would not sell or import "SWAGWAY-branded personal transporter products as well as all components thereof, packaging and manuals therefor." J.A. 560. Segway opposed the stipulation and proposed consent order based on the fact that it addressed only a subset of the claims and products at issue in the investigation, and because, according to Segway, it would allow Swagway to relitigate the issue of trademark infringement with respect to the products covered by the order.

During the investigation, the Commission granted Segway's motions to terminate the investigation as to four of the six patents. By the time the ALJ held a hearing in the investigation, only U.S. Patent Nos. 6,302,230 ("the '230 patent") and 7,275,607 ("the '607 patent"), and the '942 and '948 trademarks remained.

The ALJ scheduled a hearing in the consolidated investigation for April 18, 2017. Prior to the hearing, the ALJ held a prehearing conference during which counsel for Swagway inquired about the pending motion for consent order on which it had yet to receive a ruling. The ALJ indicated that, because of the number of versions of the consent order and the amount of briefing, "it certainly [wasn't] going to be ruled on . . . before the end of the hearing." J.A. 3034.

After the hearing, the ALJ issued a Final Initial Determination ("ID"), finding that the respondents' accused products did not infringe the asserted claims of the '230 and '607 patents, and that the technical prong of the domestic industry requirement was not satisfied for those patents. The ID also found that Swagway's use of the SWAGWAY designation, but not the SWAGTRON designation, infringed the '942 and '948 trademarks. The ALJ's trademark infringement determination was based on its analysis of six "likelihood of confusion" factors: (1) evidence of actual consumer confusion; (2) the degree of similarity in appearance and pronunciation between the marks; (3) the intent of the actor in adopting the designation; (4) the relation in use and manner of marketing between the products bearing the mark or designation; (5) the degree of care exercised by consumers of the marked or designated products; and (6) the strength of the mark.

As to the first factor, the ALJ found that there was "overwhelming evidence" of actual confusion between the SWAGWAY designation and the Segway marks. J.A. 230. But the ALJ found only de minimis actual confusion between the SWAGTRON designation and the Segway marks.

The ALJ found that the second factor weighed in favor of finding a likelihood of confusion because the Segway marks and SWAGWAY designation looked alike and had similar pronunciations. The ALJ found the opposite for the SWAGTRON designation.

The ALJ determined that Swagway's founder did not intend to infringe Segway's trademarks based on his testimony that he independently derived the SWAGWAY designation, and his testimony that he changed the designation to SWAGTRON after receiving a cease-and-desist letter from Segway's counsel. The ALJ did not definitively state whether the intent of the actor factor weighed in favor of or against a likelihood of confusion.

As to the fourth factor, the ALJ found that Segway's and Swagway's products are sold on the same websites and in the same stores. Thus, the products exist in a common commercial channel. The ALJ determined, however, that the goods offered in connection with the asserted trademarks are significantly more expensive than the SWAGWAY and SWAGTRON products. The ALJ therefore found that the

fourth factor weighed against a finding that the SWAGWAY and SWAGTRON designations were likely to cause consumer confusion.

The ALJ did not make a determination on the fifth factor because neither party presented evidence going to the degree of care exercised by consumers in purchasing products associated with the asserted trademarks or the SWAGWAY and SWAGTRON designations.

The ALJ found that the conceptual and commercial strength of the asserted trademarks was high due to the fact that the term "Segway" was coined "for the sole purpose of functioning as a trademark" and because consumers strongly associated the SEGWAY brand with the products. J.A. 235–37.

The ALJ's ID did not mention Swagway's motion for termination based on its consent order stipulation. The ALJ stated in a footnote to its ID that "[a]ny pending motion that has not been adjudicated is denied, unless otherwise noted." J.A. 62 n.2. The ID said nothing more about Swagway's motion for termination based on a consent order stipulation.

Swagway subsequently filed a petition for review of the ALJ's ID. As relevant here, Swagway appealed the denial of its consent order motion and the ID's finding that the SWAGWAY mark infringed the '942 and '948 trademarks.

The Commission issued a notice of its determination to review the ID's finding that actual confusion existed with regard to the SWAGWAY mark. The Commission determined not to review the ALJ's denial of Swagway's consent order motion.

The Commission issued an opinion reversing the ALJ's determination on the existence of actual confusion because the incidents of actual confusion were small as compared to the volume of sales of SWAGWAY-branded products, and Segway failed to rebut Swagway's argument and supporting evidence that at least some of the proffered actual confusion evidence was unreliable. The Commission therefore modified the ID, finding that evidence of actual confusion "d[id] not weigh in favor of likelihood of confusion." J.A. 38. Nonetheless, the Commission agreed with the ALJ's likelihood-of-confusion determination and its trademark infringement determination because the "[e]vidence supporting the other factors considered by the ID, including the degree of similarity between the two marks in appearance, the pronunciation of the words, and the strength of the SEGWAY marks strongly support[ed] the ID's finding of infringement." *Id.*

Swagway appeals the Commission's decision finding that Swagway infringed the '942 and '948 marks. Swagway also appeals the Commission's failure to enter the proposed consent order. We have jurisdiction over Swagway's appeal pursuant to 28 U.S.C. § 1295(a)(6).

DISCUSSION

I. Standard of Review

We review the ITC's legal determinations *de novo* and its factual findings for substantial evidence. *Converse, Inc. v. Int'l Trade Comm'n*, 909 F.3d 1110, 1115 (Fed. Cir. 2018).

The Commission's ultimate likelihood-of-confusion determination is a legal determination that we review *de novo*. *Id.*; *In re I.AM.Symbolic, LLC*, 866 F.3d 1315, 1322 (Fed. Cir. 2017) ("Likelihood of confusion is a question of law based on underlying findings of fact."). We also accord *de novo* review to the weight given to each likelihood-of-confusion factor. *Cf. Stone Lion Capital Partners, L.P. v. Lion Capital LLP*, 746 F.3d 1317, 1322 (Fed. Cir. 2014) (reviewing the weight given to the similarity-of-the-marks factor for legal error). The likelihood-of-confusion determination is based upon factual underpinnings that this Court reviews for substantial evidence. *In re Mighty Leaf Tea*, 601 F.3d 1342, 1346 (Fed. Cir. 2010). For example, the question of the similarity between two marks and the relatedness of goods are factual determinations. *See Shen Mfg. Co. v. Ritz Hotel, Ltd.*, 393 F.3d 1238, 1241 (Fed. Cir. 2004).

II. Trademark Infringement

To prove trademark infringement, the owner of the asserted trademark must demonstrate that consumers would likely confuse the alleged infringer's mark with the asserted mark. *Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1330 (Fed. Cir. 1999). Whether a likelihood of confusion exists is determined using the factors set out in *In re E.I. DuPont DeNemours & Co.*, 476 F.2d 1357 (C.C.P.A. 1973). *See In re Guild Mortg. Co.*, 912 F.3d 1376, 1378–79 (Fed. Cir. 2019).[2] The *DuPont* factors are:

> (1) The similarity or dissimilarity of the marks in their entireties as to appearance, sound, connotation and commercial impression.
>
> (2) The similarity or dissimilarity and nature of the goods or services as described in an application or registration or in connection with which a prior mark is in use.

[2] Our predecessor court articulated the *DuPont* framework in assessing likelihood of confusion for purposes of registration of trademarks. Recently, the Supreme Court ruled that "likelihood of confusion for purposes of registration is the same standard as likelihood of confusion for purposes of infringement." *B & B Hardware, Inc. v. Hargis Indus., Inc.*, 135 S. Ct. 1293, 1307 (2015). The present matter comes to us from the International Trade Commission's ruling under 19 U.S.C. § 1337 relating to trademark infringement. Accordingly, we apply our *DuPont* framework to the likelihood of confusion issue in reviewing the Commission's infringement determination.

> (3) The similarity or dissimilarity of established, likely-to-continue trade channels.
>
> (4) The conditions under which and buyers to whom sales are made, i.e. "impulse" vs. careful, sophisticated purchasing.
>
> (5) The fame of the prior mark (sales, advertising, length of use).
>
> (6) The number and nature of similar marks in use on similar goods.
>
> (7) The nature and extent of any actual confusion.
>
> (8) The length of time during and conditions under which there has been concurrent use without evidence of actual confusion.
>
> (9) The variety of goods on which a mark is or is not used (house mark, "family" mark, product mark).
>
> (10) The market interface between applicant and the owner of a prior mark ....
>
> (11) The extent to which applicant has a right to exclude others from use of its mark on its goods.
>
> (12) The extent of potential confusion, i.e., whether de minimis or substantial.
>
> (13) Any other established fact probative of the effect of use.

Id. at 1379.

In this case, the ALJ considered only six factors that are nearly identical to those outlined in *DuPont*: (1) actual confusion; (2) the intent of the actor in adopting the designation; (3) the relation in use and manner of marketing between the goods and services marked by the actor and those by the other; (4) the degree of similarity between the designation and the trademark; (5) the strength of the mark; and (6) the degree of care likely to be exercised by purchasers. The Commission need not consider every *DuPont* factor. *Shen Mfg.*, 393 F.3d at 1241. It is required to consider only those factors which are supported by evidence in the record. *Id.* Moreover, neither party challenges the Commission's choice of *DuPont* factors.

Swagway argues that the Commission accorded the wrong weight to the actual confusion factor. According to Swagway, lack of actual confusion evidence is especially probative in cases such as this where the products bearing the registered trademarked and the allegedly infringing products are sold concurrently over a substantial period of time. Swagway contends, therefore, that the Commission should have found the lack of actual confusion essentially dispositive in this case.

First, while the *DuPont* factors recognize the relevance of concurrent use without evidence of actual confusion, we have never indicated that the concurrent use factor always bars a likelihood-of-confusion finding. Instead, we have found that "[s]uch evidence weighs against a likelihood of confusion, but must then be balanced against the other evidence of record." *Guild*, 912 F.3d at 1381.

Second, the Commission never determined that the lack of actual confusion evidence cannot in any circumstance weigh against a likelihood-of-confusion finding. Instead, it found that the lack of actual confusion "d[id] not weigh in favor of a finding of a likelihood of confusion." J.A. 38. Swagway does not argue on appeal that its evidence presented below warranted a finding of long-term, concurrent use in the same channels of trade. *See Guild*, 912 F.3d at 1381 (holding that the period during which two marks are used concurrently in similar geographic markets and channels of trade is "relevant when assessing whether the absence of actual confusion is indicative of the likelihood of confusion"). Thus, it failed to establish that the absence of actual confusion evidence should even weigh against, let alone strongly against, a likelihood-of-confusion finding under our precedent.

Swagway also argues more generally that, after reversing the ALJ's determination with regard to actual confusion, the Commission failed to "properly re-weigh the likelihood-of-confusion factors." Appellant's Br. 25. The Commission did, however, reweigh the factors and found that the "[e]vidence supporting the other factors considered by the ID, including the degree of similarity between the two marks in appearance, the pronunciation of the words, and the strength of the SEGWAY marks strongly support the ID's finding of infringement." J.A. 38. To the extent that Swagway argues that the Commission erred in its determination because "only two of the six factors considered . . . favor a likelihood-of-confusion finding," while "three factors . . . weigh against such a finding," that argument is unpersuasive as a matter of both fact and law. Appellant's Br. 26.

The ALJ never stated that the "intent of the actor" factor weighed in favor of or against a likelihood-of-confusion finding. It stated only that there appeared "to be concrete actions taken by [Swagway's founder] Mr. Zhu that lend credibility to his testimony regarding his lack of intent to infringe the Segway trademarks." J.A. 232. The Commission also did not find that the lack of actual confusion evidence weighed against a likelihood-of-confusion finding. Instead, it found that the lack of such evidence did not weigh in favor of such a finding. There was, therefore, only one factor, "relation in use and

manner of marketing," that the Commission found to weigh against a likelihood of confusion between the asserted trademarks and the SWAGWAY designation.

Moreover, the likelihood-of-confusion analysis cannot be reduced to a simple tally of the factors. The factors are accorded different weights in different circumstances. *See M2 Software, Inc. v. M2 Commc'ns, Inc.*, 450 F.3d 1378, 1382 (Fed. Cir. 2006) (noting that it is necessary to consider only the *DuPont* factors relevant to and of record in a specific case, and that any one factor may control a particular case). Our precedent supports the Commission's finding that the strength of the asserted trademark, along with the comparable similarity of the asserted and allegedly infringing marks, can weigh strongly in favor of a likelihood of confusion. *See Han Beauty, Inc. v. Alberto-Culver Co.*, 236 F.3d 1333, 1336 (Fed. Cir. 2001) ("While it must consider each factor for which it has evidence, the Board may focus its analysis on dispositive factors, such as similarity of the marks and relatedness of the goods."); *I.AM.Symbolic*, 866 F.3d at 1324 (finding that the similarity of the marks weighed heavily in favor of a likelihood of confusion); *Kenner Parker Toys Inc. v. Rose Art Indus., Inc.*, 963 F.2d 350, 352 (Fed. Cir. 1992) ("The fifth [*D*]*uPont* factor . . . plays a dominant role in cases featuring a famous or strong mark."); *Specialty Brands, Inc. v. Coffee Bean Distribs., Inc.*, 748 F.2d 669, 675 (Fed. Cir. 1984) (holding that "[w]hen an opposer's trademark is a strong, famous mark, it can never be of little consequence" in a likelihood-of-confusion analysis (internal quotation marks omitted)).

Swagway also takes issue with the Commission's failure to weigh Segway's lack of survey evidence against a likelihood-of-confusion finding. According to Swagway, Segway had the financial means to conduct surveys, and thus, its failure to do so should create "an adverse inference that such a survey would not have shown a likelihood of confusion with respect to the asserted trademarks." Appellant's Br. 27. But the adverse inference Swagway encourages us to adopt belies our precedent. Consumer survey evidence is not required to show a likelihood of confusion. *Midwestern Pet Foods, Inc. v. Societe des Produits Nestle S.A.*, 685 F.3d 1046, 1054 (Fed. Cir. 2012). We have also previously declined to infer that the lack of survey evidence indicates that such evidence would be harmful to the party alleging infringement. *Id.* The Commission therefore did not err in according no weight to Segway's lack of survey evidence.

III. Consent Order Motion

The Commission's rules grant an ALJ the discretion to terminate a § 337 investigation by consent order. 19 C.F.R. § 210.21(c) ("An investigation before the Commission *may* be terminated . . . on the basis of a consent order." (emphasis added)). An ALJ's discretion in considering a motion for consent order resolution of an investigation is somewhat cabined. When an ALJ exercises discretion to grant a proposed consent order, the Commission's rules require the ALJ to consider the impact of the proposed termination by consent order on the "public interest," including "the effect of the proposed settlement on the public health and welfare, competitive conditions in the U.S. economy, the production of like or directly competitive articles in the United States, and U.S. consumers." 19 C.F.R. § 210.50(b)(2). The Commission often finds that the public interest favors entry of consent orders to conserve public resources and avoid unnecessary litigation. *See, e.g.*, *Certain Integrated Circuit Chipsets & Prod. Containing Same*, Inv. No. 337-TA-428, USITC Order No. 16 (July 26, 2000) ("In addition[,] the public interest favors settlement to avoid needless litigation and to conserve public resources."); *Certain Vehicle Sec. Sys. & Components Thereof*, Inv. No. 337-TA-355, USITC Order No. 16 (Feb. 7, 1994) (denying the motion to terminate the investigation because proceeding with the investigation would "not require a substantial expenditure of public or private resources, especially in comparison with those already used in the prehearing phase of the investigation"). The pertinent regulations do not specify the extent to which an ALJ's discretion is cabined when an ALJ decides to deny a consent order motion. We assume for purposes of this appeal, but without deciding the question, that an ALJ is guided in denying a consent order motion by the same criteria as are required when granting a motion.

A party's proposal to resolve an investigation by consent "shall be submitted as a motion to the administrative law judge with a stipulation that incorporates a proposed consent order." 19 C.F.R. § 210.21(c)(1)(ii). Commission rules specify in detail the required contents of the necessary stipulation. *See id.* § 210.21(c)(3)–(4). Such a motion may be filed at any time before the commencement of the hearing before the ALJ, but "for good cause shown, the administrative law judge may consider such a motion during or after a hearing." *Id.* § 210.21(c)(1)(ii). The filing of a consent order motion "shall not stay proceedings before the administrative law judge unless the administrative law judge so orders." *Id.* The Commission's rules further specify that if an ALJ exercises discretion to grant a consent order motion, the grant must be by issuance of an initial determination, *id.*

§ 210.42(c), "promptly file[d] with the Commission." *Id.* § 210.21(c)(1)(ii). But if discretion is exercised to deny the motion, the regulation requires that the denial be in the form of an order. *Id.* § 210.42(c).

The § 337 investigation in this case involved allegations of patent and trademark infringement. Swagway was accused of infringing six Segway patents, and two Segway trademarks. Swagway sought to resolve the trademark aspects of the case with respect to the SWAGWAY-branded products, but not with respect to the SWAGTRON-branded products, by consent order resolution. Accordingly, ten months after the investigation began in this case, on March 21, 2017, Swagway filed a § 210.21(c)(3)–(4)-compliant proposed consent order motion for resolution of the one trademark dispute, which Segway opposed. Swagway filed an amended proposed consent order motion, which Segway also opposed. On April 5, 2017, Swagway requested leave to file a response to Segway's opposition, and sought to submit a third proposed consent order. During a hearing on April 18, 2017, Swagway reminded the ALJ about the pending motions, saying, "[o]ne other issue was that swagway has a pending motion for consent order that we haven't received a ruling on." J.A. 3034. The ALJ replied, "I think we've now had how many versions of that?" *Id.* "Three, your Honor," was the answer. *Id.* The ALJ responded, "[t]hree. . . . we've had all kinds of briefing. It certainly isn't going to be ruled on . . . . before the end of the hearing. . . . The hearing moves on." *Id.* And the hearing on the merits began later that day. On August 10, 2017, the ALJ issued the final ID in the case. The second footnote to the final ID stated: "Any pending motion that has not been adjudicated is denied, unless otherwise noted." J.A. 62. Swagway's motion for consent order was thereby denied.

When the ALJ determined to proceed with a hearing on the merits, he had before him the third version of swagway's proposed consent order. By that time, considerable party and judicial resources had been expended in the case. The parties had completed fact and expert discovery, filed summary judgment motions, served both direct and rebuttal witness statements containing all the direct testimony that would be offered at the evidentiary hearing, and served all direct and rebuttal exhibits.

Swagway petitioned the Commission for review of the ALJ's final ID and remedial Order. Swagway raised the subject of the consent order motion in its petition for review. Swagway informed the Commission that the ALJ violated § 210.42(c) by denying its consent order motion in the ID rather than in a separate order. Otherwise, swagway's complaint with the denial of its consent order motion was that (a) it

fully complied with all the regulations concerning content and (b) in Swagway's view, granting the motion would have promoted the public interest. The Commission's final decision declined to review the ALJ's denial of Swagway's consent order motion. In doing so, the Commission found no error in the ALJ's disposition of the proposed consent order motion.

In its appeal to this court, Swagway shifts the focus of its complaint about the ALJ's denial of its consent order motion. Now Swagway makes a double-barrel argument that the denial is arbitrary, capricious and consequently a violation of the Administrative Procedure Act ("APA"). Swagway asks this Court to vacate the Commission's decision and remand for consideration of the consent order motion. Alternatively, Swagway requests that we reverse the Commission's denial of the consent order motion and direct the Commission to enter the proposed consent order.[3]

Swagway first argues that the Commission's failure to provide an express explanation for denial of the consent order motion violates the APA, as an action without explanation can be arbitrary and can frustrate appellate review. The caselaw, however, does not require that agencies explicitly spell out their rationale or reasoning in perfect detail or clarity as long as we can discern the path the agency followed. *See Bowman Transp., Inc. v. Arkansas-Best Freight Sys., Inc.*, 419 U.S. 281, 286 (1974) ("[W]e will uphold a decision of less than ideal clarity if the agency's path may reasonably be discerned."); *see also Ariosa Diagnostics v. Verinata Health, Inc.*, 805 F.3d 1359, 1365 (Fed. Cir. 2015) ("We may affirm an agency ruling if we may reasonably discern that it followed a proper path, even if that path is less than perfectly clear.").

Here, the ALJ's, and therefore the Commission's, reason for denying Swagway's consent order motion is clear from the record. The ALJ received three versions of a proposed consent order, and briefing on the consent order was not complete until just seven days before the evidentiary hearing. By that point, the parties had expended consid-

[3] As an initial matter, the Commission contends that this Court lacks jurisdiction over the consent order motion issue. We find that argument unpersuasive. Under 28 U.S.C. § 1295, this Court has jurisdiction to "review the final determinations of the . . . Commission relating to unfair practices in import trade, made under section 337 of the Tariff Act of 1930 (19 U.S.C. 1337)." 28 U.S.C. § 1295(a)(6). With the jurisdiction to review the Commission's final determinations also comes the jurisdiction to review matters ancillary to or affecting the validity of those final determinations. *See Refractarios Monterrey, S. A. v. Ferro Corp.*, 606 F.2d 966, 970 n.10 (C.C.P.A. 1979) ("[S]ome review of material which may be ancillary to the final determination is necessary."); *cf. Viscofan, S.A. v. U.S. Int'l Trade Comm'n*, 787 F.2d 544, 552 (Fed. Cir. 1986) (finding that we had no jurisdiction to review the Commission's refusal to declassify confidential business information because the refusal "was unrelated to the propriety of the exclusion order"). The consent order motion issue clearly affects the propriety of the final determination on the merits, and thus we have jurisdiction to review the denial of that motion.

erable resources completing fact and expert discovery, finalizing exhibits and witness statements, and preparing for the hearing. Though Swagway could have done so under the Commission's rules, it never requested that the ALJ stay the proceedings pending resolution of its consent order motion. Thus, as the ALJ remarked, "the hearing move[d] on." J.A. 3034. Because at that stage in the investigation the public interest in avoiding unnecessary litigation could no longer weigh in favor of granting the motion, the ALJ denied it. Such a decision was within the ALJ's discretion under the Commission's rules, and we can find no abuse of that discretion, and no violation of the APA.

Second, Swagway argues that the Commission's denial of the consent order motion was arbitrary and capricious because the denial occurred in a footnote to the ID, as opposed to in an order, in violation of the Commission's rules. The rule is clear: grants are in IDs and denials are in orders. 19 C.F.R. § 210.42(c)(1). In *Align Technology, Inc. v. International Trade Commission*, we held that the Commission is bound to follow and must strictly comply with its rules, including the ones in § 210.42(c), unless it waives, suspends, or amends them pursuant to 19 C.F.R. § 201.4(b). 771 F.3d 1317, 1325 (Fed. Cir. 2014). Here, the ALJ failed to follow § 210.42(c)(1), and the Commission propagated that error by refusing to correct the ALJ's mistake on review. Therefore, under *Align*, this case presents a rule violation cognizable under the APA.[4]

However, unlike the appellant in *Align*, who was harmed by the Commission's rule violation, Swagway is not entitled to relief under the APA. The APA specifies that we must take account of the rule of harmless error. 5 U.S.C. § 706 ("[A] court shall review the whole record . . . and due account shall be taken of the rule of prejudicial error."); *Shinseki v. Sanders*, 556 U.S. 396, 406 (2009) (holding that § 706 requires application of "the same kind of 'harmless-error' rule that courts ordinarily apply in civil cases"). Swagway asserts harmful error in the ALJ's denial of its consent order motion. Swagway points to a pending litigation in which Segway is accusing it of trademark infringement on the same trademarks asserted in the Commission investigation. Swagway asserts that a consent resolution of the case would have no impact on the ongoing litigation, but a decision on the merits against it might have adverse preclusive effect in the pending litigation. Such possible prejudice arises from the decision of the ALJ to deny the consent motion, not from the form in which the ALJ

[4] *Align* rejected the Commission's attempt to justify the rule violation in that case under *American Farm Lines v. Black Ball Freight Service*, 397 U.S. 532, 539 (1970). 774 F.3d at 1326 n.7. The Commission and Segway do not seek to justify the Commission's violation of § 210.42(c) in this case under *Black Ball Freight*.

expressed the denial. Swagway points to no harm to it from the form in which the consent order motion was denied, and after independent review of the record, we can find no such harm. Swagway also has not argued that the Commission's rejection of its complaint about the denial of the consent order motion precludes the Commission from benefitting from the harmless error rule.

The denial of Swagway's consent order motion by footnote in the ID is thus not a violation for which we can afford Swagway relief under the APA.

CONCLUSION

For the reasons above, we affirm the Commission's determination that the SWAGWAY-branded personal-transporter products infringe the '948 and '942 marks. We also affirm the Commission's denial of Swagway's consent order motion.

AFFIRMED

COSTS

No costs.

MYMAIL, LTD., Plaintiff-Appellant v. OOVOO, LLC, IAC SEARCH & MEDIA, INC., Defendants-Appellees

Appeal No. 2018–1758, 2018–1759

Appeals from the United States District Court for the Northern District of California in Nos. 5:17-cv-04487-LHK, 5:17-cv-04488-LHK, Judge Lucy H. Koh.

Decided: August 16, 2019

ERIC WILLIAM BUETHER, Buether Joe & Carpenter LLC, Dallas, TX, argued for plaintiff-appellant. Also represented by BLAKE WILLIAM BUETHER.

ROBERT LOUIS HAILS, JR., Baker & Hostetler LLP, Washington, DC, argued for defendants-appellees. Also represented by T. CY WALKER; KEVIN PATRICK FLYNN, Cincinnati, OH; JARED A. BRANDYBERRY, Denver, CO.

Before LOURIE, O'MALLEY, and REYNA, *Circuit Judges.*

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

Opinion dissenting filed by *Circuit Judge* LOURIE.

REYNA, *Circuit Judge.*

MyMail, Ltd. appeals the decision of the United States District Court for the Northern District of California granting ooVoo, LLC's and IAC Search & Media, Inc.'s motions for judgment on the pleadings. Because we determine that the district court erred by declining to resolve the parties' claim construction dispute before adjudging patent eligibility, we vacate and remand.

BACKGROUND

MyMail, Ltd. ("MyMail") is the assignee of U.S. Patent Nos. 8,275,863 ("the '863 patent") and 9,021,070 ("the '070 patent") (collectively, the "MyMail patents"). On November 18, 2016, MyMail filed suit against ooVoo, LLC ("ooVoo") in the United States District Court for the Eastern District of Texas for infringement of the MyMail patents. About a month later, MyMail asserted its patents against IAC Search & Media, Inc. ("IAC"), also in the Eastern District of Texas. ooVoo and IAC each moved to dismiss their respective actions for improper venue. After the Supreme Court's opinion in *TC Heartland LLC v. Kraft Foods Group Brands LLC*, 137 S. Ct. 1514 (2017), all parties agreed to transfer the lawsuits to the Northern District of California. On July 12, 2017, both cases were transferred.

On October 31, 2017, ooVoo and IAC each filed identical motions for judgment on the pleadings, asserting that the MyMail patents are directed to patent-ineligible subject matter under 35 U.S.C. § 101. MyMail opposed both motions, arguing that the claimed inventions are patent eligible, as evidenced in part by a construction of the term "toolbar" rendered by the Eastern District of Texas in an earlier

proceeding involving the '070 patent. MyMail encouraged the court to adopt the Eastern District of Texas's construction of "toolbar" as part of its § 101 analysis. ooVoo and IAC opposed the adoption of that construction. But the district court in this case did not construe "toolbar" or any other terms of the MyMail patent claims. Nor did the court address the parties' dispute. Instead, on March 16, 2018, the district court issued orders granting ooVoo's and IAC's motions for judgment on the pleadings, holding the MyMail patents invalid under § 101. MyMail timely appealed both orders and this court consolidated the appeals.

I. The MyMail Patents

The MyMail patents are directed to methods of modifying toolbars that are displayed on Internet-connected devices such as personal computers. MyMail asserts claims 1–5, 9–13, 16–17, 19–20, and 23 of the '863 patent and claims 1–13 and 15–22 of the '070 patent (the "MyMail patent claims"). The parties agree that claim 1 of the '863 patent and claim 1 of the '070 patent are representative of the claimed subject matter for each patent, respectively.[1] The representative claims for both patents are reproduced below.

Claim 1 of the '863 patent recites:

> 1. A method of modifying a toolbar, comprising the steps of:
>
> a user Internet device displaying a toolbar comprising one or more buttons, the toolbar defined by toolbar data stored in one or more toolbar-defining databases, the toolbar data comprising a plurality of attributes, each attribute associated with a button of the toolbar, wherein for each button of the toolbar, at least one of the plurality of attributes identifying a function to be performed when the button is actuated by the user Internet device;
>
> the user Internet device automatically sending a revision level of the one or more toolbar-defining databases to a predetermined network address;
>
> a server at the predetermined network address determining, from the revision level, the user Internet device should receive the toolbar update data;
>
> the user Internet device receiving toolbar update data from the Internet;

[1] The '070 patent is a continuation of U.S. Application No. 13/573,311, which in turn is a continuation of the application that became the '863 patent. The specifications of the '070 patent and the '863 patent are thus nearly identical. We refer to the '070 patent unless otherwise noted.

the user Internet device initiating without user interaction an operation to update the toolbar data in accordance with the toolbar update data received;

the user Internet device updating, by the operation, the toolbar data in accordance with the toolbar update data, thereby producing updated toolbar data, the updating comprising at least one of the following steps (a) and (b), each respectively comprising:

(a) writing at least one new attribute to the original toolbar data, wherein the writing at least one new attribute to the toolbar data comprises changing the one or more buttons of the toolbar by adding a button; and

(b) updating at least one attribute of the toolbar data; and

the user Internet device displaying the toolbar as defined by the updated toolbar data.

'863 patent col. 29 ll. 28–63.

Claim 1 of the '070 patent recites:

1. A method for dynamically modifying a toolbar, the method comprising:

displaying the toolbar, at a user Internet device, that includes one or more toolbar buttons, the toolbar defined by toolbar data stored in one or more toolbar-defining databases, the toolbar data comprising a plurality of toolbar button attributes associated with the one or more toolbar buttons of the toolbar, wherein at least one of the plurality of toolbar button attributes identifies a function to be performed by a specific toolbar button upon actuation of the specific toolbar button;

invoking, from the user Internet device without user intervention, communication of information associated with the one or more toolbar-defining databases to a server associated with a network address;

receiving, at the server, the information associated with the one or more toolbar-defining databases;

determining, based on the information associated with the one or more toolbar-defining databases, that the user Internet device should receive updated toolbar data;

receiving, at the user Internet device, the updated toolbar data in response to determining that the user Internet device should receive the updated toolbar data;

initiating, at the user Internet device and without user interaction, an operation to update the toolbar data in accordance with the received updated toolbar data;

> updating the toolbar data at the user Internet device based on the operation and in accordance with the updated toolbar data, thereby updating the toolbar data, the updating comprising at least one member of a group comprising (a) and (b):
>
> (a) updating the toolbar data to include at least one new attribute of the toolbar data to change the toolbar by adding a toolbar button to the toolbar; and
>
> (b) updating the toolbar data to modify an attribute of at least one of the one or more toolbar buttons of the toolbar; and
>
> displaying at the user Internet device the toolbar as defined by the updated toolbar data,
>
> wherein the information associated with the toolbar data includes at least one member of a group comprising a revision level, version, time, date, user ID, account owner ID, PAP ID, IP address, session keys, billing data, name, address, account information, connection history, procedures performed by a user, group ID, e-mail address, e-mail ID, e-mail password, residential address, and phone number.

'070 patent col. 29 l. 40–col. 30 l. 20.

II. The Northern District of California's § 101 Analysis

In concluding that the MyMail patent claims are patent ineligible under 35 U.S.C. § 101, the district court for the Northern District of California determined that the claims fail both steps of the Supreme Court's *Alice* test. *See Alice Corp. v. CLS Bank Int'l*, 573 U.S. 208, 216–18 (2014). The district court performed this analysis without construing the claims or addressing the parties' claim construction dispute.

At *Alice* step one, the district court found that the MyMail patent claims "are directed to a process for updating toolbar software over a network without user intervention." J.A. 17. After comparing the MyMail patent claims with those already found to be directed to abstract ideas in other cases, the district court concluded that the MyMail patent claims are directed to an abstract idea because they "fall within the category of gathering and processing information" and "recite a process comprised of transmitting data, analyzing data, and generating a response to transmitted data." J.A. 17–18. The district court also concluded that the claims are directed to an abstract idea because "they relate to using communications networks to update software stored on computers." J.A. 19.

At *Alice* step two, the district court concluded that the claims fail to provide an inventive concept sufficient to save the claims. The district court reasoned that the claims recite generic, conventional components, such as "Internet-connected computers and servers," and that the specification confirmed that toolbars, which are the subject of the invention, were already in widespread use. J.A. 22 (citing '863 patent col. 10 ll. 8–13). The court concluded that adding or changing a button on the toolbar based on data stored in a toolbar-defining database is routine and conventional, and as a result, the MyMail patents are ineligible under § 101. MyMail appealed.

We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

MyMail now raises two issues on appeal: (1) whether the district court erred by failing to construe the MyMail patent claims before ruling on ooVoo's and IAC's Rule 12(c) motions; and (2) whether the district court erred by finding the MyMail patent claims patent ineligible under § 101.

We review a district court's Rule 12(c) dismissal for judgment on the pleadings under the law of the regional circuit, here the Ninth Circuit. *Nat. Alternatives Int'l, Inc. v. Creative Compounds, LLC*, 918 F.3d 1338, 1342 (Fed. Cir. 2019) (the Rule 12(c) analysis is "functionally identical" to the standard for deciding a Rule 12(b)(6) motion to dismiss). The Ninth Circuit reviews a court's grant of judgment on the pleadings de novo. *Daewoo Elecs. Am. Inc. v. Opta Corp.*, 875 F.3d 1241, 1246 (9th Cir. 2017).

When reviewing a Rule 12(c) dismissal, the Ninth Circuit accepts all material allegations in the complaint as true and construes them in the light most favorable to the nonmoving party. *Turner v. Cook*, 362 F.3d 1219, 1225 (9th Cir. 2004). In doing so, the court may consider material that is properly submitted as part of the complaint, which includes documents not physically attached to the complaint if their authenticity is not contested and the complaint necessarily relies on them. *Lee v. City of Los Angeles*, 250 F.3d 668, 688–89 (9th Cir. 2001). The court may also take judicial notice of matters of public record. *Id.* The dismissal may be affirmed only if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations. *Turner*, 362 F.3d at 1225.

Patent eligibility under § 101 is a question of law that may involve underlying questions of fact. *Interval Licensing LLC v. AOL, Inc.*, 896 F.3d 1335, 1342 (Fed. Cir. 2018). We review the district court's ulti-

mate conclusion on patent eligibility de novo. *Id*. Patent eligibility may be determined on a Rule 12(c) motion, but only when there are no factual allegations that, if taken as true, prevent resolving the eligibility question as a matter of law. *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1125 (Fed. Cir. 2018).

We evaluate patent eligibility under the two-step test set forth in *Alice*. 573 U.S. at 216–18. First, we consider whether a claim is directed to a patent-ineligible concept such as an abstract idea, law of nature, or natural phenomenon. *Elec. Power Grp., LLC v. Alstom S.A.*, 830 F.3d 1350, 1353 (Fed. Cir. 2016) (citing *Alice*, 573 U.S. at 216–18). Second, if the claim is directed to a patent-ineligible concept, we then determine whether the claim elements, considered both individually and as an ordered combination, "'transform the nature of the claim' into a patent-eligible application," of that concept. *Id.* (quoting *Alice*, 573 U.S. at 217).

Determining patent eligibility requires a full understanding of the basic character of the claimed subject matter. *Bancorp Servs., L.L.C. v. Sun Life Assurance Co. of Can. (U.S.)*, 687 F.3d 1266, 1273–74 (Fed. Cir. 2012). As a result, if the parties raise a claim construction dispute at the Rule 12(c) stage, the district court must either adopt the non-moving party's constructions or resolve the dispute to whatever extent is needed to conduct the § 101 analysis. *See Aatrix*, 882 F.3d at 1125.

Before the district court, the parties disputed the construction of "toolbar," a claim term present in the claims of both MyMail patents. MyMail directed the district court to a construction of "toolbar" rendered in another case involving the MyMail patents, *MyMail, Ltd. v. Yahoo! Inc*., No. 2:16-cv-01000 (E.D. Tex. 2017). J.A. 733, J.A. 734 n.8, J.A. 740,[2] J.A. 750–82.

In *Yahoo!*, the court construed "toolbar" based on "definitional" language in the specification that describes "the [t]oolbar of the present invention" as capable of being "dynamically changed or updated via a Pinger process or a MOT script." J.A. 764 (emphasis omitted) (quoting '070 patent col. 10 ll. 24–26). The *Yahoo!* court found that the "toolbar" recited in the claims is "not a generic toolbar," and quoted the following definition of the "Pinger process":

> As defined in this application . . . a Pinger process comprises an entity that acts transparently as a "services" coordinator to provide and/or administer the following: 1. Heartbeat service to

[2] The parties' Rule 12(c) memoranda are practically identical in both of the district court proceedings. Unless otherwise noted, we refer to the briefing in *MyMail Ltd. v. ooVoo, LLC*, No. 5:17-cv-04488 (N.D. Cal.) (ECF Nos. 101, 109, 110), at J.A. 450–72, J.A. 722–82, J.A. 844–914.

> help maintain network connectivity with a client. 2. Authentication services that securely authenticate client access to email, commerce, and other public and private network servers and services. 3. Update services that can perform client software, database, and maintenance services during periods of inactivity.

J.A. 764 (quoting '070 patent col. 10 ll. 16–26). Ultimately, the *Yahoo!* court construed "toolbar" to mean a "button bar that can be dynamically changed or updated via a Pinger process or a MOT script" (the "*Yahoo!* construction"). J.A. 766.

In this case, MyMail argued to the district court that the *Yahoo!* construction "confirms that the claims of the '070 patent are directed to a particular technological process for improving an exclusively computer-oriented device." J.A. 740. ooVoo and IAC, on the other hand, argued that the *Yahoo!* construction was "erroneous" and "improper." J.A. 853–55. On appeal, ooVoo and IAC maintain that the *Yahoo!* construction is "wrong." Appellee Br. 29.

The district court never addressed the parties' claim construction dispute. Nor did the district court construe "toolbar" or adopt MyMail's proposed construction of "toolbar" for purposes of deciding ooVoo's and IAC's Rule 12(c) motions. *See* Appellee Br. 39 ("[T]he district court's order on appeal sets forth no findings or conclusions regarding the precise construction of the [toolbar] term."). We note that *Aatrix* issued after the parties briefed ooVoo's and IAC's Rule 12(c) motions, but before the district court granted the motions. The district court did not cite *Aatrix* in its decision. Nevertheless, the district court's failure to address the parties' claim construction dispute is error under *Aatrix*. *See* 882 F.3d at 1125.

ooVoo and IAC contend that this error is "readily dismissed" because the *Yahoo!* construction of "toolbar" is "redundant of other elements that already are present in the representative claims." Appellee Br. 29. We disagree. While ooVoo and IAC contend that "the pinger's functionality is merely redundant," *id.* at 30, and thus "adoption of MyMail's construction would have no impact on the claims' scope and, by extension, no impact on an *Alice* analysis," *id.* at 32, we decline to construe "toolbar" and the MyMail patent claims in the first instance.

We are generally hesitant to construe patent claims in the first instance on appeal. *Meyer Intellectual Props. Ltd. v. Bodum, Inc.*, 690 F.3d 1354, 1368 (Fed. Cir. 2012). Our hesitancy is intended to avoid conflating de novo review with an independent analysis. *See Wavetronix LLC v. EIS Elec. Integrated Sys.*, 573 F.3d 1343, 1355 (Fed. Cir. 2009) (citing *Nazomi Commc'ns, Inc. v. Arm Holdings, PLC*, 403 F.3d 1364, 1371 (Fed. Cir. 2005)) (noting that this court's review of claim

construction without deference is not an independent analysis in the first instance). While in some circumstances an appeal may present a record sufficiently developed to enable construction, *see, e.g., Meyer*, 690 F.3d at 1369, we do not find such a record here. ooVoo and IAC appear to agree. Appellee Br. 39 ("The proper construction of the term 'toolbar' was not fully briefed or argued to the district court on IAC's Rule 12(c) motion, and the district court's order on appeal sets forth no findings or conclusions regarding the precise construction of the term.")

Likewise, to the extent ooVoo and IAC ask us to determine in the first instance patent eligibility of the MyMail patent claims under MyMail's proposed construction, we decline to do so. The determination of patent eligibility may involve subsidiary fact questions, including whether "the claim elements or the claimed combination are well-understood, routine, [or] conventional." *Aatrix*, 882 F.3d at 1128. *See* J.A. 13–14. It is improper for us to determine factual issues in the first instance on appeal. *3M Co. v. Avery Dennison Corp.*, 673 F.3d 1372, 1378 (Fed. Cir. 2012) ("[W]e cannot resolve the parties' factual disputes on appeal.").

CONCLUSION

We have considered ooVoo's and IAC's other arguments and find them unpersuasive. We conclude that the district court erred by failing to address the parties' claim construction dispute before concluding, on a Rule 12(c) motion, that the MyMail patents are directed to patent-ineligible subject matter under § 101. We vacate and remand for further proceedings consistent with this opinion.

VACATED AND REMANDED

COSTS

No costs.

MYMAIL, LTD., Plaintiff-Appellant v. OOVOO, LLC, IAC SEARCH & MEDIA, INC., Defendants-Appellees

Appeal No. 2018–1758, 2018–1759

Appeals from the United States District Court for the Northern District of California in Nos. 5:17-cv-04487-LHK, 5:17-cv-04488-LHK, Judge Lucy H. Koh.

LOURIE, *Circuit Judge*, dissenting.

I respectfully dissent from the majority's decision to vacate a thorough and well-reasoned district court decision based on a claim construction issue that is little more than a mirage. In my view, the claims at issue are clearly abstract, regardless of claim construction. Since the majority declines to dispute that conclusion, I submit that we should resolve the legal question of eligibility and simply affirm.

Resolution of this case should have been simple. In *Electric Power Group, LLC v. Alstom S.A.*, 830 F.3d 1350 (Fed. Cir. 2016), this court, summarizing numerous precedents, held that the analysis, transmission, and display of information are, in themselves, abstract ideas. *Id.* at 1353–54. That straightforward holding dictates an affirmance in this case, where the claims do not "require[] anything other than off-the-shelf, conventional computer, network, and display technology for gathering, sending, and presenting the desired information." *Id.* at 1355. In this case, that information is toolbar software. J.A. 911 ("[S]oftware being electronically transferred would be considered data in a data stream."); *see also Affinity Labs. of Tex., LLC v. DIRECTV, LLC*, 838 F.3d 1253, 1258 (Fed. Cir. 2016) (holding that "providing out-of-region access to regional broadcast content is an abstract idea" because it comprises "information distribution that is untethered to any specific or concrete [implementation]").

The claims' breadth illustrates their abstract nature. They cover any toolbar modification, on any of the multitudes of Internet-connected devices, using generic servers and Internet functionality. *See, e.g.*,'863 patent col. 4 ll. 51–55, col. 9 ll. 17–19, col. 11 ll. 25–43, col. 13 ll. 16–19, col. 18 ll. 32–40. But any invention in using known devices in a new way to transmit data must lie in using the devices themselves differently to accomplish a new process, not simply transmitting a different type of data according to the same process. *Cf. Ansonia Brass & Copper Co. v. Elec. Supply Co.*, 144 U.S. 11, 18–19 (1892) ("[A]pplication of an old process or machine to a similar or analogous subject, with no change in the manner of application and no result substantially distinct in its nature, will not sustain a patent, even if the new form of result had not before been contemplated.") (citation omitted).

While "inventive programming" may provide an inventive concept in some circumstances, *see Elec. Pwr. Grp.*, 830 F.3d at 1355, no such programming is disclosed here. Indeed, such programming would necessarily differ widely within the nearly universal range of devices, operating systems, and Internet protocols encompassed by the claims. What remains corresponds only to the familiar abstract ideas of sending data over the Internet between a device and a server and changing the device's display accordingly, captured by the district court as "a process for updating toolbar software over a network without user intervention." *MyMail, Ltd. v. ooVoo, LLC*, 313 F. Supp. 3d 1095, 1108 (N.D. Cal. 2018). Thus, the claims are directed only to an abstract idea, not a patent-eligible invention.

Nevertheless, the majority urges the district court on remand to evaluate a factual issue about the meaning of the unclaimed "pinger process," which is the term used by MyMail to describe its claimed method of updating toolbar software. MyMail Br. 8. But the specification is clear that neither the unclaimed pinger process nor the unclaimed MOT script can be the inventive concept. The pinger process itself is not disclosed as the invention, but instead is functionality "assumed to be part of the access service provider." '863 patent col. 11 ll. 42–43. Its teaching on the "MOT script" is no more enlightening. *Id.* col. 12 ll. 50–51 ("MOT is not, however, an acronym for anything meaningful."); *see generally id.* (not disclosing any script corresponding to the MOT script). As we have said in the context of claim construction: "[The specification] is the single best guide to the meaning of a disputed term." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). And so it is here, as in many eligibility disputes. *See Cleveland Clinic Found. v. True Health Diagnostics LLC*, 760 F. App'x 1013, 1019–20 (Fed. Cir. 2019) ("There is no reason to task the district court with finding an inventive concept that the specification and prosecution history concede does not exist." (citing *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 913 (Fed. Cir. 2017))).

In any case, we need not look far to discover the pinger process; MyMail explains that it works as follows:

> When the user connects to the Internet, the user's machine dispatches an initial pinger message to the access service via the Internet. The pinger message includes information such as the current database revision levels. From this information, the access service determines if the end-user's device should receive updated toolbar data and, if so, sends the updated toolbar data.

MyMail Br. 8 (citations and quotation marks omitted). In other words, the pinger process consists of the idea of programming a generic computer to send certain data (the user's current toolbar software version) to a predetermined server at regular intervals in a conventional manner, and then having the server return certain data (updated toolbar software) in a conventional manner, when the server determines the user's toolbar version is out of date. The pinger process is, as the Appellees argued, more or less exactly what is claimed, and also undeniably an abstract idea under this court's precedent.

For these reasons, I dissent from the majority's decision to remand a case that should be affirmed.

SANOFI-AVENTIS U.S., LLC, SANOFI MATURE IP, SANOFI, Plaintiffs-Appellants v. DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., SANDOZ, INC., Defendants-Appellees FRESENIUS KABI USA, LLC, ACCORD HEALTHCARE, INC., APOTEX CORP., APOTEX INC., ACTAVIS LLC, ACTAVIS ELIZABETH LLC, MYLAN LABORATORIES LIMITED, Defendants-Cross-Appellants

Appeal Nos. 2018–1804, 2018–1808, 2018–1809

Appeals from the United States District Court for the District of New Jersey in Nos. 3:14-cv-07869-MAS-LHG, 3:14-cv-08079-MAS-LHG, 3:14-cv-08082-MAS-LHG, 3:15-cv-00287-MAS-LHG, 3:15-cv-00290-MAS-LHG, 3:15-cv-00776-MAS-LHG, 3:15-cv-01835-MAS-LHG, 3:15-cv-02520-MAS-LHG, 3:15-cv-02522-MAS-LHG, 3:15-cv-02631-MAS-LHG, 3:15-cv-03107-MAS-LHG, 3:15-cv-03392-MAS-LHG, 3:16-cv-02259-MAS-LHG, 3:16-cv-05678-MAS-LHG, Judge Michael A. Shipp.

Decided: August 14, 2019

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Before LOURIE, MOORE, and TARANTO, *Circuit Judges.*

LOURIE, *Circuit Judge*.

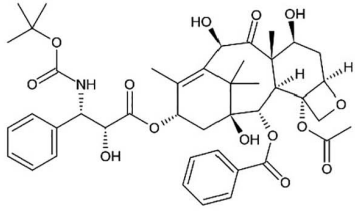
Plaintiffs-Appellants (collectively, "Sanofi") appeal from the judgment of the U.S. District Court for the District of New Jersey holding, after a bench trial, claims 7, 11, 14–16, and 26 of U.S. Patent 8,927,592 (the "'592 patent") invalid as obvious. *Sanofi-Aventis U.S. LLC v. Fresenius Kabi USA, LLC*, No. 14–7869 (D.N.J. Dec. 19, 2017) ("*Decision*"). Defendants-Cross-Appellants (collectively, "Fresenius") cross-appeal from the same judgment holding claims 1 and 2 of U.S. Patent 5,847,170 (the "'170 patent") not invalid as obvious. Because there was no case or controversy with respect to claims 7, 11, 14–16, and 26 of the '592 patent when the district court issued its decision,

we vacate the court's decision concerning those claims. We affirm the court's judgment that the '170 patent is not invalid as obvious.

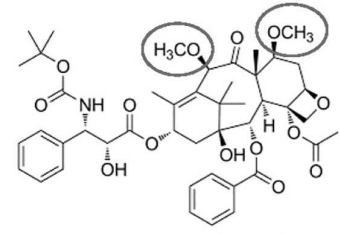
BACKGROUND

Sanofi owns the '170 and '592 patents, respectively claiming the compound cabazitaxel and methods of using it. Sanofi markets cabazitaxel under the trade name Jevtana® to treat certain drug-resistant prostate cancers. Both the '170 and '592 patents are listed in the Orange Book[1] as covering cabazitaxel.

Cabazitaxel belongs to a family of compounds called taxanes and is the third and most recent taxane drug to gain approval by the Food and Drug Administration ("FDA"). The other two are paclitaxel, approved in 1992, and docetaxel, approved in 1996. The chemical structures of docetaxel and cabazitaxel are depicted below:



Docetaxel



Cabazitaxel

As annotated above, cabazitaxel differs from docetaxel in the substitution of two methoxy groups for hydroxyl groups. The carbon atoms to which the right and left methoxy groups are bound are referred to as C7 and C10, respectively. A fully numbered cabazitaxel is depicted in Appendix A, and the carbon positions are numbered in the same way in docetaxel.[2]

Cabazitaxel was the product of a multi-year research program aimed at identifying taxane analogs with better activity than docetaxel in resistant tumors. By making substitutions at multiple positions on docetaxel with various functional groups, Sanofi scientists synthesized several hundred compounds and tested their activities. Of this group, cabazitaxel was one of two compounds that entered into human studies. It obtained FDA approval in 2010.

Fresenius and the other defendants-appellees[3] (collectively, "Defendants") filed Abbreviated New Drug Applications ("ANDAs") to mar-

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

[2] In contrast to docetaxel, paclitaxel, the other FDA-approved prior art taxane, has an acetoxy group at C10 instead of a hydroxyl. It also has a different sidechain group at C3'.

[3] Three defendants have not joined Fresenius's cross-appeal.

ket generic versions of cabazitaxel prior to the expiration of the '592 and '170 patents, prompting Sanofi to sue the Defendants for infringement in the District of New Jersey. Defendants counterclaimed for a declaratory judgment of invalidity of the '592 patent. The case ultimately proceeded to a bench trial concerning both patents.

However, while the district court case was pending, the Patent Trial and Appeal Board (the "Board") of the United States Patent and Trademark Office instituted *inter partes* review of the '592 patent. Soon after the district court trial began, the Board held claims 1–5 and 7–30 unpatentable as obvious and denied Sanofi's motion to amend its claims. Although Sanofi did appeal from the Board's denial of its motion to amend, it did not appeal from the Board's decision with respect to claims 7, 11, 14–16, and 26. And on December 8, 2017, Sanofi filed a statutory disclaimer of those claims (the "disclaimed claims") in the Patent and Trademark Office and so informed the district court. J.A. 14135–36; *see* 37 C.F.R. § 1.321(a).

Soon after the disclaimer, the district court entered a posttrial order reaching two conclusions relevant to this appeal. First, despite the statutory disclaimer of the disclaimed claims, the court concluded that a case or controversy still existed with respect to those claims and that they were invalid as obvious. *Decision*, slip op. at 45–46, 79–83. Second, the court held that the Defendants failed to prove that claims 1 and 2 of the '170 patent, claiming the cabazitaxel compound and related pharmaceutical compositions (and set forth in Appendix B), would have been obvious over the prior art. *Id.* at 42–43.[4]

Sanofi appealed from the district court's conclusion that a case or controversy still existed over the disclaimed claims after Sanofi's statutory disclaimer. Fresenius cross-appealed from the court's judgment of nonobviousness of claims 1 and 2 of the '170 patent. We have jurisdiction over both appeals under 28 U.S.C. § 1295(a)(1). We first address Sanofi's jurisdictional appeal and then turn to Fresenius's cross-appeal.

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[4] Over one year after the district court's judgment, and after the parties completed briefing in this appeal, we vacated the Board's decision denying Sanofi's motion to amend and remanded the case to the Board for further proceedings. *See Sanofi Mature IP v. Mylan Labs. Ltd.*, 757 F. App'x 988, 994 (Fed. Cir. 2019). We held that the Board erroneously placed the burden on Sanofi to prove the patentability of the amended claims, and "decline[d] to speculate as to how the Board would resolve this case under the correct legal standard." *Id.* at 991. The case remains pending before the Board. *See Mylan Labs. Ltd. v. Aventis Pharma S.A.*, No. IPR2016–00712, 2019 WL 1559904 (P.T.A.B. Apr. 9, 2019), Paper No. 108.

DISCUSSION

I

We review *de novo* whether a case or controversy existed for the district court to enter a declaratory judgment of noninfringement or invalidity, *Prasco, LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1335 (Fed. Cir. 2008), and apply Federal Circuit law, *3M Co. v. Avery Dennison Corp.*, 673 F.3d 1372, 1377 (Fed. Cir. 2012).

Sanofi argues that after it disclaimed the particular claims, there was no longer a case or controversy regarding those claims, and the district court thus lacked authority to invalidate them. Accordingly, Sanofi requests that we vacate the court's judgment invalidating the disclaimed claims.

Defendants respond that there may still have been a case or controversy over the disclaimed claims depending on the merits of their potential future issue or claim preclusion defense, which Defendants could raise if Sanofi succeeds in amending claims of the '592 patent and then asserts the amended claims against Defendants. That is, Defendants insist we must resolve this potential preclusion issue in the first instance in order to decide whether the district court had jurisdiction over the disclaimed claims.

Article III empowers federal courts to adjudicate only "Cases" and "Controversies," U.S. Const. art. III, § 2, "appropriately resolved through the judicial process," *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 560 (1992) (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 155 (1990)). To satisfy the case or controversy requirement in the declaratory judgment context, the parties' dispute must be "'real and substantial' and 'admi[t] of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts.'" *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 127 (2007) (alteration in original) (quoting *Aetna Life Ins. Co. v. Haworth*, 300 U.S. 227, 240–41 (1937)). The case or controversy analysis is highly similar to that of Article III standing. *See Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1362 (Fed. Cir. 2015). "To have standing, a plaintiff must 'present an injury that is concrete, particularized, and actual or imminent; fairly traceable to the defendant's challenged behavior; and likely to be redressed by a favorable ruling.'" *Dep't of Commerce v. New York*, 139 S. Ct. 2551, 2565 (2019) (quoting *Davis v. Fed. Election Comm'n*, 554 U.S. 724, 733 (2008)). The injury must be "'concrete and particularized' and 'actual or imminent, not conjectural or hypothetical.'" *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1548 (2016) (quoting *Lujan*, 504 U.S. at 560).

Further, "an actual controversy *must be extant at all stages of review*, not merely at the time the complaint is filed." *Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974) (emphasis added). We focus our analysis on whether there was an actual controversy when the district court entered final judgment. *See Janssen Pharmaceutica, N.V. v. Apotex, Inc.*, 540 F.3d 1353, 1362–63 & n.9 (Fed. Cir. 2008).

We agree with Sanofi that its disclaimer of the disclaimed claims mooted any controversy over them. As we explain, at the time the district court entered final judgment, the relief requested by Defendants was both speculative and immaterial to its possible future defenses, and Defendants thus failed to demonstrate an Article III case or controversy.

When Sanofi disclaimed the disclaimed claims, it "effectively eliminated those claims from the . . . patent," *Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1383 (Fed. Cir. 1998), leaving the '592 patent "as though the disclaimed claim(s) had 'never existed,'" *Genetics Inst., LLC v. Novartis Vaccines & Diagnostics, Inc.*, 655 F.3d 1291, 1299 (Fed. Cir. 2011) (quoting *Vectra*, 162 F.3d at 1383)). By leaving the '592 patent as if the disclaimed claims had never existed, Sanofi's disclaimer mooted any infringement-based dispute concerning those claims. *See Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1340 (Fed. Cir. 2013) ("[I]n 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.").

Nonetheless, Defendants contend that the district court's invalidity judgment with respect to the disclaimed claims must be preserved to provide them with "patent certainty," relying principally on our decision in *Teva Pharmaceuticals USA, Inc. v. Novartis Pharmaceuticals Corp.*, 482 F.3d 1330 (Fed. Cir. 2007). In that case, Teva brought a declaratory judgment action against four Orange Book-listed patents owned by Novartis. *Id.* at 1335. We concluded that there was a case or controversy sufficient for declaratory judgment jurisdiction concerning those patents because Teva had submitted an ANDA certifying that the patents were invalid or not infringed, and Novartis had already sued Teva on another listed patent covering the same product. *Id.* at 1340–44. The controversy in *Teva* thus related to a concrete and realistic threat posed by existing patent claims. Defendants point to no such threat created by the effectively nonexistent disclaimed claims, so Defendants' reliance on *Teva* is misplaced.

In some circumstances, patent claims may create a controversy sufficient for declaratory judgment jurisdiction even when there is no risk of infringement, but the party seeking such judicial relief must demonstrate some other concrete and imminent harm traceable to

the claims. *See Daiichi Sankyo*, 781 F.3d at 1361–62; *see also Amerigen Pharm. Ltd. v. UCB Pharma GmbH*, 913 F.3d 1076, 1083–84 (Fed. Cir. 2019). Defendants have not done so in this case.

Defendants allege that if we vacate the district court's judgment of invalidity of the disclaimed claims, then Defendants will lose the possible benefit of an issue preclusion defense based on that judgment should Sanofi obtain amended claims and assert them against Defendants. We conclude that this alleged injury did not provide a case or controversy at the time of the court's judgment for at least two reasons.

First, the relevance of the disclaimed claims to a possible issue preclusion defense was speculative. An Article III court may not "advis[e] what the law would be upon a hypothetical state of facts." *MedImmune*, 549 U.S. at 127 (internal quotation marks omitted). When the district court issued its decision, there were no enforceable amended claims. The Board had denied Sanofi's motion to amend, so any future assertion of amended claims was premised on a hypothetical appellate reversal or vacatur and remand of the Board's *inter partes* review decision.

Second, even assuming that Defendants' stake in the district court's judgment concerning the disclaimed claims was sufficiently imminent, they have not established that the judgment pertaining to those claims is material to a possible future suit. Defendants contend that they have an interest in preserving, for possible issue preclusion purposes, the court's purported finding "[i]n connection with disclaimed claim 11" that "dosages of cabazitaxel beyond 20 mg/m2 were in the prior art and used to treat docetaxel-resistant prostate cancer." Cross-Appellants' Br. 47–48. They cite two sections of the court's decision as relevant to that finding. However, the first section addresses only claims 21 and 30, not disclaimed claim 11, and thus would be entirely unaffected by vacatur of the court's decision regarding the disclaimed claims. *See Decision*, slip op. at 75 (discussing claims 21 and 30 and finding that "[t]he TROPIC trial was a trial done at a dose of 25 mg/m2 of cabazitaxel"). And while the second section does discuss claim 11, it does not examine dosages above 20 mg/m2. Defendants have thus failed to demonstrate that vacatur of the court's judgment regarding the disclaimed claims would matter to its potential issue preclusion argument.

Somewhat relatedly, Defendants ask us to consider in the first instance the claim preclusion arguments that they intend to make—based on Sanofi's previous assertion of certain nondisclaimed claims—should Sanofi secure amended claims at the Board and then assert them against Defendants. Defendants do not allege, however,

that this hypothetical defense in any way depends on the district court's judgment concerning the disclaimed claims. We cannot issue an advisory opinion on such a theoretical dispute and we decline to do so here. Defendants will have ample opportunity to raise a claim preclusion defense at the district court should Sanofi sue them again.

For these reasons, Defendants have not shown the existence of a case or controversy over the disclaimed claims at the time the district court entered judgment. The court thus lacked authority to disinter the already disclaimed claims and declare them invalid. Accordingly, we vacate the court's judgment concerning the disclaimed claims.

II

We now turn to Fresenius's cross-appeal from the district court's judgment that cabazitaxel, claimed in claims 1 and 2 of the '170 patent, would not have been obvious over docetaxel, which has been determined to be the lead compound and, in effect here, the closest prior art. 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 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).

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). "[I]n cases involving new chemical compounds, it remains necessary to identify some reason that would have led a chemist to modify a known compound in a particular manner to establish prima facie obviousness of a new claimed compound." *Takeda Chem. Indus., Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1357 (Fed. Cir. 2007). The reason need not be the same as the patentee's or expressly stated in the art. *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 419 (2007); *see In re Dillon*, 919 F.2d 688, 693–94 (Fed. Cir. 1990) (en banc). But charting a path to the claimed compound by hindsight is not enough to prove obviousness. "Any

compound may look obvious once someone has made it and found it to be useful, but working backwards from that compound, with the benefit of hindsight, once one is aware of it does not render it obvious." *Amerigen*, 913 F.3d at 1089.

In its obviousness analysis, the district court considered the testimony of seven witnesses and seventeen prior art references and ultimately concluded that Defendants failed to prove that claims 1 and 2 of the '170 patent would have been obvious. *Decision*, slip op. at 43. The court found that a person of ordinary skill would have selected docetaxel as a lead compound, and the key issue was thus whether a skilled artisan would have been motivated to replace the C7 and C10 hydroxyl groups of docetaxel with the methoxy groups of cabazitaxel. *Id.* at 30. We summarize the court's extensive findings on this issue as pertinent to this appeal.

Defendants argued at the district court that a skilled artisan would have been motivated to increase the lipophilicity of docetaxel to interfere with a protein called Pgp and thereby thwart drug resistance. Generally, the district court credited undisputed expert testimony that Pgp was involved in one of several possible mechanisms for drug resistance. *Id.* at 36. Functioning as a protein pump, Pgp can remove drug compounds from a cell and thereby hinder their therapeutic effect. The court made findings concerning two references relating to Pgp, Hait[5] and Lampidis,[6] which we review here.

Hait discussed how Pgp could contribute to multidrug resistance and proposed a binding model for Pgp inhibitors. J.A. 25093–94. The reference studied a group of Pgp inhibitors called phenothiazines, which have a tricyclic ring structure quite different from taxanes, and found that increasing lipophilicity increased sensitivity of a cancer cell line to a non-taxane therapeutic. J.A. 25093. The district court found that Hait would not have motivated a skilled artisan to modify docetaxel for several reasons. The court found that Hait addressed the effect of phenothiazines, not taxanes, on Pgp, and that phenothiazines were structurally quite different from taxanes. *Decision*, slip op. at 34. Consistent with that fact, the court observed that no prior art taxane reference of record cited Hait. *Id.* Additionally, the court found that Hait only presented a hypothetical model of Pgp binding based on the binding site of a different protein. *Id.*

The district court found similarly with respect to Lampidis. Lampidis reported that increasing the lipophilicity of a positively-charged dye beneficially increased accumulation of the dye in drug resistant cells. J.A. 16954. As with Hait, however, the district court found that

[5] William N. Hait & Dana T. Aftab, *Rational Design and PreClinical Pharmacology of Drugs for Reversing Multidrug Resistance*, 43 Biochemical Pharmacology 103 (1992).

[6] Theodore J. Lampidis et al., *Relevance of the Chemical Charge of Rhodamine Dyes to Multiple Drug Resistance*, 38 Biochemical Pharmacology 4267 (1989).

Lampidis never discussed taxanes. *Decision*, slip op. at 34. Further, the court determined that the reference focused on increasing the lipophilicity of positively-charged compounds, but taxanes do not have a positive charge. *Id.* ; *see* Lampidis, J.A. 16954 ("If our hypothesis is correct, then it would appear that, in general, as we increase the lipophilicity of *positively charged* (delocalized) *compounds* we increase their abilities to accumulate in, and subsequently kill, MDR cells." (emphasis added)).

The district court also considered the teachings of two articles that identified possible positions for substitution on taxanes. Commerçon[7] identified the C3', C7, C9, and C10 positions on paclitaxel as "flexible" and suitable for modification and also identified C2' as a possible site for certain modifications if the configuration of the group is maintained. J.A. 25161. Kingston 1994[8] was similar.

In addition to these articles, the district court addressed numerous references that investigated the activity of specific taxane analogs. We review these here.

European Patent Application 0 639 577 ("Golik") substituted a methylthiomethoxy group for the C7 hydroxyl of paclitaxel and reported that the compound had increased activity *in vitro* compared to docetaxel and paclitaxel in a drugresistant cell line. J.A. 25205–06, 25229; *Decision*, slip op. at 23. Golik also modified the C2' position with a prodrug moiety, and this analog showed promising results *in vivo*. J.A. 25208, 25261; *Decision*, slip op. at 30. The court found no evidence that Golik's methylthiomethoxy substitution at C7 would lead a skilled artisan to make a methoxy substitution at that position. *Decision*, slip op. at 31.

The other reference studying the activity of taxane analogs against drug-resistant cell lines was Ojima 1994.[9] Ojima 1994 reported that modifying C3' with certain substitutions produced much better activity than paclitaxel and docetaxel against a drug-resistant cell line. J.A. 25114–15. The reference disclosed neither a C7 nor a C10 methoxy substitution. The court found that Ojima 1994 did not teach increasing lipophilicity of C7 and C10 against drug resistant cells. *Decision*, slip op. at 34–35.

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[7] A. Commerçon et al., *Practical Semisynthesis and Antimitotic Activity of Docetaxel and Side-Chain Analogues, in* Taxane Anticancer Agents: Basic Science and Current Status 233 (G. I. Georg et al. eds., 1994).

[8] David G. I. Kingston, *Recent Advances in the Chemistry and Structure-Activity Relationships of Paclitaxel, in* Taxane Anticancer Agents: Basic Science and Current Status 206 (G. I. Georg et al. eds., 1994).

[9] Iwao Ojima et al., *Syntheses and Structure-Activity Relationships of New Taxoids, in* Taxane Anticancer Agents: Basic Science and Current Status 262 (G. I. Georg et al. eds., 1994).

U.S. Patent 6,201,140 ("Wong") disclosed a paclitaxel derivative with a methoxy substitution at C7. J.A. 25324. However, the district court found that Wong disclosed a more potent paclitaxel derivative with a C2' modification and a different ether substitution at C7. *Decision*, slip op. at 31. Further, the court found that Wong did not disclose any compound with the C10 hydroxyl of docetaxel or the C10 methoxy of cabazitaxel and did not disclose activity data from resistant cell lines. *Id.*

Another reference considered by the district court, Kant,[10] focused on substitutions at C10, including a C10 methoxy substitution. Kant did not evaluate the activity of C10 analogs in drug resistant cell lines and compared the C10-methoxy-substituted docetaxel only to paclitaxel, not docetaxel. J.A. 25311–12. Kant also did not study any C7 substitutions. Although the court observed that the C10 methoxy substitution (along with another analog) showed good results in one assay, another compound performed better in a different assay. *Decision*, slip op. at 32.

The district court proceeded to Klein,[11] which focused on substitutions at C9. Klein reported that certain C9-substituted taxanes "have increased water solubility and stability as compared to [paclitaxel] and also exhibit excellent activity in tumor models." J.A. 25173. Klein also disclosed simultaneous C7 and C9 substitutions, including a C7 methoxy with good activity, but no C10 substitutions. J.A. 25178. As with Wong and Kant, the court observed that Klein did not investigate the activity of these substituted taxanes on drug resistant cell lines. *Decision*, slip op. at 33.

Ultimately, the district court found Defendants' experts cherry-picked data in the references to reach cabazitaxel and were not credible. *Id.* at 36. The court credited Sanofi's expert's testimony that taxane modifications were considered at C2, C4, C5, C7, C8, C9, C10, C11, C12, C13, C14, C2', and C3', *id.* at 37, and concluded that it would not have been obvious to make simultaneous methoxy substitutions at C7 and C10 of docetaxel, *id.*

In addition, the district court found that some secondary considerations evidence supported nonobviousness and that there was a nexus between claims 1 and 2 and the marketed product Jevtana®. *Id.* at 37–38. Despite attempts by research groups around the world to develop effective taxane cancer treatments, the court recognized that cabazitaxel was only the third taxane to obtain FDA approval.

[10] Joydeep Kant et al., *A Chemoselective Approach to Functionalize the C-10 Position of 10-Deacetylbaccatin III. Synthesis and Biological Properties of Novel C-10 Taxol® Analogues*, 35 Tetrahedron Letters 5543 (1994).

[11] L. L. Klein et al., *Chemistry and Antitumor Activity in 9(* R*)-Dihydrotaxanes, in* Taxane Anticancer Agents: Basic Science and Current Status 276 (G. I. Georg et al. eds., 1994).

Id. at 40–41. The court thus determined that "[Sanofi's] success, where others had failed," supported nonobviousness. *Id.* at 41. The court also found that Jevtana® achieved commercial success. *Id.* at 42. In light of all the evidence, the court concluded that Defendants failed to prove obviousness by clear and convincing evidence. *Id.* at 43.

In its cross-appeal, Fresenius argues that the district court committed a "cascading series of factual and legal errors." Cross-Appellants' Br. 67. Specifically, Fresenius alleges that the court erred in rejecting its theory that a skilled artisan would have: (1) been motivated to modify docetaxel to reduce Pgp-related drug resistance; (2) knew that this could be accomplished by increasing lipophilicity of the C7 and C10 positions; and (3) determined that methoxy substitutions were the "smallest, most conservative" modification to achieve that goal. *Id.* Fresenius further argues that the evidence of secondary considerations does not overcome the evidence of obviousness.

Sanofi responds that Fresenius's obviousness theory was hindsight-driven and that the district court did not err in rejecting it.

We agree with Sanofi and conclude that Fresenius's convoluted obviousness theory lacks merit. We begin with Fresenius's contention that the district court clearly erred in finding that Hait and Lampidis would not have provided a reason to make docetaxel more lipophilic. Not only did these references not contemplate taxanes, they investigated compounds that are structurally very different from taxanes. Lampidis focused on positively-charged dyes and suggested that increasing lipophilicity of positively-charged molecules could be beneficial, but docetaxel is not positively charged. Likewise, Hait studied phenothiazines, which are much smaller than taxanes and have a three-ring structure bearing no resemblance to taxanes. Furthermore, Hait only presented a hypothetical binding site model based on a different protein than Pgp. And the evidence showed that no prior art taxane reference cited Hait. *Decision*, slip op. at 34. We conclude that the court did not clearly err in its assessment of these references or in finding that they would not have motivated a skilled artisan to modify docetaxel to obtain cabazitaxel.

Even assuming there was some general motivation to make docetaxel more lipophilic to combat drug resistance, the district court also did not clearly err in finding that Fresenius failed to establish a motivation to do so by specifically making simultaneous methoxy substitutions at C7 and C10. The court found that taxane researchers investigated substitutions at many positions, and the voluminous references in this case support that finding. For example, Commerçon disclosed that C3', C7, C9, and C10, and to a more limited extent C2',

were modifiable. And as summarized above, the other references investigated a diverse set of substitutions. Fresenius reads this panoply of teachings as rendering obvious simultaneous C7 and C10 methoxy substitutions. But despite the apparent interest in taxane analogs, not a single reference relied on by Fresenius made simultaneous substitutions of any kind at C7 and C10. And of the references that made individual methoxy substitutions at C7 or C10, none tested those taxane analogs against drug resistant cell lines or taught that the analogs would overcome drug resistance. On this record, the court did not clearly err in finding no motivation to make C7 and C10 methoxy substitutions on docetaxel to improve its activity against drug-resistant cancers.

Considering Fresenius's reference-specific arguments, we agree with the district court that they are emblematic of hindsight reasoning. Fresenius contends that Commerçon would have pointed a skilled artisan towards C7, C10, and (less desirably) C9 substitutions because those positions were "flexible," and away from C2' and C3' substitutions because those positions were "crucial." Cross-Appellants' Br. 57–58. However, this argument plainly mischaracterizes the reference. Commerçon expressly identified the sidechain position C3' as "flexible," and indicated that C2' could be modified with certain substitutions if the configuration was maintained. J.A. 25161–62.

That teaching is consistent with references such as Ojima 1994 that investigated sidechain substitutions on taxanes. *See* Ojima 1994, J.A. 25104 (C3' substitutions); Wong, J.A. 25327 (C2' substitution). Fresenius, however, contends that Ojima 1994 would motivate a skilled artisan to make a C10 methoxy substitution because it showed that "changing a hydrophilic hydroxy group to a more lipophilic methoxy group at C-10 resulted in a significant increase in potency against drug resistant cells." Cross-Appellants' Br. 62. As with its argument concerning Commerçon, Fresenius's position is premised on an incorrect characterization of the reference. The portions of Ojima 1994 in the record nowhere investigated a methoxy-substituted taxane, at C10 or anywhere else. While two of the compounds tested did have paclitaxel's C10 acetoxy group, Ojima 1994 did not even mention that fact. Rather, it emphasized the "excellent" or "noteworthy" activity associated with C3' isobutyl and isobutenyl substitutions. J.A. 25114–15. We conclude that the district court did not clearly err in rejecting Fresenius's selective reading of the reference.

Although no cited reference shows that C7 or C10 methoxy-substituted taxanes have improved properties with respect to drug resistance, Fresenius argues that a skilled artisan would have made

simultaneous C7 and C10 methoxy substitutions because they are "small, conservative changes" that increase lipophilicity. Cross-Appellants' Br. 65–67 (citing *Bristol-Myers Squibb Co. v. Teva Pharm. USA, Inc.*, 752 F.3d 967, 974–75 (Fed. Cir. 2014)). Fresenius's arguments concerning Golik are illustrative. As previously discussed, Golik disclosed a taxane analog with a methylthiomethoxy substitution at C7, which had promising qualities against drug-resistant cell lines. Rather than simply motivate a skilled artisan to investigate C7 *methylthiomethoxy* substitutions, Fresenius argues that this teaching really supports making a C7 *methoxy* substitution.

This argument stands on little more than hindsight. The district court found no evidence that the methoxy group would provide a similar benefit as the sulfur-containing methylthiomethoxy group. *Decision*, slip op. at 30–31. In contrast to the reported advantageous features of the methylthiomethoxy group in Golik and the absence of any evidence showing equivalent properties of a methoxy substitution, Fresenius directs us on appeal only to its experts' vague testimony that sulfur has some unspecified "metabolic liabilities" or "other complications." J.A. 12361–62, 13160. We conclude that the court did not clearly err in rejecting this weak testimony.

Fresenius's position concerning Ojima 1994 is similar. Fresenius argues that Ojima 1994's supposed implicit teaching of the benefits of a C10 *acetoxy* group against drug-resistant cells would actually motivate a skilled artisan to make a C10 *methoxy* substitution because it is smaller and more conservative. As with Golik, Fresenius cites no non-conclusory evidence that the methoxy group would have the same purported benefits as the acetoxy group, and offers no persuasive explanation of how the methoxy group, which was not tested in Ojima 1994, would be a more conservative choice than the C10 acetoxy already present in the FDA-approved drug paclitaxel. We consider Fresenius's argument exemplary of hindsight reasoning.

Many of Fresenius's arguments cite our decision in *Bristol-Myers Squibb*. There, we affirmed a district court's conclusion that it would have been obvious to make a single chemical change to a lead compound where there were a "small, finite number of changes to try," and the particular claimed change had already been shown to have desirable properties in a similar context. *Bristol-Myers Squibb Co.*, 752 F.3d at 975–76 (quoting *In re Cyclobenzaprine Hydrochloride Patent Litig.*, 676 F.3d 1063, 1072 (Fed. Cir. 2012)). As our review above shows, the district court's findings in this case are quite different and demand a different outcome. The court here found that numerous docetaxel modifications were under investigation, and there was no showing that making individual or simultaneous methoxy substitutions at C7 and C10 improved activity against drug-

resistant cells, the sole motivation relied on by Fresenius. We also disagree with Fresenius that small changes to a compound are necessarily *prima facie* obvious. We did not adopt such a brightline legal rule in *Bristol-Myers Squibb*, and doing so would be inconsistent with the flexible analysis inherent to the highly contextual obviousness inquiry. *See KSR*, 550 U.S. at 415.

Fresenius last challenges the district court's weighing of the evidence of secondary considerations, although it does not point to any error in the court's reasoning. We see no clear error in the court's finding that "[m]ultiple groups around the world tried unsuccessfully to develop taxanes into effective therapies and only [Sanofi] succeeded in developing a compound that showed superior activity over docetaxel, namely cabazitaxel, and obtained FDA approval." *Decision*, slip op. at 41 (citations omitted). And we agree with the court that, in this case, this finding warrants significant weight in the ultimate obviousness analysis. We also conclude that the court did not clearly err with respect to Sanofi's evidence of commercial success.

Ultimately, we agree with Sanofi that the district court correctly concluded that claims 1 and 2 of the '170 patent would not have been obvious over docetaxel. We have also considered Fresenius's other arguments but find them unpersuasive. We thus affirm the court's judgment.

CONCLUSION

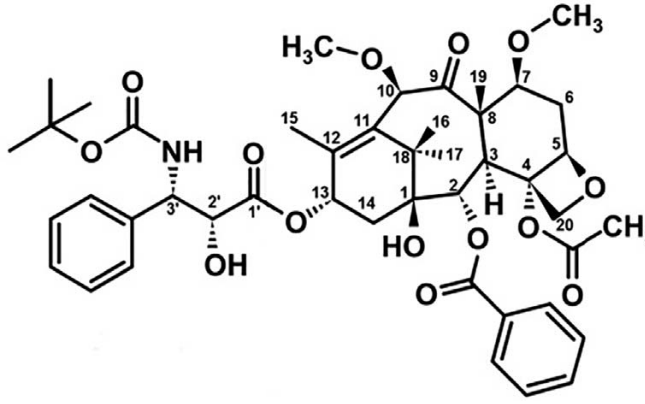
For the foregoing reasons, we vacate the district court's judgment of obviousness concerning claims 7, 11, 14–16, and 26 of the '592 patent and affirm the court's judgment of nonobviousness concerning claims 1 and 2 of the '170 patent.

AFFIRMED-IN-PART AND VACATED-IN-PART

COSTS

Costs to Sanofi.

APPENDIX A



Cabazitaxel

APPENDIX B

'170 Patent Claim 1

1. 4α-Acetoxy-2α-benzoyloxy-5β,20-epoxy-1β-hydroxy-7β,10β-dimethoxy-9-oxo-11-taxen-13α-yl(2R,3S)-3-tert-butoxycarbonylamino-2-hydroxy-3-phenylpropionate.

'170 Patent Claim 2

2. A pharmaceutical composition comprising at least the product according to claim 1 in combination with one or more pharmaceutically acceptable diluents or adjuvants and optionally one or more compatible and pharmacologically active compounds.

GENETIC VETERINARY SCIENCES, INC., dba PAW PRINTS GENETICS, Plaintiff-Appellee v. LABOKLIN GMBH & CO. KG, THE UNIVERSITY OF BERN, Defendants-Appellants

Appeal No. 2018–2056

Appeal from the United States District Court for the Eastern District of Virginia in No. 2:17-cv-00108-HCM-DEM, Senior Judge Henry C. Morgan, Jr.

SEALED OPINION ISSUED: July 29, 2019
PUBLIC OPINION ISSUED: August 9, 2019*

MARK P. WALTERS, Lowe Graham Jones PLLC, Seattle, WA, argued for plaintiff-appellee.

JOHANNA WILBERT, Quarles & Brady, LLP, Milwaukee, WI, argued for defendants-appellants. Also represented by MICHAEL PIERY; NIKIA L. GRAY, Washington, DC.

Before WALLACH, HUGHES, and STOLL, *Circuit Judges.*

WALLACH, *Circuit Judge.*

Appellee Genetic Veterinary Sciences, Inc., d/b/a Paw Prints Genetics ("PPG") sued Appellants LABOKLIN GmbH & Co. KG ("LABOKLIN") and the University of Bern ("the University") (together, "Appellants") in the U.S. District Court for the Eastern District of Virginia ("District Court"), seeking a declaratory judgment that claims 1–3 ("Asserted Claims") of the University's U.S. Patent No. 9,157,114 ("the '114 patent") are patent-ineligible under 35 U.S.C. § 101 (2012).[1] J.A. 50–57 (Complaint). Appellants filed a motion to dismiss the Complaint for, inter alia, lack of subject-matter jurisdiction and lack of personal jurisdiction, *see* J.A. 58–60, which the District Court denied, *see* J.A. 302–16 (Order). Following the close of the parties' evidence during a jury trial but before submitting the case to the jury, the District Court granted PPG's motion for judgment as a matter of law ("JMOL") and held the Asserted Claims patent-ineligible under § 101. *See Genetic Veterinary Scis., Inc. v. LABOKLIN GmbH & Co., KG*, 314 F. Supp. 3d 727, 728 (E.D. Va. 2018), *appeal dismissed*, No. 18–1625, 2018 WL 6334978 (4th Cir. June 5, 2018); *see also* J.A. 1 (Final Judgment).

Appellants appeal the District Court's conclusions as to jurisdiction and patent-ineligibility. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1) (2012). We affirm.

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* This opinion was originally filed under seal and has been unsealed in part with the remaining sealed portions modified to omit confidential information from the public opinion.

[1] Congress did not amend § 101 when it passed the Leahy-Smith America Invents Act ("AIA"). *See generally* Pub L. No. 112–29, 125 Stat. 284 (2011).

BACKGROUND

The University is the owner of the '114 patent and an agent or instrumentality of the Swiss Confederation, "having a place of business in Bern, Switzerland." J.A. 1090. In 2013, the University granted an exclusive license of its '114 patent to the German company LABOKLIN, J.A. 1091, whose "principal place of business is in Bad Kissingen, Germany," J.A. 1090; *see* J.A. 173–218 (Confidential License Agreement). Among many conditions of the License Agreement, LABOKLIN was required to commercialize the invention in North America "within [a specific time period] of the Effective date." J.A. 214–15. Subsequently, and at the time of the filing of Appellants' Motion to Dismiss, LABOKLIN had entered into two sublicenses in the United States. *See* J.A. 309, 349–51 (referencing California and Michigan sublicensees). The License Agreement required both LABOKLIN and the University to obtain the other's consent prior to sending any cease-and-desist letter to a potential infringer. J.A. 217. The License Agreement further stated that if the infringing activity "d[oes] not abate within [a specific time period]" and the University gives LABOKLIN written notice of its election not to bring suit, LABOKLIN has a right to sue for infringement. J.A. 218.

PPG is a corporation headquartered in the State of Washington. J.A. 302. It offers laboratory services for testing for genetic variations and mutations known to cause certain diseases in dogs, including a test for "detect[ing] the presence of a mutation in the SUV39H2 gene." J.A. 302. Relevant to the facts of this case, PPG would accept a customer's request to test sample DNA received "from all over the world" and once the DNA test was concluded, would send the results back to the customer. *See* J.A. 101–02, 68. In January 2017, after obtaining the University's consent to send PPG a cease-and-desist letter, *see* J.A. 312, 349, 353, counsel for LABOKLIN sent a cease-and-desist letter to PPG at its business location in Spokane, Washington, *see* J.A. 99–104. The cease-and-desist letter explained that "[LABOKLIN] is the exclusive license holder of [the '114 patent]," J.A. 100, as well as the exclusive licensee of the related European and German patents, *see* J.A. 99, all of which were attached as enclosures, and the letter stated that given "[PPG] make[s] use of the patent as defined in above-mentioned patent claim 1[,] . . . you [PPG] have committed an act of patent infringement," J.A. 102. After receiving the cease-and-desist letter, PPG brought suit against both LABOKLIN and the University, requesting declaratory judgment that the Asserted Claims of the '114 patent are ineligible under § 101 for failing to claim patent-eligible subject matter, and ultimately

asserting that PPG therefore cannot be liable for infringing the Asserted Claims. *See* J.A. 50–57.[2]

LABOKLIN and the University moved to dismiss the Complaint under, inter alia, Federal Rules of Civil Procedure 12(b)(1) for lack of subject-matter jurisdiction and 12(b)(2) for lack of personal jurisdiction. J.A. 35. Following an evidentiary hearing, the District Court issued its Order finding jurisdiction established over both LABOKLIN and the University. *See* J.A. 302–16. First, applying Federal Rule of Civil Procedure 4(k)(2), and considering the cease-and-desist letter and LABOKLIN's licensing activities in the United States, the District Court held that it may exercise personal jurisdiction over LABOKLIN because LABOKLIN had sufficient minimum contacts with the United States to comport with due process. J.A. 310; *see* Fed. R. Civ. P. 4(k)(2) (explaining how personal jurisdiction is established for a federal claim outside state-court jurisdiction). Second, the District Court held that jurisdiction was established over the University as a foreign sovereign in the United States because, inter alia, the University had engaged in "commercial activity" sufficient to trigger an exception to jurisdictional immunity under 28 U.S.C. § 1605(a)(2) by "obtain[ing] a patent and then threaten[ing] PPG by proxy with litigation." J.A. 314.

Appellants subsequently asserted counterclaims for infringement of the '114 patent, J.A. 317–28; however, PPG stipulated to infringement of the Asserted Claims, and the only issue that proceeded to trial was PPG's invalidity defense, J.A. 1088, 1089–116 (containing, in a draft final pretrial order, the stipulated facts of both parties). Following the close of both parties' evidence at trial but before submitting the case to the jury, the District Court granted PPG's Motion for JMOL and held the Asserted Claims patent-ineligible under § 101. *See Genetic Veterinary*, 314 F. Supp. 3d at 728. This appeal followed.

JURISDICTION

Appellants aver that the District Court: (1) "lacks personal jurisdiction over LABOKLIN" because LABOKLIN lacks sufficient contacts with the forum; and (2) "lacks personal and subject[-]matter jurisdiction over the University because the University enjoys sovereign immunity." Appellants' Br. 16. We address each issue in turn.

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[2] Counsel for PPG also responded to counsel for Appellants in a letter dated after the filing of the declaratory judgment. *See* J.A. 68.

I. Personal Jurisdiction Over LABOKLIN

A. Standard of Review and Legal Standards

"Personal jurisdiction is a question of law that we review de novo." *Autogenomics, Inc. v. Oxford Gene Tech. Ltd.*, 566 F.3d 1012, 1016 (Fed. Cir. 2009) (citation omitted). We apply Federal Circuit law to questions of personal jurisdiction because the issue "is intimately involved with the substance of the patent laws." *Grober v. Mako Prods., Inc*., 686 F.3d 1335, 1345 (Fed. Cir. 2012) (internal quotation marks and citation omitted); *see Hildebrand v. Steck Mfg. Co.,* 279 F.3d 1351, 1354 (Fed. Cir. 2002) (applying Federal Circuit law to determinations of personal jurisdiction over out-of-state defendant-patentees in patent infringement cases and declaratory judgment cases). Where the district court's disposition as to personal jurisdiction is based on affidavits and other written materials in the absence of an evidentiary hearing, a plaintiff need only make a prima facie showing that defendants are subject to personal jurisdiction. *See Elecs. For Imaging, Inc. v. Coyle*, 340 F.3d 1344, 1349 (Fed. Cir. 2003). Where discovery is conducted, however, the plaintiff bears the burden of proving by a preponderance of the evidence the facts necessary to establish personal jurisdiction over the defendant. *Pieczenik v. Dyax Corp.*, 265 F.3d 1329, 1334 (Fed. Cir. 2001). We review any underlying factual findings for clear error. *Grober*, 686 F.3d at 1345. A factual finding is "clearly erroneous" only when the entire record leaves the reviewing court "with the definite and firm conviction that a mistake has been committed." *Anderson v. City of Bessemer City*, 470 U.S. 564, 573–74 (1985).

Federal Rule of Civil Procedure 4(k)(2) states, in relevant part: "For a claim that arises under federal law, serving a summons . . . establishes personal jurisdiction over a defendant if: (A) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction; and (B) exercising jurisdiction is consistent with the United States Constitution and laws." Fed. R. Civ. P. 4(k)(2). In applying and interpreting Rule 4(k)(2), we therefore allow a court to exercise personal jurisdiction over a nonresident if: "(1) the plaintiff's claim arises under federal law, (2) the defendant is not subject to jurisdiction in any state's courts of general jurisdiction, and (3) the exercise of jurisdiction comports with due process." *Synthes (U.S.A.) v. G.M. Dos Reis Jr. Ind. Com de Equip. Medico*, 563 F.3d 1285, 1293–94 (Fed. Cir. 2009).

For the assertion of jurisdiction to comport with due process, a nonresident defendant must have "certain minimum contacts with [the forum] such that the maintenance of the suit does not offend

traditional notions of fair play and substantial justice." *Int'l Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (internal quotation marks and citation omitted). Relevant here, "if Rule 4(k)(2) supplies the due process analysis, then the forum is the United States," "as opposed to the state in which the district court sits [i.e. Virginia]." *Synthes (U.S.A.)*, 563 F.3d at 1291, 1295.

We have summarized the Supreme Court's due process jurisprudence for specific personal jurisdiction[3] as a three-part test: "(1) whether the defendant purposefully directed its activities at residents of the forum; (2) whether the claim arises out of or relates to the defendant's activities with the forum; and (3) whether assertion of personal jurisdiction is reasonable and fair." *Inamed Corp. v. Kuzmak*, 249 F.3d 1356, 1360 (Fed. Cir. 2001) (internal quotation marks and citation omitted). "The first two factors correspond with the 'minimum contacts' prong of the [*International Shoe*] analysis, and the third factor corresponds with the 'fair play and substantial justice' prong of the analysis." *Id.* "We have consistently rejected attempts to satisfy the defendant-focused 'minimum contacts' inquiry by demonstrating contacts between the plaintiff (or third parties) and the forum State." *Walden*, 571 U.S. at 284.

Related to the third factor regarding whether assertion of personal jurisdiction is "reasonable and fair," "[w]here a defendant who purposefully has directed his activities at forum residents seeks to defeat jurisdiction, he must present a compelling case that the presence of some other considerations would render jurisdiction unreasonable." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 476 (1985) (emphasis added). In *Burger King*, the Supreme Court identified five considerations relevant to the reasonableness inquiry:

> [C]ourts in "appropriate case[s]" may evaluate [1] "the burden on the defendant," [2] "the forum State's interest in adjudicating the dispute," [3] "the plaintiff's interest in obtaining convenient and effective relief," [4] "the interstate judicial system's interest in obtaining the most efficient resolution of controversies," and [5] the "shared interest of the several States in furthering fundamental substantive social policies."

Id. at 477 (second alteration in original) (quoting *World-Wide Volkswagen Corp. v. Woodson,* 444 U.S. 286, 292 (1980)).

[3] "Specific" jurisdiction "depends on an 'affiliatio[n] between the forum and the underlying controversy,' (i.e., an activity or an occurrence that takes place in the forum State and is therefore subject to the State's regulation)." *Walden v. Fiore*, 571 U.S. 277, 283 n.6 (2014). This case concerns the "minimum contacts" necessary to create *specific* jurisdiction because PPG relies on specific jurisdiction only. *See* Appellee's Br. 13–16, 18.

B. The District Court Had Personal Jurisdiction over LABOKLIN

The District Court determined that "in addition to [sending] the cease-and-desist letter to PPG," LABOKLIN conducted business in the United States by entering into sublicenses in California and Michigan in accordance with an exclusive license granted to it on the disputed '114 patent. J.A. 309; *see* J.A. 307–09. Taken together, the District Court held that these contacts establish fair and reasonable "specific personal jurisdiction over LABO[KLIN]." J.A. 310. Appellants argue that the District Court lacks personal jurisdiction over LABOKLIN because "LABOKLIN does not have sufficient contacts to satisfy due process" and a cease-and-desist letter along with licensing activity in the forum is not "enough to confer jurisdiction." Appellants' Br. 17, 18. We disagree with Appellants.

The District Court's exercise of personal jurisdiction over LABOKLIN comports with due process. As it relates to the application of the first and second requirements of Rule 4(k)(2)(A), the parties do not dispute the District Court's findings "that [PPG's] claim arises under federal law and that LABO[KLIN agreed it was] not subject to jurisdiction in any state's courts of general jurisdiction." J.A. 307. Thus, the dispositive inquiry is whether the exercise of personal jurisdiction here comports with a due process analysis under the third requirement of Rule 4(k)(2)(B), and, more specifically, LABOKLIN's conduct and contacts within the entire United States as the forum. *See Synthes*, 563 F.3d at 1295. We therefore turn to the three-pronged due process inquiry. *See Inamed*, 249 F.3d at 1360.

As it relates to the first two factors of the due process inquiry for specific personal jurisdiction—i.e. the "minimum contacts" prong—these factors are met based upon LABOKLIN's sending of the cease-and-desist letter together with its commercial sublicenses. Here, LABOKLIN's cease-and-desist letter was clearly directed to PPG at its United States address, and the cease-and-desist letter threatened PPG's domestic testing business by accusing PPG of "commit[ting] an act of patent infringement" when it identified its patent portfolio including the '114 patent. J.A. 102. As counsel for LABOKLIN testified, LABOKLIN sent the letter "[b]ecause it was aware that PPG *was and is still infringing* the ['114] patent and wanted to inform PPG that it was infringing." J.A. 347–48 (emphasis added). Counsel for LABOKLIN also "[sought] for PPG to either cease its conduct or enter into a licensing agreement whereby it was a sublicensee of [LABOKLIN]." J.A. 348. PPG's claim for declaratory judgement arises out of or relates to LABOKLIN's patent sublicensing and its enforcement activities in the United States pursued in a cease-and-desist letter from

LABOKLIN's counsel. *See Jack Henry & Assocs., Inc. v. Plano Encryption Techs. LLC*, 910 F.3d 1199, 1205 (Fed. Cir. 2018) (applying due process considerations and reversing a district court's determination that it did not have jurisdiction where, inter alia, "[appellee had] undertaken a licensing program, with threats of litigation, directed to the [appellants] conducting banking activity in the Northern District" of Texas); *cf. Genetic Implant Sys. v. CoreVent Corp.,* 123 F.3d 1455, 1458–59 (Fed. Cir. 1997) (holding that the licensee of a patent assignee not being incorporated in the forum state did not preclude a finding that the assignee "had sufficient minimum contacts" with a state to support personal jurisdiction over the assignee because it nonetheless conducted business there based on its agreement with the licensee that had promoted and sold patented "dental implants" instate). Thus, the cease-and-desist letter taken together with both of LABOKLIN's successful efforts to commercialize by sublicensing the '114 patent within the United States satisfy the "minimum contacts" element of the due process inquiry for specific personal jurisdiction.

As it relates to the third factor of the due process inquiry for specific personal jurisdiction, exercising jurisdiction over LABOKLIN is "reasonable and fair" because LABOKLIN has purposefully availed itself of the benefits and protections of U.S. laws through its commercial sublicensing as well as its enforcement of a U.S. patent. J.A. 348. In assessing such relevant factors as "the forum State's interest in adjudicating the dispute" and "the plaintiff's interest in obtaining convenient and effective relief," *Burger King*, 471 U.S. at 477, LABOKLIN's enforcement of a U.S. patent, as well as the interest of PPG in determining whether it could be potentially liable for infringement, weigh in favor of finding jurisdiction reasonable, *see Synthes*, 563 F.3d at 1299 ("[T]he United States has a 'substantial interest' in enforcing the federal patent laws."). This is further supported by the fact that "no other . . . forum is available to [PPG] for its . . . claim." *Id.* at 1300.

Moreover, where a defendant's "activities are shielded by the benefits and protections of the forum's laws it is *presumptively* not unreasonable to require him to submit to the burdens of litigation in that forum as well." *Burger King*, 471 U.S. at 476 (emphasis added) (internal quotation marks omitted). Such is the case here. As the District Court aptly pointed out, here, "LABO[KLIN] is not merely a remote patentee assisting a U.S. company with enforcement, but instead, it *is* the U.S. enforcer." J.A. 310. For this reason, the burden placed on LABOKLIN by litigating in the United States is outweighed by the other fairness factors. *See World-Wide Volkswagen,* 444 U.S. at 294 ("[P]rogress in communications and transportation

has made the defense of a suit in a foreign tribunal less burdensome." (quoting *Hanson v. Denckla*, 357 U.S. 235, 250–51 (1958))).

Appellants argue that "[m]erely sending a [cease-and-desist] letter does not create specific personal jurisdiction over LABOKLIN," while relying on *Red Wing Shoe Company v. Hockerson-Halberstadt* and *Avocent Huntsville Corporation v. Aten International Company* for the proposition that patent enforcement letters cannot provide the basis for jurisdiction without "some 'other activity' related to PPG's claim [] connect[ing] LABOKLIN to the forum beyond the letter" in a declaratory judgment action. Appellants' Br. 18 (first citing *Red Wing Shoe*, 148 F.3d 1355, 1360 (Fed. Cir. 1998); then citing *Avocent*, 552 F.3d 1324, 1334 (Fed. Cir. 2008)). This argument fails. As we have expressly stated, "*Red Wing Shoe* and *Avocent* did not create such a [bright-line] rule, and doing so would contradict the Court's directive to 'consider a variety of interests' in assessing whether jurisdiction would be fair." *Jack Henry*, 910 F.3d at 1206 (citing *Bristol-Myers Squibb Co. v. Superior Court of Cal.*, 137 S.Ct. 1773, 1780 (2017)). Here, Appellants have failed to sufficiently rebut the presumption that personal jurisdiction would be reasonable and fair. As we have found above, the factors outlined in *Burger King* favor the establishment of jurisdiction over LABOKLIN. *Cf. Deprenyl Animal Health, Inc. v. Univ. of Toronto Innovations Found.*, 297 F.3d 1343, 1356 (Fed. Cir. 2002) ("Just as a state has a substantial interest in preventing patent infringement within its borders, it also has a substantial interest in protecting its residents from claims of patent infringement that may be unwarranted[.]"). Therefore, the facts of this case establish that LABOKLIN's activities satisfy the minimum contacts requirement without offense to due process; thus, personal jurisdiction over LABOKLIN in the District Court is reasonable and fair.

II. Personal and Subject-Matter Jurisdiction Over The University

A. Standard of Review and Legal Standard

The Foreign Sovereign Immunities Act ("FSIA") "provides the sole basis for obtaining jurisdiction" over a foreign sovereign in the United States. *Saudi Arabia v. Nelson,* 507 U.S. 349, 355 (1993); *see* 28 U.S.C. §§ 1330 *et. seq*. In reviewing a district court order regarding subject-matter jurisdiction, we apply the standard of review of the regional circuit—here the Fourth Circuit—unless the issue pertains to or is unique to patent law. *Intel Corp. v. Commonwealth Sci. & Indus. Research Org.*, 455 F.3d 1364, 1369 (Fed. Cir. 2006). The Fourth Circuit reviews the existence of sovereign immunity and subject-matter jurisdiction de novo. *In re Tamimi*, 176 F.3d 274, 277 (4th Cir. 1999). Pursuant to the FSIA, "a foreign state is presump-

tively immune from the jurisdiction of United States courts; unless a specified exception applies, a federal court lacks subject-matter jurisdiction over a claim against a foreign state." *Saudi,* 507 U.S. at 355. Relevant to this appeal, if a foreign state engages in "commercial activity . . . in the United States," an exception to sovereign immunity applies. 28 U.S.C. § 1605(a)(2). [4] We have stated that a defendant's "acts of (1) obtaining a United States patent and then (2) enforcing its patent so it could reap the profits thereof—whether by threatening litigation or by proffering licenses to putative infringers—certainly" are commercial activity.[5] *Intel Corp*., 455 F.3d at 1370. Determining whether subject-matter jurisdiction exists "entails an application of the substantive terms of the [FSIA] to determine whether one of the specified exceptions to immunity applies." *Verlinden B.V. v. Central Bank of Nigeria*, 461 U.S. 480, 498 (1983).

B. The District Court Had Personal and Subject-Matter Jurisdiction over the University

The District Court held that jurisdiction exists over the University because the University is an agent or instrumentality of a foreign state that engaged in commercial activity sufficient to trigger an exception to immunity under § 1605(a)(2) as it had "obtained a [U.S.] patent and then threatened PPG by proxy with litigation." J.A. 314. Appellants argue that the University is "presumptively immune from the jurisdiction of U.S. courts" under the FSIA because "the District Court erred in finding that "[the commercial activity] exception [under the FSIA] applies to the University's immunity." Appellants' Br. 23 (capitalizations modified). We disagree with Appellants.

The University cannot claim immunity in the District Court because it obtained a U.S. patent and then participated in licensing and enforcing the '114 patent, which constitutes "commercial activity"

[4] Specifically, 28 U.S.C. § 1605(a) provides that:

> A foreign state shall not be immune from the jurisdiction of courts of the United States or of the States in any case . . . (2) in which the action is based upon a commercial activity carried on in the United States by the foreign state; or upon an act performed in the United States in connection with a commercial activity of the foreign state else-where; or upon an act outside the territory of the United States in connection with a commercial activity of the foreign state elsewhere and that act causes a direct effect in the United States[.]

[5] "Commercial activity" is "either a regular course of commercial conduct or a particular commercial transaction or act." 28 U.S.C. § 1603(d). The FSIA further indicates that "[t]he commercial character of an activity shall be determined by reference to the nature of the course of conduct or particular transaction or act, rather than by reference to its purpose." *Id.*

under the FSIA. *See* 28 U.S.C §§ 1603(d), 1605(a)(2). As an initial matter, the presumption of sovereign immunity applies to the University because it is undisputedly an "agency or instrumentality of a foreign state" here, the Swiss Confederation. J.A. 303; *see* Appellants' Br. 23. The commercial activity exception of § 1605(a)(2), however, provides a basis for jurisdiction over the University within U.S. district courts. Here, the University obtained a U.S. patent and consented to LABOKLIN sending the cease-and-desist letter relating to that patent in accordance with the terms of the Licensing Agreement. *See* J.A. 353–54. These actions constitute "commercial activity" having a direct effect in the United States. *See* 28 U.S.C §§ 1603(d), 1605(a)(2). By consenting to the cease-and-desist letter, the University directly participated in the act of threatening infringement-related litigation, and did so in order to benefit from this commercial activity. The University's involvement is further underscored by the fact that it had the first option in deciding whether to proceed with litigation in the United States, and was required to notify LABOKLIN within ninety days of the sending of the cease-and-desist letter of its decision in that regard.

We have found similar conduct to fall under the "commercial activity" exception to the FSIA jurisdictional immunity. In *Intel*, we determined that the actions of Australia's national science agency constituted a commercial exception to jurisdictional immunity because it had obtained a U.S. patent and sought to enforce it against U.S. entities—"whether by threatening litigation or by proffering licenses to putative infringers"—so that it "could reap the profits thereof." 455 F.3d at 1370. We further recognized that we had previously held "that 'a patentee's attempt to conduct license negotiations is a commercial activity.'" *Id*. (quoting *Phillips Plastics Corp. v. Hatsujou Kabushiki Kaisha,* 57 F.3d 1051, 1054 (Fed. Cir. 1995), *abrogated on other grounds by MedImmune, Inc. v. Genentech, Inc*., 549 U.S. 118 (2007)). Here, LABOKLIN, on behalf of the University, admitted that it "[sought] for PPG to either cease its conduct or enter into a licensing agreement whereby it was a sublicensee of [LABOKLIN]." J.A. 348. Contrary to the University's assertion on appeal, it matters not to this analysis that it was LABOKLIN that physically wrote and sent the cease-and-desist letter to PPG, because the University conceded that it still retained substantial rights in the patent, such that the University, as the sole "patentee," ultimately controlled enforcement of the '114 patent. *See* J.A. 359–61; *see also* J.A. 360 ("[T]he [U]niversity did not transfer all substantial rights.").

Moreover, the Supreme Court has held, in the context of § 1605(a)(2), that "based on" means that a foreign state's commercial activity forms "those elements of a claim that, if proven, would entitle a plaintiff to relief under his theory of the case." *Saudi Arabia,* 507 U.S. at 357. PPG's lawsuit for a declaratory judgment on the '114 patent is based upon the University's steps to commercialize the '114 patent's claimed technology by engaging LABOKLIN as an exclusive licensee and then affirmatively consenting to LABOKLIN's threat of infringement against PPG. *See* J.A. 214–15, 348–49. The University's conduct can, and here does, qualify under § 1605(a)(2)'s exceptions for "commercial activity carried on in the United States by the foreign state" or "an act performed in the United States in connection with a commercial activity of the foreign state elsewhere." 28 U.S.C. § 1605(a)(2); *Republic of Arg. v. Weltover, Inc*., 504 U.S. 607, 614 (1992) (determining that a district court properly asserted jurisdiction under the FSIA and stating that actions are determined to be commercial if they "are the *type* of actions by which a private party engages in trade and traffic or commerce" (internal quotation marks omitted)). Accordingly, the commercial activity exception to sovereign immunity applies such that the District Court properly exercised subject-matter jurisdiction over the University pursuant to § 1605(a).[6]

DISCUSSION

Patent Eligibility Under § 101

I. Standards of Review and Legal Standard

We apply regional circuit law when "reviewing the grant or denial of JMOL," *ABT Sys., LLC v. Emerson Elec. Co.*, 797 F.3d 1350, 1354 (Fed. Cir. 2015), here, the Fourth Circuit. The Fourth Circuit reviews JMOL rulings de novo. *In re Wildewood Litig*., 52 F.3d 499, 502 (4th Cir. 1995). Pursuant to Federal Rule of Civil Procedure 50, before submitting the case to a jury during a jury trial and after a party is fully heard on an issue, the district court may grant JMOL if the court finds "there is no legally sufficient evidentiary basis for a reasonable jury to have found for that party with respect to that issue." Fed. R. Civ. P. 50(a). "In deciding a JMOL motion, all reasonable inferences [are to be drawn] in favor of the nonmoving party without making

[6] Moreover, the University having waived service, J.A. 33–34 (evidencing, as part of the District Court's docket report, the issuance and waiver of service of summons to and by the University), the District Court's exercise of personal jurisdiction over the University was also proper, *see* 28 U.S.C. § 1330(b) (providing that "[p]ersonal jurisdiction over a foreign state shall exist as to every claim for relief over which the district courts have jurisdiction under [§ 1605(a)] where service has been made").

credibility assessments or weighing the evidence." *ABT Sys.*, 797 F.3d at 1350 (internal quotation marks and citations omitted) (applying the Fourth Circuit standards of review when reviewing a §101 challenge).

"We review issues unique to patent law, including patent eligibility under § 101, consistent with our circuit's precedent." *Smart Sys. Innovations, LLC v. Chi. Transit Auth.*, 873 F.3d 1364, 1367 (Fed. Cir. 2017) (internal quotation marks and citation omitted). Although a district court's determination of patent eligibility under § 101 is typically an issue of law, which we review de novo, *see Intellectual Ventures I LLC v. Erie Indem. Co.*, 850 F.3d 1315, 1325 (Fed. Cir. 2017), "[t]he patent eligibility inquiry may contain underlying issues of fact," *Berkheimer v. HP Inc.*, 881 F.3d 1360, 1365 (Fed. Cir. 2018).

"Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of" Title 35 of the United States Code. 35 U.S.C. § 101. "The Supreme Court, however, has long interpreted § 101 and its statutory predecessors to contain an implicit exception: 'laws of nature, natural phenomena, and abstract ideas' are not patentable." *Content Extraction & Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343, 1346 (Fed. Cir. 2014) (quoting *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 573 U.S. 208, 217 (2014)).

The Supreme Court's *Alice* and *Mayo Collaborative Services v. Prometheus Laboratories, Inc.* decisions provide the two-stage framework by which we assess patent eligibility under § 101. *See* 573 U.S. at 216–18; 566 U.S. 66, 70–80 (2012). A patent

> claim falls outside § 101 where (1) it is "directed to" a patent-ineligible concept, *i.e.*, a law of nature, natural phenomenon, or abstract idea, and (2), if so, the particular elements of the claim, considered "both individually and 'as an ordered combination,'" do not add enough to "'transform the nature of the claim' into a patent-eligible application."

Elec. Power Grp., LLC v. Alstom S.A., 830 F.3d 1350, 1353 (Fed. Cir. 2016) (quoting *Alice*, 573 U.S. at 217). It is against this framework that we analyze the Asserted Claims.

II. The Asserted Claims

Entitled "Method of Determining the Genotype Relating to Hereditary Nasal Parakeratosis [('HNPK')] and Nucleic Acids Usable in Said Method," the '114 patent generally relates to in vitro methods for genotyping Labrador Retrievers, in order to discover whether the dog

might be a genetic carrier of the disease HNPK. *See* '114 patent col. 1 ll. 15–20. HNPK is a disease that causes "crusts and fissur[es]" to appear on the nose of dogs "at a young age," but the dogs are otherwise considered healthy. *Id.* col. 1 ll. 27–28. HNPK is a "recessive" condition that only passes to a puppy when both of the dog's parents are "carriers" of the gene that causes HNPK. *Id.* col. 1 ll. 34, 38–39. Therefore, "a genetic test method that can discriminate the three genotypes" of "free," "carrier," and "affected" is "highly valuable for dog breeding as well as for veterinary medicine to confirm the diagnosis of suspicious cases." *Id.* col. 1 ll. 46–50; *see id*. Abstract ("The invention also concerns polypeptide[-]based methods for determining said disorder. Further, nucleic acids, polypeptides and antibodies usable in said method are disclosed."). The '114 patent describes how the University's professor discovered that the presence of HNPK in Labrador Retrievers resulted from a point mutation in gene SUV39H2. *See id.* col. 7 ll. 8–21.

Claims 1–3 of the '114 patent recite:

> 1. An in vitro method for genotyping a Labrador Retriever comprising:
>
> a) obtaining a biological sample from the Labrador Retriever;
>
> b) genotyping a SUV39H2 gene encoding the polypeptide of SEQ ID NO: 1[;] and
>
> c) detecting the presence of a replacement of a nucleotide T with a nucleotide G at position 972 of SEQ ID NO: 2.
>
> 2. The method according to claim 1, wherein the genotyping is achieved by [polymerase chain reaction ("PCR")], real-time PCR, melting point analysis of double-stranded DNA, mass spectroscopy, direct DNA sequencing, restriction fragment length polymorphism (RFLP), single strand conformation polymorphism (SSCP), high performance liquid chromatography (HPLC), or single base primer extension.
>
> 3. The method of claim 1, wherein the genotyping utilizes a primer pair compris[ed] of a first primer and a second primer, each compromising a contiguous span of at least 14 nucleotides of the sequence SEQ ID NO: 2 or a sequence complementary thereto, wherein:
>
> a) said first primer hybridizes to a first DNA strand of the SUV39H2 gene;
>
> b) said second primer hybridizes to the strand complementary to said first DNA strand of the SUV39H2 gene; and

> c) the 3' ends of said first and second primers are located on regions flanking the position 972 of SEQ ID NO: 2, or of nucleotide positions complementary thereto.

Id. col. 15 l. 11–col. 16 l. 14.

III. The District Court Did Not Err in Granting JMOL Because It Correctly Determined that the Asserted Claims Are Patent-Ineligible Under § 101

A. The Asserted Claims Are Directed to a Natural Phenomenon

The District Court held that the Asserted Claims, both individually and in combination, are "directed to patent ineligible subject matter, namely the discovery of the genetic mutation that is linked to HNPK." *Genetic Veterinary*, 314 F. Supp. 3d at 730. Appellants argue that the Asserted Claims "are directed to a patent-eligible application" of the discovery of the "underlying natural phenomenon" because the Asserted Claims "claim a man-made laboratory procedure." Appellants' Br. 37–38. They further contend that "[n]o one in the industry was even studying the SUV39H2 gene, let alone developing genotyping methods for Labrador Retrievers." *Id*. at 45. We disagree with Appellants.

We begin our analysis by examining previous eligibility determinations. *See, e.g.*, *Mayo*, 566 U.S. at 72, 74–77 (evaluating eligibility by comparing the challenged claims "in light of the Court's precedents" and holding that the claims were directed to the relationship between the concentration of metabolites in the blood and the likelihood that a drug dose will be ineffective, which it referred to as a law of nature). We have applied the Supreme Court's guidance in *Alice* and *Mayo* to find claims "directed to a patent-ineligible concept when they amounted to nothing more than observing or identifying the ineligible concept itself." *Rapid Litig. Mgmt. v. CellzDirect, Inc.*, 827 F.3d 1042, 1048 (Fed. Cir. 2016) (internal quotation marks omitted). For example, in *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, we held that claims reciting methods for detecting paternally inherited cell-free fetal DNA ("cffDNA") mutations were directed to a patent-ineligible law of nature because they were "generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon, cffDNA in maternal plasma or serum." 788 F.3d 1371, 1376 (Fed. Cir. 2015). Similarly, in *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litigation*, we concluded that the claims were directed to a patent-ineligible law of nature because the claims' "methods, directed to identification of alterations of the gene, require[d] merely comparing the patient's gene with the wild-type gene and identifying

any differences that ar[o]se." 774 F.3d 755, 763 (Fed. Cir. 2014). In each of these cases, "the end result of the process, the essence of the whole, was a patent-ineligible concept." *CellzDirect*, 827 F.3d at 1048.

In contrast, we held that the claims in *CellzDirect* were not directed to "an observation or detection of the ability of [liver cells] to survive multiple freeze thaw cycles" but, instead, were directed to a "new and improved technique[] for producing a tangible and useful result," i.e., preserving those cells for later use. *Id.* at 1048, 1050. Therefore, we recognized that the claims fell "squarely outside those categories of inventions that are directed to patent-ineligible concepts." *Id.* at 1050 (internal quotation marks omitted). Similarly, in *Vanda Pharmaceuticals, Inc. v. West-Ward Pharmaceuticals International Ltd.*, we held that a claimed method of treating schizophrenia with the drug iloperidone was directed to patent-eligible subject matter because it taught "a specific method of treatment for specific patients using a specific *compound* at specific *doses* to achieve a specific *outcome*." 887 F.3d 1117, 1136 (Fed. Cir. 2018) (emphases added). There, the representative claim taught "'a new way of using an existing drug' that is safer for patients," *id.* at 1135, specifically involving the steps of determining a particular genotype in a patient and then "administering specific dose ranges" of the drug based on that genotype, *id.* at 1134. Finally, in *Natural Alternatives International, Inc. v. Creative Compounds, LLC*, we held that a patent claiming methods for use of dietary supplements, dietary supplements, and uses of beta-alanine in manufacturing a human dietary supplement to increase the anaerobic working capacity of muscle and other tissue was directed to patent-eligible subject matter. 918 F.3d 1338, 1346–47 (Fed. Cir. 2019). We explained that the claims were not directed to a law of nature or a natural product because the claims "require[d that] specific [claimed] steps be taken in order to bring about a change in a subject, altering the subject's natural state." *Id.* at 1345.

Here, the Asserted Claims are not directed to a new and useful method for discovery because they begin and end with the point discovery of the HNPK mutation in the SUV39H2 gene. *See, e.g., Ariosa*, 788 F.3d at 1380 ("We do not disagree that detecting cffDNA in maternal plasma or serum that before was discarded as waste material is a positive and valuable contribution to science. But even such valuable contributions can fall short of statutory patentable subject matter[.]"). The parties do not dispute that the mutation itself is a naturally occurring phenomenon. *See* Appellants' Br. 39; Appellee's Br. 37.

Looking to the claim language, claim 1 breaks down, into three parts, the "in vitro method for genotyping a Labrador Retriever"[7] for detection of this mutation. '114 patent col. 15 l. 11. As explained by the parties' experts, first, step (a) "obtaining a biological sample" requires a sample of DNA from a dog, which both parties' experts testified usually requires obtaining a blood sample or cheek swab from the dog, *see* J.A. 1366, 1493; second, step (b) "genotyping a SUV39H2 gene encoding the polypeptide of SEQ ID NO: 1," identifies the location of the genetic mutation, *see* J.A. 1496; and third, step (c) "detect[ing] the presence of a replacement of a nucleotide" at a specific base pair position identifies the location of the equivalent normal gene, *see* J.A. 1496, 1598; *see also* '114 patent col. 15 ll. 14–19. In other words, claim 1 simply states that the search for the mutation involves the laboratory examination of Labrador Retriever DNA, which resulted in the revelation of the mutation. *See id*. col. 15 ll. 11–19. The mutation location itself and the fact that it is inherited through male and female dog carriers mating are both natural phenomena. *See Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 590 (2013) ("Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them."). Taken together, the plain language of claim 1 demonstrates that it is directed to nothing more than "observing or identifying" the natural phenomenon of a mutation in the SUV39H2 gene. *See Cellz-Direct*, 827 F.3d at 1048. Claims 2 and 3 depend from independent claim 1 and add only generic methods of detecting the natural phenomenon. Thus, the Asserted Claims are directed to natural phenomenon at *Alice* step one.

B. The Asserted Claims Do Not Recite an Inventive Concept

Because the Asserted Claims are directed to a natural phenomenon, the second step of the *Alice* § 101 analysis requires us to determine whether the subject patent's claims—when viewed individually and as an ordered combination of elements—contain "an inventive concept sufficient to transform the claimed [natural law] into a patent-eligible application." *Alice*, 573 U.S. at 221 (internal quotation marks omitted). A claim contains an inventive concept if it "include[s] additional features," *id.*, that are more than "well-understood, routine, [or] conventional activities," *id.* at 225 (internal quotation marks, brackets, and citations omitted).

[7] The scientific term "in vitro means outside of the main organism . . . in a petri dish or in a test tube," J.A. 1365 (deposition testimony of PPG's expert), and "genotyping . . . refers to determining the order or the composition of the nucleotides or bases in DNA," J.A. 1493 (deposition testimony of LABOKLIN's expert).

The District Court determined "the additional steps and claims [of the '114 patent]" lack "any inventive concept to transform it from patent ineligible subject matter to patent eligible subject matter." *Genetic Veterinary*, 314 F. Supp. 3d at 733. Appellants argue that "the claimed methods . . . apply a new discovery" of the SUV39H2 gene and develop novel "genotyping methods for Labrador Retrievers." Appellants' Br. 45. We disagree with Appellants.

The Asserted Claims do not recite an inventive concept that transforms the observation of a natural phenomenon into a patentable invention. Nothing in claim 1's language suggests the invention of a new *method* for genotyping. *See* '114 patent col. 15 l. 16 (claiming "genotyping" but not explaining specific steps of *how* to genotype). Rather, instructive to our analysis is that LABOKLIN's expert agreed that the genotyping method in claim 1 uses conventional or known laboratory techniques to observe the newly discovered mutation in the SUV39H2 at position 972. *See, e.g.,* J.A. 1520 (agreeing with counsel that claim 1 is "not talking about a particular way to genotype the [SUV39H2] gene encoding"). Conducting conventional detection in a laboratory does not transform the discovery of a natural phenomenon into patent eligible subject matter. Rather, similar to the claims at issue in *Mayo*, a natural phenomenon, together with well-understood, conventional activity, is not patent-eligible under § 101. *See Mayo*, 566 U.S. at 73, 79–80.

Claims 2 and 3 also do not move the natural phenomenon into eligible § 101 territory. For example, claim 2 limits the method of claim 1 to specific techniques, including "genotyping achieved by PCR, [and] real-time PCR," *see* '114 patent col. 15 l. 21; however, we have recognized that laboratory techniques, such as using "[PCRs] to amplify and detect cffDNA," are well-understood, routine, conventional activities in the life sciences when they are claimed in a merely generic manner (e.g., at a high level of generality) or as insignificant extra-solution activity, *Genetic Techs. v. Merial LLC*, 818 F.3d 1369, 1377–78 (Fed. Cir. 2016); *see id.* at 1379–80 (finding claims patent-ineligible and stating that the physical steps of "detecting a coding region of a person's genome by amplifying and analyzing a linked noncoding region of that person's genome" did not provide an inventive concept necessary to render the claim patent-eligible). Additionally, LABOKLIN's expert confirmed that claim 2 contained techniques that "have been around for years," J.A. 1521, and had no specific order or requirement to use these techniques a particular way, *see* J.A. 1526–27; *see also* J.A. 1368–75, 1429, 1490–91, 1498. As for claim 3, which recites "utiliz[ing] a primer pair" as the means for locating the mutation, '114 patent col. 15 l. 28, LABOKLIN's expert

testified that while he had never used primer pairs to genotype base pair position 972 in the SUV39H2 gene, primer pairs is a "decades old" technique "just like boiling or baking," J.A. 1528–29. As the Supreme Court explained in *Mayo*, "simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." *Mayo*, 566 U.S. at 82. Therefore, the Asserted Claims are patent-ineligible at *Alice* step two.

We are unpersuaded by Appellants' primary counter-argument that the District Court erred because the Asserted Claims "do not merely recite the underlying natural phenomenon, the causative mutation of HNPK, but instead recite a particular application of that discovery." Appellants' Br. 39. Appellants argue further that the "claimed steps of obtaining a biological sample, genotyping a SUV39H2 gene, and detecting the presence of the replacement nucleotide do not recite or even mention the correlation between the point mutation and HNPK." *Id*. Appellants rely heavily upon our precedent in *CellzDirect*, to argue that "[s]imilar to the inventors in *CellzDirect*, [the '114 patentee] discovered that the existence of the replacement nucleotide at position 972 of a specific gene indicates [that] the Labrador Retriever is a carrier of HNPK." *Id*. at 40 (citing 827 F.3d at 1052). However, any reliance on *CellzDirect* is misguided. As we stated above, the claims at issue in *CellzDirect* were directed to a "new and improved technique[] for producing a tangible and useful result," i.e., *preserving* those cells for later use. *CellzDirect*, 827 F.3d at 1048. Here, the Asserted Claims provide no tangible result save the observation and detection of a mutation in a dog's DNA. While a positive and valuable contribution, these claims fall short of statutory patentable subject matter.

CONCLUSION

We have considered the parties' remaining arguments and find them unpersuasive. Accordingly, the Final Judgment of the U.S. District Court for the Eastern District of Virginia is

AFFIRMED

ELI LILLY and COMPANY, Plaintiff-Appellee v. HOSPIRA, INC., Defendant-Appellant

Appeal No. 2018–2126, 2018–2127

Appeals from the United States District Court for the Southern District of Indiana in No. 1:16-cv-03460-TWP-MPB, Judge Tanya Walton Pratt.

ELI LILLY and COMPANY, Plaintiff-Appellee v. DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES, INC., Defendants-Appellants

Appeal No. 2018–2128

Appeal from the United States District Court for the Southern District of Indiana in No. 1:16-cv-00308-TWP-MPB, Judge Tanya Walton Pratt.

Decided: August 9, 2019

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Before LOURIE, MOORE, and TARANTO, *Circuit Judges.*

LOURIE, *Circuit Judge.*

Hospira Inc. ("Hospira"), Dr. Reddy's Laboratories Ltd., and Dr. Reddy's Laboratories Inc. (collectively, "DRL") appeal from two judgments of the United States District Court for the Southern District of Indiana in two infringement suits brought by Eli Lilly & Company ("Lilly") under the Hatch-Waxman Act, 21 U.S.C. § 355. The district court held in each case that the defendant's submission of a New Drug Application pursuant to 21 U.S.C. § 355(b)(2) infringed U.S. Patent 7,772,209 (the "'209 patent") under 35 U.S.C. § 271(e)(2). *See Eli Lilly & Co. v. Hospira, Inc.*, No. 1:16-cv-03460-TWP-MPB, 2018 WL 3008570 (S.D. Ind. June 15, 2018) ("*Hospira Decision*"); *Eli Lilly & Co. v. Dr. Reddy's Labs., Ltd.*, 323 F. Supp. 3d 1042 (S.D. Ind. 2018) ("*DRL Decision*"); *see also Eli Lilly & Co. v. Dr. Reddy's Labs., Ltd.*, No. 1:16-cv-00308-TWP-MPB, 2017 WL 6387316 (S.D. Ind. Dec. 14, 2017) ("*DRL Summary Judgment Decision*"). Accordingly, the district court entered orders under 35 U.S.C. § 271(e)(4)(A) prohibiting FDA approval of the products at issue until the expiration of the '209 patent. *Eli Lilly & Co. v. Hospira, Inc.*, No. 1:16-cv-03460-TWP-MPB (S.D. Ind. June 27, 2018), ECF No. 94; *Eli Lilly & Co. v. Dr. Reddy's Labs., Ltd.*, No. 1:16-cv-00308-TWP-MPB, 2018 WL 3616715 (S.D.

Ind. July 27, 2018). We decide these appeals together in this combined opinion.[1]

We reverse the district court's finding of literal infringement in the *Hospira Decision* as clearly erroneous in light of the court's claim construction of "administration of pemetrexed disodium." Because the district court did not err in its application of the doctrine of equivalents in either decision, we affirm both judgments of infringement. Thus, the *Hospira Decision* is affirmed-in-part and reversed-in-part, and the *DRL Decision* is affirmed.

BACKGROUND

Lilly markets the compound pemetrexed in the form of a disodium salt as Alimta®, which is indicated, both alone and in combination with other active agents, for treating certain types of non-small cell lung cancer and mesothelioma. Pemetrexed is an antifolate, a class of molecules which, at the time of the invention in 2001, was "one of the most thoroughly studied classes of antineoplastic agents." '209 patent col. 1 ll. 19–20. Antifolates are structurally similar to folic acid and work by competitively binding to certain enzymes that use folic acid metabolites as cofactors in several steps of de novo nucleotide synthesis. *Id.* col. 1 ll. 40–41. Unlike folic acid, antifolates do not enable these synthetic steps, but instead inhibit them. Pemetrexed inhibits several of these enzymes, including thymidylate synthase, which methylates deoxyuridine in the final step of deoxythymidine synthesis. *Id.* col. 1 ll. 59–61. By inhibiting the creation of these nucleotides, antifolates slow down DNA and RNA synthesis, and with it, cell growth and division. Cancer cells tend to grow rapidly, so antifolate therapy affects them disproportionately, but healthy cells can also be damaged.

Pemetrexed had been known for at least a decade in 2001. Lilly's U.S. Patent 5,344,932 ("Taylor") disclosed that certain glutamic acid derivatives with pyrrolo[2,3-d]pyrimidine heterocyclic ring structures, exemplified by pemetrexed, are "particularly active . . . inhibitors of thymidylate synth[ase]," Taylor col. 1 ll. 59–60; *see also id.* col. 19 l. 37–col. 20 l. 25 (disclosing data indicating that pemetrexed inhibits thymidylate synthase activity in vitro in human cell lines and in vivo in mice). The Taylor patent also disclosed that its compounds could be employed as "pharmaceutically acceptable salt[s]," *id.* col. 2 l. 35, and that the disodium salt form was particularly

[1] We refer to the joint appendices in these appeals by reference to each appellant. Lilly's brief in the Hospira appeal is referred to as "Lilly Br. I" and its brief in the DRL appeal as "Lilly Br. II."

advantageous, *id.* col. 2 ll. 47–48. U.S. Patent 4,997,838 ("Akimoto"), to which Lilly took a license, disclosed a large genus of compounds containing pyrrolo[2,3-d]pyrimidine heterocyclic ring structures and a glutamic acid functional group, and that encompassed pemetrexed. The Akimoto patent discloses nearly fifty exemplary compounds, col. 14 l. 61–col. 16 l. 48, none of which is pemetrexed. Akimoto further discloses that its compounds may be prepared as salts of "pharmaceutically acceptable bases," such as "alkali metals, alkali earth metals, non-toxic metals, ammonium, and substituted ammonium." *Id.* col. 14 ll. 44–47.

By 2001, Lilly had also published the results of several clinical trials investigating the use of pemetrexed disodium as a treatment for different types of cancer. *See, e.g.*, W. John et al., "Activity of Multitargeted Antifolate (Pemetrexed Disodium, LY231514) in Patients with Advanced Colorectal Carcinoma: Results from a Phase II Study," *Cancer*, 88(8):1807–13 (2000). In the course of conducting these studies, Lilly discovered that pemetrexed disodium caused severe hematologic and immunologic side effects, resulting in infections, nausea, rashes, and even some deaths. *See id.*; *see also Neptune Generics, LLC v. Eli Lilly & Co.*, 921 F.3d 1372, 1377–78 (Fed. Cir. 2019) (discussing Lilly's response to adverse clinical data), *and Neptune Generics, LLC v. Eli Lilly & Co.*, No. IPR2016–00240, 2017 WL 4466557, at *28–30 (P.T.A.B. Oct. 5, 2017) (same). As the '209 patent teaches, such side effects are not uncommon among antifolates. *See* '209 patent col. 1 ll. 11–14. Some researchers hypothesized that folic acid deficiency caused these side effects and suggested supplementing pemetrexed disodium treatment with folic acid. DRL J.A. 7870 (citing J.F. Worzalla et al., "Role of Folic Acid in Modulating the Toxicity and Efficacy of the Multitargeted Antifolate, LY231514," *Anticancer Research*, 18:3235–40 (1998)).

The invention of the '209 patent is an improved method of treatment with antifolates, particularly pemetrexed disodium, through supplementation with a methylmalonic acid lowering agent and folic acid. Doing so, according to the patent, lessens antifolate toxicity without sacrificing efficacy. *See* '209 patent col. 10 ll. 17–53 (reporting that pre-supplementation regimen of vitamin B12 and folic acid in clinical studies substantially reduced pemetrexed-induced toxicity and deaths while delivering a superior chemotherapeutic response rate). The '209 patent lists preferred antifolates, including some then-existing antifolate therapies, as well as "derivatives described in" several patents including the Akimoto patent, and "most preferred, Pemetrexed Disodium." *Id.* col. 4 ll. 28–43. Each of the claims of the '209 patent requires administration of pemetrexed disodium follow-

ing administration of folic acid and a methylmalonic acid lowering agent, specified in some claims, as well as the Alimta® label, as vitamin B12. Claim 12 is representative[2]:

> 12. An improved method for administering pemetrexed disodium to a patient in need of chemotherapeutic treatment, wherein the improvement comprises:
>
> a) administration of between about 350 μg and about 1000 μg of folic acid prior to the first administration of pemetrexed disodium;
>
> b) administration of about 500 μg to about 1500 μg of vitamin B12, prior to the first administration of pemetrexed disodium; and
>
> c) administration of pemetrexed disodium.

In a parent application, Application 10/297,821 (the "'821 application"), Lilly originally sought broad claims to methods of administering an antifolate in conjunction with a methylmalonic acid lowering agent, with or without folic acid. The original independent claims 2 and 5 read:

> 2. (Original) A method of reducing the toxicity associated with the administration of an antifolate to a mammal comprising
>
> administering to said mammal an effective amount of said antifolate in combination with a methylmalonic acid lowering agent.
>
> 5. (Original) A method of reducing the toxicity associated with the administration of an antifolate to a mammal comprising
>
> administering to said mammal an effective amount of said antifolate in combination with a methylmalonic acid lowering agent and FBP binding agent.

DRL J.A. 7860. A dependent claim further limited the antifolate to pemetrexed disodium. *Id.* at 7861.

Claim 2 was rejected as anticipated by F.G. Arsenyan et al., "Influence of Methylcobalamin on the Antineoplastic Activity of Methotrexate," *Onkol. Nauchn.*, 12(10):1299–1303 (1978), which disclosed experiments treating mice with various tumors with a combination of methotrexate, an antifolate, and methylcobalamin, a vitamin B12 derivative. The rest of the pending claims, including Claim 5, were rejected as obvious over a collection of references: U.S. Patent 5,431,925 ("Ohmori")—which taught treatment of

[2] The district court treated claim 12 as representative, *DRL Summary Judgment Decision*, 2017 WL 6387316, at *1–2; *Hospira Decision*, 2018 WL 3008570, at *2, and no party has disputed that determination on appeal. *See, e.g.*, DRL Opening Br. 8–9; Hospira Opening Br. 23.

chemotherapeutically-induced immunosuppression with a combination of vitamins that could include folic acid and vitamin B12—Worzalla, John, and Arsenyan. '821 application, Sept. 27, 2004, Office Action; DRL J.A. 7868–72.

In response, Lilly amended both claims to narrow "antifolate" to "pemetrexed disodium" and cancelled its dependent claim limited to pemetrexed disodium. '821 application, Jan. 25, 2005, Response to Office Action; DRL J.A. 7877–84. In its remarks, Lilly asserted that the amendment to claim 2 overcame the anticipation rejection because Arsenyan does not disclose pemetrexed disodium. *Id*. To overcome the obviousness rejection of claim 5 and its dependents, Lilly generally argued that, while John discloses hematologic and immunologic toxicities from administration of pemetrexed disodium, it never suggests vitamin supplementation, and none of the other references "teach the use of [vitamin B12] to reduce toxicities associated with an antifolate." *Id.* The examiner then withdrew the anticipation rejection and later withdrew the obviousness rejection. The '821 application issued as U.S. Patent 7,053,065, and the '209 patent later issued from a continuation application.

These appeals were taken from cases which are among the latest in a series of patent disputes about Alimta® that reaches back more than a decade.[3] In this most recent chapter, DRL, Hospira, and Actavis[4] submitted New Drug Applications under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(b)(2), relying on Lilly's clinical data for pemetrexed disodium. But each applicant seeks to market different pemetrexed salts—in DRL's and Hospira's applications, pemetrexed ditromethamine. Both DRL and Hospira represented to the FDA that their choice of the tromethamine cation was immaterial because pemetrexed dissociates from its counterion in solution, DRL J.A. 8555–57; Hospira J.A. 124, and tromethamine was known to be safe for pharmaceutical use, DRL J.A. 8555, 8557.

Lilly then asserted the '209 patent against each of these NDA applicants in the United States District Court for the Southern District of Indiana. In the DRL case, the district court construed the

[3] This is the fourth appeal we have decided concerning Alimta® and the third specifically concerning the '209 patent. *See Neptune Generics*, 921 F.3d 1372; *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 845 F.3d 1357 (Fed. Cir. 2017); *Eli Lilly & Co. v. Teva Parenteral Meds., Inc.*, 689 F.3d 1368 (Fed. Cir. 2012).

[4] Lilly also sued Actavis LLC ("Actavis") for infringement of the '209 patent, *Eli Lilly & Co. v. Actavis LLC*, No. 1:17-cv-00982-TWP-MPB (S.D. Ind. Mar. 30, 2017), ECF No. 1, but the parties stipulated to be bound by the district court's decision in the DRL case that neither prosecution history estoppel nor the disclosure-dedication rule bars Lilly's assertion of infringement through the doctrine of equivalents. Actavis Br. 2. Actavis filed a brief in the DRL appeal as amicus curiae requesting reversal of that portion of the district court's decision.

phrase "administration of pemetrexed disodium" to mean "liquid administration of pemetrexed disodium," which "is accomplished by dissolving the solid compound pemetrexed disodium into solution." *DRL Summary Judgment Decision*, 2017 WL 6387316, at *4. The district court denied DRL's motion for summary judgment of noninfringement, holding that prosecution history estoppel does not bar Lilly from asserting that DRL's proposed pemetrexed ditromethamine product would infringe through the doctrine of equivalents because the reason for Lilly's amendment was to distinguish other antifolates and was therefore only tangential to pemetrexed ditromethamine. *Id.* at *6–7. The district court also rejected DRL's argument that Lilly dedicated pemetrexed ditromethamine to the public under the disclosure-dedication rule through its reference to Akimoto's antifolate compounds because Akimoto is not incorporated by reference into the '209 patent and in any event discloses pemetrexed ditromethamine only within a genus of thousands of compounds, which the district court held does not constitute the requisite disclosure of an identifiable alternative under this court's precedent. *Id.* at *7–8; *see, e.g.*, *SanDisk Corp. v. Kingston Tech. Co.*, 695 F.3d 1348, 1363 (Fed. Cir. 2012).

Following a bench trial, the district court's opinion largely followed its rationale in the *DRL Summary Judgment Decision* with respect to the applicability of prosecution history estoppel and the disclosure-dedication rule. *DRL Decision*, 323 F. Supp. 3d at 1046–48. In addition, the court found that DRL's proposed product would be administered in a manner that would meet the "administration of pemetrexed disodium" step of the asserted claims under the doctrine of equivalents, *id.* at 1049, regardless of the "differences in chemical properties between pemetrexed disodium and pemetrexed ditromethamine," *id.* at 1050.

In the Hospira case, the parties similarly disputed the doctrine of equivalents, but Lilly also asserted literal infringement because Hospira's proposed product label allows reconstitution of its pemetrexed ditromethamine salt in saline. *Hospira Decision*, 2018 WL 3008570, at *2–3; Hospira J.A. 229. After the district court issued the *DRL Summary Judgment Decision*, Hospira conceded, contingent upon its right to appeal, that its product would infringe under the claim construction of "administration of pemetrexed disodium" set forth in that opinion and that its doctrine of equivalents arguments were likewise foreclosed. Hospira Br. 18. The district court, "rel[ying] heavily" on the *DRL Summary Judgment Decision*, granted Lilly's motion for summary judgment of infringement, both literally and under the

doctrine of equivalents. *Hospira Decision*, 2018 WL 3008570, at *1 n.2, *6.

These appeals followed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review a district court's grant of summary judgment according to the law of the regional circuit. *Kaneka Corp. v. Xiamen Kingdomway Grp. Co.*, 790 F.3d 1298, 1303 (Fed. Cir. 2015) (citing *Halo Elecs., Inc. v. Pulse Elecs., Inc.*, 769 F.3d 1371, 1377 (Fed. Cir. 2014)). In the Seventh Circuit, summary judgment is reviewed *de novo*, construing all facts and drawing all inferences in favor of the non-movant. *Wis. Alumni Research Found. v. Apple Inc.*, 905 F.3d 1341, 1352 (Fed. Cir. 2018) (citing *Austin v. Walgreen Co.*, 885 F.3d 1085, 1087 (7th Cir. 2018)). 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) (citing *Brown & Williamson Tobacco Corp. v. Philip Morris Inc*., 229 F.3d 1120, 1123 (Fed. Cir. 2000)). 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).

Claim construction is ultimately an issue of law, which we review *de novo*. *Shire Dev., LLC v. Watson Pharm., Inc.*, 787 F.3d 1359, 1364 (Fed. Cir. 2015). We review *de novo* the district court's findings of fact on evidence "intrinsic to the patent (the patent claims and specification[], along with the patent's prosecution history)," and review for clear error extrinsic findings of fact. *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 841 (2015). While infringement is a question of fact, *Lucent Techs., Inc. v. Gateway, Inc.*, 580 F.3d 1301, 1309 (Fed. Cir. 2009), we review *de novo* the district court's grant of summary judgment of noninfringement, *Unwired Planet, LLC v. Apple Inc.*, 829 F.3d 1353, 1356 (Fed. Cir. 2016). To prove infringement, a patentee "must supply sufficient evidence to prove that the accused product or process contains, either literally or under the doctrine of equivalents, every limitation of the properly construed claim." *Seal-Flex, Inc. v. Athletic Track & Court Const.*, 172 F.3d 836, 842 (Fed. Cir. 1999). The patentee has the burden of proving infringement by a preponderance of the evidence. *SmithKline Diagnostics, Inc. v. Helena Labs. Corp.*, 859 F.2d 878, 889 (Fed. Cir. 1988).

Hospira requests reversal of the district court's finding that its submission of a § 505(b)(2) NDA for its pemetrexed product literally infringed the claims of the '209 patent. DRL and Hospira both argue,

as does the amicus curiae Actavis, that the district court erred as a matter of law by refusing to apply prosecution history estoppel to bar Lilly's doctrine of equivalents claim, and DRL further contends that the disclosure-dedication rule precludes Lilly's equivalents claim. Finally, DRL disputes the district court's finding that administration of pemetrexed ditromethamine is equivalent to the claim element "administration of pemetrexed disodium." We address each argument in turn.

A. Literal Infringement

Hospira argues that it cannot literally infringe the claims of the '209 patent because intravenous administration of pemetrexed ditromethamine dissolved in saline—a solution which contains pemetrexed and chloride anions alongside sodium and tromethamine cations—is not "administration of pemetrexed disodium." Hospira also notes that such a solution will, in any case, contain far more than two sodium cations per pemetrexed anion. Finally, Hospira appears to make a perfunctory argument that, in the alternative, we should reverse the district court's construction and hold that the term encompasses any route of administering pemetrexed disodium, not just liquid, as the district court's construction requires.

Lilly counters that Hospira's view improperly imposes a "source limitation," requiring that the pemetrexed disodium salt exist in solid form before administration, even though Hospira's proposed product label, like that of Alimta®, calls for administration of a solution containing pemetrexed anions and sodium cations. Lilly also contends that Hospira's claim construction arguments are irrelevant because Hospira's proposed product will be administered intravenously anyway.

We agree with Hospira. It was clearly erroneous for the district court to hold that the "administration of pemetrexed disodium" step was met because Hospira's pemetrexed ditromethamine product will be dissolved in saline before administration. A solution of pemetrexed and chloride anions and tromethamine and sodium cations cannot be deemed pemetrexed disodium simply because some assortment of the ions in the solution consists of pemetrexed and two sodium cations. As Lilly acknowledges throughout its brief, pemetrexed disodium is a salt. *See, e.g.*, Lilly Br. I 12 (pemetrexed toxicity is caused "by pemetrexed itself once dissociated in solution," not pemetrexed disodium); *see also* Hospira J.A. 1596 (October 2017 Alimta® Label referring to the drug substance as the "disodium salt" of pemetrexed). Once diluted, the salt's crystalline structure dissolves, and the individual

ions dissociate. *See* Hospira J.A. 2820 (declaration of Lilly's expert). In other words, pemetrexed disodium no longer exists once dissolved in solution, and, as a corollary, a different salt of pemetrexed dissolved in saline is not pemetrexed disodium.

We conclude that to literally practice the "administration of pemetrexed disodium" step under the district court's claim construction, the pemetrexed disodium salt must be itself administered. *See DRL Summary Judgment Decision*, 2017 WL 6387316, at *4 ("'[A]dministration of pemetrexed disodium' . . . refer[s] to a liquid administration of pemetrexed disodium. . . ., accomplished by dissolving the solid compound pemetrexed disodium into solution . . . ."); *see also Tex. Instruments Inc. v. Cypress Semiconductor Corp.*, 90 F.3d 1558, 1563 (Fed. Cir. 1996) ("To literally infringe, the accused . . . process must contain every limitation of the asserted claim." (citing *Laitram Corp. v. Rexnord, Inc.*, 939 F.2d 1533, 1535 (Fed. Cir. 1991))). There is no dispute that Hospira has only sought approval to market pemetrexed ditromethamine, Lilly Br. I 4, and that neither its proposed product nor methods of administering it will constitute administering the pemetrexed disodium salt. Accordingly, Hospira will not practice the step of "administration of pemetrexed disodium," and the district court's finding of literal infringement must be reversed.

B. Doctrine of Equivalents

Few propositions of patent law have been so consistently sustained by the Supreme Court as the doctrine of equivalents. *See Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushki Co.*, 535 U.S. 722, 733 (2002) ("*Festo VIII*") ("[E]quivalents remain a firmly entrenched part of the settled rights protected by the patent."); *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997) ("[W]e adhere to the doctrine of equivalents."); *Graver Tank & Mfg. Co. v. Linde Air Prods. Co.*, 339 U.S. 605, 608 (1950) ("Originating almost a century ago in the case of *Winans v. Denmead*, [56 U.S. 330 (1853)] . . . [the doctrine of equivalents] has been consistently applied by this Court and the lower federal courts, and continues today ready and available for utilization when the proper circumstances for its application arise."). It is settled that a patentee is entitled "in all cases to invoke to some extent the doctrine of equivalents," *Seymour v. Osborne*, 78 U.S. 516, 555 (1870), without a "judicial exploration of the equities of a case" beforehand. *See Warner-Jenkinson*, 520 U.S. at 34.

Yet the Supreme Court has also acknowledged that the doctrine of equivalents, "when applied broadly, conflicts with the definitional and public-notice functions of the statutory claiming requirement,"

Warner-Jenkinson, 520 U.S. at 29, and that, without the proper balance between these two imperatives, the doctrine may "take[] on a life of its own, unbounded by the patent claims." *See id.* at 28–29. We have emphasized, moreover, that the doctrine of equivalents is "the exception, however, not the rule," and not merely "the second prong of every infringement charge, regularly available to extend protection beyond the scope of the claims." *London v. Carson Pirie Scott & Co.*, 946 F.2d 1534, 1538 (Fed. Cir. 1991). Patent infringement is principally determined by examining whether the accused subject matter falls within the scope of the claims.

To that end, courts have placed important limitations on a patentee's ability to assert infringement under the doctrine of equivalents. *See, e.g.*, *Festo VIII*, 535 U.S. at 737–41 (prosecution history estoppel); *Warner-Jenkinson*, 520 U.S. at 39 n.8 ("[A] theory of equivalence [cannot] entirely vitiate a particular claim element . . . ."); *Graver Tank*, 339 U.S. at 608 (accused equivalent cannot differ substantially from the claimed invention); *Johnson & Johnston Assocs. Inc. v. R.E. Serv. Co.*, 285 F.3d 1046, 1054 (Fed. Cir. 2002) (en banc) (subject matter disclosed but not claimed is dedicated to the public) (citing *Maxwell v. J. Baker, Inc.*, 86 F.3d 1098 (Fed. Cir. 1996)); *Wilson Sporting Goods Co. v. David Geoffrey & Assocs.*, 904 F.2d 677, 683 (Fed. Cir. 1990) ("[T]he asserted scope of equivalency [cannot] encompass the prior art . . . ." (Rich, J.) (citations omitted)). These appeals implicate several of these limitations.

1. Prosecution History Estoppel

The main dispute in these appeals is whether Lilly has rebutted the presumption of prosecution history estoppel that attached to its amendment in the '821 application. Prosecution history estoppel arises when a patent applicant narrows the scope of his claims during prosecution for a reason "substantial[ly] relating to patentability." *See generally Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 344 F.3d 1359, 1366–67 (Fed. Cir. 2003) (en banc) ("*Festo X*"). Such a narrowing amendment is presumed to be a surrender of all equivalents within "the territory between the original claim and the amended claim," but the presumption is overcome if the patentee can show the applicability of one of the few exceptions identified by the Supreme Court. *Festo VIII*, 535 U.S. at 740–41 (citing *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136–37 (1942)). Whether prosecution history estoppel applies to bar a doctrine of equivalents claim is a question of law, reviewed *de novo*. *See Regents of Univ. of*

Cal. v. Dakocytomation Cal., Inc., 517 F.3d 1364, 1371 (Fed. Cir. 2008) (citing *Pharmacia & Upjohn Co. v. Mylan Pharm., Inc.*, 170 F.3d 1373, 1376 (Fed. Cir. 1999)).

Lilly does not dispute that the amendment in question was both narrowing and made for a substantial reason relating to patentability. Lilly Br. II 21. Furthermore, Lilly relies on only one exception to giving effect to the presumption as to the scope of surrender: that the rationale of its amendment "[bore] no more than a tangential relation to the equivalent in question." *Festo VIII*, 535 U.S. at 740. As a result, the parties' dispute about whether prosecution history estoppel applies is confined to whether Lilly's amendment narrowing "an antifolate" to "pemetrexed disodium" was only tangential to pemetrexed ditromethamine, which is the accused compound. Whether the tangential exception applies is a question of law, *Integrated Tech. Corp. v. Rudolph Techs., Inc.*, 734 F.3d 1352, 1356 (Fed. Cir. 2013), and a patentee seeking to use the exception "must base his arguments solely upon the public record of the patent's prosecution." *Festo X*, 344 F.3d at 1369–70 (citation omitted).

The Appellants argue that Lilly failed to explain why it did not pursue a narrower amendment literally encompassing pemetrexed ditromethamine, and they emphasize our statement that the tangential exception is "very narrow." *Integrated*, 734 F.3d at 1358 (quoting *Cross Med. Prods., Inc. v. Medtronic Sofamor Danek, Inc.*, 480 F.3d 1335, 1342 (Fed. Cir. 2007)). The Appellants further point out that Lilly cannot be said to have "lacked the words to describe" pemetrexed ditromethamine, *see Festo VIII*, 535 U.S. at 734, because Lilly's previous patents, as well as the European companion to the '209 patent, claimed pemetrexed salts generally and pemetrexed disodium in a dependent claim. They also assert that the district court erred by focusing on whether Lilly actually needed to relinquish pemetrexed ditromethamine to overcome the Arsenyan anticipation rejection because "the tangential exception is not a patentee's-buyer's-remorse exception." DRL Br. 39.

In response, Lilly argues that the district court properly held that the reason for its amendment was to distinguish pemetrexed from antifolates generally and that the different salt type is a merely tangential change with no consequence for pemetrexed's administration or mechanism of action within the body. Lilly also contends that it is not barred from asserting the tangential exception simply because pemetrexed ditromethamine is within "the territory between the original claim and the amended claim." *Festo VIII*, 535 U.S. at

740. Finally, Lilly argues that Appellants' view that courts must "consider hypothetical alternative amendments" that would literally encompass the alleged equivalent "would eviscerate the tangentiality exception." Lilly Br. II 44.

We agree with Lilly. As a general matter, we find Appellants' view of prosecution history estoppel, and the tangential exception in particular, too rigid. Tangential means "touching lightly or in the most tenuous way." Webster's Third New International Dictionary (2002). The reason for Lilly's amendment, as the district court concluded, was to narrow original claim 2 to avoid Arsenyan, which only discloses treatments using methotrexate, a different antifolate. *See* DRL J.A. 7879–80 (overcoming the Arsenyan anticipation rejection by arguing that it "does not disclose pemetrexed disodium"). To overcome a clear anticipation, Lilly opted to narrow its original claim 2 and its dependents to more accurately define what it actually invented, an improved method of administering pemetrexed. In other words, the particular type of salt to which pemetrexed is complexed relates only tenuously to the reason for the narrowing amendment, which was to avoid Arsenyan. We therefore hold that Lilly's amendment was merely tangential to pemetrexed ditromethamine because the prosecution history, in view of the '209 patent itself, strongly indicates that the reason for the amendment was not to cede other, functionally identical, pemetrexed salts.

The prosecution record confirms our understanding. Original claim 5, which, like all the current claims of the '209 patent, required supplementation with both vitamin B12 and folic acid, was never rejected as anticipated over Arsenyan. Instead, the art cited against original claim 5 and its dependent claims in the obviousness ground of rejection was replete with information about pemetrexed disodium; John disclosed clinical trials using pemetrexed disodium, reporting both its efficacy and its toxic side effects, and in response, DRL J.A. 7869–70, Worzalla suggested folic acid supplementation to counteract these side effects, DRL J.A. 7870–71. The prosecution record implies that Lilly's amendment, inartful though it might have been, was prudential in nature and did not need or intend to cede other pemetrexed salts.

Hospira argues that the amendment was made to overcome the obviousness rejection over Ohmori and John and that Lilly has provided no reason for the amendment relative to that rejection. Like Lilly, we find this argument makes little sense. John discloses the results of a clinical trial of pemetrexed disodium and explicitly

suggests the toxicities caused by pemetrexed; as we concluded above, narrowing "antifolate" to "pemetrexed disodium" could not possibly distinguish the art cited in the obviousness ground of rejection.

DRL also insists that we have held that an applicant's remorse at ceding more claim scope than necessary is not a reason for the tangential exception to apply. *See, e.g.*, *Lucent Techs., Inc. v. Gateway, Inc.*, 525 F.3d 1200, 1218 (Fed. Cir. 2008); *Schwarz Pharma, Inc. v. Paddock Labs., Inc.*, 504 F.3d 1371, 1377 (Fed. Cir. 2007). This is generally true, but DRL overreads the holdings of these cases. After all, the tangential exception only exists because applicants overnarrow their claims during prosecution. Amendments are not construed to cede only that which is necessary to overcome the prior art, *see Schwarz*, 504 F.3d at 1377, nor will the court "speculat[e]" whether an amendment was necessary, *see Kinzenbaw v. Deere & Co.*, 741 F.2d 383, 389 (Fed. Cir. 1984). But the reason for an amendment, where the tangential exception is invoked, cannot be determined without reference to the context in which it was made, including the prior art that might have given rise to the amendment in the first place. *See Festo X*, 344 F.3d at 1370. Here, it is unlikely that a competitor would have been "justified in assuming that if he [made an equivalent pemetrexed salt], he would not infringe [the '209 patent]." *Kinzenbaw*, 741 F.2d at 389; *cf. Festo VIII*, 535 U.S. at 738 ("There is no reason why a narrowing amendment should be deemed to relinquish equivalents . . . beyond a fair interpretation of what was surrendered.").

Furthermore, Appellants' suggestion that Lilly must prove that it could not have drafted a claim that literally encompassed pemetrexed ditromethamine is unsupported by our precedent on prosecution history estoppel, not to mention excessive. We do not demand perfection from patent prosecutors, and neither does the Supreme Court. *See Festo VIII*, 535 U.S. at 738 ("It does not follow . . . that [an] amended claim becomes so perfect in its description that no one could devise an equivalent."). Lilly's burden was to show that pemetrexed ditromethamine was "peripheral, or not directly relevant," to its amendment, *Festo X*, 344 F.3d at 1369. And as we concluded above, Lilly has done so.

In addition, the Appellants maintain that when a patentee submits an amendment adding two claim limitations, it cannot later argue that the reason for the amendment was tangential to an accused equivalent containing only one of the added limitations simply because the second limitation was unnecessary to overcome the prior

art. They offer *Felix v. American Honda Motor Co.*, 562 F.3d 1167 (Fed. Cir. 2009), as an illustration of this principle.[5] In that case, we held that prosecution history estoppel applied to a claim directed to a vehicle bed storage system—limited in response to a rejection to having a channel with a flange and a gasket mounted on that flange—barring assertion of equivalence with respect to a product that met the channel aspect, but not the gasket aspect, of the limitation. *Id.* at 1184–85.

But as Lilly points out, this holding was determined by that patent's prosecution history, *Felix*, 562 F.3d at 1184, and we have also held that prosecution history estoppel does not apply in similar circumstances, where the prosecution record differed. *See, e.g.*, *Regents*, 517 F.3d at 1376–78 (amendment narrowing "disabling hybridization capacity of [nucleic acid] sequences" to methods using a "blocking nucleic acid" was merely tangential to unclaimed repetitive sequence nucleic acids); *Insituform Techs., Inc. v. CAT Contracting, Inc.*, 385 F.3d 1360, 1368 (Fed. Cir. 2004) (amendment narrowing method of inserting resin into tube using a vacuum to one using "a cup" to do so was merely tangential to a multiple cup embodiment because the number of cups bore no relationship to the cited prior art or the rationale behind the narrowing amendment). Thus, our cases demonstrate that prosecution history estoppel is resistant to the rigid legal formulae that Appellants seek to extract from them. *See Intervet Inc. v. Merial Ltd.*, 617 F.3d 1282, 1291 (Fed. Cir. 2010) ("[T]here is no hard-and-fast test for what is and what is not a tangential relation . . . .").

Finally, DRL also contends that our precedent squarely forecloses Lilly's tangentiality argument, and it invites us to read those cases to hold that "where the reason for the amendment and the equivalent in question both relate to the same claim element, the tangential exception does not apply." DRL Br. 47. We decline this invitation because such a bright-line rule is both contrary to the equitable nature of prosecution history estoppel, as articulated in *Festo VIII*, 535 U.S. at 738, and inconsistent with the equitable spirit that animates the

[5] The parties argue at length about which of our cases are properly analogous to the facts presented in these appeals. Here, in applying the Supreme Court's framework, we find the analogies to other cases less helpful than a direct consideration of the specific record of this case and what it shows about the reason for amendment and the relation of that reason to the asserted equivalent. This case-specific focus, within the governing framework, comports with the equitable nature of prosecution history estoppel. *See Festo VIII*, 535 U.S. at 738 ("[The Supreme Court has] consistently applied the doctrine in a flexible way, not a rigid one."); *cf. Heckler v. Cmty. Health Servs. of Crawford Cty., Inc.*, 467 U.S. 51, 59 (1984) ("Estoppel is an equitable doctrine invoked to avoid injustice in particular cases. . . . [and] a hallmark of the doctrine is its flexible application . . . .").

doctrine of equivalents, *see Graver Tank*, 339 U.S. at 608–09 (the doctrine is one of "wholesome realism"). Instead, we reaffirm that whether an amendment was merely tangential to an equivalent must be decided in the context of the invention disclosed in the patent and the prosecution history. *Festo X*, 344 F.3d at 1370.

DRL's intuition—that an amendment that narrows an existing claim element evinces an intention to relinquish that claim scope—is often correct. Indeed, as we have found in previous cases, it is a powerful indication that an amendment was not merely tangential. *See, e.g., Honeywell Int'l, Inc. v. Hamilton Sundstrand Corp.*, 523 F.3d 1304, 1315–16 (Fed. Cir. 2008); *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1306 (Fed. Cir. 2005). But here, we conclude that this consideration is not dispositive because the rest of the prosecution history, and the '209 patent itself, show that it is implausible that the reason for Lilly's amendment was to surrender other pemetrexed salts. Indeed, such a relinquishment would effectively dedicate the entirety of Lilly's invention to the public and thereby render the '209 patent worthless, and it would have been irrelevant for distinguishing the prior art. Again, the prosecution history strongly indicates a less sweeping and more sensible reason for Lilly's amendment: to surrender antifolates other than pemetrexed. Thus, we conclude on this prosecution record that Lilly's amendment was merely tangential to pemetrexed ditromethamine.

2. Disclosure-Dedication Rule

DRL next argues that the disclosure-dedication rule bars Lilly from asserting infringement under the doctrine of equivalents. The '209 patent sets forth its invention as an improved method of administering antifolates, '209 patent col. 2 ll. 47–58, and teaches that the derivatives described in the Akimoto patent are preferred examples of antifolates, *id.* col. 4 ll. 34–40. DRL contends that one of these derivatives is pemetrexed ditromethamine and that it was dedicated to the public when Lilly declined to claim it. DRL asserts that the district court erred because it both required express incorporation of Akimoto by reference into the '209 patent and concluded that Akimoto does not specifically disclose pemetrexed ditromethamine.

Lilly counters that the disclosure-dedication rule requires express disclosure of the subject matter in question in the specification except in narrow circumstances, such as when that subject matter is disclosed in a priority application, *see Abbott Labs. v. Sandoz, Inc.*, 566 F.3d 1282, 1297 (Fed. Cir. 2009), or prior art expressly incorporated by reference, *SanDisk*, 695 F.3d at 1366. Lilly also argues that the district court correctly determined that the relevant portion of

Akimoto discloses only a generic formula from which a skilled artisan would not be able to recognize pemetrexed ditromethamine.

We agree with Lilly and hold that the disclosure-dedication rule is inapplicable to this case because the '209 patent does not disclose methods of treatment using pemetrexed ditromethamine, and, as a result, Lilly could not have dedicated such a method to the public.

Under the disclosure-dedication rule, subject matter disclosed by a patentee, but not claimed, is considered dedicated to the public. *See Johnson & Johnston*, 285 F.3d at 1054. The reason for the doctrine is that members of the public reading a disclosure of particular subject matter are entitled, absent a claim to it, to assume that it is not patented and therefore dedicated to the public (unless, for example, claimed in a continuation or other application based on the disclosure). *Cf. Maxwell*, 86 F.3d at 1107 (failure to claim inventive subject matter "is clearly contrary to 35 U.S.C. § 112, which requires that a patent applicant 'particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention'"). Subject matter is considered disclosed when a skilled artisan "can understand the unclaimed disclosed teaching upon reading the written description," but not "any generic reference . . . necessarily dedicates all members of that particular genus." *PSC Comput. Prod., Inc. v. Foxconn Int'l, Inc.*, 355 F.3d 1353, 1360 (Fed. Cir. 2004).

DRL further contends that the disclosure-dedication rule does not impose a § 112 requirement for sufficiency of disclosure, *see Toro Co. v. White Consol. Indus., Inc.*, 383 F.3d 1326, 1334 (Fed. Cir. 2004), and that a skilled artisan reading the '209 patent would both look for a disclosure of pemetrexed in Akimoto, and also seek to use a well-known cation like tromethamine, which it maintains is generically disclosed in Akimoto in the form of "substituted ammonium" base salts.

We are unpersuaded by DRL's arguments. As the district court noted, Akimoto's formula, col. 1 l. 49–col. 2 l. 3, includes seven functional group variables and encompasses thousands of compounds, and while Akimoto discloses about fifty exemplary compounds, none of them is pemetrexed. Moreover, Akimoto does not even disclose tromethamine expressly but only generically among dozens of other salts. At most, Akimoto discloses ammonium salts generally, which is far from a description of tromethamine. In similar circumstances, we have held that "sufficient description of a genus" requires that a skilled artisan be able to "'visualize or recognize' the members of the genus." *See Ariad Pharm., Inc. v. Eli Lilly & Co.*, 598 F.3d 1336, 1350 (Fed. Cir. 2010) (quoting *Regents of the Univ. of Cal. v. Eli Lilly & Co.*, 119 F.3d 1559, 1568–69 (Fed. Cir. 1997)). Akimoto does not so describe

pemetrexed ditromethamine, and we see no reason why a skilled artisan would set out on DRL's winding path to cobble together pemetrexed ditromethamine. While the '209 patent teaches that pemetrexed disodium is the "most preferred" antifolate, that knowledge would not change the skilled artisan's understanding of what Akimoto discloses.

Because Akimoto contains only a "generic reference" to pemetrexed ditromethamine, *PSC Comput.*, 355 F.3d at 1360, we conclude that it was not dedicated to the public.

3. Merits

A component in an accused product or process may be equivalent to a claim element if the two are insubstantially different with respect to the "role played by [the] element in the context of the specific patent claim." *Warner-Jenkinson*, 520 U.S. at 39–40. Relevant differences can include the function each serves, the way in which each works, and the result each obtains, *id.* at 39, and, especially in biochemical cases, structural or pharmacological characteristics, *Mylan Inst. LLC v. Aurobindo Pharm. Ltd.*, 857 F.3d 858, 869 (Fed. Cir. 2017). "The determination of equivalency *vel non* is a question of fact," *Canton Bio Med., Inc. v. Integrated Liner Techs., Inc.*, 216 F.3d 1367, 1369 (Fed. Cir. 2000) (citing *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1218 (Fed. Cir. 1995)), which we review for clear error in an appeal from a bench trial, *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359 (Fed. Cir. 2007).

DRL argues that the district court erred in finding that its proposed pemetrexed ditromethamine product will be administered in an insubstantially different way from the claimed method. DRL maintains that the district court focused on the fact that each product treats the same diseases by delivering pemetrexed intravenously, when the relevant context is the manner of administration. In DRL's view, the chemical differences between sodium and tromethamine—*e.g.*, pH, buffering capacity, or solubility—DRL Br. 20–21, render the methods in which each is administered to a patient substantially different.

Lilly responds that the relevant context is treatment of a patient "in need of chemotherapeutic treatment." '209 patent claim 12. Lilly agrees with the district court that the chemical differences between sodium and tromethamine are clinically irrelevant because each undisputedly lacks therapeutic activity.

We see no clear error in the district court's findings. As the district court found, DRL's product will accomplish an identical aim, furnishing the same amount of pemetrexed to active sites in the body; in exactly the same way, by diluting a pemetrexed salt in an aqueous

solution for intravenous administration. Indeed, after dilution and immediately before administration, DRL's product is functionally identical to Lilly's in that it contains the same amount of diluted pemetrexed anion. DRL J.A. 8557. And DRL declines to identify the relevance of any of the chemical differences it identifies. *See UCB, Inc. v. Watson Labs. Inc.*, 927 F.3d 1272, 1284–86 (Fed. Cir. 2019) (chemical differences may not be relevant if the equivalent has known interchangeability in the context of the claimed composition). We find DRL's arguments unconvincing and therefore affirm the district court's findings.

In summary, these cases are eminently suitable for application of the doctrine of equivalents, and we conclude that neither prosecution history estoppel nor the disclosure-dedication rule bars Lilly from asserting infringement through equivalence.

CONCLUSION

We have fully considered each party's further arguments but find them unpersuasive. For the foregoing reasons, we reverse the district court's finding of literal infringement in the *Hospira Decision* but affirm its judgment of infringement under the doctrine of equivalents. The judgment of infringement under the doctrine of equivalents in the *DRL Decision* is likewise affirmed.

AFFIRMED-IN-PART AND REVERSED-IN-PART IN APPEAL NOS. 2018–2126, 2018–2127

AFFIRMED IN APPEAL NO. 2018–2128

COSTS

Each party shall bear its own costs.

ANZA TECHNOLOGY, INC., Plaintiff-Appellant v. MUSHKIN, INC., dba ENHANCED NETWORK SYSTEMS, INC., Defendant-Appellee

Appeal No. 2019–1045

Appeal from the United States District Court for the District of Colorado in No. 1:17-cv-03135-MEH, Magistrate Judge Michael E. Hegarty.

Decided: August 16, 2019

COLBY BRIAN SPRINGER, Polsinelli LLP, San Francisco, CA, argued for plaintiff-appellant. Also represented by MIYA YUSA; MICHAEL DULIN, Denver, CO; HANNAH THERESA YANG, Kilpatrick Townsend & Stockton LLP, San Francisco, CA.

D. SCOTT HEMINGWAY, Hemingway & Hansen, LLP, Dallas, TX, argued for defendant-appellee. Also represented by THOMAS S. RICE, Senter Goldfarb & Rice LLC, Denver, CO.

Before PROST, *Chief Judge,* NEWMAN and BRYSON, *Circuit Judges.*

BRYSON, *Circuit Judge.*

Plaintiff Anza Technology, Inc., ("Anza") appeals from a decision of the United States District Court for the District of Colorado granting a motion by defendant Mushkin, Inc., dba Enhanced Network Systems, Inc., ("Mushkin") to dismiss Anza's second amended complaint. The dismissal followed from the court's finding that Anza's claim of damages for patent infringement was barred by the six-year statute of limitations in the Patent Act, 35 U.S.C. § 286. That ruling was based in turn on the court's determination that the claims in Anza's second amended complaint did not relate back to the date of Anza's original complaint and were therefore time-barred. Because the district court's application of the relation back doctrine was overly restrictive, we reverse in part, vacate in part, and remand for further proceedings.

I

A

Anza filed this action on March 28, 2017, in the United States District Court for the Eastern District of California, alleging that Mushkin had infringed claims 1, 14, and 16 of Anza's U.S. Patent No. 7,124,927 ("the '927 patent"), in violation of 35 U.S.C. § 271(a) and (g). The '927 patent, entitled "Flip Chip Bonding Tool and Ball Placement Capillary," relates to "dissipative and insulative ceramic flip chip bonding tools and capillaries for ball placement for bonding electrical connections." '927 patent, col. 1, ll. 39–41.

The specification of the '927 patent discusses two techniques for bonding electronic components, such as semiconductor integrated circuit ("IC") chips, to substrates, circuit boards, or carriers. The two

techniques are referred to as "wire bonding" and "flip chip bonding." '927 patent, col. 1, ll. 60–65. In wire bonding, the chip is oriented face-up, so that there is no direct electrical connection between the leads of the chip and the bond pads on the substrate. A wire is then used to connect the chip to the substrate. *Id.* at col. 1, ll. 43–61. In flip chip bonding, the chip is oriented face-down, which allows for a direct electrical connection between the chip and the substrate. The direct electrical connection is facilitated by conductive solder balls that are deposited on the chip; the solder balls provide the conductive path from chip to substrate. *Id.* at col. 1, ll. 61–65; col. 2, ll. 9–10; Fig. 3.

Under either technique, the bonding process requires the use of bonding tools. The '927 patent explains that the problem with prior art bonding tools was that "an electrostatic discharge (ESD) from the bonding tool or transient currents from the machine [that uses the tool] can damage the very circuit the tool is bonding." *Id.* at col. 2, ll. 47–49. According to the specification, "[c]ertain prior art devices have a one-or-more volt emission when the tip makes bonding contact. This could present a problem, as a one-volt static discharge can . . . cause the integrated circuit to fail." *Id.* at col. 2, ll. 53–59.

To avoid damage to the electronic devices from such an electrostatic discharge, the '927 patent recites a bonding tool tip for flip chip bonding that "conducts electricity at a rate sufficient to prevent charge buildup but not at so high a rate as to overload the device being bonded." *Id.* at col. 2, line 67, through col. 3, line 2.

Claims 1, 14, and 16 of the '927 patent, all independent claims, recite a system, a component, and a method, respectively. Claim 1 provides as follows:

> 1. A flip chip bonding tool and ball placement capillary system for connecting leads on integrated circuit bonding pads, comprising a dissipative material having a resistance low enough to prevent a discharge of a charge to a device being bonded and high enough to stop current flow large enough to damage the device being bonded.

Claim 14 recites:

> 14. An ESD-preventive device comprising:
>
> a flip chip bonding tool and ball placement capillary, comprising a dissipative material and configured to come in contact with a device being bonded, wherein a current produced by static charge generated during bonding is allowed to flow; wherein the dissipative material has a resistance low enough to prevent a discharge of charge to the device being bonded and high enough to stop all current flow to the device being bonded.

Claim 16 recites "[a] method of utilizing a flip chip bonding tool . . . in a microelectronic assembly." The claimed method recites the use of a bonding machine capable of being equipped with a flip chip bonding tool, which has a tip comprising a dissipative material having the same properties as recited in claims 1 and 14.

B

On September 6, 2017, Anza filed its first amended complaint, which joined Avant Technology, Inc., as a co-defendant.[1] Thereafter, Mushkin filed a motion to dismiss or to sever the claims against Mushkin from those against Avant, and either to stay the case against Mushkin or to transfer the case to the District of Colorado. The California district court severed Anza's claims against Mushkin and transferred the case against Mushkin to the District of Colorado.

Following the transfer, Anza served infringement contentions against Mushkin pursuant to the District of Colorado's Local Patent Rules 4 and 5. The infringement contentions accused Mushkin of directly infringing claims 1 and 14, but did not refer to claim 16. Noting in its infringement contentions that discovery had not commenced and a formal scheduling order had not been entered, Anza stated that it reserved "the right to supplement these contentions as appropriate based upon further discovery and the schedule of this case, including but not limited to assertions related to new claims and/or patents as may be allowed through amendment of the operative pleading."

The parties then engaged in mediation. In the course of the mediation, Mushkin provided Anza with a declaration of George Stathakis, Mushkin's president, regarding the technology used by Mushkin. The Stathakis declaration stated, *inter alia*, that Mushkin "did not bond IC chips to boards or modules." Instead, according to the declaration, "[t]he memory products purchased by Mushkin, Inc. from suppliers were IC memory chips that were already . . . bonded on printed circuit boards or memory module boards." Additionally, the declaration stated that Mushkin's supplier "does not place or position solder ball connectors on the IC chip for use in bonding the IC chip to a printed circuit board or memory module board."

The district court held a hearing to address Mushkin's motion to dismiss. In light of information in the Stathakis declaration, Anza

[1] The first amended complaint alleged that Avant was "the sole aggregator of all Mushkin-based memory modules and board products . . . by virtue of Avant having acquired certain assets of Defendant Mushkin in accordance with an asset purchase agreement dated April 1, 2012." Because there is no material difference between the original complaint and the first amended complaint for purposes of the issues in this case, we focus on the differences between the original complaint and the second amended complaint.

"agreed that its present claims [were] no longer viable." Based on that concession, the district court granted Mushkin's motion. However, the court ruled that Anza would be permitted to file an amended complaint and that Mushkin would be allowed to file a motion to dismiss that complaint.

C

Anza filed its second amended complaint on June 8, 2018. In the second amended complaint, Anza removed the infringement allegations regarding the '927 patent and alleged infringement of two new patents: U.S. Patent Nos. 6,354,479 ("the '479 patent") and 6,651,864 ("the '864 patent"). The new complaint alleged that Mushkin had infringed those patents under 35 U.S.C. § 271(g). Anza also omitted ten of the sixteen products that had been accused in the original complaint and added two new products that had not previously been accused.

The '479 and '864 patents, entitled "Dissipative Ceramic Bonding Tip" and "Dissipative Ceramic Bonding Tool Tip," respectively, claim priority to the same U.S. provisional application as the '927 patent. Like the '927 patent, the '479 and '864 patents recite the use of "dissipative ceramic bonding tips for bonding electrical connections." '479 patent, col. 1, ll. 12–13;'864 patent, col. 1, ll. 20–21. The patents offer the same solution to the problem of electrostatic discharge damage during the bonding process—providing a bonding tool tip that conducts electricity "at a rate sufficient to prevent charge buildup, but not at so high a rate as to overload the device being bonded." '479 patent, col. 2, ll. 4–6;'864 patent, col. 2, ll. 11–13. The '479 and '864 patents differ from the '927 patent in that they are directed to bonding tool tips for wire bonding, rather than for flip chip bonding. In addition, in contrast to the system and component claims of the '927 patent, the asserted claims of the '479 and '864 patents (claims 39 and 28, respectively), are method claims. Claim 37 of the '479 patent, from which asserted claim 39 depends, recites as follows:

37. A method of using a bonding tip, comprising:

> bonding a device using a bonding tip made with a dissipative material that has a resistance low enough to prevent a discharge of charge to said device and high enough to avoid current flow large enough to damage said device.

Similarly, independent claim 28 of the '864 patent recites:

> 28. A method of using an electrically dissipative bonding tool tip, having a resistance in the range of 10^5 to 10^{12} ohms, comprising:
>
> providing the electrically dissipative bonding tool tip;

bonding a material to a device;

allowing an essentially smooth current to dissipate to the device, the current being low enough so as not to damage said device being bonded and high enough to avoid a build up of charge that could discharge to the device being bonded and damage the device being bonded.

D

Mushkin filed a motion to dismiss the second amended complaint. It argued, *inter alia*, that the new patent claims against Mushkin do not relate back to the date of Anza's original complaint. In support of that argument, Mushkin relied on Rule 15(c)(1)(B) of the Federal Rules of Civil Procedure, which provides: "An amendment to a pleading relates back to the date of the original pleading when . . . the amendment asserts a claim or defense that arose out of the conduct, transaction, or occurrence set out—or attempted to be set out—in the original pleading."

The district court granted Mushkin's motion, ruling that the new infringement claims did not relate back to the date of the original complaint. The court explained that new infringement claims relate back to the date of the original complaint when the claims involve the same parties, the same products, and similar technology—i.e., when the claims are "part and parcel" of the original complaint. The court ruled that newly asserted claims of infringement do not relate back if the new claims are not an integral part of the claims in the original complaint and if proof of the new claims will not entail the same evidence as proof of the original claims.

With respect to the patent claims asserted in the original complaint as compared with those asserted in the second amended complaint, the district court found that "[a]lthough the claims involve the same parties, they do not relate to identical products and technology." Comparing the '864 and '479 patents with the '927 patent, the district court found that the asserted claims of the '864 and '479 patents "protect a method of using a wire bonding tool, while the '927 claims involved a flip chip bonding and solder ball placement tool." The district court acknowledged that the patent claims have the "same purpose—bonding integrated circuit chips to printed circuit boards while minimizing electrostatic discharge." But because it found that "different processes and technologies are used to achieve this purpose," the district court held that the patent claims are "not part and parcel of one another." As for the accused products, the court noted

that the second amended complaint added two new accused products and omitted a number of accused products as compared with the original complaint.[2]

The district court added that "proving infringement of the initial and new claims would not involve substantially the same evidence." The district court explained:

> Proving the '927 patent claims would require evidence of the flip chip bonding method and how the flip chip bonding and ball placement tool was used in making the allegedly infringing products. Conversely, proving the newly asserted claims requires evidence of the wire bonding process and how a wire bonding tool tip was used to produce the allegedly infringing products.

In particular, the court noted, the new claims would entail different evidence because Anza's infringement contentions had dropped claim 16 of the '927 patent, which the district court considered to be the claim from the first amended complaint that was most similar to the newly asserted claims.

The district court then addressed the effect of its rulings on the statute of limitations for patent claims, 35 U.S.C. § 286, which bars recovery for any infringement "committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action." Because Anza acknowledged that Mushkin's allegedly infringing activity all took place more than six years before the filing date of the second amended complaint, the court held that the effect of ruling that the second amended complaint did not relate back to the filing date for the original complaint was that all the asserted claims in the second amended complaint were time-barred.

II

A

A preliminary question is whether Federal Circuit law, rather than regional circuit law, governs whether newly alleged claims in an amended complaint relate back to the date of the original complaint when the new claims are based on newly asserted patents.

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[2] The district court misspoke with regard to the number of accused products omitted from the second amended complaint. The court stated that the second amended complaint omitted eleven of the products that were accused in the original complaint, but in fact the number of omitted products was ten. *Compare* Second Amended Complaint at 13, *Anza Tech., Inc. v. Mushkin, Inc.*, No. 1:17-cv-03135-MEH (D. Colo. June 8, 2018), ECF No. 75, *with* Complaint at 6–7, *Anza Tech., Inc. v. Mushkin, Inc.*, No. 1:17-cv-03135-MEH (D. Colo. Mar. 28, 2017), ECF No. 1.

We have previously held that "[a] procedural issue that is not itself a substantive patent law issue is nonetheless governed by Federal Circuit law if the issue pertains to patent law, if it bears an essential relationship to matters committed to our exclusive control by statute, or if it clearly implicates the jurisprudential responsibilities of this court in a field within its exclusive jurisdiction." *O2 Micro Int'l Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1364 (Fed. Cir. 2006) (quoting *Midwest Indus., Inc. v. Karavan Trailers, Inc.*, 175 F.3d 1356, 1359 (Fed. Cir. 1999)(en banc in relevant part)).

One example of such a procedural issue is a motion to sever in a patent case. We have held that "motions to sever are governed by Federal Circuit law because joinder in patent cases is based on an analysis of the accused acts of infringement, and this issue involves substantive issues unique to patent law." *In re EMC Corp.*, 677 F.3d 1351, 1354 (Fed. Cir. 2012). As in the case of motions to sever, the determination of whether newly alleged infringement claims relate back to the original complaint also turns on "an analysis of the accused acts of infringement." *Id*. Therefore, we hold that this determination is also governed by Federal Circuit law.

B

The next question is what standard governs this court's review of a district court's application of the relation back doctrine.

Anza argues that this court should apply a *de novo* standard of review. Anza bases that argument on the fact that the district court dismissed the second amended complaint after holding the relation back doctrine inapplicable, and that dismissals of a complaint under Fed. R. Civ. P. 12(b)(6) are subject to *de novo* review.

The problem with Anza's argument is that the dismissal in this case was the necessary consequence of the court's determination that the relation back doctrine does not apply, since without the benefit of the relation back doctrine, it is clear that the statute of limitations would bar all of Anza's claims against Mushkin. What Anza is challenging is not the dismissal itself, but whether the district court properly applied the relation back doctrine under Rule 15(c). The standard of review that applies to a dismissal under Rule 12(b)(6) therefore has nothing to do with the critical issue in this case, which is whether the court properly determined not to apply the relation back doctrine to the second amended complaint. For that reason, Anza's argument sheds no light on what standard should be applied in reviewing that issue.

Mushkin argues that the district court's ruling on the relation back issue should be reviewed under the abuse of discretion standard. In

arguing for that standard, Mushkin relies on two decisions of this court, but the cases Mushkin cites do not support its argument. In the first case, *Fromson v. Citiplate, Inc.*, the court merely stated that it found "no reversible error" in the district court's conclusion that the amended complaint related back to the date of the original complaint. 886 F.2d 1300, 1304 (Fed. Cir. 1989). The court did not specify what standard of review it applied in reaching that conclusion. The second case, *Datascope Corp. v. SMEC, Inc.*, 962 F.2d 1043 (Fed. Cir. 1992), did not deal with the relation back doctrine at all. The court in that case merely held that the district court's refusal to permit amendment of the complaint was not an abuse of discretion. *Id.* at 1047. While *Datascope* applied the abuse of discretion standard to the question whether the district court erred in denying a motion to amend a complaint under Fed. R. Civ. P. 15(a), nothing in *Datascope* speaks to the standard of review to be applied to the separate question of whether an amended pleading relates back to the date of the original pleading under Fed. R. Civ. P. 15(c).

Mushkin's suggestion that we review the district court's relation back ruling under an abuse of discretion standard would be contrary to the law of most of the other circuits, which have adopted a *de novo* standard when reviewing decisions regarding whether an amended pleading relates back to the date of the original pleading. *See Glover v. FDIC*, 698 F.3d 139, 144 (3d Cir. 2012); *Robinson v. Clipse*, 602 F.3d 605, 607 (4th Cir. 2010); *Slayton v. Am. Express Co.*, 460 F.3d 215, 227–28 (2d Cir. 2006); *Young v. Lepone*, 305 F.3d 1, 14 (1st Cir. 2002); *Miller v. Am. Heavy Lift Shipping*, 231 F.3d 242, 246–47 (6th Cir. 2000); *Delgado-Brunet v. Clark*, 93 F.3d 339, 342 (7th Cir. 1996); *Slade v. U.S. Postal Serv.*, 875 F.2d 814, 815 (10th Cir. 1989); *Percy v. S.F. Gen. Hosp.*, 841 F.2d 975, 978 (9th Cir. 1988). *Contra Powers v. Graff*, 148 F.3d 1223, 1226 (11th Cir. 1998) (application of Rule 15(c) is reviewed for abuse of discretion, while findings of fact necessary for application of the rule are reviewed for clear error).

We adopt the majority rule. The rationale underlying that rule, when it has been expressed, is that the *de novo* standard of review applies because determining whether the amended claim "arose out of the conduct, transaction, or occurrence" set forth in the original complaint requires the reviewing court to apply the legal standard of Rule 15(c) "to a given set of facts," which is "a task we are no less suited to perform than the district court." *Miller*, 231 F.3d at 247; *accord Percy*, 841 F.2d at 978; *Lundy v. Adamar of N.J., Inc.*, 34 F.3d 1173, 1177 (3d Cir. 1994). In some instances, however, factual issues may need to be addressed as part of the district court's analysis of the relation back issue. With respect to any disputed facts that are ma-

terial to the relation back issue, we are not as well situated as the district court to make the appropriate findings. Therefore, in the event that such factual issues arise, we would review any findings by the district court on those issues for clear error, as we do in analogous circumstances. *See, e.g.*, *Presidio Components, Inc. v. Am. Tech. Ceramics Corp.*, 875 F.3d 1369, 1375 (Fed. Cir. 2017) (indefiniteness); *Par Pharm., Inc. v. TWI Pharm., Inc.*, 773 F.3d 1186, 1194 (Fed. Cir. 2014) (obviousness); *Alcon Research Ltd. v. Barr Labs., Inc.*, 745 F.3d 1180, 1188 (Fed. Cir. 2014) (enablement); *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372, 1377 (Fed. Cir. 2007) (presence of a case or controversy); *Rambus Inc. v. Infineon Techs. AG*, 318 F.3d 1081, 1087–88 (Fed. Cir. 2003) (attorney fee award); *In re Emert*, 124 F.3d 1458, 1460 (Fed. Cir. 1997) (double patenting).

C

The Supreme Court has interpreted the relation back doctrine liberally, to apply if an amended pleading "relate[s] to the same general conduct, transaction and occurrence" as the original pleading. *Tiller v. Atl. Coast Line R.R. Co.*, 323 U.S. 574, 580–81 (1945) (holding, in a railroad negligence case that even though the amended complaint alleged a different theory of negligence, the new charge related back to the original complaint because "[t]he cause of action now, as it was in the beginning, is the same—it is a suit to recover damages for the alleged wrongful death of the deceased."). That liberal interpretation of the relation back rule reflects the rationale of Rule 15(c), which is that "a party who has been notified of litigation concerning a particular occurrence has been give all the notice that statutes of limitations were intended to provide." *Baldwin Cty. Welcome Ctr. v. Brown*, 466 U.S. 147, 149 n.3 (1984).

Our predecessor court, the Court of Claims, embraced that liberal, notice-based interpretation of Rule 15(c). *See Snoqualmie Tribe of Indians v. United States*, 372 F.2d 951, 961 (Ct. Cl. 1967) ("A restrictive view would limit application of the rule to minor pleading mistakes. We think modern practice requires a more imaginative approach, and that [Rule 15(c)] should be read liberally to permit an amended pleading to relate back where there is sufficient notice."); *see also Vann v. United States*, 420 F.2d 968, 974 (Ct. Cl. 1970) ("The test for determining whether the new matter in an amended petition arose from the 'conduct, transaction, or occurrence' first pleaded is whether the general fact situation or the aggregate of the operative facts underlying the claim for relief in the first petition gave notice to the [accused party] of the new matter."); *United States v. N. Paiute Nation*, 393 F.2d 786, 790 (Ct. Cl. 1968) ("Sufficient notice to the

Government is the test . . . with our inquiry focusing on the notice given by the general fact situation set forth in the original pleading.") (citations and footnote omitted)).

Federal Circuit cases have applied a similar approach to Rule 15(c). *See Korody-Colyer Corp. v. Gen. Motors Corp.*, 828 F.2d 1572, 1575 (Fed. Cir. 1987) ("Under Rule 15(c) . . . an amendment may relate back when the earlier complaint gave adequate notice of the new claim."); *see also Barron Bancshares, Inc. v. United States*, 366 F.3d 1360, 1369–70 (Fed. Cir. 2004); *Intrepid v. Pollock*, 907 F.2d 1125, 1130 (Fed. Cir. 1990).

The notice-based interpretation of Rule 15(c) is consistent with the approach used under Rules 13(a) and 20(a) of the Federal Rules of Civil Procedure. Those rules, which share the "same transaction or occurrence" standard used in Rule 15(c), have been interpreted to require that counterclaims (in the case of Rule 13(a)) or the claims of the plaintiffs to be joined (in the case of Rule 20(a)) be logically related to the claims in the original complaint. *See In re EMC Corp.*, 677 F.3d at 1357–58.

The "logical relationship" standard contemplates a "liberal approach to the concept of same transaction or occurrence." 7 Charles Alan Wright et al., *Federal Practice & Procedure* § 1653, at 410–11 (3d ed. 2001). It asks whether the facts underlying the alleged claims "share an aggregate of operative facts." *In re EMC Corp.*, 677 F.3d at 1359. For purposes of the logical relationship test, "all logically related events entitling a person to institute a legal action against another generally are regarded as comprising a transaction or occurrence." 7 Charles Alan Wright et al., *Federal Practice & Procedure* § 1653, at 409.

In light of the similarity in the language used in Rule 15(c) and Rules 13(a) and 20(a), cases applying the logical relationship test in the patent context are particularly instructive in applying the relation back doctrine. Those cases suggest that pertinent considerations bearing on whether claims are logically related include the overlap of parties, products or processes, time periods, licensing and technology agreements, and product or process development and manufacture. *See In re EMC Corp.*, 677 F.3d at 1359–60; *Futurewei Techs., Inc. v. Acacia Research Corp.*, 737 F.3d 704, 710 (Fed. Cir. 2013) ("Here, the logical relationship is strong: the license agreement gives rise to Huawei's alterego claim, to SmartPhone's affirmative right to enforce the patents in the Texas case, and to Huawei's defense in that case . . . ."); *see also In re Rearden LLC*, 841 F.3d 1327, 1332 (Fed. Cir. 2016) (noting that the logical relationship test is one of three tests

used to determine whether the transaction-or-occurrence test is met under Rule 13(a), and finding the counterclaim compulsory because, *inter alia*, "the claims and counterclaims share a close, logical relation: the ownership and rightful use of the technology claimed and disclosed in the MOVA patents").

Several district courts have addressed the issue of whether newly alleged claims, based on separate patents, relate back to the date of the original complaint. Most of those courts have employed a similar analysis, asking whether the newly asserted patents are "part and parcel" of the original controversy. For example, in *Halo Electronics, Inc. v. Bel Fuse Inc.,* No. C-07–06222 RMW, 2008 WL 1991094, at *3 (N.D. Cal. May 5, 2008), the court found that the six Halo patents that were the subjects of the new claims were not "part or parcel" of the original complaint, which involved another patent, because "the Halo patents involve[d] different technologies and products." On the other hand, the court in *PerfectVision Manufacturing, Inc. v. PPC Broadband, Inc.*, 951 F. Supp. 2d 1083, 1093, 1093–94 (E.D. Ark. 2013), found that the amended complaint related back to the date of the original complaint, after considering whether the patents cited in the two complaints involved "the same field of art, the same fundamental science and technology . . . [,] the same allegedly infringing devices, and, in any damages analysis, the same pricing, sales, and related market data."

Accordingly, in determining whether newly alleged claims, based on separate patents, relate back to the date of the original complaint, we will consider the overlap of parties, the overlap in the accused products, the underlying science and technology, time periods, and any additional factors that might suggest a commonality or lack of commonality between the two sets of claims. At bottom, however, the question remains whether the general factual situation or the aggregate of operative facts underlying the original claim for relief gave notice to Mushkin of the nature of the allegations it was being called upon to answer.

D

On appeal, Anza challenges the district court's conclusion that the second amended complaint did not relate back to the date of the original complaint. Anza argues that the '864, '479, and '927 patents all seek to solve the same problem—avoiding damage to delicate devices as a result of ESD—and that the three patents all employ the same solution to address that problem—using dissipative ceramic tips on the bonding tools.

Anza also argues that there is a significant overlap of properties between the two sets of accused Mushkin products. According to Anza, each accused product in both the original complaint and the second amended complaint requires the use of certain techniques and methods to guard against damaging ESD events, which include compliance with standards that "involve[] the use of manufacturing tools made of dissipative materials having resistance ranges low enough to prevent a discharge of a charge to an ESD sensitive device but high enough to avoid current flows that may damage the device."

Mushkin disagrees. According to Mushkin, the allegations in the second amended complaint are significantly different from the initial "flip chip" infringement allegations, for several reasons.

Mushkin first argues that the fact that the second amended complaint withdrew all prior claims of infringement under the "flip chip" '927 patent and substituted claims from the two "wire bonding" patents indicates that the two complaints address entirely different bonding techniques. We disagree.

While the patents address different bonding techniques, they all share the same underlying technology. All three patents are focused on solving the same problem by the same solution, using a bonding tool tip made of a dissipative material having a resistance low enough to prevent the discharge of a charge to a device being bonded and high enough to avoid current flow to that device. '927 patent, col. 2, line 64, through col. 3, line 2; '479 patent, col. 2, ll. 3–6; '864 patent, col. 2, ll. 11–13. Moreover, while the specifications of the '479 and '864 patents discuss only wire bonding, the asserted claims of those patents are not limited to the wire bonding technique. Both claim 39 of the '479 patent and claim 28 of the '864 broadly recite methods of using bonding tips more generally.

The use of bonding tool tips made of a dissipative material is the basis for the charges of infringement alleged in each of the complaints. According to the complaints, industry-recognized standards-setting organizations have set standards for certain ESD-sensitive devices, including IC chips, that require the use of manufacturing tools made of dissipative materials. The complaints thus target products assembled or manufactured in ways that meet or exceed industry standards for reducing the risk of damage to ESD-sensitive devices. This technological overlap suggests that the aggregate of operative facts underlying infringement under the '927 patent in the original complaint gave notice of the substance of the claims of infringement under the '479 and '864 patents in the second amended complaint.

To be sure, the original complaint differs from the second amended complaint in that the original complaint was limited to products

manufactured using flip chip bonding. But the type of bonding technique is of secondary importance compared with the use of manufacturing tools made of dissipative material. Contrary to the district court's conclusion, proving infringement would only require evidence that certain bonding tools were used, not evidence as to how those tools were used. That determination would not be likely to result in a substantially different evidentiary showing to prove infringement of the claims asserted in the second amended complaint.

Mushkin next argues that, before the filing of the second amended complaint, Anza narrowed its infringement claims in a way that distinguished its claims from the claims set forth in its original complaint. In what the district court characterized as Anza's "informal infringement contentions," Anza did not assert the previously pleaded 35 U.S.C. § 271(g) statutory basis for infringement, and it did not assert its previously pleaded allegations regarding "method of use" claim 16 of the '927 patent. The infringement contentions thus asserted only system and component claims 1 and 14, and alleged a theory of direct infringement only under 35 U.S.C. § 271(a). Subsequently, however, in the second amended complaint, Anza asserted infringement of "method of use" claims from the two new patents and alleged infringement under 35 U.S.C. § 271(g).

In light of this sequence of events, Mushkin argues that the second amended complaint changed not only the type of claims asserted, but also the statutory basis for infringement and the party alleged to have conducted the accused bonding activity (a shift from Mushkin to an upstream manufacturer). Those changes between the theory of infringement set forth in the infringement contentions and allegations in the second amended complaint, according to Mushkin, show that there were substantial differences between the new and old claims.

Mushkin treats the infringement contentions as irreversibly narrowing the scope of the original complaint. In fact, however, Anza asserted that the infringement contentions were "preliminary, and based solely on public information." Moreover, in the infringement contentions, Anza reserved the right "to supplement the[] contentions as appropriate based upon further discovery and the schedule of th[e] case."

Apart from Anza's reservation of the right to supplement, the District of Colorado Local Patent Rules permit amendments to infringement contentions. According to Rule 16 of the Local Patent Rules, amendments to the infringement contentions, including the addition of accused products or processes, are permissible upon a showing of good cause, such as the discovery of previously undiscovered infor-

mation. D. Colo. Local Patent Rule 16(a)(3); *see O2 Micro*, 467 F.3d at 1366 ("If a local patent rule required the final identification of infringement and invalidity contentions to occur at the outset of the case, shortly after the pleadings were filed and well before the end of discovery, it might well conflict with the spirit, if not the letter, of the notice pleading and broad discovery regime created by the Federal Rules."). The discoveries made as a result of the Stathakis declaration, including that Mushkin does not bond IC chips to boards or modules, but instead purchases prebonded chips from suppliers, would likely constitute good cause to supplement Anza's infringement contentions by adding claim 16 and the section 271(g) theory of infringement.

Setting aside Mushkin's assertion that Anza's infringement contentions waived claim 16 and the section 271(g) theory of infringement, Mushkin's arguments largely fall away. The original complaint alleged infringement of "each of the limitations of independent claims 1, 14, and 16 of the '927 patent in violation of 35 U.S.C. § 271(a) and (g)." Complaint at 8, *Anza Tech., Inc. v. Mushkin, Inc.*, No. 1:17-cv-03135-MEH (D. Colo. Mar. 28, 2017), ECF No. 75. Similarly, the second amended complaint asserted infringement of "method of use" claims of the '479 and '864 patents under 35 U.S.C. § 271(g). Second Amended Complaint at 17, 20, *Anza Tech., Inc. v. Mushkin, Inc.*, No. 1:17-cv-03135-MEH (D. Colo. June 8, 2018), ECF No. 75. Both complaints therefore alleged infringement of "method of use" claims under 35 U.S.C. § 271(g), such that the allegations of infringement in both the old and new claims would entail activities conducted by upstream manufacturers. Accordingly, there is a substantial overlap in the underlying facts alleged in each of the complaints.

Mushkin's next argument is that the time frame when infringement liability was allegedly incurred is significantly different in the second amended complaint compared to the original complaint. According to Mushkin, the second amended complaint changed the relevant time period from infringement that occurred within the six-year period preceding March 2017 to infringement that occurred between March 2011 and April 1, 2012. *See* Appellee Br. 38. But Mushkin fails to explain how the second time period, which is wholly encompassed within the first, can be regarded as distinctly different from the first. There is no lack of notice and no substantial prejudice to Mushkin from having to defend against independent claims over a *shorter* period than the period set forth in the original complaint.

At several points, Mushkin argues that Anza's admission that the infringement allegations in the original complaint were non-viable dooms its relation back argument. Mushkin reasons that if the in-

fringement claims in the second amended complaint are similar enough to the infringement claims in the original complaint to relate back to the date of the original complaint, the infringement claims in the second amended complaint must also be non-viable. Alternatively, Mushkin argues that if the current claims are viable because they are not the same as the original ones, the current claims should not relate back to the date of the original complaint.

That argument falls with its premise. Amended claims do not have to be the same as the original claims to relate back. Rather, the claims must arise out of the same conduct, transaction, or occurrence. In any event, the record contains no explanation for the non-viability of the original claims, so there is no basis for concluding that Anza's concession that the original claims were non-viable means that the claims in the second amended complaint must be so different from the original claims that they cannot relate back to the date of the original complaint.

Mushkin further contends that applying the relation back doctrine in this case would allow litigants to evade the statute of limitations by bootstrapping old claims onto new ones, thus rendering the statute of limitations a nullity. To the contrary, while the relation back doctrine alters the starting point for the statute of limitations, that starting point can never be earlier than the filing date of the original complaint. And in order for the relation back doctrine to apply at all, the allegations of the amended complaint must be tethered to the conduct, transactions, or occurrences underlying the original claims.

Finally, Mushkin argues that "[w]ith the filing of the Second Amended Complaint, two-thirds of the accused products changed, including the addition of two new accused products." That characterization of the change in the set of accused products is misleading. In fact, the second amended complaint omits ten of the original sixteen products from the list of accused products. The omission of those products has no prejudicial effect on Mushkin and does not deprive Mushkin of notice of any new allegations. The other six products—Redline, Blackline, Radioactive, Silverline, Proline, and Essentials—have been accused in all three complaints. With regard to those six products, the second amended complaint and the original complaint would likely present closely related issues.

The same, however, is not true for the two remaining products, the Ridgeback and Apple products, which were added for the first time in the second amendment complaint. Courts that have addressed the issue of whether newly alleged claims, based on separate patents, relate back to the date of the original complaint, have regarded the presence of newly accused products as a substantial factor weighing

against the application of the relation back doctrine. *See PerfectVision*, 951 F. Supp. 2d at 1093–94; *Halo Elecs.*, 2008 WL 1991094, at *3; *see also Mann Design Ltd. v. Bounce, Inc.*, 138 F. Supp. 2d 1174, 1179 (D. Minn. 2001) (finding no relation back, in part because "[t]here are no allegations in the Complaint or the Amended Complaint indicating that the products accused of infringing the '061 patent are the same as those which allegedly infringe either the '559 and '053 patent."). The rationale for that rule is that it is improbable that allegations regarding different products, involving different patents, would have a common core of operative facts. It is therefore an open question whether the allegations regarding the two newly accused products, which are alleged to have infringed the latter two patents, are too far afield from the original complaint to put Mushkin on notice of the allegations against which it would be required to defend.

Resolution of that issue requires an analysis of facts that are not before us and as to which the district court is uniquely situated to rule. A remand for further proceedings is therefore necessary so that the district court can determine whether the infringement claims as to those two products are sufficiently similar to the infringement claims in the original complaint to justify application of the relation back doctrine to those products.

III

We hold that the claims in the second amended complaint that relate to the six originally accused products—the Redline, Blackline, Radioactive, Silverline, Proline, and Essentials products—relate back to the date of the original complaint under Rule 15(c). For those products, section 286 does not wholly bar an award of damages. The grant of the motion to dismiss as to those products must therefore be reversed. For the products that were added for the first time in the second amended complaint—the Ridgeback and Apple products—we vacate the order of dismissal and remand for the district court to determine, based on a factual analysis in light of the legal standard set forth above, whether the allegations regarding those products should relate back to the filing date of the original complaint.

REVERSED IN PART, VACATED IN PART, AND REMANDED