United States Court of Appeals for the Federal Circuit

BELCHER PHARMACEUTICALS, LLC,
Plaintiff-Appellant

v.

HOSPIRA, INC.,
Defendant-Appellee

2020-1799

Appeal from the United States District Court for the District of Delaware in No. 1:17-cv-00775-LPS, Judge Leonard P. Stark.

Decided: September 1, 2021

PETER MCCREERY LANCASTER, Dorsey & Whitney LLP, Minneapolis, MN, argued for plaintiff-appellant. Also represented by KENNETH LEVITT.

MATTHEW S. FREIMUTH, Willkie Farr & Gallagher LLP, New York, NY, argued for defendant-appellee. Also represented by DEVON WESLEY EDWARDS, THOMAS J. MELORO.

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

REYNA, *Circuit Judge*.

This is an appeal from a decision of the U.S. District Court for the District of Delaware that U.S. Patent No. 9,283,197, which Appellant Belcher Pharmaceuticals, LLC asserted against Appellee Hospira, Inc. in a patent infringement suit under the Hatch-Waxman Act, is unenforceable for inequitable conduct. The district court concluded that Belcher's Chief Science Officer engaged in inequitable conduct by withholding material information from the U.S. Patent and Trademark Office during prosecution of the '197 patent with the requisite deceptive intent. For the reasons below, we affirm.

BACKGROUND

Epinephrine

Epinephrine (also called adrenaline) is a hormone as well as a grandfathered drug product that has been on the market since approximately 1938 and used for a variety of medical purposes. It has long been understood that epinephrine degrades in two ways pertinent to this appeal: racemization and oxidation. Racemization involves a change in the arrangement of a molecule around a "chiral center," such that levorotatory epinephrine ("l-epinephrine"), the more potent isomer, converts to dextrorotatory epinephrine ("d-epinephrine"), the less potent isomer. Oxidation involves a change in a compound's chemical composition due to reaction with oxygen or other oxidizing agents. Oxidation of l-epinephrine yields adrenalone, which is deemed an impurity in l-epinephrine drug products.

A handbook for pharmacists published in 1986 explained that, in l-epinephrine solutions, there is an inverse relationship between racemization and pH and a proportional relationship between oxidation and pH. *See* KENNETH A. CONNORS ET AL., CHEMICAL STABILITY OF PHARMACEUTICALS: A HANDBOOK FOR PHARMACISTS 438–47 (John Wiley & Sons 2d. ed. 1986) [hereinafter Connors] (J.A. 1335–46). In other words, when an epinephrine

solution becomes more acidic (i.e., pH decreases), racemization increases and oxidation decreases, and when the solution becomes more basic (i.e., pH increases), oxidation increases and racemization decreases. *Id.* Accordingly, Connors taught that "there is an optimum pH at which racemization and oxidation can be balanced to minimize loss of intact drug by these two routes; this is approximately pH 3.0-3.8." *Id.* at 441.

Belcher's NDA

On November 30, 2012, Belcher Pharmaceuticals, LLC ("Belcher") submitted New Drug Application ("NDA") No. 205029 for a 1 mg/mL injectable l-epinephrine formulation. J.A. 1559, 1562. The NDA was literature-based, meaning that Belcher did not perform any clinical or nonclinical studies on its epinephrine formulation to support its application. J.A. 1560. The NDA described the development of Belcher's formulation. It first discussed Swiss company Sintetica SA's ("Sintetica") "original formulation" of 1 mg/mL injectable l-epinephrine, which Sintetica developed in the 1930s and registered in Switzerland in 1947. J.A. 1564–65. The formulation included sodium metabisulphite as an antioxidant preservative and about a 10 percent overage[1] of epinephrine to ward off activity loss, and it had a pH range of 2.2 to 4.0. J.A. 1565–66. The manufacturing process involved a continuous flow of nitrogen gas to remove oxygen and thereby enhance stability. J.A. 1566.

According to the NDA, in the early 2000s, market demand shifted to epinephrine formulations that did not include "preservatives and sulfites," which had been found to cause side effects. J.A. 1566. The NDA explained that

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[1] An overage refers to an added amount of the active ingredient or excipient compared to what is described in the product's label.

"[t]he switch was very simple" and involved increasing the sodium chloride concentration and increasing the epinephrine overage from 10 percent to 15 percent. J.A. 1566–67. The NDA described the new composition as having a pH range of 2.8 to 3.3. J.A. 1567. Given the removal of the sulfite antioxidant, "careful attention was paid to the nitrogen purge during the whole process" to maximize stability in the absence of the antioxidant. *Id.*

Belcher's NDA named as reference product Sintetica's preservative- and sulfite-free 1 mg/mL epinephrine formulation manufactured for the U.S. market by American Regent Laboratories, Inc. J.A. 1575. Belcher submitted data from four batches of the reference product, made from November 2002 to April 2003, for validation of the product's stability. J.A. 1578–82. This data showed that the batches included overages of 10 to 15 percent and maintained, over a 24-month period, a pH range of 3.1 to 3.3, and undetectable levels of the impurity adrenalone. J.A. 1578–82. According to Belcher, this data met U.S. Pharmacopeia ("USP") specifications, including the requirement for a pH between 2.2 and 5.0. J.A. 1578; *see also* J.A. 1595.

Belcher's NDA also described the sterilization process and the "in[-]process pH" value. J.A. 1584–95. Belcher explained that lowering the in-process pH from a range of 2.8 to 3.3 (called "old") to a range of 2.4 to 2.6 (called "new"), when coupled with effective removal of oxygen using a nitrogen purge, "reinforces the manufacturing process robustness and reproducibility" and "reduces the impact of possible residues of oxygen in the solution." J.A. 1595.

On February 7, 2013, the U.S. Food and Drug Administration ("FDA") sent a letter to Belcher asking for certain additional information, including (i) "data that support evaluation of [the] drug product for potential racemization from manufacturing process conditions and over the shelf life," and (ii) clarification on whether the Sintetica batches on which Belcher relied for stability validation were

manufactured in the same way as that proposed for marketing. J.A. 1483. Belcher forwarded the letter to Sintetica asking for assistance in responding to the FDA's requests. J.A. 1481.

Belcher responded to the FDA on March 8, 2013. Addressing the FDA's question on racemization, Belcher explained that "[r]acemization of the enantiomerically pure L-Epinephrine isomer in injectable formulations of epinephrine is a well-known process," citing literature authored by Fylligen[2] and Stepensky.[3] J.A. 1430. Responding to the FDA's inquiry on manufacturing process for the stability validation batches, Belcher stated that the only difference between the relied-upon Sintetica batches and Belcher's proposed formulation "is related to the in[-]process pH" and that it "consider[ed] the in[-]process pH change to be a very minor change not requiring additional stability studies." J.A. 1432. Belcher also explained that the release specification of 2.2 to 5.0 "complies with [the] USP specification and stays unchanged between all the batches." *Id.*

The FDA responded on October 4, 2013, asking Belcher to evaluate the effect of an in-process pH range of 2.4 to 2.6 on racemization. *Belcher Pharms., LLC v. Hospira, Inc.*, 450 F. Supp. 3d 512, 524 (D. Del. 2020). On October 17, 2013, Belcher's regulatory consultants, INC Research, recommended that Belcher revert to the 2.8 to 3.3 pH range shown in the Sintetica batch data because deviating from that range would delay the FDA's approval. *Id.*; *see also*

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[2] G. Fyllingen et al., *Racemization and oxidation in adrenaline injections*, 2(5) ACTA PHARM. NORD. 355–62 (1990).

[3] D. Stepensky et al., *Long-term stability study of L-adrenaline injections: kinetics of sulfonation and racemization pathways of drug degradation*, 93(4) J. PHARM. SCI. 969–80 (April 2004).

J.A. 668–69 (Trial Tr. 138:5–139:11). Belcher followed that advice. In its response to the FDA, Belcher stated that it had "refocused [its] studies on determining the effect of the in-process pH of 2.8 - 3.3 on the formation of d-epinephrine during each step of the manufacturing process, which was used to manufacture the 3 primary stability batches . . . provided in the NDA." J.A. 1464. Belcher accordingly requested approval of the drug proposed in the NDA "with the exception[] of changing the [in-process] pH from 2.4 - 2.6 back to the initial pH of 2.8 - 3.3." J.A. 1471. The FDA approved the NDA on July 29, 2015.

The '197 Patent

On August 15, 2014, Jugal Taneja, Belcher's CEO, filed U.S. Patent Application No. 14/460,845 ("'845 application"), which issued as U.S. Patent No. 9,283,197 ("the '197 patent"). J.A. 1003–27. The application was directed to certain epinephrine formulations and was entitled "More Potent and Less Toxic Formulations of Epinephrine and Methods of Medical Use." J.A. 1016, 1025–27. Mr. Taneja later assigned the application to Belcher.

The patent describes the problem of l-epinephrine's degradation and the resulting need for product overages and sulfite antioxidants, and it claims to provide an answer to this need. '197 patent col. 2 ll. 50–59. According to the patent, an answer "seemed impossible" and "had never been accomplished before." *Id.* at col. 4 ll. 31–35. The patent similarly states that the idea of raising the in-process pH above the range of 2.2 to 2.6 "was contradictory to one skilled in the art" before the claimed invention. *Id.* at col. 4 ll. 41–47. But "[i]nadvertently," the patent states, "increasing the in-process pH to 2.8-3.3[] unexpectedly reduced the racemization of l-epinephrine to d-epinephrine at release by approximately two-thirds, from 14% to 5%, respectively." *Id.* at col. 4 ll. 48–51. The inventor's alleged discovery of raising the pH "led to new methods of manufacturing sulfite-free, l-epinephrine solution with an in-

process pH of 2.8 to 3.3, approximately 3.0, which was a nonobvious solution to the problem of racemization. Most importantly, with these new methods, overages could greatly be reduced." *Id.* at col. 4 ll. 55–59.

Claims 6 and 7 of the '197 patent, which are at issue in this appeal, cover pharmaceutical epinephrine formulations having a pH between 2.8 and 3.3 and certain concentrations of l-epinephrine, d-epinephrine, and adrenalone at the time of release and 12 months later. These claims read as follows:

> 6. An injectable liquid pharmaceutical formulation of l-epinephrine sterile solution; said liquid pharmaceutical formulation having a pH between 2.8 and 3.3; said injectable liquid pharmaceutical formulation compounded in an aqueous solution as 1.0 to 1.06 mg/mL l-epinephrine, and further including a tonicity agent; said liquid pharmaceutical formulation including no more than about 6% d-epinephrine and no more than about 0.5% adrenalone at release, and no more than about 12% d-epinephrine and no more than about 0.5% adrenalone over a shelf-life of at least 12 months.
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> 7. The said injectable liquid pharmaceutical formulation of claim 6 further having a concentration of 1 mg per mL l-epinephrine.

'197 patent col. 7 ll. 1–13.

The prosecution of the '197 patent involved a single office action. On August 15, 2014, the examiner rejected the claims as obvious based on Canadian Patent Application No. 2002643 A ("Helenek") in view of additional references. *See* J.A. 1042. Helenek, the examiner explained, taught a 1 mg/mL epinephrine injection that was free of preservatives and antioxidants, was made in an oxygen free (i.e., nitrogen) environment, and had a pH range of 2.2 to 5.0. J.A. 1042–43.

On November 5, 2015, Mr. Tajena's counsel responded arguing that Helenek's 2.2 to 5.0 pH range failed to render obvious the claimed range of 2.8 to 3.3 because the claimed range "was unexpectedly found to be critical by the Applicant to reduce the racemization of l-epinephrine." J.A. 1073; *see also* J.A. 1074 (arguing that "[t]he Applicant has '[shown] that that [sic] the particular range is critical, generally by showing that the claimed range achieves unexpected results relative to the prior art range'" (second alteration in original) (quoting *In re Woodruff*, 919 F.2d 1575, 1578 (Fed. Cir. 1990))).

On December 16, 2015, after holding an interview, the examiner withdrew the pending rejections, made an examiner's amendment approved by the applicant, and allowed the patent. J.A. 1086–88, 1091. In discussing the reasons for allowance, the examiner explained that the cited art failed to render the claims unpatentable "in view of Applicant's demonstration of criticality of a pH range between 2.8 and 3.3." J.A. 1088. According to the examiner,

> Applicant has demonstrated that pH range of between 2.8 and 3.3 is critical to prevent racemization of l-epinephrine . . . . [T]here is nothing in the prior art that would teach or suggest the instantly claimed pH range of between 2.8 and 3.3 would result in the limited racemization and impurities as instantly claimed.

Id.

The '197 patent issued on March 15, 2016, and the FDA thereafter listed the '197 patent for Belcher's NDA No. 205029 in its publication called "Approved Drug Products with Therapeutic Equivalent Evaluations" (often referred to as the "Orange Book"). *Belcher*, 450 F. Supp. 3d at 518–19.

Procedural History

Hospira, Inc. ("Hospira") submitted NDA No. 209359 to the FDA seeking approval of a 0.1 mg/mL injectable l-epinephrine formulation ("Hospira's NDA product"). *Id.* at 518. Hospira's NDA included a certification under 21 U.S.C. § 355(b)(2)(A)(iv) (commonly known as "Paragraph IV") that the '197 patent's claims are invalid, unenforceable, and/or not infringed by Hospira's NDA product. *Id.* at 519.

On June 16, 2017, Belcher sued Hospira for infringing the '197 patent based on Hospira's submission of its NDA seeking approval for its NDA product. *Id.* Belcher asserted claims 6 and 7. *Id.* The parties stipulated that Hospira's NDA product did not literally infringe those claims. *Id.* The district court accordingly held a two-day bench trial in June 2019 on Belcher's theory of infringement under the doctrine of equivalents, as well as Hospira's affirmative defenses and counterclaims of non-infringement, invalidity, and unenforceability. *Id.* at 518–19.

The trial witnesses included Mr. Darren Rubin, Belcher's Chief Science Officer. Mr. Rubin testified that he was a consultant for Belcher from 2010 to 2014 and became its Chief Science Officer in 2015. J.A. 675–76 (Trial Tr. 145:20–146:1). He holds degrees in biology, medical sciences, and business but is neither a registered patent agent nor an attorney. J.A. 675–76 (Trial Tr. 145:12–146:21). Within Belcher, Mr. Rubin was referred to as the head of intellectual property. *See, e.g.*, J.A. 2071. His job responsibilities included overseeing regulatory approval, product development, and working on intellectual property matters including patent application drafting, prosecution, and litigation. J.A. 675–76 (Trial Tr. 145:22–146:21). Mr. Rubin explained that he was involved in the development of Belcher's NDA product and participated in drafting the NDA. *Id.*

Mr. Rubin also testified that he was involved in the prosecution of the '197 patent. He helped draft the application, including its claims and specification, and helped respond to the examiner's office action. J.A. 679 (Trial Tr. 149:13–19), 695 (Trial Tr. 165:14–22). In fact, he served as liaison between named inventor Mr. Taneja, Belcher's patent prosecution attorney, and the U.S. Patent and Trademark Office ("PTO"). J.A. 679–80 (Trial Tr. 149:13–150:18). He "project-managed everything" in that role, and "it all led to [him]." J.A. 680 (Trial Tr. 150:15–18). He prepared a response to the examiner's office action during the '197 patent's prosecution and "dug into the case law." J.A. 681–82 (Trial Tr. 151:21–152:4). In an email, he asserted that he "made sure" to get claim 6 allowed without a preservative-free or sulfite-free limitation. J.A. 2069–70.

Mr. Rubin testified that he possessed knowledge of certain facts pertinent to this appeal before and during the '197 patent's prosecution. For example, he knew of Sintetica's epinephrine formulations that had a pH range of 2.8 to 3.3 and that Belcher's NDA described that range as "old." J.A. 682 (Trial Tr. 152:5–19), 723–24 (Trial Tr. 193:5–194:15). Mr. Rubin also admitted that he knew of Stepensky before the '197 patent was filed. J.A. 705 (Trial Tr. 175:15–25). Indeed, Belcher cited Stepensky in two separate communications to the FDA during the approval process. J.A. 1430, 1472 n.5. Mr. Rubin had also sent Belcher's regulatory consultant an email attaching Stepensky and quoting a portion of it. *See* J.A. 1509–22.

Mr. Rubin also admitted that, by October 29, 2013, he possessed a label for a 1 mg/mL epinephrine product that a company named JHP had already introduced to the market. J.A. 711–12 (Trial Tr. 181:21–182:21). JHP's label described its epinephrine product as having a pH in the range of 2.2 to 5.0. J.A. 1503. Belcher also acquired three batches of the JHP product and sent them to Sintetica for testing, which showed that the JHP product had a pH within the

range of 2.8 to 3.3 (specifically 2.9, 2.9, and 3.1) at 15 months, i.e., three months before the expiration of its 18-month shelf life. J.A. 1523.

On March 31, 2020, the district court decided, among other things, that the '197 patent is unenforceable for inequitable conduct. Regarding materiality, the district court credited the testimony of Hospira's expert witness, Dr. Pinal, that each of the three pieces of information that Mr. Rubin withheld (JHP's product, Sintetica's product, and Stepensky) were but-for material to patentability because they disclosed two aspects of the asserted claims: the pH range and the impurity levels. *Belcher*, 450 F. Supp. 3d at 535, 547–48; J.A. 760–61 (Trial Tr. 230:19–231:10).

The district court also concluded that clear and convincing evidence demonstrated that Mr. Rubin acted with requisite intent to deceive the PTO. *Belcher*, 450 F. Supp. 3d at 550. The district court explained that Mr. Rubin knew of JHP's product, Sintetica's product, and Stepensky before and during the '197 patent's prosecution. *Id.* at 549–50. It also noted that Mr. Rubin was a key player in the FDA approval process as well as the '197 patent's prosecution. *Id.* at 548–50. From his dealings with the FDA, Mr. Rubin knew that Belcher described the claimed pH range of 2.8 to 3.3 as "old"; that Belcher disclosed Stepensky, which teaches an overlapping pH range of 3.25 to 3.70; that Belcher had submitted data on Sintetica's and JHP's products showing a pH within the claimed range; and that Belcher switched from a lower pH range to the claimed 2.8 to 3.3 pH range at least in part to expedite FDA approval because that range matched the pH range of Sintetica's products. *Id.*

But when dealing with the PTO, the district court explained, Mr. Rubin did not merely withhold this information but also used emphatic language to argue that the claimed pH range of 2.8 to 3.3 was a "critical" innovation that "unexpectedly" reduced racemization. *Id.* at 549–50.

The district court found implausible Mr. Rubin's testimony at trial that he withheld JHP's product, Sintetica's product and Stepensky because he believed that they were irrelevant given their high overages. *Id.* at 548–50. The court further found that Mr. Rubin's "repeated efforts to evade questioning and inject attacks of the prior art into his answers raised serious questions as to his credibility." *Id.* at 549. The district court therefore concluded that the facts, taken together, persuaded it that Mr. Rubin's deceptive intent was "the only reasonable inference that can be drawn." *Id.* at 550. Belcher appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

STANDARD OF REVIEW

We review a district court's determination of inequitable conduct under a two-tiered standard. Specifically, we review factual determinations of materiality and intent for clear error. *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). We further review the ultimate decision on inequitable conduct for an abuse of discretion. *Id.* An abuse of discretion occurs when the trial court's decision is clearly unreasonable, arbitrary, or fanciful; when the court's decision is based on an erroneous construction of the law; when the court's factual findings are clearly erroneous; or when the record contains no evidence upon which the court rationally could have based its decision. *Larson Mfg. Co. of S.D. v. Aluminart Prods.*, 559 F.3d 1317, 1327 (Fed. Cir. 2009) (citation omitted).

DISCUSSION

Inequitable conduct is a defense to patent infringement that, if proven, renders the asserted patent unenforceable. *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285 (Fed. Cir. 2011). "To prevail on an inequitable conduct defense, a defendant must establish both the materiality of the withheld reference and the applicant's intent to deceive the PTO." *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324, 1334 (Fed. Cir. 2012).

Materiality

A prior art reference may constitute material information, even where the reference is not sufficient to invalidate the claim in district court, if the disclosure of the reference would have blocked the issuance of a patent under the PTO's evidentiary standards. *Aventis*, 675 F.3d at 1334 (quoting *Therasense*, 649 F.3d at 1292). Thus, prior art is but-for material information if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. *Therasense*, 649 F.3d at 1291. "[T]he standard for establishing but-for materiality in the inequitable conduct context only requires a preponderance of the evidence, 'giv[ing] claims their broadest reasonable construction.'" *Aventis*, 675 F.3d at 1334 (quoting *Therasense*, 649 F.3d at 1291–92).

Belcher does not challenge the district court's decision that the asserted claims are invalid as obvious based on, *inter alia*, JHP's epinephrine product, testing of which showed the product had a pH within the claimed range.[4] *See Belcher*, 450 F. Supp. 3d at 545; Appellant's Br. 30 ("Belcher does not appeal the obviousness finding."). Because that is the case, the product is "necessarily material to patentability." *Aventis*, 675 F.3d at 1334; *see also Therasense*, 649 F.3d at 1276 ("[I]f a claim is properly invalidated in district court based on the deliberately withheld reference, then that reference is necessarily material because a finding of invalidity in a district court requires

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[4] The district court also found inequitable conduct based on the withholding of Stepensky and Sintetica's prior epinephrine product. *Belcher*, 450 F. Supp. 3d at 550–51. We do not recount the entire factual analysis performed by the district court, *TransWeb, LLC v. 3M Innovative Properties Co.*, 812 F.3d 1295, 1304 (Fed. Cir. 2016), but focus our analysis only on those aspects that are key to our decision.

clear and convincing evidence, a higher evidentiary burden than that used in prosecution at the PTO.").

We further reject Belcher's argument that the withheld art, including the JHP product, is immaterial because it is "cumulative" of Helenek's disclosure of "epinephrine formulations with pH between 2.2 and 5.0, including epinephrine solutions with a pH range of 3.0 to 4.0." Appellant's Br. 54–55. Belcher's argument is directly at odds with its argument during prosecution that the claimed range was "critical," J.A. 1074, which is one way to circumvent obviousness when a claimed range overlaps with a range disclosed in the prior art, *see, e.g.*, *E.I. DuPont de Nemours & Co. v. Synvina C.V.*, 904 F.3d 996, 1008 (Fed. Cir. 2018) ("[W]here there is a range disclosed in the prior art, and the claimed invention falls within that range, the burden of production falls upon the patentee to come forward with evidence of teaching away, unexpected results or criticality, or other pertinent objective indicia indicating that the overlapping range would not have been obvious in light of that prior art." (internal citations and quotation marks omitted)). The examiner allowed the claims only after accepting Belcher's criticality argument. J.A. 1088. The trial record later established that the JHP product had a pH within the alleged critical range of 2.8 to 3.3. Belcher's alleged critical improvement over the prior art was therefore already within the public domain, just not before the examiner. As such, we see no clear error in the district court's determination that this information would have been but-for material to patentability.

Intent

"To satisfy the intent requirement, 'the accused infringer must prove by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.'" *Aventis*, 675 F.3d at 1334–35 (quoting *Therasense*, 649 F.3d at 1290). "[I]nequitable conduct requires clear and

convincing evidence of a specific intent to deceive the PTO and that 'the specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence.'" *Aventis*, 675 F.3d at 1335 (quoting *Therasense*, 649 F.3d at 1290) (citation and quotation marks omitted).

The district court explained that, although there was no direct evidence of deceptive intent, the evidence of record persuaded it "clearly and convincingly[] that this is the only reasonable inference that can be drawn." *Belcher*, 450 F. Supp. 3d at 550. The court specifically noted that Mr. Rubin was an active participant in the FDA approval process and understood that Belcher had stated to the FDA that the 2.8 to 3.3 pH range was an "old" range. *Id.* Mr. Rubin also understood that Belcher had reverted from its original pH range (2.4 to 2.6) to the 2.8 to 3.3 range because the latter range corresponded to the reference product made by Sintetica, and therefore using that range would expedite FDA approval. *Id.* When later drafting the patent application and through his communications with the PTO during prosecution, however, Mr. Rubin performed an about-face and emphatically and repeatedly advanced the position that the 2.8 to 3.3 pH range was a "critical" innovation contrary to the knowledge of a person of ordinary skill in the art that yielded "unexpected results," namely reducing racemization of l-epinephrine. However, the district court found that this argument was "false" and a "fiction" because Mr. Rubin knew about the prior art's teachings of that pH range. *Id.* at 549–50.

It is in this context that we consider Mr. Rubin's withholding of the prior art, including the JHP product, that disclosed the pH range of 2.8 to 3.3. Mr. Rubin claimed at trial that he withheld the references because he believed that they were irrelevant—even though they directly undercut the most important patentability argument—because they were different from the asserted claims in certain respects, including their high overages. *Id.* at 550.

Belcher adopts this argument on appeal and contends that Mr. Rubin withheld the references not because he had deceptive intent, but because he genuinely believed that the withheld products, including the JHP product, were irrelevant given their high overages. Appellant's Br. 61, 63. Belcher appears to argue that while Mr. Rubin was acting in a "self-serving manner in order to . . . maintain an existing patent," *id.* at 63–64 (quoting *Chen v. Bouchard*, 347 F.3d 1299, 1309 (Fed. Cir. 2003)), that behavior by itself is not enough to establish that he had a deceptive intent. According to Belcher, the record provides corroboration that his mental state was a genuine belief about the irrelevance of the references, rather than a desire to deceive the PTO. Appellant's Br. 63–64.

In *Aventis*, we rejected similar post hoc rationales for withholding material prior art. *See* 675 F.3d at 1335–37. There we found no clear error in the district court's finding of intent where it "did not rely solely on its finding that [the inventor] was not credible but instead viewed [his] testimony in light of the other evidence to reach its intent conclusion." *Id.* at 1336. The same is true here. The district court found Mr. Rubin's reasons for withholding the JHP product to be implausible and not credible. *Belcher*, 450 F. Supp. 3d at 549. But the district court also relied on other record evidence to support its intent finding, including Mr. Rubin's prior knowledge of the JHP product, his central role in both FDA approval and patent prosecution, and his arguments to the examiner about the "criticality" of the 2.8 to 3.3 pH range despite knowing that Sintetica's batches used the same range. *See id.* at 548–51. As in *Aventis*, we conclude that the district court did not clearly err in finding that the single most reasonable inference is that Mr. Rubin possessed the specific intent to deceive the PTO when withholding the JHP product.

CONCLUSION

We conclude that the district court did not clearly err in making its factual findings regarding materiality and intent, nor did it abuse its discretion in ultimately deciding that the '197 patent is unenforceable for inequitable conduct. We have considered Belcher's remaining arguments and find them unpersuasive. We therefore affirm.

AFFIRMED

COSTS

No costs.