NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

BIOFER S.P.A.,
Plaintiff-Appellant

v.

VIFOR (INTERNATIONAL) AG,
Defendant-Appellee

2025-1005

Appeal from the United States District Court for the Eastern District of New York in No. 1:22-cv-02180-AMD-SJB, Judge Ann Donnelly.

Decided: September 3, 2026

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

SANYA SUKDUANG, Norton Rose Fulbright US LLP, Washington, DC, argued for defendant-appellee. Also represented by JONATHAN DAVIES, RACHEL PRESTON.

Before DYK, LINN, and REYNA, *Circuit Judges*.

Case 1:22-cv-02180-AMD-SJB Document 49-1 Filed 09/03/2026 Page 2 of 11 PageID #: 10729

REYNA, *Circuit Judge*.

Biofer S.p.A. appeals a judgment of non-infringement entered by the United States District Court for the Eastern District of New York. On appeal, Biofer challenges the claim construction on which the judgment rests. For the reasons stated below, we affirm.

BACKGROUND

On April 15, 2022, Biofer S.p.A. ("Biofer") sued Vifor (International) AG ("Vifor") in the United States District Court for the Eastern District of New York for infringing U.S. Patent No. 8,759,320 ("'320 patent").

The '320 patent, titled "Process for the Preparation of Trivalent Iron Complexes with Mono-, Di- and Polysaccharide Sugars," issued on June 24, 2014. J.A. 26. It discloses an improved process for making a complex of iron and sugar that can be used to treat iron deficiency in patients. J.A. 28, 1:6–18. The specification explains that because iron/sugar complexes are produced to be administered to patients, they must have fundamental characteristics, such as physical and chemical stability, low toxicity, and good bioavailability. J.A. 28, 1:24–31. It further explains that prior art manufacturing processes produce unstable or toxic iron/sugar complexes. J.A. 28, 1:19–23; *see generally* J.A. 29–30, 3:32–5:61.

To solve the problems in the prior art, the specification describes a four-step manufacturing process: (1) activation of a sugar, (2) complexation of the activated sugar with an iron compound, (3) purification of the iron/sugar complex, and (4) stabilization of the iron/sugar complex. J.A. 31, 8:54–67. This appeal concerns only the first step, which both parties refer to as the "activation" or "oxidation" step.

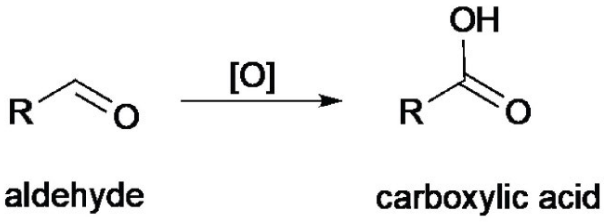
Case 1:22-cv-02180-AMD-SJB Document 49-1 Filed 09/03/2026 Page 3 of 11 PageID #: 10730

The parties agree that claim 1, reproduced below, is directed to this step.[1]

> 1. A process for the preparation of an activated sugar comprising the step of reacting a sugar having an aldehyde end group with bromine in a solution at a pH between 7.0 and 9.0 with the specific oxidation of the end aldehyde, wherein
>
> i) said sugar is selected from the group consisting of dextrins and dextrans and wherein
>
> ii) said bromine is produced in situ through the addition of a hypochlorite and an alkaline or earth alkaline metal bromide to said solution, said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups, wherein said hypochlorite is added instant by instant, such that an excess of hypochlorite in solution is never present.

J.A. 35, 16:44–56.

In the context of the '320 patent, oxidation or activation is a chemical reaction in which a specific part of a sugar molecule is transformed by adding an oxygen atom. Specifically, an aldehyde (–CHO) portion of a sugar is converted to a carboxylic acid (–COOH), as shown below:



[1] Although Biofer asserted other claims against Vifor, J.A. 1751, only claim 1 is subject to this appeal.

J.A. 377. Oxidation can occur by reacting a sugar with bromine in a solution, as recited in claim 1. Such oxidation can be controlled by adjusting the solution's pH. J.A. 31, 7:5–6.

The two sugars identified in claim 1, dextrin and dextran, are large molecules with multiple aldehyde sites where oxidation can occur. The specification explains that it is desirable to selectively oxidize only the aldehyde sites on the ends of these sugars. J.A. 30–31, 6:30–7:5. Oxidizing other aldehyde sites can cause the sugars to break down, which the patent refers to as the "depolimerization phenomena." J.A. 31, 7:14–18. To avoid this undesirable outcome, the specification explains "it is important to maintain the reaction pH in the range between 5.0 and 12.0, preferably, between 7.0 and 9.0." J.A. 31, 7:18–22.

On March 29, 2024, the district court issued a *Markman* order construing the phrase "pH between 7.0 and 9.0," recited in claim 1. The district court characterized the parties' claim construction dispute as "whether the claim encompasses only a process which occurs *entirely* at a pH between 7.0 and 9.0, or if the claim covers a process where the pH falls within that range at any time, even briefly." J.A. 14–15 (emphasis in original). It reasoned that "the intrinsic record supports that the pH range must be maintained throughout the process." J.A. 17. For instance, the district court relied on a passage in the specification, stating "[t]hroughout the activation reaction of the sugar, the pH value is *controlled and maintained in the fixed range,* preferably between 7.0 and 9.0." J.A. 16 (emphasis in original) (quoting J.A. 32, 9:24–27). It also noted that "*each* example which mentions the pH between 7.0 and 9.0 instructs that the pH is to be maintained during oxidation." *Id.* (emphasis in original). Thus, the district court construed "pH between 7.0 and 9.0" to mean that "pH is maintained in the interval separating 7.0 and 9.0." J.A. 6.

Case 1:22-cv-02180-AMD-SJB Document 49-1 Filed 09/03/2026 Page 5 of 11 PageID #: 10732

Biofer moved for clarification of the *Markman* order. Specifically, Biofer sought clarity on whether the district court's construction required that the pH must be maintained throughout the duration of the oxidation reaction. J.A. 1746–49. The district court denied the motion, explaining that the *Markman* order "speaks for itself" and "[t]here is no ambiguity and nothing to clarify." J.A. 4–5.

During discovery, Biofer's testing confirmed that Vifor's manufacturing process operates within the pH range of 7.0–9.0 for "approximately 90%" of the oxidation reaction. J.A. 1747 n.1. Based on this evidence, Biofer agreed to stipulate that Vifor's process does not infringe under the district court's claim construction. Appellant Br. 14 n.8. The parties filed a stipulation of non-infringement and requested entry of judgment in favor of Vifor. J.A. 1751–55. The stipulation noted that, under the *Markman* order, Biofer "cannot establish infringement of any of the [a]sserted [c]laims of the ['320 patent], specifically and solely because [Biofer] cannot establish that the pH is maintained throughout the process in the interval separating 7.0 and 9.0." J.A. 1752. It also explained that Biofer "intends to appeal" the district court's construction of "pH between 7.0 and 9.0." *Id.*

On August 30, 2024, the district court entered judgment of non-infringement in favor of Vifor. J.A. 1–3. Biofer timely appealed. We have jurisdiction under 28 U.S.C. § 1295(a)(1).

DISCUSSION

I

Biofer appeals the district court's construction of the term "pH between 7.0 and 9.0" found in claim 1.

We review a district court's ultimate interpretation of claim terms de novo. *Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 574 U.S. 318, 329 (2015). We review a district court's interpretation of intrinsic evidence de novo and its

Case 1:22-cv-02180-AMD-SJB Document 49-1 Filed 09/03/2026 Page 6 of 11 PageID #: 10733

subsidiary factual findings concerning extrinsic evidence for clear error. *Id.* at 331–33. Here, we review the district court's claim construction de novo, as the district court's construction was based solely on intrinsic evidence.

Claim terms are generally given their plain and ordinary meaning, which is the meaning that one of ordinary skill in the art would ascribe to a term when read in the context of the claims, specification, and prosecution history. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313–17 (Fed. Cir. 2005) (en banc). The specification is the "single best guide to the meaning of a disputed term." *Id.* at 1315 (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). "The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction." *Id.* at 1316 (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998)).

A

The dispute between the parties boils down to whether pH must be "maintained" within the recited range of 7.0 to 9.0 throughout the oxidation reaction described in claim 1.

Biofer's principal argument is that the meaning of the term "pH between 7.0 and 9.0" is "clear on its face and no special construction is otherwise compelled by the intrinsic evidence." Appellant Br. 22. Specifically, Biofer argues that the word "between" serves the role of a hyphen, "defining a range of values spanning the numerical endpoints," and does not impose "a functional requirement of *maintaining* the pH in the range of pH 7.0 to 9.0 *throughout* the oxidation reaction," as the district court concluded. Appellant Br. 24 (emphasis in original). Biofer argues that, to the extent a construction is necessary, the term should be construed to mean simply "pH range of between 7.0 and 9.0." Appellant Br. 20.

Case 1:22-cv-02180-AMD-SJB Document 161-1 Filed 09/03/2026 Page 7 of 11 PageID #: 10734

Vifor urges us to affirm the district court's construction—"pH is maintained in the interval separating 7.0 and 9.0." It argues that the language of claim 1 confirms it "refers to the entirety of the oxidation reaction, not some undefined or limited portion of the reaction," and that the specification and prosecution history describe, and even emphasize, the importance of maintaining pH between 7.0 and 9.0 during the oxidation step. Appellee Br. 30, 35.

B

We begin with the claim language. *Biagro W. Sales, Inc. v. Grow More, Inc.*, 423 F.3d 1296, 1302 (Fed. Cir. 2005) ("It is elementary that claim construction begins with, and remains focused on, the language of the claims."). Claim 1 recites a "process for the preparation of an activated sugar comprising *the step of reacting a sugar* having an aldehyde end group with bromine in a solution at a pH between 7.0 and 9.0." J.A. 35, 16:44–46 (emphasis added). Grammatically, the phrase "in a solution at a pH between 7.0 and 9.0" modifies "the step of reacting a sugar." The plain language of the claim makes clear that the recited pH range applies to "the step of reacting a sugar." There is no dispute that the "step" referred to here is the entire oxidation step of the four-step manufacturing process disclosed in the patent. The claimed pH range thus defines the solution's environment for the duration of the oxidation step.

The specification discloses that pH is "maintained" throughout the oxidation step. As noted above, the specification explains that to avoid undesirable depolymerization, "it is important to *maintain* the reaction pH in the range between 5.0 and 12.0, preferably, between 7.0 and 9.0." J.A. 31, 7:18–22 (emphasis added). The specification also discloses that, "[t]hroughout the activation reaction of the sugar, the pH value is controlled and *maintained* in the fixed range, preferably between 7.0 and 9.0, by adjusting the addition rate of the hypochlorite." J.A. 32, 9:24–27 (emphasis added). Further, the three examples in the

Case 1:22-cv-02180-AMD-SJB Document 49-1 Filed 09/03/2026 Page 8 of 11 PageID #: 10735

specification relating to the oxidation step of claim 1—Examples 5, 6, and 7—each describe the reaction while "*maintaining* the pH" value between 7.0 and 9.0. J.A. 34–35 (emphasis added). Where, as here, "a patent 'repeatedly and consistently' characterizes a claim term in a particular way, it is proper to construe the claim term in accordance with that characterization." *GPNE Corp. v. Apple Inc.*, 830 F.3d 1365, 1370 (Fed. Cir. 2016) (quoting *VirnetX, Inc. v. Cisco Sys., Inc.*, 767 F.3d 1308, 1318 (Fed. Cir. 2014)). The specification's repeated and consistent references to maintaining pH during the oxidation step suggest that the claim similarly carries this meaning.

The prosecution history also supports the district court's claim construction. During prosecution, Biofer submitted a declaration from one of the named inventors, Dr. Egidio Marchi, "to corroborate the criticality" of the claimed pH interval. J.A. 882. Dr. Marchi recreated the oxidation reaction described in Example 5 of the specification, which falls within the scope of claim 1. *Id.* Based on his experiments, he concluded that running the reaction while "maintaining the pH between 7.8 and 8.2" was highly selective without increasing depolymerization, while "maintaining the pH between 9.8 and 10.2" led to a depolymerizing attack on the sugar. *Id.*; J.A. 886–88. Relying on Dr. Marchi's declaration, Biofer explained that "outside the claimed range," the reaction "is not effective in preventing destructive attack" on the sugar. J.A. 883. The claims were allowed on this basis. J.A. 927. Thus, the prosecution history supports that to achieve selective oxidation, i.e., the recited "specific oxidation," and to accomplish one of the stated purposes of the invention, i.e., avoiding depolymerization, pH must be maintained between 7.0 and 9.0.

Biofer argues that the district court's construction improperly limits the claim to a preferred embodiment because, even if maintaining pH between 7.0 and 9.0 during the oxidation reaction is preferred, the specification explains that maintaining pH between 5.0 and 12.0 is

Case 1:22-cv-02180-AMD-SJB Document 49-1 Filed 05/08/26 Page 9 of 11 PageID #: 10736

suitable to avoid depolymerization. For this reason, Biofer contends that, "[i]t does not follow that the pH must be maintained within the preferred range of 7.0 and 9.0 to accomplish that goal." Appellant Br. 38.

"[W]hen the patent describes multiple embodiments, every claim does not need to cover every embodiment. This is particularly true when the plain language of a limitation of the claim does not appear to cover that embodiment." *Apple Inc. v. Andrea Elecs. Corp.*, 949 F.3d 697, 708 (Fed. Cir. 2020) (citation modified) (quoting *Pacing Techs., LLC v. Garmin Int'l, Inc.*, 778 F.3d 1021, 1026 (Fed. Cir. 2015)). Here, the specification discloses a wide pH range (5.0 to 12.0), including maintaining the pH within this wide range. *E.g.*, J.A. 31, 7:18–22 ("Therefore, it is important to maintain the reaction pH in the range between 5.0 and 12.0, preferably, between 7.0 and 9.0, since in this pH range the bromine consumption takes place at a high rate leading to the oxidation of the aldehyde end group."). Claim 1, however, recites only a narrower range (7.0 to 9.0). Thus, construing the claim to require maintaining that narrower range does not, contrary to Biofer's argument, improperly read in a preferred embodiment. *See Andrea*, 949 F.3d at 708.

At oral argument, counsel for Biofer argued that the correct construction is one that captures an oxidation reaction occurring primarily between a pH of 7.0 and 9.0 with "brief excursions" outside this range so long as the reaction achieves the recited "specific oxidation." Oral Arg. at 12:05–13:28.[2] Counsel, however, was unable to identify where Biofer advanced this argument to the district court. *Id.* at 28:18–31:00. In fact, Biofer presented the converse argument to the district court, arguing there that the

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[2] *Available at* https://www.cafc.uscourts.gov/05-08-2026-2025-1005-biofer-spa-v-vifor-international-ag-audio-uploaded/.

Case 1:22-cv-21805-JEM Document 161-1 Filed 09/26/23 Page 10 of 11 PageID #: 10737
Case: 25-1005 Document: 41 Page: 10 Filed: 09/03/2026

solution pH needs to hit the 7.0 to 9.0 range for merely a millisecond. J.A. 1931. As a result, this "brief excursions" argument is forfeited. *Conoco, Inc. v. Energy & Env't Int'l, L.C.*, 460 F.3d 1349, 1358–59 (Fed. Cir. 2006) ("[A] party may not introduce new claim construction arguments on appeal or alter the scope of the claim construction positions it took below.").

For these reasons, we agree with the district court that "pH between 7.0 and 9.0" is properly construed to mean "pH is maintained in the interval separating 7.0 and 9.0." Biofer concedes that, under this construction, Vifor does not infringe any asserted claim of the '320 patent. J.A. 1752. We therefore affirm the district court's judgment of non-infringement.

II

Biofer also argues that the district court erred in its construction of another term from claim 1: "said hypochlorite being added in stoichiometric quantities with respect to the aldehyde end groups." We conclude, however, that this issue is not properly before us.

The parties' stipulation and the subsequent judgment of non-infringement were not based on and did not implicate this claim term. J.A. 1–3; J.A. 1751–55. Under these circumstances, we decline to review the district court's construction of this term. *See AlterWAN, Inc. v. Amazon.com, Inc.*, 63 F.4th 18, 24 (Fed. Cir. 2023) (declining to consider claim construction dispute over "a term that [was] not included in the stipulation" because it was "not implicated by the district court's judgment").

CONCLUSION

We have considered Biofer's other arguments, and we do not find them persuasive. For these reasons, we affirm the district court's judgment of non-infringement of the '320 patent.

AFFIRMED

COSTS

Costs to Vifor.