NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

PAR PHARMACEUTICAL, INC., PAR STERILE PRODUCTS, LLC, ENDO PAR INNOVATION COMPANY, LLC,
Plaintiffs-Appellees

v.

HOSPIRA, INC.,
Defendant-Appellant

2020-1273

Appeal from the United States District Court for the District of Delaware in No. 1:17-cv-00944-JFB-SRF, Senior Judge Joseph F. Bataillon.

Decided: November 23, 2020

DANIEL BROWN, Latham & Watkins LLP, New York, NY, argued for plaintiffs-appellees. Also represented by JENNIFER KOH, San Diego, CA; GABRIEL BELL, Washington, DC.

THOMAS J. MELORO, Willkie Farr & Gallagher LLP, New York, NY, argued for defendant-appellant. Also

represented by DEVON WESLEY EDWARDS, MATTHEW S. FREIMUTH.

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

TARANTO, *Circuit Judge*.

The plaintiffs (collectively, Par) own and have exclusive rights to U.S. Patent Nos. 9,119,876 and 9,295,657, which claim particular compositions containing epinephrine, the active ingredient in Par's Adrenalin® products, as well as methods of administering such compositions to patients. In 2017, Hospira, Inc. filed an Abbreviated New Drug Application (ANDA) with the Food and Drug Administration, seeking permission to manufacture and market a generic version of Par's Adrenalin® epinephrine injection, 1 mg/mL, product. Par sued Hospira for patent infringement under 35 U.S.C. § 271(e), alleging that the ANDA was for a product, and use of a product, claimed in the '876 and '657 patents. As relevant on appeal, Hospira responded by disputing infringement on the ground that its ANDA product would not meet several limitations of the asserted claims. After a bench trial, the district court ruled for Par and against Hospira, finding that Hospira's ANDA was for a product that meets the disputed claim limitations. *Par Pharm., Inc. v. Hospira, Inc.*, 420 F. Supp. 3d 256 (D. Del. 2019) (*Par*). Hospira appeals the infringement determination. We affirm.

I

A

The '876 and '657 patents share a specification. The patents describe a "pharmaceutical composition comprising epinephrine," which is used for "emergency treatment of allergic reactions." '876 patent, col. 2, lines 57–59. Par's product, Adrenalin®, is an example of such a composition. *Id.*, col. 1, lines 30–39. Previous formulations of

epinephrine, the patent states, tended to have short shelf lives because epinephrine degrades by three different mechanisms (oxidation, racemization, and sulfonation), and scientists found it difficult to control degradation by one mechanism without exacerbating degradation by another. *Par*, 420 F. Supp. 3d at 262; J.A. 240–41; J.A. 530–38; '876 patent, col. 1, lines 51–67. A predecessor company of Par eventually developed an improved formulation of Adrenalin® that met FDA standards for stability and quality, and Par secured the '876 patent on the composition in September 2015, then the '657 patent on use of the composition in March 2016. *Par,* 420 F. Supp. 3d at 262; J.A. 4127–28.

The '876 and '657 patents each have only one independent claim. Claim 1 of the '876 patent recites:

> A composition comprising:
>
> > in the range of about 0.5 to 1.5 mg/mL of epinephrine and/or salts thereof,
> >
> > in the range of ***about 6 to 8 mg/mL of a tonicity regulating agent***,
> >
> > in the range of about 2.8 to 3.8 mg/mL of a pH raising agent,
> >
> > in the range of about 0.1 to 1.1 mg/mL of an antioxidant,
> >
> > in the range of ***about 0.001 to 0.010 mL/mL of a pH lowering agent***, and
> >
> > in the range of ***about 0.01 to 0.4 mg/mL of a transition metal complexing agent***,
> >
> > wherein the antioxidant comprises sodium bisulfite and/or sodium metabisulfite.

'876 patent, col. 28, lines 2–14 (emphases added). Claim 1 of the '657 patent claims "a method of treating a condition"

by "administering" a composition with the same components and same concentration ranges as those identified in claim 1 of the '876 patent. '657 patent, col. 28, lines 28–47. Although additional limitations appear in claim 1 of the '657 patent and in both patents' other asserted claims (each dependent on its patent's claim 1), the only limitations at issue in this court appear in claim 1 of the '876 patent—specifically, the limitations (emphasized above) that address (1) the tonicity regulating agent, (2) the transition metal complexing agent, and (3) the pH lowering agent.

Tonicity is the "effective osmotic pressure equivalent of a solution or composition." '876 patent, col. 8, lines 47–49. For living cells to maintain their physical integrity without shrinking or swelling, the osmotic pressure outside the cell must not exert too little (hypotonic) or too much (hypertonic) tension on the cells' walls. J.A. 542–44. A tonicity regulating agent ensures that fluid injected into the blood remains isotonic, *i.e.*, exerts the same pressure as human physiological fluid on the surrounding cells. J.A. 542–45.

A "transition metal complexing agent" reduces degradation of epinephrine through epinephrine's binding to transition metals (*e.g.*, copper and gold) in the formulation. Hospira identifies such transition metals as "elemental impurities." Hospira Op. Br. 18 n.6 ("Elemental impurities include transition metals that may be present in the composition."). Such a complexing agent can achieve that reduction by binding to the transition metals, making the bound molecules unavailable for binding to the epinephrine. J.A. 412–14. One type of transition metal complexing agent performing that function is a "chelating agent," which is an agent that forms "two or more separate coordinate bonds" with metal ions. '876 patent, col. 7, lines 11–14.

A "pH lowering agent," according to the parties' agreed-upon claim construction, is a "[c]omponent to lower the composition's pH." J.A. 76. Claim 1 requires not only a pH

lowering agent but also a pH raising agent, each within prescribed ranges. The patents state that "the pH raising agent" may include "a buffer system," which itself "may comprise . . . more than one agent, such as a weak acid and its conjugate base," *i.e.*, a combination of a lowering agent (acid) and a raising agent (base). '876 patent, col. 3, lines 44–50; *see also id.*, col. 8, lines 43–45 ("In certain embodiments, the pH lowering agent may be a portion of the buffer system in conjugation with a pH raising agent.").

B

In June 2017, Hospira notified Par that it had submitted an ANDA to the FDA for approval to "manufacture, use, [sell], offer [to sell], and/or [import]" a generic version of Adrenalin®. J.A. 4129. On July 13, 2017, Par filed a complaint for patent infringement against Hospira in the District of Delaware under 35 U.S.C. § 271(e)(2), which provides that it is "an act of infringement to submit" an ANDA if the ANDA is "for a drug claimed in a patent or the use of which is claimed in a patent." Par contended that Hospira's ANDA was "for" a product that comes within claim 1 of the '876 patent (and other claims of the '876 patent dependent on claim 1) and whose use comes within claim 1 of the '657 patent (and other claims of the '657 patent dependent on claim 1). J.A. 4033. Hospira denied that infringement allegation. *Par*, 420 F. Supp. 3d at 260, 264.[1]

During discovery, the parties submitted agreed-upon claim constructions, including one for the term "about," which appears in all the numerical-range claim limitations at issue. J.A. 76. They agreed that "about" should be construed as having its "plain and ordinary meaning, *i.e.*, approximately." *Id.* In a pretrial order, the district court

[1] Hospira also asserted invalidity, but the district court rejected that assertion, *Par*, 420 F. Supp. 3d at 279–80, and Hospira has not appealed that ruling.

stated that "[t]he extent of the term 'about' must be determined using a functional approach because 'it is impossible to "capture the essence" of the claimed invention in strict numeric terms.'" *Par Pharm., Inc. v. Hospira, Inc.*, No. 1:17-cv-944, 2019 WL 2571165, at *2 (D. Del. June 21, 2019) (quoting *Cohesive Techs., Inc. v. Waters Corp.*, 543 F.3d 1351, 1369–71 (Fed. Cir. 2008)). The court added that the proper scope of the concentration range encompassed by "about" "requires a factual inquiry as to the purpose of the limitation." *Id.*

We summarize the key trial evidence regarding literal infringement. Given our affirmance of the finding of literal infringement, we omit mention of the evidence regarding infringement under the doctrine of equivalents.

Regarding tonicity, Par's expert, Dr. Elder, testified at trial that "about 6 to 8 mg/mL of a tonicity regulating agent," as construed, would be understood in light of the stated purpose of the tonicity regulating agent—to maintain the integrity of living cells following the injection of epinephrine into the bloodstream. J.A. 158; *see also* '876 patent, col. 8, lines 46–53 (explaining that the tonicity regulating agent's purpose is to "maintain the tonicity of the composition in a physiological acceptable range"). He noted that sodium chloride is "the prefer[red] . . . tonicity regulating agent," '876 patent, col. 8, lines 58–59, and that Hospira's ANDA identifies sodium chloride in its product as included for "isotonicity," J.A. 1290. *See* J.A. 152, 158. He also noted that the ANDA identifies 9 mg/mL of sodium chloride as a component of the covered composition, J.A. 1290, and that Hospira's test batches contained sodium chloride in amounts as low as 8.55 mg/mL, *See* J.A. 152–53. Dr. Elder opined, on those facts, that Hospira's ANDA product would fall within the contemplated "physiologically acceptable" range and therefore literally infringe the claim limitation. J.A. 152–53, 155–58.

Dr. Pinal, Hospira's expert, did not dispute the facts about the role of sodium chloride or the amounts covered by Hospira's ANDA. Rather, he disagreed with Dr. Elder about whether the amounts came within the claimed "about" range. He opined that a relevant artisan would understand "about" to encompass only slight deviations from a specific target concentration, *e.g.*, due to measurement errors, and not to embrace the amounts covered by Hospira's ANDA. J.A. 553–56.

Regarding the transition metal complexing agent claim limitation, the evidence showed that Hospira's ANDA specifies a particular concentration of citric acid, a known chelating agent, J.A. 1290, and also states that the ANDA product's "elemental impurities" (which include transition metals, as noted *supra*) satisfy the requirements of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Humane Use (ICH) Q3D guidelines, J.A. 1043; ICH Guidelines, J.A. 2485. The referred-to ICH Q3D guidelines specify that (to avoid the need for additional controls) elemental impurities in drug products be less than 30% of the specified permitted daily exposure (PDE). J.A. 2496–97. In the table it presented to the FDA, Hospira represented that "[d]rug product testing is not required" because "[e]lemental impurity levels for potential elements tested were found to be consistently less than 30% of the . . . PDE." J.A. 1043 (cleaned up). Par's expert, Dr. Toste, explained that using the upper limit of potential metals for his calculations was appropriate "[b]ecause the ANDA says [Hospira] could have up to that amount [of transition metals] and still be able to sell [its product]." J.A. 483. Using the 30% figure, Dr. Toste calculated the amount of citric acid that would act as a transition metal complexing agent for that level of transition metals—an amount that comes within the claimed range of 0.01 to 0.4 mg/mL. J.A. 426–35.

Hospira's expert, Dr. Gokel, admitted that the ANDA product includes a specified concentration of citric acid, *see* J.A. 1290, and that citric acid has known chelating properties, allowing it to complex with transition metals. J.A. 741, 754–55. Dr. Gokel did not disagree with Dr. Toste's calculation of the amount of citric acid serving as a transition metal complexing agent if one used the 30% level for the calculation. But Dr. Gokel rejected the use of the upper limit of the ICH guidelines to calculate the amount of transition metal complexing agent in the ANDA product, testifying that the proper concentration of transition metals should be the amounts measured in test batches of Hospira's product. J.A. 763–65. Using the test batches, Dr. Gokel opined that the amount of citric acid that would serve as a transition metal complexing agent in the ANDA product would be far below the "about 0.01 to 0.4 mg/mL" claimed in Par's patents. J.A. 766.

Regarding the claim requirement of "about 0.001 to 0.010 mL/mL of a pH lowering agent," the trial evidence established that Hospira's ANDA covered a product containing a buffer system of citric acid and its conjugate base, sodium citrate, which together are considered the pH raising agent.[2] J.A. 591. And it is undisputed that citric acid, being an acid, itself is a pH lowering agent. *See*, *e.g.*, J.A. 406–07, 409, 693. Par's expert, Dr. Toste, identified the amount of citric acid covered by Hospira's ANDA, subtracted the amount that could serve as a complexing agent

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[2] The parties' agreed-upon claim constructions state that "pH raising agent" means a "[c]omponent to raise the composition's pH, which may comprise a buffer system," and a "buffer system" is a "[c]omponent present in a composition or solution, which may provide a resistance to significant change in pH caused by a strong acid or base; may comprise a single agent or more than one agent, such as a weak acid and its conjugate base." J.A. 76.

with transition metals, then concluded that the remaining citric acid would come within the claimed range for a pH lowering agent—even while those same citric-acid molecules would be part of the buffer system (citric acid combined with sodium citrate) that would serve as a pH raising agent. J.A. 449–53.

Dr. Pinal, testifying for Hospira, disagreed with counting the non-metal-complexing molecules of citric acid both as a pH lowering agent and as part of the pH raising agent. On that basis, he viewed only the hydrochloric acid in Hospira's ANDA product as a pH lowering agent. J.A. 590–91. It is undisputed that the hydrochloric acid in the ANDA product is below the low end of the range stated in the pH-lowering-agent claim limitation. Accordingly, Dr. Pinal opined, that limitation is not met. *Id.*

The district court resolved the foregoing issues in Par's favor. First, the court determined that the sodium chloride permitted by Hospira's ANDA comes within the claim limitation requiring "about 6 to 8 mg/mL" of a tonicity regulating agent. *Par*, 420 F. Supp. 3d at 277–78. (The court added that, in the alternative, the limitation is met under the doctrine of equivalents. *Id.* at 278.) Second, the court determined that the ANDA covered a product having citric acid that would serve as a transition metal complexing agent in an amount that comes within the claimed-required range. *Id.* Third, the court found that Hospira's ANDA covered a product having citric acid that served as a pH lowering agent in an amount that comes within the claim-required range. *Id.* at 277.

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

II

We review the district court's conclusions of law de novo and its findings of fact for clear error. Fed. R. Civ. P. 52(a)(6); *Vanda Pharm., Inc. v. West-Ward Pharm.*

International Ltd., 887 F.3d 1117, 1123 (Fed. Cir. 2018). Infringement in this context, *i.e.*, whether an ANDA is "for" a patent-claimed drug or a patent-claimed use of a drug under 35 U.S.C. § 271(e)(2), is an issue of fact whose resolution by the district court is reviewed for clear error. *Vanda*, 887 F.3d at 1125.

On appeal, Hospira argues that the district court committed clear error in finding that its ANDA product contains: (1) "about 6 to 8 mg/mL of a tonicity regulating agent"; (2) "about 0.01 to 0.4 mg/mL of a transition metal complexing agent"; and (3) "about 0.001 to 0.010 mL/mL of a pH lowering agent." We reject each argument.

A

Hospira first argues that its ANDA product would not come within the claim requirement of "about 6 to 8 mg/mL of a tonicity regulating agent" given that its ANDA specifies a target concentration of 9 mg/mL of sodium chloride. Hospira Op. Br. 34–50. The parties agreed in the district court that the term "about" had its "[p]lain and ordinary meaning; *i.e.*, approximately." J.A. 76. Hospira did not propose any further narrowing construction. On appeal, Hospira contends that the district court, in applying the plain-meaning construction to the ANDA, improperly departed from this court's decision in *Cohesive Techs. v. Water Corp.*, 543 F.3d 1351 (Fed. Cir. 2008), concerning an "about" term in a claim range. We disagree.

"When 'about' is used as part of a numeric range, 'the use of the word "about" avoids a strict numerical boundary to the specified parameter.'" *Cohesive*, 543 F.3d at 1368 (citing *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995)). The authorized extension beyond the stated numbers in the range is cabined to what "a person having ordinary skill in the art . . . would reasonably consider 'about . . .' to encompass." *Monsanto Tech. LLC v. E.I. DuPont de Nemours & Co.*, 878 F.3d 1336, 1342 (Fed. Cir. 2018). Where, as here, there is no narrowing claim

construction proposed based on particular intrinsic-evidence statements or actions, the general considerations set forth in *Cohesive* govern. The extension effected by "about" must be tied to "the purpose of the *limitation* in the claimed invention—not the purpose of the invention itself." *Id.* It also requires examination of whether the extension is by a "modest amount," *Conopco, Inc. v. May Dep't Stores Co.*, 46 F.3d 1556, 1562 (Fed. Cir. 1994), considering the "criticality of the [numerical limitation] to the invention," *Cohesive*, 543 F.3d at 1368 (quoting *Ortho-McNeil Pharm., Inc. v. Caraco Pharm. Labs., Ltd.*, 476 F.3d 1321, 1327 (Fed. Cir. 2007)) (alteration in original), as well as the "technologic and stylistic context" of the invention, *Pall*, 66 F.3d at 1217. Thus, in *Conopco*, we concluded that the ordinary and customary meaning of "about" could not extend the upper bound of "'about 40:1 to 1:1'" "as far as the prior art would allow" and could not reach as far as "162.9:1," given the criticality of the ratio and that such an interpretation would result in an impermissible "expansion" of the term "about," as opposed to a mere "stretch[]" by "a modest amount." 46 F.3d at 1560–62.

Although defining the outer reaches of "about" in a claimed range can be a matter of claim construction, "[w]hen the claims are applied to an accused device, it is a question of technologic fact whether the accused device meets a reasonable meaning of 'about' in the particular circumstances." *Modine Manufacturing Co. v. U.S. Int'l Trade Comm'n*, 75 F.3d 1545, 1554 (Fed. Cir. 1996), *abrogated on other grounds by Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 234 F.3d 558 (Fed. Cir. 2000), *rev'd*, 535 U.S. 722 (2002).

The district court's analysis is consistent with our precedents. The parties agreed that "about" should be construed to have its "plain and ordinary meaning" of "approximately," J.A. 76, with no further refinement as a claim-construction matter. The district court therefore properly focused on whether Hospira's ANDA product,

even the target 9 mg/mL sodium-chloride concentration, would come within the "about" range as a matter of fact. *See Par*, 420 F. Supp. 3d at 277; *see also Modine*, 75 F.3d at 1549. And the court reasonably concluded that it would: based on the analytic framework of *Cohesive*, the evidence supported a finding that "about 8" encompasses 9, considering the purpose of the upper limit.

The court credited Dr. Elder's testimony on this point, *Par*, 420 F. Supp. 3d at 264–66, 277, which focused on the technological facts, the importance of the purpose of the limitation, and the limitation's noncriticality. J.A. 155, 158, 162–63. Dr. Elder explained the purpose of both ends of the claim range—to avoid hypertonicity of the solution (which would lead to cell shrinkage) and to avoid hypotonicity of the solution (which would lead to cell swelling) and thereby achieve isotonicity, which is the stated goal of Hospira's inclusion of sodium chloride. J.A. 156–58. And he explained why it was clear that a "physiologically acceptable" concentration would include concentrations as high as 9 mg/mL, there being nothing critical to the exact numbers in the claimed range given the purposes of the upper and lower limits. J.A. 160–61. The district court reasonably accepted this evidence, noting that Hospira's Dr. Pinal "did not provide a meaningful analysis of the technologic context or the function of the claimed amount of tonicity regulating agent." *Par*, 420 F. Supp. 3d at 277. We thus find no clear error with the district court's finding, which "did not unduly interfere with the intended function of the claims, and did not eviscerate the plain meaning of the term 'about.'" *Conopco*, 46 F.3d at 1562.

Hospira contends that, years after the '876 and '657 patent issued, Par made statements suggesting that 8.5 mg/mL might be too high to be "about 6 to 8" in the course of prosecuting a continuation-in-part application that named a different inventor group, that had different claims, and that Par eventually abandoned. Hospira Op. Br. 41; J.A. 3958–59, 4008–09. We need not explore the

force that such statements might have had if Hospira had proposed a narrowing claim construction; Hospira did not do so. With the agreed-upon "plain and ordinary meaning" construction adopted, the remaining issue was what a relevant artisan would reasonably understand to come within "about 6 to 8 mg/mL" given the "modest amount" by which the range is expanded, *Conopco*, 46 F.3d at 1562, and the purposes and absence of criticality of the bounds of the range in the '876 and '657 patents. Hospira has cited no authority that would make Par's later statements, made in a different context, controlling over the evidence that the district court relied on here to find in Par's favor on this claim limitation.

B

Hospira next argues that the district court erred in accepting Par's testimony that Hospira's ANDA is for a product containing "about 0.01 to 0.4 mg/mL of a transition metal complexing agent." Hospira's argument is that the analysis should have focused entirely on the characteristics of the composition that Hospira was likely to sell, not on what compositions the ANDA, if approved, would allow Hospira to market. Hospira Op. Br. 51–60. We disagree.

As a threshold matter, the district court did not commit clear error in finding that citric acid acts as a transition metal complexing agent in Hospira's ANDA product. *See Par*, 420 F. Supp. 3d at 278. Hospira represented to the FDA that its citric acid buffer has a "chelating effect" allowing it to complex with transition metals. J.A. 4499. Hospira's experts acknowledged at trial that citric acid has "chelating properties" and therefore could bind with elemental impurities in its product. J.A. 376, 754–55. It is not necessary that Hospira intended the citric acid to function as a chelating agent if, as the district court could readily find, the citric acid actually does so. *Global-Tech Appliances, Inc. v. SEB S.A.*, 563 U.S. 754, 761 n.2 (2011)

(citing *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476, 484 (1964)).

The infringement statute for ANDAs states that submission of an ANDA is "an act of infringement" if the ANDA is "for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2). Applying that language, we have held that "[w]hat a generic asks for and receives approval to market, if within the scope of a valid claim, is an infringement." *Sunovion Pharm., Inc. v. Teva Pharm., USA, Inc.*, 731 F.3d 1271, 1279 (Fed. Cir. 2013); *id.* at 1278 ("[I]f a product that an ANDA applicant is asking the FDA to approve for sale falls within the scope of an issued patent, a judgment of infringement must necessarily ensue."). Even where internal documents suggest that a generic product will not meet a claim limitation in practice, representations about the ANDA's scope control the infringement analysis. *Id.* at 1279. That does not mean that the filing of an ANDA suffices to show that a generic product meets *any* claim limitation not excluded by the ANDA. *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562, 1569–70 (Fed. Cir. 1997). When an ANDA is silent with respect to a claim limitation, *Sunovion* does not govern; it is the product that the generic company is likely to sell that guides the infringement analysis. *Ferring B.V. v. Watson Labs., Inc.,-Fla.*, 764 F.3d 1382, 1387–88 (Fed. Cir. 2014).

Here, we conclude, *Sunovion* governs. Hospira's sole contention to the contrary is that the ANDA is silent about the presence of components that would establish whether the product meets the limitation requiring a defined amount of a transition metal complexing agent, *i.e.*, whether the ANDA sets an upper limit on such an agent. We reject Hospira's contention: Hospira's ANDA is not silent on the point. Whether or not the ANDA identifies a lower limit on the amount of a component that would meet the limitation, a point about which Hospira does not present any separate argument, the ANDA does identify an upper limit bearing directly on the limitation at issue.

It is not disputed before us that the amount of transition metal complexing agent is a simple function of the amount of elemental impurities in the form of transition metals in the composition. The ANDA states in a line entry in a table that its product satisfies the ICH Q3D guidelines, meaning that it can market and sell a product with up to 30% of the permitted daily exposure of transition metal impurities. J.A. 1043. That line entry was added by Hospira in response to an FDA request for "adequate information" showing that its ANDA product would comply with ICH Q3D. J.A. 4528 ¶ 8; *see also* J.A. 4545 (Hospira informed the FDA that its "specifications [were] updated" to demonstrate that its product met the required elemental impurity guidelines). These disclosures to the FDA are sufficient to support the district court's finding that "there are clearly metals" in Hospira's ANDA product and that the amount of transition metals can "vary," as Hospira's Dr. Gokel admitted, and is "not subject to control." *Par*, 420 F. Supp. 3d at 278; J.A. 166–67.

Thus, unlike in *Ferring*, the ANDA is not silent as to whether Hospira's product could contain sufficient concentrations of elemental impurities such that citric acid would complex with the transition metals in a high enough concentration to satisfy the limitation requiring "about 0.01 to 0.4 mg/mL of a transition metal complexing agent." *See Ferring*, 764 F.3d at 1387–88. *Sunovion* therefore applies. We reject Hospira's challenge regarding this claim limitation.

C

Finally, Hospira argues that the trial court erred in finding—without sufficient analysis—that its ANDA covers a product containing "about 0.001 to 0.010 mL/mL of a pH lowering agent." Specifically, Hospira argues that the trial court improperly accepted Par's counting not just hydrochloric acid but also citric acid as a pH lowering agent. Hospira contends that citric acid—specifically, the citric

acid that remains after subtracting the amount that serves as a transition metal complexing agent—cannot be a pH lowering agent because it is already included in the buffer system that counts toward meeting the claim limitation requiring a certain amount of pH raising agent. Hospira Op. Br. 60–63. We disagree.

Hospira has not made and preserved a claim-construction argument that, in these patents, an acid, *i.e.*, a pH lowering agent, cannot also be part of an agent that overall serves to raise pH. Indeed, the passages of the specification of the '876 and '657 patents that discuss a "buffer system" made up of an acid and a base, quoted *supra*, at least strongly suggest the opposite. Rather than disputing the suggestion, Hospira agreed to claim constructions based directly on the specification passages. *See* J.A. 76; note 2, *supra*. We therefore reject Hospira's argument that citric-acid molecules must be allocated between the pH raising agent limitation and the pH lower agent limitation. And with that argument rejected, there is no clear error in the district court's finding that Hospira's ANDA product would have a pH lowering agent (citric acid, after subtracting those molecules that bind to transition metals) in an amount that comes within the concentration range required by the claims. *Par*, 420 F. Supp. 3d at 270–71, 277–78.

III

The district court's judgment is affirmed.

Each party shall bear its own costs.

AFFIRMED