United States Court of Appeals for the Federal Circuit

OTSUKA AMERICA PHARMACEUTICAL, INC., AVANIR PHARMACEUTICALS, LLC, FKA AVANIR PHARMACEUTICALS INC.,
Plaintiffs-Appellees

v.

HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-III, CAMBER PHARMACEUTICALS INC.,
Defendants-Appellants

2025-2016

Appeal from the United States District Court for the District of Delaware in No. 1:25-cv-00647-GBW, Judge Gregory Brian Williams.

Decided: July 1, 2026

ERIC C. STOPS, Quinn Emanuel Urquhart & Sullivan, LLP, New York, NY, argued for plaintiffs-appellees. Also represented by JAMES BAKER, FRANCIS DOMINIC CERRITO, JOHN GALANEK, ELLYDE R. THOMPSON; ALEXANDRA KIM, Boston, MA.

EHAB M. SAMUEL, Orbit IP, LLP, Newport Beach, CA, argued for defendants-appellants. Also represented by DAVID A. RANDALL, Los Angeles, CA.

Before DYK, BRYSON, and STOLL, *Circuit Judges*.

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

Opinion dissenting-in-part and concurring-in-part filed by *Circuit Judge* DYK.

BRYSON, *Circuit Judge*.

Hetero Labs Limited ("Hetero") appeals from an order granting a preliminary injunction in this patent case. The district court's order enjoined Hetero from introducing a generic drug to compete with Nuedexta, a drug used for treating neurological disorders. In granting the preliminary injunction, the court concluded that Otsuka America Pharmaceutical, Inc., and its subsidiary, Avanir Pharmaceuticals, LLC (collectively, "Otsuka"), would be likely to succeed in proving that Hetero's product would infringe U.S. Patent No. 7,659,282 ("the '282 patent"), owned by Avanir, and that the relevant equitable factors favored granting the injunction.

The issues on appeal are (1) whether the district court properly interpreted the terms "dextromethorphan" and "quinidine" in the weight-to-weight ratio limitation in claim 1 of the '282 patent, and (2) whether the district court permissibly waived the requirement imposed by Federal Rule of Civil Procedure 65(c) that Otsuka post a bond pending appeal. We affirm the district court's construction of the disputed claim terms, but we vacate the district court's order waiving the requirement of a bond pending appeal.

I

The '282 patent covers a method for treating pseudobulbar affect or emotional lability, which is the inability to control emotions exhibited by patients with neurodegenerative diseases or after a stroke or other brain injury. '282 patent, col. 1, ll. 39–51; col. 2, ll. 7–21. The patented

method involves administering the drug dextromethorphan in combination with a second drug, quinidine. Dextromethorphan provides the therapeutic effect, while quinidine protects the dextromethorphan from rapid metabolism by the liver. *Id.* at col. 2, ll. 19–21; col. 14, ll. 6–28. The '282 patent is scheduled to expire on August 13, 2026. J.A. 263.

Independent claim 1 of the '282 patent reads as follows:

> 1. A method for treating pseudobulbar affect or emotional lability, the method comprising administering to a patient in need thereof dextromethorphan in combination with quinidine, wherein the amount of dextromethorphan administered comprises from about 20 mg/day to about 80 mg/day and wherein the amount of quinidine administered comprises from about 10 mg/day to less than about 30 mg/day with the proviso that the weight to weight ratio of dextromethorphan to quinidine is 1:0.5 or less.

'282 patent, col. 78, ll. 2–10.

Nuedexta, a branded pharmaceutical drug owned by Otsuka, combines dextromethorphan and quinidine in their salt forms. J.A. 17 at n.1; J.A. 21 at n.3. Nuedexta capsules each contain 20 milligrams ("mg") of dextromethorphan hydrobromide and 10 mg of quinidine sulfate. J.A. 861; *see* J.A. 17, 20. In August 2024, the U.S. Food and Drug Administration ("FDA") approved Hetero's Abbreviated New Drug Application ("ANDA") for a generic product with the same indications as Nuedexta, including the same amounts of dextromethorphan hydrobromide and quinidine sulfate. J.A. 17, 336.

When Hetero signaled its intention to launch its generic product on or after July 10, 2025, Otsuka filed a lawsuit in the United States District Court for the District of Delaware seeking a temporary restraining order and a preliminary injunction to prevent Hetero from entering the

market. J.A. 2, 18. After first issuing a temporary restraining order, the district court granted Otsuka's motion for a preliminary injunction on July 23, 2025. J.A. 14, 33–34. The district court did not require Otsuka to post a bond pending appeal, because it found that "the equities weigh[ed] strongly in favor of waiving the Rule 65(c) bond." J.A. 32. Hetero appeals the district court's grant of the preliminary injunction and the court's order waiving the bond requirement.

II

We review the grant of a preliminary injunction for an abuse of discretion, which "may be established by showing that the court made a clear error of judgment in weighing relevant factors or exercised its discretion based upon an error of law or clearly erroneous factual findings." *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1049 (Fed. Cir. 2010) (quoting *Amazon.com, Inc. v. Barnesandnoble.com, Inc.*, 239 F.3d 1343, 1350 (Fed. Cir. 2001)). Claim construction is a question of law that we review de novo, while reviewing any underlying factual determinations for clear error. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 332–33 (2015).

Because the bond requirement in Rule 65(c) is not a matter specific to patent law, we apply regional circuit law to that issue, which in this case is Third Circuit law. In the Third Circuit, the requirement to impose a bond is "strictly interpreted," and waiver is appropriate only under certain limited exceptions. *See Elliott v. Kiesewetter*, 98 F.3d 47, 59–60 (3d Cir. 1996); *Zambelli Fireworks Mfg. Co. v. Wood*, 592 F.3d 412, 425–26 (3d Cir. 2010). A court's decision as to the amount of the bond is reviewed for an abuse of discretion. *Boynes v. Limetree Bay Ventures LLC*, 110 F.4th 604, 611 (3d Cir. 2024) (citation omitted).

III

The primary issue in this case involves the construction of the terms "dextromethorphan" and "quinidine" as used in the weight-to-weight ratio recited in claim 1 of the '282 patent. According to the claim, "the weight to weight ratio of dextromethorphan to quinidine is 1:0.5 or less." It is undisputed that the '282 patent provides for the administration of dextromethorphan and quinidine in the form of their pharmaceutically acceptable salts. The claim construction dispute concerns the method for calculating the ratio of dextromethorphan to quinidine when the dextromethorphan and quinidine are administered in their salt forms. While at first blush it is appealing to construe the terms "dextromethorphan" and "quinidine" to refer only to the free base forms of those compounds, a close analysis of the claims and specification of the '282 patent leads us to construe those terms as referring to the compounds whether in free base or salt form.

Hetero argues that the correct construction of the disputed terms requires the weight-to-weight ratio of the two compounds to be calculated based on the weight of the active moiety components of the compounds that are administered to the patient. According to Hetero, if those compounds are administered in salt form, the weight of the active moiety component of each compound must be used as the basis for determining the weight-to-weight ratio of the two compounds.

Applying the conversion ratio disclosed in the patent, 20 mg of dextromethorphan hydrobromide contains 15.4 mg of the dextromethorphan component of the compound, and 10 mg of quinidine sulfate contains 8.7 mg of the quinidine component of the compound. *See* '282 patent, col. 17, line 63, through col. 18, line 14. Using that method of determining the weight of the dextromethorphan and quinidine components, the weight-to-weight ratio of Hetero's generic product would be 1:0.56, which falls outside the

ratio of "1:0.5 or less" recited in claim 1 of the '282 patent. Based on that calculation, Hetero contends that the district court erred in finding that Otsuka was likely to succeed on the merits of its infringement claims, and that the court should not have granted the preliminary injunction. Br. 47–48.

According to Otsuka, such a conversion is not required because the weight-to-weight ratio should be calculated based on the amounts of the dextromethorphan and quinidine compounds administered to the patient, regardless of whether those compounds are in free base or salt form. Br. 43. Following Otsuka's construction, a formulation consisting of 20 mg of dextromethorphan hydrobromide and 10 mg of quinidine sulfate results in a weight-to-weight ratio of 1:0.5. Likewise, a formulation consisting of 20 mg of dextromethorphan and 10 mg of quinidine in their free base forms would result in the same ratio. Under Otsuka's construction, both Nuedexta and Hetero's generic product fall within the scope of claim 1, while under Hetero's construction, neither product would be covered by claim 1.

Based on the references to the salt forms of dextromethorphan and quinidine in the dependent claims and the specification's discussion of the salt forms of the compounds, the district court was unpersuaded by Hetero's argument that "the compounds listed in the '282 patent . . . should be construed to mean those compounds in their 'free base' forms." J.A. 21. We agree with the district court that Otsuka's proposed construction is more consistent with the manner in which the terms "dextromethorphan" and "quinidine" are used in the patent, and that Otsuka's proposed construction is preferable to Hetero's.

A

We begin with the intrinsic evidence and look first to the claims. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–17 (Fed. Cir. 2005) (en banc). Claim differentiation

and consistent usage of the term in claim 1 point toward Otsuka's construction.

To begin with, the claims as a whole indicate that the terms "dextromethorphan" and "quinidine" refer not only to the free base forms of dextromethorphan and quinidine, but to the salt forms as well. Claim 7, which depends from claim 1, requires that the dextromethorphan or quinidine "is in a form of a pharmaceutically acceptable salt." '282 patent, col. 78, ll. 26–28. Dependent claim 8 similarly refers to "at least one of the quinidine and the dextromethorphan . . . in a form of a pharmaceutically acceptable salt." *Id.* at col. 78, ll. 29–31. Because the dependent claims include administration of those compounds in salt form, the references to "dextromethorphan" and "quinidine" in the independent claim from which those claims depend must also be understood to include the salt forms of the two compounds. Underscoring that point, the fact that claim 7 refers to dextromethorphan and quinidine "in the form of a pharmaceutically acceptable salt" further indicates that the salts of those compounds fall within the definition of dextromethorphan and quinidine as those terms are used in the patent.[1]

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[1] Hetero argues (Br. 38) that Otsuka and the district court have adopted the "false premise" that Hetero's claim construction position "excludes salts and limits claim 1 to the 'free base' form." Instead, Hetero contends that its argument is simply that the weight-to-weight ratio limitation compares the weights of the active moiety components of dextromethorphan and quinidine, not their salt weights. But there is no textual support for that argument. Claim 1 refers throughout to "dextromethorphan" and "quinidine," so under Hetero's theory, those terms either must have a different meaning in the ratio limitation of claim 1 than elsewhere in the claims—a position Hetero does not advance, and that would not be plausible in any event, *see*

B

The specification provides additional support for Otsuka's construction. Several references to "dextromethorphan" and "quinidine" in the specification point away from Hetero's construction requiring the weight-to-weight ratio in claim 1 to be calculated using only the weight of the free base forms of those compounds, even when the compounds are administered in salt form.

Not only does the specification include express language indicating that the references to dextromethorphan and quinidine include the salt forms of those compounds, but it specifically defines the active ingredients as including not only the free base forms of dextromethorphan and quinidine, but also their salt forms. *See* '282 patent, col. 3, ll. 21–23; col. 4, ll. 23–25; col. 5, ll. 22–25; col. 6, ll. 19–21 (stating, with respect to all 16 embodiments, that "the quinidine includes quinidine sulfate and the dextromethorphan includes dextromethorphan hydrobromide"). The specification notes that the invention includes "dextromethorphan in combination with quinidine, or pharmaceutically acceptable salts of dextromethorphan and/or quinidine, as the active ingredient." *Id.* at col. 17, ll. 32–35.[2]

Phillips, 415 F.3d at 1314—or the terms "dextromethorphan" and "quinidine" must refer to the free base form of those compounds throughout the claims.

[2] The dissent points out that the specification provides chemical structures for "dextromethorphan" and "quinidine," which depict the free base forms of those compounds. However, the specification's later use of those terms to include the salt forms indicates that the depicted structures were not intended to suggest that the terms "dextromethorphan" and "quinidine" in the patent refer exclusively

In discussing a series of clinical studies conducted to test the performance of the claimed formulations, the specification uses the terms "dextromethorphan" and "quinidine" to refer to both the free base and the salt forms of those compounds, and frequently as a shorthand for the respective salt forms of the compounds.

In Clinical Study #3, for example, participants were given capsules with varying dosages of dextromethorphan hydrobromide and quinidine sulfate. '282 patent, col. 25, ll. 31–65. In describing the results of that study, the quantity of the salts that the participants received is referred to as a "dose of dextromethorphan" and "quinidine doses," even though the amounts of those doses referred to the amounts of the salts given to the participants in Clinical Study #3, not the amount of the active moiety components of those salts. *E.g.*, *id.* at col. 28, line 7; col. 33, ll. 1–3. That is, the dose of "dextromethorphan" and "quinidine" described in the study is the amount of those compounds that was administered in salt form in the capsules.

In Clinical Study #3, the specification refers to the administration of dextromethorphan and quinidine in doses of 30 mg, 45 mg, and 60 mg. Although the specification notes that those doses were administered in the form of dextromethorphan hydrobromide and quinidine sulfate, the specification repeatedly describes those doses as "dextromethorphan" and "quinidine." *See, e.g., id.* at col. 25, ll. 12–18, 31–65; col. 26, ll. 39–40 (referring to "60 mg and 45 mg dextromethorphan doses"); col. 29, ll. 17–19 (referring to "a 60 mg dose of dextromethorphan"); col. 33, ll. 1–3 (same); col. 34, ll. 12–14; col. 35, ll. 14–15 (referring to "the effect of quinidine doses on a 45 mg dose of

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to the free base forms of those compounds. *See* '282 patent, col. 9, ll. 22–34; col. 14, ll. 8–23.

dextromethorphan"); col. 36, ll. 14–15 (referring to "a 60 mg dose of dextromethorphan"); col. 38, ll. 17–18 (same).

At the conclusion of the discussion of Clinical Study #3, the specification summarizes the results of that study by stating that "the lowest effective dose of quinidine that inhibits the metabolism of 45 and 60 mg dextromethorphan is 30 mg. Thus, a 30 mg quinidine dose is recommended for dextromethorphan." *Id.* at col. 40, ll. 52–67. That 30 mg quinidine dose clearly refers to the 30 mg of quinidine sulfate that was administered to some subjects of Clinical Study #3 who were given 45 and 60 mg of dextromethorphan (in the form of dextromethorphan hydrobromide). *See id.* at col. 25, ll. 36–39, 49–52. In light of the statement in the specification that 30 mg of quinidine sulfate provides an "effective dose" of 30 mg of quinidine, it is reasonable to read the limitation in claim 1 requiring a range of "about 10 mg/day to less than about 30 mg/day" of quinidine as referring to the amount of the quinidine compound as administered, whether in its salt form or in its free base form.

Beyond that, the specification uses the abbreviation DM to refer to dextromethorphan, *see* '282 patent, col. 8, ll. 12–13, and the abbreviation Q to refer to quinidine, *id.* at col. 8, ll. 27, 30. The specification then repeatedly uses those terms to refer to the salt forms of both compounds. In Clinical Study #5, the specification reports that participants were given "capsules containing dextromethorphan hydrobromide and quinidine sulfate (DM/Q)." *Id.* at col. 54, ll. 12–13. Participants "received capsules containing 30 mg DM/30 mg Q or 15 mg DM/30 mg Q in increasing dosages." *Id.* at col. 55, ll. 18–19. Table 38, which contains a list of the contents of the capsules, indicates that participants were given capsules containing dextromethorphan hydrobromide monohydrate and quinidine sulfate dihydrate, which are labeled in the table as "DM" and "Q." *Id.* at col. 55, ll. 25–42.

Table 38 includes notes indicating that 31.50 mg of the monohydrate form of dextromethorphan hydrobromide is equivalent to 30.0 mg of dextromethorphan hydrobromide. '282 patent, col. 55, line 39. Likewise, the table reports that 31.40 mg of the dihydrate form of quinidine sulfate is equivalent to 30.0 mg of quinidine sulfate. *Id.* at col. 55, line 41. No such note is listed to convert dextromethorphan's salt form to its free base form (dextromethorphan hydrobromide to dextromethorphan). Nor is there a note explaining any need to convert quinidine sulfate to quinidine. More significantly, the reference to "30 mg DM/30 mg Q or 15 mg DM/30 mg Q" matches the amount of dextromethorphan hydrobromide and quinidine sulfate in the capsules, thus making clear that the patentees were using the quantity of the salt forms to refer to the amounts of dextromethorphan and quinidine in the dosages.[3] *See id.* at col. 55, ll. 18–19.

C

The prosecution history also supports Otsuka's proposed construction, as it indicates that the examiner understood that the references in the claims to dextromethorphan and quinidine included the salt forms of those two compounds. When analyzing the original claims of the application, the examiner referred to claims 1 through 10 as comprising "the administration of from about 20 mg/day to about 200 mg/day of dextromethorphan or dextromethorphan hydrobromide in combination with about 10 mg/day to less than about 50 mg/day of quinidine or quinidine sulfate." Patent Application No. 11/035,213 at

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[3] The results of Clinical Study #4 follow a similar pattern referring to the dosages as "30DM/30Q, or 30 mg DM, or 30 mg Q" but listing the dosages as containing 31.50 mg of "DM," or dextromethorphan hydrobromide monohydrate, and 31.40 mg of "Q," or quinidine sulfate dihydrate. '282 patent, col. 42, ll. 1–19.

6 (Oct. 3, 2008) (Non-Final Rejection). The examiner subsequently used the same characterization of identical language in a co-pending application. J.A. 972–73 (citing Patent Application No. 12/181,962 at 88–89 (July 29, 2008) (Claims)) (Final Rejection). Those comments make it clear that the examiner shared Otsuka's understanding of the terms "dextromethorphan" and "quinidine" in the application that became the '282 patent to include the salt forms of those compounds.

We disagree with the dissent's characterization of the examiner's statement in allowing the claims as indicating that as of that time the applicants and the examiner understood the terms "dextromethorphan" and "quinidine" to refer to the free base forms of those two compounds. Immediately after discussing the weight-to-weight ratio of the compounds, the examiner referred to declarations submitted by Otsuka, including a declaration by inventor Dr. Laura E. Pope. J.A. 1034. The Pope declaration features an exhibit in which dextromethorphan and quinidine are abbreviated as "DM" and "Q," J.A. 1018–19, and doses of DM and Q are in the salt forms of dextromethorphan hydrobromide monohydrate and quinidine sulfate dihydrate—not the free base forms. J.A. 1020.

D

Extrinsic evidence also confirms Otsuka's construction. As noted, Nuedexta contains 20 mg of dextromethorphan hydrobromide and 10 mg of quinidine sulfate. J.A. 861. With Hetero's conversion, the salts in Nuedexta contain 15.41 mg of dextromethorphan and 8.69 mg of quinidine. That means that Otsuka's Nuedexta formulation under Hetero's construction would fall outside the weight-to-weight ratio of claim 1. It is highly improbable that Avanir would have drafted or amended the '282 patent claims in a manner that would exclude the very product that the patent was intended to protect. *See Osram GmbH v. Int'l*

Trade Comm'n, 505 F.3d 1351, 1358 (Fed. Cir. 2007).[4] An inadvertent exclusion of Nuedexta in a later amendment, as suggested by the dissent, seems highly unlikely.

E

Hetero makes several arguments in support of its proposed claim construction. First, Hetero argues that because the specification includes information as to the amount of dextromethorphan and quinidine in 30 mg of dextromethorphan hydrobromide and quinidine sulfate, the terms "dextromethorphan" and "quinidine" in claim 1 must refer to the weight of the dextromethorphan and quinidine components in each of those compounds, not the weight of the salt forms. The specification notes that 30 mg of dextromethorphan hydrobromide provides an effective dose of approximately 22 mg of dextromethorphan, and 30 mg of quinidine sulfate provides an effective dose of approximately 25 mg of quinidine. '282 patent, col. 17, line 60, through col. 18, line 2. That passage of the specification, however, does not bear on the proper claim construction, because the claims do not refer to "an effective dose," or an "effective weight" under the dissent's characterization, of dextromethorphan or quinidine. *See id.* at col. 78,

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[4] Hetero seeks to distinguish *Osram* on two grounds: (1) that *Osram* concerned excluding disclosed embodiments, while in this case "none of the embodiments discloses the claimed ranges or the 1:0.5 ratio"; and (2) that unlike in *Osram*, Nuedexta was covered by a different patent, which has expired. Reply Br. 12. To the contrary, the embodiments in this patent encompass the ranges claimed, *see, e.g.,* '282 patent, col. 2, ll. 22–29, and expressly include the 1:0.5 ratio, *see id.* at col. 15, ll. 22–34. And the entry for Nuedexta in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (known as "the Orange Book") notes that Nuedexta is covered by the patent in suit in this case.

ll. 1–41.[5] The dissent contends that comparing the salt forms distorts the compounds' relative weights, but a skilled artisan could just as easily use the conversion to find the amount of salt required for a desired amount of the active moiety. The drafter's choice of weight comparison is one way of defining the claim scope and is not contrary to the purpose of the invention.

Hetero contends that to justify construing "dextromethorphan" and "quinidine" in claim 1 to include the salts of those compounds, the claim would need to include the words "or a salt thereof," or the equivalent. Following that line of reasoning would suggest that the claim language should include "an effective dosage of" to conform with Hetero's construction. Claim 1 specifies neither. While the inclusion of such language would have removed all doubt, we find the indications in the patent to be sufficient to support the claim construction proposed by Otsuka and adopted by the district court.

Next, Hetero points to the original claims, which included a dependent claim, claim 9, with a range for quinidine sulfate of about 30 mg/day to 60 mg/day, exceeding the independent claim's upper limit of 50 mg/day of quinidine. J.A. 955. Hetero asserts that the range in claim 1, the independent claim, must refer to the free base forms of quinidine and dextromethorphan because 60 mg of quinidine sulfate is approximately equivalent to 50 mg of free base

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[5] Significantly, claim 1 of the provisional application referred to a "therapeutically effective quantity of dextromethorphan in combination with a therapeutically effective quantity of quinidine," but that language was omitted from the non-provisional application, which supports an inference that the applicants did not intend the terms "dextromethorphan" and "quinidine" to be limited to the therapeutically effective portions of those compounds, i.e., the active moiety components.

quinidine. In the next amendment, however, the applicant reduced the range of the quinidine sulfate in claim 9 to a range of 10 mg/day to 30 mg/day. Patent Application No. 11/035,213 Amendment at 2–3 (Oct. 23, 2008) (Amendments to the Claims). If the applicants intended the reference to quinidine in claim 1 to be limited to the free base form, the lower limit of the amount of quinidine sulfate in dependent claim 9 would be outside the range set in independent claim 1 because the amount of free base quinidine in 10 mg of quinidine sulfate is less than 10 mg. That outcome would be contrary to the basic principle that a dependent claim may not be broader than the claim from which it depends. Moreover, as noted, the examiner clearly did not draw the inference from the language of original claim 9 on which Hetero relies, as she characterized the reference to "quinidine" in claim 1 of the application as referring to "quinidine or quinidine sulfate." Patent Application No. 11/035,213 at 6 (Oct. 3, 2008) (Non-Final Rejection). For those reasons, the portion of the prosecution history relating to original claim 9, which was ultimately canceled in any event, does not provide the support for Hetero's proposed claim construction that Hetero asserts.[6]

Hetero relies (Br. 34–37) on the report of its expert, Dr. Graham Buckton, who offered the opinion that a person of skill in the art would understand the weight-to-weight ratio in claim 1 of the '282 patent to refer to the weights of the active moiety in the drug administered to patients, even if the drug was administered in salt form. *See* J.A. 635–42. Dr. Buckton stated that in his view the terms "dextromethorphan" and "quinidine" would be understood to refer to "the active drug compounds." The problem with

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[6] Original claim 9 was canceled in the subsequent amendment of July 7, 2009, which also added the weight-to-weight ratio limitation to claim 1. *See* J.A. 983–84.

his construction is that it requires that the terms "dextromethorphan" and "quinidine" be understood to refer to the active drug compounds throughout the patent, a conclusion that is inconsistent with much of the specification and pertinent portions of the prosecution history, as discussed above. Dr. Buckton's report thus constitutes extrinsic evidence that is at odds with the intrinsic evidence in this case; as such, we give greater weight to the intrinsic evidence. *See Phillips*, 415 F.3d at 1317–18.

Hetero also argues that to adopt Otsuka's construction would render the asserted claims indefinite because of the numerous possible salt and free base compound combinations that would satisfy the claims under that construction. In a specific pharmaceutical product, however, the dextromethorphan and quinidine, whether in free base or salt form, will be administered in measurable amounts. Under Otsuka's construction, the calculation of the weight-to-weight ratio would be straightforward and not indeterminate. For a product containing salts of dextromethorphan and quinidine, only the particular salts used in the product, such as dextromethorphan hydrobromide and quinidine sulfate, would be used to calculate the weight-to-weight ratio. It is possible under Otsuka's construction that a party could find a combination of salt-to-salt or even salt-to-free-base that falls outside the scope of the weight-to-weight ratio limitation while remaining within the other claim limitations. That possibility, however, does not lead to indefiniteness, because there is still only one way to calculate the weight-to-weight ratio regardless of the particular combination chosen. A party could choose from a range of pharmaceutically acceptable salts, but only the selected salt or salts could be used to calculate the ratio for a particular formulation. In the end, as Otsuka points out (Br. 46), the claim language is not indefinite because it simply

directs that "you measure the weight of the form that is 'administered.'"[7]

As evidence that a salt-to-free-base conversion is required, Hetero points to the label for "Nuedexta 15 mg/9 mg hard capsules," a product Otsuka sells in Europe. J.A. 1374. The composition information for that product states that "[e]ach capsule contains dextromethorphan hydrobromide monohydrate, equivalent to 15.41 mg dextromethorphan and quinidine sulfate dihydrate, equivalent to 8.69 mg quinidine." J.A. 1374. The use of the terms "dextromethorphan" and "quinidine" in the European label as a shorthand for the active moiety in the administered drugs does not speak to the proper construction of the terms "dextromethorphan" and "quinidine" in the '282 patent.

Finally, Hetero argues that it was improper for the district court to rely on the prior litigation involving the '282 patent, in which the district court found that other generic drug manufacturers had infringed the '282 patent. *See Avanir Pharms., Inc. v. Actavis S. Atl. LLC*, 36 F. Supp. 3d 475 (D. Del. 2014), *aff'd sub nom. Avanir Pharms. Inc. v. Par Pharm. Inc.*, 612 F. App'x 613 (Fed. Cir. 2015). Hetero argues that the previous case has no bearing on this one because (1) Hetero was not a party to the *Avanir* case, (2) the defendants in *Avanir* stipulated to infringement, so the

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[7] By analogy, suppose a claim referred to two interacting molecules, both of which had two enantiomers, and the court concluded that the claim was broad enough to encompass both enantiomers of each of the two compounds. The court's construction would not render the claim indefinite, even though the claim, as construed, would be broad enough to cover four possible combinations of the molecules rather than one.

court in *Avanir* was not required to address the claim construction issues presented to the district court in this case, and (3) the court in *Avanir* did not address indefiniteness.[8] The court in this case, however, did not treat the decision in *Avanir* as binding, but merely regarded it as "instructive." The court relied on other reasons for finding that Otsuka was likely to succeed on the merits. *See* J.A. 7.

F

Based principally on the guidance provided by the specification, we find Otsuka's proposed claim construction more persuasive than the construction offered by Hetero. We construe the terms "dextromethorphan" and "quinidine" in the '282 patent, including their use in the weight-to-weight ratio of claim 1, to refer to the form in which those compounds are administered. Applying that construction, we hold that the district court did not err in finding that Otsuka was likely to succeed in proving that Hetero infringed the '282 patent.

We have considered the other arguments raised by Hetero in challenging the district court's preliminary injunction order and find them unpersuasive. We therefore conclude that the district court acted within its discretion in granting a preliminary injunction in this case.

IV

According to Federal Rule of Civil Procedure 65(c), a court "may issue a preliminary injunction . . . only if the movant gives security in an amount that the court considers proper to pay the costs and damages sustained by any

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[8] Although the district court in the *Avanir* litigation did not expressly address indefiniteness, the defendants in that case raised indefiniteness as a ground for invalidating the '282 patent, and the district court nonetheless held the patent not invalid. *See* 36 F. Supp. 3d at 510.

party found to have been wrongfully enjoined or restrained." The Third Circuit has recognized limited exceptions to the Rule 65(c) bond requirement, but has noted that waiver is "so rare that the requirement is almost mandatory." *Frank's GMC Truck Ctr., Inc. v. Gen. Motors Corp.*, 847 F.2d 100, 103 (3d Cir. 1988).

The Third Circuit has held that the bond requirement may be waived if "there is no risk of monetary loss to the defendant." *Id.* (citing *Sys. Operations, Inc. v. Sci. Games Dev. Corp.*, 555 F.2d 1131, 1145–46 (3d Cir. 1977)). The court has also held that the bond requirement may be waived under circumstances such as those described in *Temple University v. White*, 941 F.2d 201, 219–20 (3d Cir. 1991). That case explained that a court may excuse compliance with the bond requirement "at least in non-commercial cases . . . [upon] consider[ing] the possible loss to the enjoined party together with the hardship that a bond requirement would impose on the applicant." *Id.* at 219 (quoting *Crowley v. Local No. 82, Furniture & Piano Moving*, 679 F.2d 978, 1000 (1st Cir. 1982), *rev'd on other grounds*, 467 U.S. 526 (1984)). An exception to the bond requirement may also apply in "suits to enforce important federal rights or public interests, arising out of comprehensive federal health and welfare statutes." *Id.* at 220 (quoting *Crowley*, 679 F.2d at 1000) (citation modified).

Applying the first *Temple* exception, the district court found the risk to financial harm to Hetero "speculative at best" and expressed concern regarding "a chilling effect on access to justice" if a multi-million-dollar bond were required in this case. J.A. 31 (citation omitted). Thus, the court waived the requirement for Otsuka to post security under Rule 65(c). J.A. 32.

We are bound to follow the Third Circuit's narrow exceptions to Rule 65(c). And the Third Circuit has "never excused a [d]istrict [c]ourt from requiring a bond where an injunction prevents commercial, money-making activities."

Zambelli, 592 F.3d at 426. Hetero's attempt to enter the market with its generic pharmaceutical product is clearly a commercial, money-making activity. Accordingly, we vacate the Rule 65(c) bond waiver and remand the bond issue to the district court for reconsideration.

On remand, the district court may exercise its discretion in determining an appropriate amount to require as a security in light of the limited time remaining before the '282 patent expires. With regard to the district court's concern about imposing a large expense for a bond on the plaintiffs, we note that under the Local Rules for the United States District Court for the District of Delaware, the "reasonable premiums or expenses paid on bonds or security stipulations shall be allowed" as taxable costs when those amounts are "furnished by requirements of the law or rule of Court . . . or where required to enable a party to receive or preserve some right accorded the party in an action or proceeding." D. Del. R. 54.1(b)(10).

V

In summary, we affirm the district court's grant of Otsuka's motion for a preliminary injunction. We vacate and remand for reconsideration the district court's decision to waive the Rule 65(c) bond requirement.

AFFIRMED IN PART, VACATED IN PART, AND REMANDED

COSTS

No costs.

United States Court of Appeals for the Federal Circuit

OTSUKA AMERICA PHARMACEUTICAL, INC., AVANIR PHARMACEUTICALS, LLC, FKA AVANIR PHARMACEUTICALS INC.,
Plaintiffs-Appellees

v.

HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-III, CAMBER PHARMACEUTICALS INC.,
Defendants-Appellants

2025-2016

Appeal from the United States District Court for the District of Delaware in No. 1:25-cv-00647-GBW, Judge Gregory Brian Williams.

DYK, *Circuit Judge*, dissenting-in-part and concurring-in-part.

I respectfully dissent from the majority's claim construction, its conclusion on infringement, and its decision sustaining the preliminary injunction.[1]

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[1] I join the majority's opinion as to the district court's erroneous waiver of the bond requirement.

The question is what the terms "dextromethorphan" and "quinidine" mean in the claims of the '282 patent. The majority concludes that they refer to both (1) those molecules alone, and (2) a broader class of salt compounds that contain those molecules as active moieties and also a carrier ion that has no therapeutic significance. While administration via salt forms is covered by the claims because the salt forms contain quinidine and dextromethorphan as active moieties, the claimed weight measurements are designed to only take into account the weight of those active moieties, that is, the quinidine or dextromethorphan ions contained within the salt compound. The majority's construction, which calculates the weight-to-weight ratio either using the weight of the active moiety (when administered in the pure "free base" form) or the total weight of a salt compound (when administered in the salt form), is inconsistent with the objective of the invention and is unsupported by the specification and prosecution history.

I

The '282 patent covers methods for administering dextromethorphan in combination with quinidine to treat emotional lability, a neurological disorder. Independent claim 1 is representative and recites:

> A method for treating pseudobulbar affect or emotional lability, the method comprising administering to a patient in need thereof dextromethorphan in combination with quinidine, wherein the amount of dextromethorphan administered comprises from about 20 mg/day to about 80 mg/day and wherein the amount of quinidine administered comprises from about 10 mg/day to less than about 30 mg/day with the proviso that the weight to

> weight ratio of dextromethorphan to quinidine is 1:0.5 or less.[2]

'282 patent, claim 1 (emphasis added).

The specification of the '282 patent identifies two key pieces of prior art, U.S. Patent No. 5,166,207 (the "'207 patent") and U.S. Patent No. 5,206,248 (the "'248 patent"). '282 patent, col. 14 ll. 28–30. These patents disclosed the combined use of dextromethorphan and quinidine to treat emotional lability. Dextromethorphan provides the neurological effect and quinidine "reduces the degradation of dextromethorphan . . . which therefore increases dextromethorphan concentrations in the blood." '248 patent, col. 2 ll. 56–61. When dextromethorphan was administered on its own, it resulted in "extremely low [blood] plasma levels of dextromethorphan or levels which were less than 5 ng/ml" because of the fast metabolism of the molecule in the body. '207 patent, col. 5 ll. 59–63. However, when administered with quinidine, dextromethorphan levels in the blood plasma "ranged from 28–46 ng/ml," even with a lower dose of dextromethorphan because the quinidine prevented that metabolization. *Id.* col. 5 ll. 63–67. At the same time, it was known that quinidine can cause undesirable side effects, so it was desired to administer no more quinidine than necessary.

The purpose of the invention claimed in the '282 patent is thus to decrease the blood level of quinidine while maintaining a therapeutically effective blood level of dextromethorphan in a patient that is receiving this treatment. *See* J.A. 985 (patentee describing the invention during prosecution as "*low-dose* quinidine formulations" that "resolve[] FDA concerns about the safety and tolerability [of] previously tested high-dose quinidine formulations" (emphasis

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[2] It is undisputed that "or less" modifies the amount of quinidine in the claimed ratio rather than the ratio itself.

in original)); J.A. 1035 (examiner describing the claimed invention as achieving "a [dextromethorphan] blood level that is effective in the treatment of . . . emotional lability," while reducing the amount of quinidine administered).

The claimed invention has a weight-to-weight ratio "of dextromethorphan to quinidine [being] 1:0.5 or less." '282 patent, claim 1. The claim terms "dextromethorphan" and "quinidine," which are measured and compared by weight, must be construed in light of the purpose of the invention. As we stated in *Sequoia Technology, LLC v. Dell, Inc.*, "[w]e have explained that a patent's express purpose of the invention 'informs the proper construction of claim terms.'" 66 F.4th 1317, 1326 (Fed. Cir. 2023) (quoting *Kaken Pharm. Co. v. Iancu*, 952 F.3d 1346, 1352 (Fed. Cir. 2020)). *See also Nevro Corp. v. Boston Sci. Corp.*, 955 F.3d 35, 44 (Fed. Cir. 2020) (noting the relevance of the "purpose of the claimed invention" to claim construction).

Nothing in the intrinsic record indicates that administering quinidine or dextromethorphan in the form of a salt (as opposed to the free base form) has any therapeutic effect related to the efficacy of the combination or that it affects the blood levels of dextromethorphan and quinidine. As salts are ionic compounds, the chemical structure of both dextromethorphan and quinidine remains the same in a salt form as it would be in the free base form. When quinidine is administered as quinidine sulfate, its strength is diluted because there is less quinidine for each gram of quinidine sulfate than there is in each gram of free base quinidine. *See* '282 patent col. 17 l. 63–col. 18 l. 2. When dextromethorphan is administered as dextromethorphan hydrobromide, its strength is also diluted. *See id.* Measuring salt weights (as opposed to the weight of just the active moieties) distorts the relative measurement, changing the weight-to-weight ratio of the active moieties, and thereby changing the resulting levels of dextromethorphan and quinidine in the blood.

The purpose of the invention is to achieve reduced blood levels of quinidine in relation to the amount of dextromethorphan. It would defeat the aims of the claimed invention to compare the weight of diluted dextromethorphan with that of an undiluted quinidine, or vice versa. Even if both are diluted by being administered as salts, the salt forms are diluted in different proportions such that the ratio of pure quinidine to pure dextromethorphan is greater than if administered in the undiluted forms. Measuring the salt compound as a whole instead of the active moiety inherently results in different calculations of the effective components. Such a result is absurd because it is contrary to the inventive purpose of achieving a lower blood level of quinidine while maintaining a therapeutically significant level of dextromethorphan. A skilled artisan could not conclude this construction is correct, as the only expert testimony supplied by the parties indicates. As Hetero's expert testified without rebuttal, "the various salt and hydrate forms are merely formulation tools to deliver the active drug compounds so that those compounds (dextromethorphan and quinidine) can provide the desired activity in the human body" so "[t]o precisely calculate the weight of the effective dosage of an active drug in a particular formulation, a [skilled artisan] would use the molecular weights of the active drugs and the form at issue." J.A. 630–31.

The majority offers no coherent theory as to how its claim construction is consistent with the purpose of the claimed invention and the patent's concern with the proportions of the active moieties administered. The majority states:

> The dissent contends that comparing the salt forms distorts the compounds' relative weights, but a skilled artisan could just as easily use the conversion to find the amount of salt required for a desired amount of the active moiety. The drafter's choice of weight comparison is one way of defining

> the claim scope and is not contrary to the purpose of the invention.

Op. at 14. This appears to suggest that a skilled artisan would adjust the relative proportions of the active moieties by adjusting the salt formulations to reflect the desired amount of the active moieties in the salt forms. But this is exactly why computing the weight ratio based on the active moieties is the only meaningful comparison and why the comparison of the salt formulation weights is not consistent with the purpose of the invention.

II

The majority also ignores other compelling intrinsic support for Hetero's construction. Claim 1 indicates that it is the weight of dextromethorphan and quinidine, regardless of the form of administration, that matters. Both "quinidine" and "dextromethorphan" are unambiguous terms that describe "very specific compound[s]" with "discernible chemical structure." *SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1339–40 (Fed. Cir. 2005). If Otsuka wanted to claim doses based on the weights of pharmaceutically acceptable salts, Otsuka "had the ability to draft the claim that way but it did not." *Source Vagabond Sys. Ltd. v. Hydrapak, Inc.*, 753 F.3d 1291, 1300 (Fed. Cir. 2014); *see also Helmsderfer v. Bobrick Washroom Equip., Inc.*, 527 F.3d 1379, 1383 (Fed. Cir. 2008) ("Courts cannot rewrite claim language."); *Alnylam Pharms., Inc. v. Moderna, Inc.*, 138 F.4th 1326, 1333 (Fed. Cir. 2025) ("[T]he intrinsic evidence must 'clearly set forth' or 'clearly redefine' a claim term so as to put one reasonably skilled in the art on notice . . . ." (quoting *Bell Atl. Network Servs., Inc. v. Covad Commc'ns Grp., Inc.*, 262 F.3d 1258, 1268 (Fed. Cir. 2001))).

The specification confirms that this plain reading of the claims is the correct one. The specification explicitly defines "dextromethorphan" and "quinidine" as specific molecules with specific atoms arranged in specific structures.

'282 patent, col. 9 ll. 22–34; col. 14 ll. 8–23; *see also Allergan, Inc. v. Apotex Inc.*, 754 F.3d 952, 960 (Fed. Cir. 2014) (recognizing a patent may define a compound with its chemical structure). In the claims, the salt forms are described using the same terminology ("dextromethorphan" and "quinidine"), but the claimed weights refer to the weight of the active moieties contained in the salt. The specification provides instructions to convert the weights of dextromethorphan hydrobromide and quinidine sulfate (the salt forms) into "effective weights" reflecting only the dextromethorphan and quinidine ions in those salt formulations. *Id.* col. 17 l. 60–col. 18 l. 14. This conversion guidance underscores the importance of understanding how much quinidine and dextromethorphan are contained within doses administered as salts.

In the disclosed clinical trials, patentee chose to refer to doses that clearly contain specific amounts of quinidine sulfate and dextromethorphan hydrobromide as "Q" and "DM" or the "quinidine dose[]" or the "dose of dextromethorphan," Op. at 9–11 (quoting '282 patent, col. 28 l. 7, col.33 ll. 1–3, col. 54 ll. 12–13, col. 55 ll. 25–42). But nothing indicates that this use of shorthand to refer to doses that contain quinidine and dextromethorphan has any relevance to the claim language.[3]

The majority's reliance on other aspects of the specification to support Otsuka's construction is also misplaced.

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[3] The majority also argues that the specification fails to provide conversion instructions to calculate the weight of quinidine present in a sample of quinidine sulfate or the weight of dextromethorphan present in a sample of dextromethorphan hydrobromide. Op. at 11. That is incorrect, as the patent clearly teaches the conversion ratio for each, '282 patent, col. 17 l. 60–col. 18 l. 14, something the majority's opinion later recognizes, Op. at 13–14.

While the claims are read in light of the specification, aspects of the specification must be given less weight where the intrinsic record shows they lack relevance. *See Trs. of Colum. Univ. in City of New York v. Symantec Corp.*, 811 F.3d 1359, 1368 (Fed. Cir. 2016); *see also Honeywell Inc. v. Victor Co. of Japan, Ltd.*, 298 F.3d 1317, 1327 (Fed. Cir. 2002).

The specification and original claims were directed to a broad range of dosing regimens but largely lacked any weight ratio. When the examiner determined the original claims were unpatentable as obvious, patentee was then forced to disclaim much of the original scope and claim a specific weight-to-weight ratio limitation to distinguish the prior art. In developing the current iteration of the claims, patentee relied on developments made in a study conducted in 2004 and communications from the FDA in 2006, both after the asserted priority date. The result of this mid-prosecution pivot is a disconnect between the claimed invention and aspects of the specification, which is also almost entirely populated by embodiments unclaimed under either party's construction of the asserted claims.

In this context, the majority's reliance on quotes from the specification that "with respect to all 16 embodiments . . . 'the quinidine includes quinidine sulfate and the dextromethorphan includes dextromethorphan hydrobromide'" is unpersuasive. Op. at 8 (quoting '282 patent, col. 3 ll. 21–23). The majority excludes the latter part of the sentence, which makes clear that the quoted statement is not a general claim that references to "quinidine" and "dextromethorphan" always encompass the salt forms. *E.g.*, '282 patent, col. 3 ll. 21–27 ("In aspects of the . . . embodiments, the quinidine includes quinidine sulfate and the dextromethorphan includes dextromethorphan hydrobromide, *and wherein an amount of quinidine sulfate administered includes from about 30 mg/day to 60 mg/day and wherein an amount of dextromethorphan hydrobromide administered includes from about 30 mg/day to about*

60 mg/day."). The majority also ignores that to the extent that the 16 described embodiments describe doses and weight-to-weight ratios, they do not describe the claimed doses and ratio in the asserted claims. Instead, they map onto the dosages originally claimed, which were determined to be obvious and then disclaimed through amendment.

The majority's reliance on *Osram GmbH v. International Trade Commission* is similarly misplaced. Op. at 12–13 (citing 505 F.3d 1351, 1358 (Fed. Cir. 2007)). In that case, the parties contested whether claim language referring to the "mean grain diameter" should calculate the "mean" based on the number of grains or the volume. *Osram*, 505 F.3d at 1355. After concluding that the specification indicated that a number-based average was the appropriate measure, we noted that a volume-based measure would exclude the product that the patents were designed to cover, likening that situation to a patent that excludes a preferred embodiment. *Id.* at 1357–58. However, here, neither the preferred embodiments nor Otsuka's product are instructive. Patentee sought a patent with a broader scope that would have undisputably covered its Nuedexta product. It then had to give up much of that scope to avoid an obviousness rejection. In light of the prosecution history, it is not unusual that Otsuka's product, like the vast majority of the described embodiments, now falls outside the scope of the claims. This context undermines the relevance of the product to construction of the claim terms.

III

The majority also incorrectly relies on a prosecution statement made by the examiner describing the original claims as claiming administration of "dextromethorphan or dextromethorphan hydrobromide" and "quinidine or quinidine sulfate" to conclude that it is "clear that the examiner shared Otsuka's understanding of the terms." Op. at 12 (quoting '213 application at 6 (Oct. 3, 2008) (Non-Final

Rejection)). That statement says nothing about the computation of the weight-to-weight ratios and is merely an imprecise summary of several claims that does not define the scope of those claims, let alone the claims that were actually granted.

When allowing the current version of the claims, the examiner chose different terms and, without mentioning the salt forms, described the claimed invention as simply the administration of "dextromethorphan" and "quinidine." J.A. 1033. The examiner described the '207 and '248 patents as "[t]he closest prior art." *Id.* Those patents involved administering the molecules in the free base form, but the examiner concluded that they "do not specifically teach a weight to weight ratio of dextromethorphan to quinidine of 1:0.5 or less." J.A. 1034. Thus, the examiner specifically noted the weight-to-weight ratio limitation in the context of a ratio computed from the amounts of the pure forms. Once the purpose of the invention became reducing the amount of quinidine administered and the weight-to-weight ratio became central to the claimed invention, the examiner understood the limitations to be based on the relative weight of the dextromethorphan and quinidine molecules themselves, not the relative weight of their salt forms.

Because, under the correct claim construction, Hetero has raised a substantial question of noninfringement, I would reverse the preliminary injunction. *See Metalcraft of Mayville, Inc. v. Toro Co.*, 848 F.3d 1358, 1364 (Fed. Cir. 2017). I respectfully dissent.