

NOTE: This disposition is nonprecedential.

**United States Court of Appeals
for the Federal Circuit**

NESTLE USA, INC.,
Appellant

v.

STEUBEN FOODS, INC.,
Appellee

2016-1750

Appeal from the United States Patent and Trademark Office, Patent Trial and Appeal Board in No. IPR2014-01235.

Decided: May 9, 2017

THOMAS H. JENKINS, Finnegan, Henderson, Farabow, Garrett & Dunner, LLP, Washington, DC, argued for appellant. Also represented by TYLER MICHAEL AKAGI; VIRGINIA L. CARRON, KEVIN D. RODKEY, Atlanta, GA.

THOMAS FISHER, Oblon, McClelland, Maier & Neustadt, LLP, Alexandria, VA, argued for appellee. Also represented by SCOTT ANTHONY MCKEOWN; CHARLIE AVIGLIANO, W. COOK ALCIATI, Steuben Foods, Inc., Jamaica, NY.

Before REYNA, MAYER, and HUGHES, *Circuit Judges*.

HUGHES, *Circuit Judge*.

Nestle USA, Inc. appeals from a final decision of the Patent Trial and Appeal Board finding that claims 18–20 of U.S. Patent No. 6,945,013 were not obvious in view of certain prior art. Because the Board erroneously construed the term “aseptic,” we vacate the Board’s decision and remand for further proceedings.

I

Nestle petitioned the Patent Trial and Appeal Board for *inter partes* review (IPR) of claims 18–20 of U.S. Patent No. 6,945,013. The claims at issue cover “method[s] for automatically aseptically bottling aseptically sterilized foodstuffs,” where bottles are “aseptically disinfect[ed]” “at a rate greater than 100 bottles per minute,” and “aseptically fill[ed] . . . with aseptically sterilized foodstuffs.”

The Board instituted IPR and construed the term “aseptic,” as used in claims 18–20, to mean “aseptic to any applicable United States FDA standard, and in the absence of any such standard, aseptic assumes its ordinary meaning of free or freed from pathogenic microorganisms.” J.A. 14. Based on that construction, and in light of the prior art references, the Board concluded that an ordinarily skilled artisan would not have attained the invention claimed in claims 18–20 with a reasonable expectation of success. Nestle timely appealed, and we have jurisdiction under 28 U.S.C. § 1295(a)(4)(A).

II

On appeal, Nestle argues that the Board’s construction of “aseptic” is erroneous because it incorporates “any applicable United States FDA standard” rather than only

FDA regulations governing “aseptic packaging.” We agree.

“Pursuant to *Teva’s* framework and our review of Board determinations, we review the Board’s ultimate claim constructions de novo and its underlying factual determinations involving extrinsic evidence for substantial evidence.” *Microsoft Corp. v. Proxyconn, Inc.*, 789 F.3d 1292, 1297 (Fed. Cir. 2015). Where “the intrinsic record fully determines the proper construction,” our review is de novo. *Id.* In an IPR, the Board must construe terms according to their “broadest reasonable construction.” *Cuozzo Speed Techs., LLC v. Lee*, 136 S. Ct. 2131, 2144 (2016). Of course, “giving claims their broadest reasonable interpretation . . . does not include giving claims a legally incorrect interpretation.” *Proxyconn*, 789 F.3d at 1298 (quoting *In re Skvorecz*, 580 F.3d 1262, 1267 (Fed. Cir. 2009)) (alteration in original).

“Although words in a claim are generally given their ordinary and customary meaning, a patentee may choose to be his own lexicographer . . .” *Vitronics Corp. v. Conceptoronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). “When a patentee explicitly defines a claim term in the patent specification, the patentee’s definition controls.” *Martek Biosciences Corp. v. Nutrinova, Inc.*, 579 F.3d 1363, 1380 (Fed. Cir. 2009). Here, the specification twice defines the term “aseptic” as the United States “FDA level of aseptic.” ’013 patent col. 1 l. 67–col. 2 l. 2, col. 4 ll. 28–29. That is a binding lexicography, and therefore, we construe aseptic to mean the “FDA level of aseptic.”

The question then is the scope of the phrase “FDA level of aseptic.” *See Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 976 (Fed. Cir. 1995) (The purpose of claim construction is to “determin[e] the meaning and scope of the patent claims . . .”). According to Steuben Foods, “FDA level of aseptic” incorporates the full “panoply of FDA standards.” Appellee’s Br. at 39 n.2. Similar-

ly, the Board construed the phrase to incorporate “any applicable United States FDA standard.” J.A. 14. Both interpretations have the effect, according to their adherents, of requiring anything “aseptically” packaged to satisfy the regulatory requirement of 21 C.F.R. § 178.1005(d) that the final product have a hydrogen peroxide residue of less than 0.5 ppm.

We disagree. Where the patentee wished to claim embodiments requiring less than 0.5 ppm of hydrogen peroxide residue, it did so using express language. *See* ’013 patent col. 16 ll. 58–60 (“wherein a residual level of hydrogen peroxide is less than 0.5 PPM”). Moreover, the FDA’s hydrogen peroxide residue standard applies to *all* foodstuffs, regardless of whether they are aseptically packaged. Accordingly, the scope of “aseptic” cannot include regulations that apply to foods that are not aseptically packaged. Instead, we confine an “FDA level of aseptic” to FDA regulations related to aseptic packaging. This approach is supported by the specification’s explanation that the prior art systems failed to “provi[de] a high output aseptic filler that complies with the stringent United States FDA standards *for labeling a packaged product as ‘aseptic.’*” ’013 patent col. 1 ll. 64–67 (emphasis added).

Though the FDA does not define “aseptic” outright, at the time of the application, it defined “aseptic processing and packaging” as “the filling of a commercially sterilized cooled product into presterilized containers, followed by aseptic hermetical sealing, with a presterilized closure, in an atmosphere free of microorganisms.” 21 C.F.R. § 113.3(a) (1999). And “commercial sterility” was defined as “free of viable microorganisms having public health significance, as well as microorganisms of nonhealth significance, capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.” *Id.* § 113.3(e) (1999). These regulations are consistent with the specification, which itself describes

certain microorganism reduction features of the invention immediately after defining the term “aseptic.” *See* ’013 patent col. 4 ll. 29–33. We find that the FDA definitions recited above set forth a reasonable understanding of the term “aseptic” within the meaning of the ’013 patent.¹

Accordingly, we conclude that the Board’s construction of “aseptic” as incorporating “any applicable United States FDA standard” rather than only FDA regulations governing “aseptic packaging” was erroneous. Because the Board erred in its construction, we vacate the Board’s opinion and remand for further proceedings consistent with this opinion.

VACATED AND REMANDED

¹ We briefly note a separate infirmity with the Board’s approach. The Board created a two-step construction: first, purporting to apply lexicography, then using the plain and ordinary meaning as a default. But a claim term cannot mean different things simultaneously. A patentee cannot partially serve as a lexicographer for a claim term: either the specification includes a binding definition of that term by way of lexicography, or it is to be read consistent with the plain and ordinary meaning.