NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

IN RE: STRONGBRIDGE DUBLIN LTD.,
Appellant

2023-2302, 2023-2303

Appeals from the United States Patent and Trademark Office, Patent Trial and Appeal Board in Nos. 17/151,405, 17/675,660.

Decided: March 10, 2025

WILLIAM MILLIKEN, Sterne Kessler Goldstein & Fox PLLC, Washington, DC, argued for appellant. Also represented by KRISTINA CAGGIANO KELLY, ANNA G. PHILLIPS, DEBORAH STERLING.

KAKOLI CAPRIHAN, Office of the Solicitor, United States Patent and Trademark Office, Alexandria, VA, argued for appellee Coke Morgan Stewart. Also represented by SARAH E. CRAVEN, ROBERT J. MCMANUS, AMY J. NELSON, FARHEENA YASMEEN RASHEED.

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

DYK, *Circuit Judge*.

Strongbridge Dublin Ltd. ("Strongbridge") appeals from two decisions of the United States Patent and Trademark Office ("PTO") Patent Trial and Appeal Board ("Board"), affirming the PTO examiner's rejection of claim 16 of U.S. Patent Application No. 17/151,405 (the "'405 application") and claim 13 of U.S. Patent Application No. 17/675,660 (the "'660 application") as anticipated by the prior art reference Sansone. We *affirm-in-part*, *vacate-in-part*, and *remand* for further proceedings consistent with this opinion.

BACKGROUND

I

The claims at issue in the '405 and '660 applications concern administering the drug dichlorphenamide, a drug used for treating patients with primary hyperkalemic periodic paralysis or primary hypokalemic periodic paralysis (collectively "PPP") while also "avoiding" the administration of other drugs that fall into a class of drugs known as organic anion transporter-1 ("OAT1") substrates. The '405 application concerns avoiding famotidine, and the '660 application concerns avoiding methotrexate. Famotidine, also known as PEPCID®, is an OAT1 substrate used to treat stomach ulcers, heartburn or acid indigestion, and gastroesophageal reflux disease. Methotrexate, also an OAT1 substrate, "is an anti-metabolite most commonly used in chemotherapy and as an immunosuppressant in treating autoimmune diseases." Appellant's Br. 9 (citing J.A. 47; J.A. 420–421; J.A. 565, J.A. 575, J.A. 577).

Claim 16 of the '405 application recites:

> A method of administering dichlorphenamide to treat primary hyperkalemic periodic paralysis or primary hypokalemic periodic paralysis in a human patient in need thereof, comprising:

> administering dichlorphenamide in tablet form to the patient at an initial dose of 50 mg, once or twice daily, while also avoiding concomitant administration to said human patient of an organic anion transporter-1 (OAT1) substrate, wherein the OAT1 substrate is famotidine.

J.A. 33. Claim 13 of the '660 application recites:

> A method of administering dichlorphenamide to treat primary hyperkalemic periodic paralysis or primary hypokalemic periodic paralysis in a human patient in need thereof, comprising:
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> administering dichlorphenamide in a tablet form to said patient at an initial dose of 50 mg once or twice daily, while also avoiding concomitant administration of methotrexate to said patient.

J.A. 58.

II

In final office actions, the examiner rejected claim 16 of the '405 application and claim 13 of the '660 application under 35 U.S.C § 102(a)(1) as anticipated by the prior art reference Sansone.[1] Sansone describes a clinical trial where patients with PPP were administered 50 mg of dichlorphenamide twice a day, the treatment for PPP recited in the claims of the '405 and '660 applications. In rejecting the claims over Sansone, the examiner noted that Sansone "does not explicitly teach[] . . . 'avoiding concomitant administration of [the claimed OAT1 substrate] to said

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[1] *See* Valeria A. Sansone et al., *Randomized, Placebo-controlled Trials of Dichlorphenamide in Periodic Paralysis*, 86 Neurology 1408 (2016) (listed on clinicaltrials.gov as NCT00494507); J.A 666–83.

human patient,'" J.A. 564,[2] but "by staying silent regarding[] [this claim limitation, Sansone] inherently teaches that [the claimed OAT1 substrate] was NOT co-administered with dichlorphenamide, unless [Strongbridge] can demonstrate that it was customary to administer [the claimed OAT1 substrate] with dichlorphenamide in order to treat [PPP]," J.A. 565. The examiner determined that Strongbridge did not make this showing.

Strongbridge appealed the examiner's final section 102(a)(1) rejections to the Board. On appeal, the Board first interpreted "concomitant" and "avoiding concomitant administration of [famotidine or methotrexate] to said patient" to mean that the claimed OAT1 substrate "is not being administered at the same time as when the patient is being treated with dichlorphenamide, i.e., the patient is not taking [the claimed OAT1 substrate] in addition to the dichlorphenamide during the treatment regimen." *Ex parte Cohen*, No. 22-004501, at 4 (P.T.A.B. Aug. 1, 2023) ("'405 Decision"); *see also Ex parte Cohen*, No. 23-001681, at 47–48 (P.T.A.B. Aug. 1, 2023) ("'660 Decision") (similar).[3] The Board then sustained the examiner's rejections that the claims were inherently anticipated by Sansone's silence. '405 Decision at 10; '660 Decision at 55. The Board agreed with the examiner that, by staying silent, Sansone inherently teaches that neither famotidine nor

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[2] For ease of review, citations here are to the final office action for the '660 application, but the final office action for the '405 application is substantively similar. *See* Final Office Action, *In re Cohen*, No. 17/151,405 (U.S.P.T.O Nov. 17, 2021).

[3] The Board's decisions can also be found in the Corrected Joint Appendix at J.A. 1–11 and J.A. 45–56. Because the Board's decisions are not paginated, pincites here are to the appendix. For example, '405 Decision at 4 refers to J.A. 4, and '660 Decision at 47 refers to J.A. 47.

methotrexate were administered in the clinical trial. '405 Decision at 5; '660 Decision at 49. It further found that famotidine and methotrexate are not used to treat PPP and were not required for the Sansone clinical trial. Then, it concluded that Strongbridge did not provide evidence that any of the disease indications treated by famotidine or methotrexate are associated with PPP or establish a relationship between patients in need of these OAT1 substrates and patients in need of dichlorphenamide such that a skilled artisan would believe the drugs were taken concomitantly.

Strongbridge timely appealed. We have jurisdiction pursuant to 35 U.S.C. § 1295(a)(4)(A).

DISCUSSION

Strongbridge makes two principal arguments on appeal. First, it argues that the Board improperly construed "administering dichlorphenamide . . . while also avoiding concomitant administration of" famotidine or methotrexate. Second, it argues Sansone does not anticipate claim 16 of the '405 application and claim 13 of the '660 application even under the Board's claim construction.

I

A

Strongbridge argues that, contrary to the Board's claim construction, "avoiding concomitant administration" of dichlorphenamide and famotidine or methotrexate requires affirmative activity or an active step, including discontinuing the OAT1 substrate before administering dichlorphenamide or instructing a patient who might otherwise need the OAT1 substrate to not take it.

As a threshold matter, we address whether Strongbridge forfeited this claim construction argument. Where a party fails to present an argument to the Board and thus

"deprives this court of the benefit of the Board's informed judgment," a party forfeits that argument. *Voice Tech Corp. v. Unified Pats., LLC*, 110 F.4th 1331, 1340 (Fed. Cir. 2024).

We conclude that Strongbridge did not forfeit its claim construction argument as to the '660 application because it argued, both in its appellate brief before the Board and during oral argument, that the "avoiding concomitant administration" limitation is an "active," "separate method step that must be performed by the physician." J.A. 601–02. As to the '405 application, Strongbridge did not make similar arguments in its appellate brief before the Board (but did so during oral argument). Nonetheless, we decline to find forfeiture in this case as the construction is equally relevant to both applications. *Medtronic, Inc. v. Teleflex Innovations S.à.r.l.*, 69 F.4th 1341, 1345 n.6 (Fed. Cir. 2023) (explaining that even if arguments are otherwise forfeited, the court has "discretion to reach them on appeal").

B

Since there are no factual disputes as to extrinsic evidence, we review the ultimate claim construction de novo. *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 322, 326 (2015). "During examination, claim terms are given their broadest reasonable interpretation consistent with the specification as understood by those of ordinary skill in the art." *In re Hodges*, 882 F.3d 1107, 1115 (Fed. Cir. 2018).

The '405 and '660 applications do not define the term "avoiding concomitant administration" nor "concomitant" or "avoiding." Strongbridge argues that the ordinary meaning of "avoid," which is "to keep away from" or "stop oneself from doing something," connotes deliberate activity. Appellant's Br. 22–23 (citing dictionary definitions of avoid). We do not read "avoid" as requiring affirmative activity such as discontinuing OAT1 substrate treatment or

being instructed by a physician to not take an OAT1 substrate while taking dichlorphenamide. The plain and ordinary meaning of "avoid" is also consistent with claim coverage in situations in which patients are simply not taking famotidine or methotrexate while they are taking dichlorphenamide. By way of example, a person who drives one route home from work avoids or keeps away from a traffic jam that takes place on an alternative route home even if that person does not take the active step of deciding to avoid that traffic jam. So, too, may a patient who is in need of dichlorphenamide treatment "avoid concomitant administration" by simply not taking famotidine or methotrexate.

The prosecution history also demonstrates that the claims are not limited to active steps under the broadest reasonable interpretation. During prosecution, Strongbridge filed claims requiring active steps related to famotidine or methotrexate, but it cancelled those claims. In particular, in the '660 application, Strongbridge submitted the following claims:

> 1. A method for treating a disease chosen from primary hyperkalemic periodic paralysis, primary hypokalemic periodic paralysis, and related variants in a subject in need thereof, wherein the subject is being administered an [OAT1] substrate for the treatment of a disease or disorder, the method comprising:
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> > discontinuing administration of the OAT1 substrate, and
> >
> > administering to the subject a therapeutically effective amount of dichlorphenamide, or a pharmaceutically acceptable salt thereof,
> >
> > thereby <u>avoiding the use of dichlorphenamide, or a pharmaceutically acceptable salt</u>

> thereof in combination with the OAT1 substrate.
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> 2. The method of claim 1, further comprising informing the subject or a medical care worker that co-administration of the dichlorphenamide, or a pharmaceutically acceptable salt thereof, and the OAT1 substrate may result in increased exposure of the OAT1 substrate.

J.A. 86 (emphasis added). Strongbridge cancelled those claims and filed the claims at issue on appeal. In the '405 application, Strongbridge cancelled a similar claim reciting discontinuing administration of famotidine and filed a claim that is the same as the claim now at issue on appeal. *Compare* Response, *In re Cohen*, No. 17/151,405, at 6–7 (U.S.P.T.O. Nov. 4, 2021) *with* Response, *In re Cohen*, No. 17/151,405, at 7 (U.S.P.T.O. June 30, 2021). Then, after cancelling its claims, Strongbridge amended the claim of the '405 application to recite "wherein the patient is also in need of treatment with famotidine," J.A. 269, only to again revert on this amendment.

Strongbridge now attempts to rewrite the claims to confine them to the very claims it cancelled. *See* Appellant's Br. 25 (arguing "[t]he broadest reasonable construction of the claim . . . is . . . that a doctor or clinician must either discontinue treatment with methotrexate or famotidine . . . or withhold concomitant administration of dichlorphenamide and methotrexate or famotidine from a patient who may otherwise be indicated for those treatments."). Strongbridge's cancellation of claims reciting affirmative activity and substitution with broader claims that did not require such affirmative activity support the Board's construction. *See Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 (Fed. Cir. 2004) (finding cancellation of narrower claims supported broader construction). We conclude the Board's claim construction was correct.

II

We now turn to the Board's rejection of the claims as anticipated by Sansone. The Board affirmed the examiner's determination that Sansone inherently anticipates the claims, concluding that the examiner properly relied on inherent anticipation by silence—i.e., the fact that Sansone does not disclose administration of famotidine or methotrexate—to teach "avoiding concomitant administration" of these drugs and shifted the burden to Strongbridge to establish the contrary. *See* '405 Decision at 5 ("The [e]xaminer did not err in relying on the so-called 'silence' of Sansone to teach 'avoiding concomitant administration to said human patient of . . . famotidine"); '660 Decision at 53 ("The [e]xaminer's finding that Sanso[n]e does not disclose that any of its patients were administered methotrexate was sufficient to shift the burden to Appellant. . . ."). On appeal, Strongbridge argues that, under our holding in *Novartis Pharmaceuticals Corp. v. Accord Healthcare, Inc.*, 38 F.4th 1013 (Fed. Cir. 2022), silence in the prior art cannot anticipate unless that particular negative limitation "would always be understood by skilled artisans as being necessarily excluded from a particular claimed method or apparatus if that limitation is not mentioned." Appellant's Br. 32 (quoting *id.* at 1018).

The Board's focus on inherency was not the correct inquiry in this case. It was not necessary for the examiner to establish that, following Sansone's approach, a patient necessarily avoided taking famotidine or methotrexate. Nor do we see any basis for shifting the burden to the patentee.

As the Board recognized in other parts of its Decisions, the correct anticipation inquiry in this case is whether the examiner established on a preponderance of evidence that only one patient in Sansone was not taking famotidine or methotrexate. *See Hewlett-Packard Co. v. Mustek Sys., Inc.*, 340 F.3d 1314, 1326 (Fed. Cir. 2003); *In re*

Cyclobenzaprine, 676 F.3d 1063, 1080 n.7 (Fed. Cir. 2012). For negative limitations, a prior art reference "need not state a feature's absence in order to disclose" it. *AC Techs. S.A. v. Amazon.com, Inc.*, 912 F.3d 1358, 1367 (Fed. Cir. 2019). Instead, even if a prior art reference "does not expressly disclose . . . [a limitation,] . . . . [it] might nevertheless be anticipating if a person of ordinary skill in the art would understand [it] as disclosing [the limitation] and if such a person could have combined the [prior art reference's] description of the invention with his own knowledge to make the claimed invention." *Helifix Ltd. v. Blok-Lok, Ltd.*, 208 F.3d 1339, 1347 (Fed. Cir. 2000); *accord Almirall, LLC v. Amneal Pharms. LLC*, 28 F.4th 265, 273 (Fed. Cir. 2022) (recognizing prior art reference disclosed excluding an ingredient where "a skilled artisan would recognize that the reference discloses a complete formulation—excluding the possibility of an additional active ingredient"); *AC Techs.,* 912 F.3d at 1367; *Süd-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1004–05 (Fed. Cir. 2009); *WAG Acquisition, LLC v. WebPower, Inc.*, 781 F. App'x 1007, 1012–13 (Fed. Cir. 2019) (non-precedential).

The Board found that "[t]here is no mention of famotidine [or methotrexate]" in Sansone and that neither is "a required drug in Sansone's clinical trial." '405 Decision at 10; '660 Decision at 54. The Board further found that "[t]he patient classes [taking dichlorphenamide (as in Sansone)] are unrelated" to the patient classes who take famotidine or methotrexate. '405 Decision at 7; '660 Decision at 51–52. The Board's findings are relevant but not substantial evidence in and of themselves. There must be something more to suggest that the silence is significant, or other reasons that establish by a preponderance of the evidence that it is likely that one or more of the patients in Sansone were not taking famotidine or methotrexate at some time during the nine week and/or fifty-two-week length of the study. This could include, for example, proof

from the structure of the study, the results of the study, or statistical analysis as to the likelihood that at least one patient was not taking famotidine or methotrexate. Given Sansone reports that 36 PPP patients were treated with dichlorphenamide for at least nine weeks and many up to fifty-two weeks, it may well be that at least one of those patients was not taking famotidine or methotrexate.[4] But the Board's existing findings are not substantial evidence to establish that one patient in Sansone was not taking the avoided drugs.

We thus vacate the Board's rejection, and we remand, leaving to the Board to determine what a person of ordinary skill in the art would have understood from Sansone's disclosures as to whether one or more patients were not taking famotidine or methotrexate.

CONCLUSION

We affirm the Board's claim construction and vacate its determination that claim 16 of the '405 application and claim 13 of the '660 application are inherently anticipated under this construction. We remand to the Board for further consideration consistent with this opinion.

AFFIRMED-IN-PART, VACATED-IN-PART, AND REMANDED

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[4] For example, Sansone discloses that only one of the patients treated with dichlorphenamide experienced gastroesophageal reflux disease, for which famotidine is indicated, perhaps suggesting that other patients were not taking famotidine. Among other adverse events, Sansone also reports adverse events like certain neoplasms, rash, pain, and musculoskeletal and connective tissue disorders. This also might be relevant to whether patients were not taking methotrexate.

COSTS

No costs.