United States Court of Appeals for the Federal Circuit

2008-1459, -1476

MARTEK BIOSCIENCES CORPORATION,

Plaintiff-Cross Appellant,

v.

NUTRINOVA, INC.,
NUTRINOVA NUTRITION SPECIALTIES AND FOOD INGREDIENTS GMBH,
and LONZA, LTD.,

Defendants-Appellants.

Gregory A. Castanias, Jones Day, of Washington, DC, argued for plaintiff-cross appellant. With him on the brief were Gidon D. Stern, of New York, New York, and Samuel B. Abrams, Dechert LLP, of New York, New York.

George Pazuniak, Womble Carlyle Sandridge & Rice PLLC, of Wilmington, Delaware, argued for defendants-appellants. With him on the brief were Oleh V. Bilynsky, and Stephen J. MacKenzie.

Appealed from: United States District Court for the District of Delaware

Chief Judge Gregory M. Sleet

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Defendants-Appellants.

Appeals from the United States District Court for the District of Delaware in case no. 03-CV-896, Chief Judge Gregory M. Sleet.

DECIDED: September 3, 2009

Before NEWMAN, LOURIE, RADER, GAJARSA, and MOORE, Circuit Judges.

Opinion for the court filed by Circuit Judge GAJARSA, in which Circuit Judges NEWMAN and MOORE join. Opinion dissenting in part filed by Circuit Judge LOURIE, in which Circuit Judge RADER joins.

GAJARSA, Circuit Judge.

In this patent infringement action, Nutrinova, Inc.; Nutrinova Nutrition Specialties and Food Ingredients GmbH; and Lonza, Ltd. (collectively "Lonza") appeal from the final judgment of the United States District Court for the District of Delaware that Lonza infringed certain specified claims of Martek's U.S. Patent Nos. 5,340,594 ("the '594 patent") and 6,410,281 ("the '281 patent"). See Martek Biosciences Corp. v. Nutrinova

Inc., 520 F. Supp. 2d 537 (D. Del. 2007) ("Martek I"). Specifically, Lonza appeals the district court's denial of its motions for judgment as a matter of law ("JMOL") that the '594 patent claims are invalid and that Lonza does not infringe the '281 patent claims, the district court's exclusion of its prior inventorship evidence, and the district court's construction of the claim term "non-chloride sodium salt." Martek Biosciences Corp. ("Martek") cross appeals the district court's grant of Lonza's motion for JMOL that the asserted claims of Martek's U.S. Patent No. 6,451,567 ("the '567 patent") are invalid and the district court's construction of the claim term "animal" in Martek's U.S. Patent No. 5,698,244 ("the '244 patent"). As to the points of error argued by Lonza on appeal, we affirm. As to the points of error asserted by Martek on cross appeal, we reverse.

Background

I. The Technology and Patents

Docosahexaenoic acid ("DHA") is an essential omega-3 fatty acid that plays an important role in the development of organs such as the heart, brain, and eyes, and is reported to have many additional health benefits. Because the human body produces limited quantities of DHA, it is desirable to provide supplemental DHA.

Martek and Lonza make and sell DHA products. They obtain DHA by extracting lipids from fermented microorganisms—specifically certain microalgae. The patents at issue relate to specified microorganisms that are useful for the commercial production of DHA because they produce high levels of DHA. Three of the patents at issue are directed to "heterotrophic organisms and a process for culturing them for the production of lipids with high concentrations of omega-3 highly unsaturated fatty acids (HUFA) suitable for human and animal consumption as food additives or for use in

pharmaceutical and industrial products." '594 Patent col.1 ll.25–30; '281 Patent col.1 ll.38–43; '567 Patent col.1 ll.47–52. The '594 patent claims a food product that contains omega-3 and omega-6 HUFA produced by microorganisms of the genus Thraustochytrium, the genus Schizochytrium, or a mixture of microorganisms from both genera. '594 Patent col.36 l.67–col.38 l.26. The '281 patent claims methods for fermenting (i.e., growing) microorganisms, including those of the Thraustochytrium and Schizochytrium genera, using a medium containing a non-chloride sodium salt, which reduces corrosion in the fermentor during fermentation of the microorganisms. '281 Patent col.25 l.38–col.28 l.47. The '567 patent claims a process for producing lipids by extracting them from euryhaline microorganisms fermented under specified conditions. '567 Patent col.27 l.26–col.28 l.34. The '244 patent is directed to methods for increasing the concentration of omega-3 HUFA in animals by feeding them microorganisms of the order Thraustochytriales, which includes the Thraustochytrium and Schizochytrium genera, or lipids extracted from such microorganisms. '244 Patent col.1 ll.21–23, col.8 ll.15–17, col.9 l.44–col.10 l.58.

II. Proceedings before the District Court

Before the district court, Martek asserted that Lonza infringes the '594, '281, '597, and '244 patents. Lonza asserted defenses of invalidity under 35 U.S.C. §§ 102, 103, and 112. The district court held a Markman hearing to construe the contested claim terms. Based on the district court's claim constructions, Martek stipulated that Lonza does not infringe the '244 patent and preserved its right to appeal the court's construction of "animal." A jury trial followed. At trial, Martek argued that Lonza infringes claims 1, 3, and 7 of the '594 patent; claims 17, 31, 41, and 47 of the '281

patent; and claims 1, 4, 5, 7, 10, 11, and 14 of the '567 patent. Lonza argued that the asserted claims of the '567 and '594 patents are invalid—specifically arguing that the '567 and '594 patent claims are invalid as anticipated and the '567 patent claims are invalid for lack of enablement. The jury found the asserted claims infringed and not invalid. Moreover, the jury found that Lonza's infringement of the '281 patent claims was willful.[1]

Both parties filed post-trial motions. Lonza moved for JMOL that it does not infringe the '281 patent claims and that the '594 and '567 patent claims are invalid, and Martek moved for a permanent injunction. The district court granted Lonza's motion for JMOL that the '567 patent claims are invalid for lack of enablement and Martek's motion for a permanent injunction. Martek I, 520 F. Supp. 2d at 543, 558.

The parties timely appealed to this court. The district court had jurisdiction under 28 U.S.C. § 1338(a), and this court has jurisdiction over the appeals under 28 U.S.C. § 1295(a)(1).[2]

[1] More particularly, Martek asserted that two processes performed by Lonza infringe the '281 patent. The jury found that Lonza's "Process #1" literally infringes the '281 patent and that such infringement was willful. The jury found that Lonza's "Process #2" does not literally infringe the '281 patent but does infringe under the doctrine of equivalents. After trial, on Martek's motion, the district court held that Process #2 literally infringes the '281 patent as a matter of law. Martek I, 520 F. Supp. 2d at 547.

[2] We heard this appeal as a five-judge panel pursuant to our statutory authority under 28 U.S.C. § 46(b), which provides that the "Federal Circuit . . . may determine by rule the number of judges, not less than three, who constitute a panel." See also Fed. Cir. R. 47.2(a) ("Cases and controversies will be heard and determined by a panel consisting of an odd number of at least three judges, two of whom may be senior judges of the court.").

Discussion

On appeal, Lonza asserts that the district court erred by denying its motion for JMOL that the '594 patent claims are invalid as anticipated, by denying its motion for JMOL that it does not infringe the '281 patent claims, by excluding Lonza's evidence of prior invention by Dr. Long, and by construing the claim term "non-chloride sodium salt" to include sodium hydroxide (NaOH). On cross appeal, Martek argues that the district court erred by granting Lonza's motion for JMOL that the '567 patent claims are invalid for lack of enablement and by erroneously construing the claim term "animal" to exclude humans. We first address the issues raised by Lonza's appeal and then turn to the issues raised by Martek's cross appeal.

I. Validity of the '594 Patent Claims

Lonza moved for JMOL, asserting that the '594 patent claims are invalid as anticipated by WO 89/00606 and that substantial evidence does not support the jury's determination that WO 89/00606 is not prior art against the '594 patent. The district court denied Lonza's motion. Martek I, 520 F. Supp. 2d at 551–53.

Here, we exercise plenary review over the district court's ruling on a JMOL motion, applying the same standard as was applied by the district court. Agrizap, Inc. v. Woodstream Corp., 520 F.3d 1337, 1341–42 (Fed. Cir. 2008) (citing Gagliardo v. Connaught Labs., Inc., 311 F.3d 565, 568 (3d Cir. 2002)). If the evidence is such that a reasonable jury could find in favor of the non-movant, JMOL is inappropriate. See Fed. R. Civ. Proc. 50(a). We may not substitute our view of the evidence or our credibility determinations for those of the jury. See Agrizap, 520 F.3d at 1342.

The '594 patent is a member of a family of patents, each of which claims priority to an abandoned patent application filed in 1988, U.S. Ser. No. 07/241,410 ("the 1988 application"). "In order to gain the benefit of the filing date of an earlier application under 35 U.S.C. § 120, each application in the chain leading back to the earlier application must comply with the written description requirement of 35 U.S.C. § 112." Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1571 (Fed. Cir. 1997). "[T]he test for sufficiency of support in a parent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.'" Ralston Purina Co. v. Far-Mar-Co, Inc., 772 F.2d 1570, 1575 (Fed. Cir. 1985) (quoting In re Kaslow, 707 F.2d 1366, 1375 (Fed. Cir. 1983)). In other words, "the earlier application need not describe the claimed subject matter in precisely the same terms as found in the claims at issue." Tech. Licensing Corp. v. Videotek, Inc., 545 F.3d 1316, 1331 (Fed. Cir. 2008). Whether the written description requirement is met is a question of fact. Wang Labs., Inc. v. Toshiba Corp., 993 F.2d 858, 865 (Fed. Cir. 1993). Thus, we will uphold the jury's finding that the '594 patent claims are adequately described by the 1988 patent application so long as that finding is supported by substantial evidence in the record. See United States v. Coyle, 63 F.3d 1239, 1243 (3d Cir. 1995) (reviewing the jury's factual determination for substantial evidence).[3]

[3] Specifically, the jury determined that Lonza failed to prove by clear and convincing evidence that the '594 patent claims are not entitled to the benefit of the priority date of the 1988 patent application, which pre-dates the allegedly anticipating prior art offered by Lonza. Because the parties framed the relevant question regarding priority as whether the 1988 application meets the written description requirement for the '594 patent claims, which is a question of fact, we review the jury's priority verdict for substantial evidence.

Lonza argues that substantial evidence does not support the jury's finding that the '594 patent claims are entitled to the priority date of the 1988 application. The parties limit their arguments to independent claim 1 of the '594 patent. It reads:

> A food product, comprising:
>
> a) lipids extracted from a fermentation process for growing microorganisms selected from the group consisting of microorganisms of the genus Thraustochytrium, microorganisms of the genus Schizochytrium and mixtures thereof, wherein said microorganisms are capable of effectively producing lipids containing mixtures of omega-3 and omega-6 highly unsaturated fatty acids under conditions comprising:
>
> i) salinity levels less salinity levels found in seawater;
>
> ii) a temperature of at least about 15° C.; and
>
> b) food material.

'594 Patent col.36 l.67–col.37 l.13. Lonza argues that the 1988 application fails to provide the required written description for two limitations of that claim: (1) extracting lipids from a mixed culture of fermenting/growing Thraustochytrium and Schizochytrium cells and (2) combining the extracted lipids with a food material to make a food product. Because substantial evidence supports the jury's finding that the written description requirement is met, we hold the district court did not err in denying Lonza's JMOL motion.

A. The mixed culture limitation

Lonza argues that substantial evidence does not support the finding that the 1988 application discloses the process of extracting lipids from a mixed culture of fermenting Thraustochytrium and Schizochytrium microorganisms. We disagree. Dr. Wang, Martek's expert, explained how a person of ordinary skill in the art would recognize that disclosure in at least one passage in the 1988 application. That passage reads:

> The unicellular fungal strains isolated by the method described readily flocculate and settle, and this process can be enhanced by adjusting the pH of the culture to pH <7.0. A 6-fold concentration of the cells within 1-2 minutes can be facilitated by this process. The method can therefore be employed to preconcentrate the cells prior to harvesting, or to concentrate the cells to a very high density prior to nitrogen limitation. Nitrogen limitation (to induce higher lipid production) can therefore be carried out in a much smaller reactor, or the cells from several reactors consolidated into one reactor.

1988 Application at 23. First, Dr. Wang explained that the 1988 application discloses unicellular fungal strains of the Thraustochytrium and Schizochytrium genera as useful for practicing the invention. J.A. at 7635. Although the application discloses many strains for use in the claimed invention, Dr. Barclay, the inventor of the patents in suit, testified that almost all of the disclosed strains are of the Thraustochytrium or Schizochytrium genus. J.A. at 7470–71. Thus, Dr. Wang explained that the disclosed consolidation process, which is applicable to all "unicellular fungal strains isolated by the method described," 1988 Application at 23, describes the use of Thraustochytrium and Schizochytrium strains in that process. J.A. at 7637.

Second, Dr. Wang explained that the statement that "cells from several reactors [can be] consolidated into one reactor" describes the process of mixing strains of the Thraustochytrium and Schizochytrium genera. He explained that the quoted passage discloses the use of unicellular fungal "strains"—as in "more than one" strain—in the described consolidation process. Id. Moreover, Dr. Wang testified that the quoted passage, when considered in light of the entire application, discloses a process comprising the following steps: (1) different strains are independently grown under conditions optimized for each strain; (2) the cells from all strains are combined into one reactor; and (3) nitrogen limitation is employed to increase the omega-3 fatty acid content of the cells. Id. Thus, the text of the 1988 application, in light of Dr. Wang's

testimony, provides substantial evidence to support the finding that the application meets the written description requirement for the mixed culture limitation.

Lonza argues that the jury could not reasonably rely on Dr. Wang's interpretation of the text of the 1988 application. First, Lonza notes that the 1988 application contains no working examples that consolidate cells from different strains. However, a patent claim is not necessarily invalid for lack of written description just because it is broader than the specific examples disclosed. See Bilstad v. Wakalopulos, 386 F.3d 1116, 1123 (Fed. Cir. 2004) ("'We cannot agree with the broad proposition . . . that in every case where the description of the invention in the specification is narrower than that in the claim there has been a failure to fulfill the description requirement in section 112.'" (quoting In re Smythe, 480 F.2d 1376, 1382 (CCPA 1973))); In re Rasmussen, 650 F.2d 1212, 1215 (CCPA 1981) (explaining that, in the context of written description, the fact "that a claim may be broader than the specific embodiment disclosed in a specification is in itself of no moment"); see also Tex. Instruments, Inc. v. Int'l Trade Comm'n, 805 F.2d 1558, 1563 (Fed. Cir. 1986) ("This court has cautioned against limiting the claimed invention to preferred embodiments or specific examples in the specification.").

Second, Lonza criticizes Dr. Wang's testimony as "conclusory" and unsupported by the text of the 1988 application. Appellant's Br. at 27. We disagree. Dr. Wang provided more than a mere conclusion that the 1988 application discloses the claim limitations. He relied on specific statements in the 1988 application and explained how, in his opinion, a person of ordinary skill in the art would understand those statements. When the jury considered whether the 1988 application provides adequate written description support for claim 1, it was required to consider how an ordinarily skilled

artisan would understand the text of the application, see PowerOasis, Inc. v. T-Mobile USA, Inc., 522 F.3d 1299, 1306 (Fed. Cir. 2008); In re Wertheim, 541 F.2d 257, 262 (CCPA 1976), and the jury was entitled to credit Dr. Wang's opinion on that matter.

Finally, Lonza argues that Dr. Wang's testimony cannot support the jury's finding because the 1988 application teaches away from the requirement of claim 1 that cells of the Thraustochytrium and Schizochytrium genera be grown together, rather than simply mixed together after each strain is grown in a separate reactor. We disagree. Neither Dr. Wang's testimony nor the text of the 1988 application indicates that strains of the Thraustochytrium genus cannot be grown with strains of the Schizochytrium genus. The application's disclosure that Thraustochytrium strains respond more favorably to phosphate than Schizochytrium strains, see 1988 Application at 20, does not teach that Thraustochytrium strains could not or should not be grown together with Schizochytrium strains. Likewise, the fact that the working examples disclose different preferred growth conditions for Thraustochytrium cells as compared to Schizochytrium cells, see id. at 31–34, does not teach away from growing strains of the two genera together. In fact, the application describes growth conditions generally suitable for all disclosed strains, rather than specifically useful for any particular strain, see id. at 19–21, thus indicating that the disclosed strains share growth attributes and may be cultured together. Moreover, the jury could reasonably conclude that the portion of the 1988 application relied upon by Dr. Wang discloses a mixed culture of growing Thraustochytrium and Schizochytrium cells because neither Dr. Wang's testimony nor the application itself indicates that the growth process is completed prior to consolidation of the strains. See id. at 23; J.A. at 7637.

Because substantial evidence supports the jury's finding that the 1988 application adequately describes the mixed culture limitation of claim 1, the district court did not err in denying JMOL.

B. The food product limitation

Regarding the food product limitation of claim 1, we also hold that substantial evidence supports the jury's finding that the 1988 application adequately describes combining extracted lipids with a food material. The application discloses that "[t]he cells can also be broken or lysed and the lipids extracted into vegetable or other edible oil." 1988 Application at 24. Dr. Wang explained that vegetable and edible oils are understood to be "food materials," and thus, the 1988 application discloses combining the extracted lipids with food materials, as recited in claim 1. J.A. at 7634–35. Moreover, the 1988 application discloses "the production of lipids with high concentrations of omega-3 highly unsaturated fatty acids suitable for human and animal consumption as food additives." 1988 Application at 1 (emphasis added); see also id. at 6 (discussing the use of "omega-3 highly unsaturated fatty acids as a food additive"). Thus, the text of the 1988 application, in light of Dr. Wang's testimony, provides substantial evidentiary support for the jury's finding that the 1988 application meets the written description requirement for the claimed food product comprising extracted lipids and food material.

For the foregoing reasons, substantial evidence supports the jury's finding that the '594 patent claims are entitled to the priority date of the 1988 application. Thus, the district court did not err when it denied Lonza's JMOL motion.

II. Infringement of the ’281 Patent Claims

All of the ’281 patent claims recite the following functional limitation: “the culture medium containing the non-chloride sodium salt as the primary source of sodium results in reduced fermentor corrosion compared to the culture medium containing sodium chloride as the primary source of sodium.” ’281 Patent col.25 l.48–col.28 l.45. The trial court construed that limitation to mean “the culture medium causes less chemical wearing of the vessel in which the microorganisms are grown as compared to the level of chemical wearing away to a vessel caused by a culture medium comprising sodium chloride as the primary source of sodium.” Order Construing the Terms of U.S. Patent Nos. 5,340,594; 5,698,244; 6,410,567; 6,451,456; and 6,607,900 at 2, Martek Biosciences Corp. v. Nutrinova, Inc., No. 03-896 (D. Del. Dec. 12, 2005) (“Claim Construction Order”). Lonza moved for JMOL, asserting that Martek failed to prove infringement as a matter of law by failing to conduct comparative testing to demonstrate that Lonza’s culture medium causes less chemical wear as compared to a culture medium containing sodium chloride (NaCl) as the primary source of sodium. Because substantial evidence supports the jury’s infringement verdict, we hold the district court did not err when it denied Lonza’s motion.

A patentee may prove infringement by “any method of analysis that is probative of the fact of infringement,” Forest Labs. v. Abbott Labs., 239 F.3d 1305, 1312 (Fed. Cir. 2001), and circumstantial evidence may be sufficient, Liquid Dynamics Corp. v. Vaughan Co., Inc., 449 F.3d 1209, 1219 (Fed. Cir. 2006). To demonstrate that Lonza’s accused process meets the functional claim limitation, Martek presented testimony from two experts, each of whom concluded that Lonza’s culture medium—which contains

NaOH as the primary sodium source—causes less corrosion as compared to the hypothetical culture medium—which contains NaCl as the primary sodium source. Dr. Duquette, an expert in the field of corrosion, testified that Lonza's process uses fermentors made of 304-type stainless steel, which is highly susceptible to corrosion. J.A. at 7681. Second, he explained that he need not conduct actual tests in order to conclude that Lonza's culture medium causes less fermentor corrosion than the hypothetical medium because "the literature is quite clear" regarding the corrosive effects of chlorides on stainless steels. J.A. at 7680. Moreover, Dr. Duquette explained: "And it's just not a rule of thumb, it's a scientific fact that if you increase the chloride concentrations in any aqueous medium as far as stainless steel is concerned, you will cause more corrosion . . . ." J.A. at 7688.

Dr. Wang, Martek's fermentation science expert, also testified that Lonza's process causes reduced corrosion as compared to the hypothetical medium. J.A. at 7306. He reviewed Lonza's fermentation records and testified that he had calculated the concentration of chloride ions present in Lonza's culture medium as compared to the concentration of chloride ions present in the hypothetical medium. J.A. at 7305–06. He concluded that Lonza's culture medium contains about one-third of the chloride ions as the hypothetical medium. J.A. at 7306. Dr. Wang then explained that decreasing the chloride content of the medium will cause less corrosion on 304-type stainless steel and thus concluded that Lonza's culture medium would be less corrosive than the hypothetical medium. Id. Based on the testimony of Drs. Duquette and Wang, the jury could have reasonably concluded that Lonza's culture medium causes less chemical

wear as compared to a culture medium containing NaCl as the primary source of sodium.

Our decision in Kim v. ConAgra Foods, Inc., 465 F.3d 1312 (Fed. Cir. 2006), is not to the contrary. In that case, this court considered whether the district court correctly granted JMOL of noninfringement of a "consisting essentially of" product claim when the patentee failed to present "any examinations or tests of the actual accused products." Kim, 465 F.3d at 1320. Although the accused products contained all claimed ingredients in the claimed amounts, id. at 1319, we explained that because the claim at issue is a "consisting essentially of" claim, it is not infringed as a matter of law if the accused products contain "additional, unclaimed ingredients that materially affect the basic and novel properties of the invention." Id. at 1319–20 (citing PPG Indus. v. Guardian Indus. Corp., 156 F.3d 1351, 1354 (Fed. Cir. 1998)). Kim, a food chemist who qualified as an expert, testified that the accused products necessarily infringe because they include the same ingredients as her patented composition. Id. at 1320. ConAgra's expert disagreed, testifying that the accused products do not infringe because they contain additional ingredients that affect functionality. Id. The jury found for Kim, but we held that Kim's testimony was insufficient to support the infringement verdict because it was merely "conclusory testimony that the additional ingredients would not have materially affected the pertinent characteristics of the bread" and "did not support this determination with any examinations or tests of the actual accused products." Id. Thus, we held the district court did not err by granting JMOL of noninfringement because Kim "presented no testimony based on the accused products themselves that supported a finding of infringement." Id.

The present case is unlike Kim. Martek did not rely on conclusory expert testimony to demonstrate that Lonza's medium reduces corrosion. As detailed above, Martek presented testimony from two experts, each of whom conceptually analyzed the accused process and testified that it must meet the functional claim limitation based on the composition of Lonza's culture medium and the known effects of chloride concentration on stainless steel corrosion. Contrary to Lonza's reading of Kim, we did not articulate a general rule requiring one who alleges infringement of a claim containing functional limitations to perform actual tests or experiments on the accused product or method. Instead, we stated only that "Kim did not prove infringement because she presented no testimony based on the accused products themselves that supported a finding of infringement." Id. Here, Martek presented expert testimony based on the accused process that supports a finding of infringement.

Because Martek presented substantial evidence supporting the jury's infringement verdict, the district court did not err when it denied Lonza's JMOL motion.

III. Exclusion of Lonza's Prior Inventorship Evidence

The Patent Act provides that "[a] person shall be entitled to a patent unless . . . before such person's invention thereof, the invention was made in this country by another inventor who had not abandoned, suppressed, or concealed it." 35 U.S.C. § 102(g)(2). Lonza argues that the district court improperly excluded its evidence that the claimed invention is not patent eligible because it was previously made by another inventor, Dr. Long. Because Lonza sought to introduce the testimony of an alleged prior inventor under § 102(g) for the purpose of invalidating a patent, Lonza was required to produce evidence corroborating Dr. Long's testimony. See

Finnigan Corp. v. Int'l Trade Comm'n, 180 F.3d 1354, 1367 (Fed. Cir. 1999) ("'[T]he case law is unequivocal that an inventor's testimony respecting [the] facts surrounding a claim of derivation or priority of invention cannot, standing alone, rise to the level of clear and convincing proof.'" (quoting Price v. Symsek, 988 F.2d 1187, 1194 (Fed. Cir. 1993))); see also id. at 1369 ("[C]orroboration is required of any witness whose testimony alone is asserted to invalidate a patent, regardless of his or her level of interest.").

We review evidentiary rulings under regional circuit law, except to the extent that such rulings implicate substantive patent law. ATD Corp. v. Lydall, Inc., 159 F.3d 534, 548 (Fed. Cir. 1998). Here, we review the district court's pretrial evidentiary ruling for abuse of discretion. See Glass v. Phila. Elec. Co., 34 F.3d 188, 191 (3d Cir. 1994). "An abuse of discretion arises when 'the district court's decision rests upon a clearly erroneous finding of fact, an errant conclusion of law[,] or an improper application of law to fact.'" NLRB v. Frazier, 966 F.2d 812, 815 (3d Cir. 1992) (quoting Int'l Union, UAW v. Mack Trucks, Inc., 820 F.2d 91, 95 (3d Cir. 1987)). When determining whether an alleged inventor's testimony is sufficiently corroborated, we apply a rule-of-reason analysis and consider all pertinent evidence. Sandt Tech., Ltd. v. Resco Metal & Plastics Corp., 264 F.3d 1344, 1350 (Fed. Cir. 2001). The purpose of this corroboration requirement is to prevent fraud, namely to "provide[] an additional safeguard against courts being deceived by inventors who may be tempted to mischaracterize the events of the past through their testimony." Medichem, S.A. v. Rolabo, S.L., 437 F.3d 1157, 1170 (Fed. Cir. 2006). We note that Lonza "faces a particularly high hurdle in attempting to demonstrate abuse of discretion in light of the stringent standard for

corroboration." See Tex. Digital Sys. v. Telegenix, Inc., 308 F.3d 1193, 1218 (Fed. Cir. 2002).[4]

To corroborate Dr. Long's testimony that he had reduced the claimed invention to practice prior to Martek's date of invention, Lonza offered: (1) Dr. Long's 1987 abandoned patent application and (2) evidence that the examples originally disclosed in that abandoned application were later reproduced, generating the results described in the application. On Martek's pretrial motion, the district court excluded Lonza's proffered evidence based on its determination that the evidence could not sufficiently corroborate Dr. Long's testimony. J.A. at 7220. We hold that was not an abuse of discretion.

The district court did not err when it determined that the proffered abandoned patent application was insufficient to corroborate Dr. Long's testimony. An alleged prior inventor "must provide independent corroborating evidence in addition to his own statements and documents," Hahn v. Wong, 892 F.2d 1028, 1032 (Fed. Cir. 1989), such as "'testimony of a witness, other than [the] inventor, to the actual reduction to practice

[4] In Texas Digital, we were considering whether the district court abused its discretion when it excluded witness testimony regarding a prior use based on its determination that the testimony could not be sufficiently corroborated. Although the witness testimony at issue in the present case regards prior invention, as opposed to prior use, the principles articulated in Texas Digital and related cases remain relevant to our analysis because the corroboration requirement applies whether the witness claims to be a prior inventor under § 102(g) or a prior user under § 102(a) or § 102(b). See Finnigan Corp., 180 F.3d at 1367 ("[T]he case law is unequivocal that an inventor's testimony respecting facts surrounding a claim of derivation or priority of invention cannot, standing alone, rise to the level of clear and convincing proof. No principled reason appears for applying a different rule when other subsections of § 102 are implicated: a witness's uncorroborated testimony is equally suspect as clear and convincing evidence if he testifies concerning the use of the invention in public before invention by the patentee (§ 102(a)), use of the invention in public one year before the patentee filed his patent (§ 102(b)), or invention before the patentee (§ 102(g))." (internal quotation marks and citation omitted)).

or . . . evidence of surrounding facts and circumstances independent of information received from the inventor,'" id. at 1032–33 (quoting Reese v. Hurst, 661 F.2d 1222, 1225 (CCPA 1981). "Documentary or physical evidence that is made contemporaneously with the inventive process provides the most reliable proof that the inventor's testimony has been corroborated." Sandt Tech., 264 F.3d at 1350–51. Such contemporaneous documentary evidence could include an abandoned patent application. However, while an abandoned patent application is evidence of conception, it is insufficient to corroborate testimony that an alleged prior inventor reduced the invention to practice. See Tex. Digital, 308 F.3d at 1218 (holding the district court did not abuse its discretion when it excluded testimony of a prior public use because an unissued patent application was the only evidence of events prior to or contemporaneous with invention); In re Schlittler, 234 F.2d 882, 885 (CCPA 1956), overruled on other grounds by In re Borst, 342 F.2d 851, 854 (CCPA 1965) (stating that abandoned applications may be "evidence of conception" but "furnish no evidence that the processes or things they describe were ever made or used anywhere" (citation omitted)); see also Singh v. Brake, 222 F.3d 1362, 1370 (Fed. Cir. 2000) ("[T]o corroborate a reduction to practice, [we apply] a more stringent standard than that required to corroborate a conception. Indeed, a notebook page may well show that the inventor conceived what he wrote on the page, whereas it may not show that the experiments were actually performed, as required for a reduction to practice." (citation omitted)); In re Costello, 717 F.2d 1346, 1350 (Fed. Cir. 1983) ("[A]n abandoned application, with which no subsequent application was copending, cannot be considered a constructive reduction to practice. It is inoperative for any purpose, save as evidence

of conception."). Thus, the district court correctly determined that the 1988 application could not sufficiently corroborate Dr. Long's testimony as a matter of law.

Nonetheless, Lonza argues that an abandoned patent application may be sufficient to corroborate an alleged prior inventor's testimony under the law as articulated in Sandt Technology and Smith v. Hall, 301 U.S. 216 (1937). We disagree with Lonza's reading of the case law. In the cases cited, the corroborating evidence that was found to be sufficient was far more extensive than what Lonza has offered. In each case, an abandoned patent application was offered in addition to other evidence from a time prior to or contemporaneous with the alleged invention. In Sandt Technology, four pieces of evidence were offered to corroborate the alleged inventor's testimony, including "other contemporaneous documents [i.e., other than the abandoned patent application] to document the inventor's testimony," statements from an uninterested witness, and "a great deal of physical evidence made contemporaneously with [the] invention." 264 F.3d at 1351–52. In Smith, the alleged prior user's testimony was "abundantly corroborated by disinterested witnesses and contemporary photographs and publications describing it." 301 U.S. at 228. Lonza cites to no case, and we have identified no case, in which an abandoned patent application alone was deemed sufficient to meet the corroboration requirement. The only additional evidence offered by Lonza is a post hoc replication of experiments cited in the abandoned application, which does not qualify as evidence from a time prior to or contemporaneous with the alleged prior invention. Thus, we find Lonza's argument that it complied with the corroboration requirement as articulated in Sandt Technology and Smith unpersuasive.

For the foregoing reasons, we hold the district court did not abuse its discretion when it determined that Lonza could not corroborate Dr. Long's testimony and thus excluded Lonza's evidence of prior inventorship. See Tex. Digital, 308 F.3d at 1218 (holding the district court did not abuse its discretion by excluding an alleged prior user's testimony for lack of corroboration when the only contemporaneous corroborating evidence offered was an unissued patent application).

IV. Claim Construction of "Non-Chloride Sodium Salt"

Finally, Lonza also argues that the district court misconstrued the claim term "non-chloride sodium salt," as used in the '281 patent, by allowing that term to encompass sodium hydroxide (NaOH). We review assertions that the district court legally erred in construing a claim term de novo. Cybor Corp. v. FAS Techs., Inc., 138 F.3d 1448, 1456 (Fed. Cir. 1998) (en banc).

Because the district court's claim construction comports with the intrinsic and extrinsic evidence of record in this case, we affirm. First, although the '281 patent specification does not discuss NaOH, the prosecution history explicitly states that NaOH is a non-chloride sodium salt, J.A. at 4329—a clear indication that the applicant used the term "non-chloride sodium salt" in a manner broad enough to encompass NaOH. Moreover, Martek presented extrinsic evidence to support its position. Specifically, Martek produced two treatises, each of which teaches that NaOH can be considered a salt. See Charles W. Keenan & Jesse H. Wood, General College Chemistry 121–22 (4th ed. 1971); Wesley E. Lingren, Inorganic Nomenclature: A Programmed Approach 114 (1980). In contrast, Lonza cites no evidence that NaOH cannot be considered a salt. Although Lonza argues in its opening brief that NaOH cannot be considered a salt

because it is a base, Appellant's Br. at 44, Lonza concedes in its reply brief that we need not decide whether NaOH is technically a salt. Specifically, Lonza states:

> Whether NaOH is . . . technically a 'salt' and whether the reaction product of sodium and water can be considered a reaction of a sodium base and a non-chloride acid are difficult scientific questions that need not be considered, because the intrinsic record clearly excludes NaOH from the scope of the claims. . . . [T]he critical issue is that the prosecution history demonstrates that NaOH was excluded from the claims.

Appellant's Reply Br. at 23–24.

Thus, Lonza's primary argument on appeal is that Martek disclaimed coverage of NaOH during prosecution of the application that issued as the '281 patent. That argument fails. To support its assertion, Lonza cites selected statements spanning two pages of the prosecution history. Although the selected statements arguably support Lonza's assertion, those statements are undercut considerably by additional statements recited in the same two pages of prosecution history relied upon by Lonza: (1) the applicant's explicit statement that NaOH is a non-chloride sodium salt, and (2) the applicant's statements distinguishing the prior art at issue from the claimed invention on alternative grounds unrelated to the way NaOH was used in the prior art reference. Thus, under this court's precedent, Martek committed no clear and unmistakable disavowal of claim scope. See, e.g., Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1325–26 (Fed. Cir. 2003) ("[F]or prosecution disclaimer to attach, our precedent requires that the alleged disavowing actions or statements made during prosecution be both clear and unmistakable."); Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1252 (Fed. Cir. 2000) ("In determining whether there has been a clear and unmistakable surrender of subject matter, the prosecution history must be examined as a whole.").

For these reasons, we uphold the district court's claim construction.

V. Validity of the '567 Patent Claims

Martek appeals the district court's grant of JMOL that all asserted claims of the '567 patent are invalid for lack of enablement. See Martek I, 520 F. Supp. 2d at 556–58. Martek asserts that the district court erred by considering only the limitations of independent claim 1 and failing to specifically address the additional limitations of dependent claims 4 and 5. Martek asserts that the evidence of record supports the jury's verdict that claims 4 and 5 are enabled and that JMOL was thus inappropriate as to those claims. We agree.

Claim 1 of the '567 patent is directed to a process for extracting lipids from euryhaline organisms having specified properties. Claim 1 reads:

> A process for producing lipids comprising: (a) growing euryhaline microorganisms in a fermentation medium, wherein said euryhaline microorganisms are capable of producing about 1.08 grams per liter of the fermentation medium per day of long chain omega-3 fatty acids per 40 grams of sugar per liter of the fermentation medium at a sodium ion concentration in the fermentation medium of 60% seawater; and (b) extracting lipids from said euryhaline microorganisms.

'567 Patent col.27 ll.28–37. Claims 4 and 5 are dependent on claim 1, with each claim encompassing all limitations of claim 1 plus one additional limitation. Claim 4 additionally requires that the "euryhaline microorganisms are microorganisms of the order Thraustochytriales." Id. at col.28 ll.7–9. Claim 5 additionally requires that the "euryhaline microorganisms are selected from the group consisting of Thraustochytrium, Schizochytrium, and mixtures thereof." Id. at col.28 ll.10–12.

Each issued patent claim is presumptively valid. 35 U.S.C. § 282. Here, Lonza had the burden to prove by clear and convincing evidence that each asserted claim of the '567 patent is invalid. See Ethicon, Inc. v. Quigg, 849 F.2d 1422, 1427 (Fed. Cir.

1988). To meet the enablement requirement, "the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993) (internal quotation marks omitted). "Whether undue experimentation is needed is not a single, simple factual determination, but rather is a conclusion reached by weighing many factual considerations." In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). As we have explained:

> Factors to be considered in determining whether a disclosure would require undue experimentation . . . include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

Id. "Enablement is a matter of law that we review without deference; however, this Court reviews the factual underpinnings of enablement for substantial evidence." Koito Mfg. Co. v. Turn-Key-Tech, LLC, 381 F.3d 1142, 1149 (Fed. Cir. 2004). Regarding claims 4 and 5 of the '567 patent, the evidence of record supports the jury's implicit factual findings and ultimate verdict. Thus, we reverse the district court's grant of JMOL as to those claims.

In overturning the jury's enablement verdict, the district court focused exclusively on element (a) of claim 1, which is directed to growing euryhaline organisms that have stated characteristics. See Martek I, 520 F. Supp. 2d at 556–58. The district court relied primarily on the testimony of Dr. Ward, Lonza's expert, who similarly considered only element (a) of claim 1. J.A. at 7314–16. Dr. Ward testified that claim 1 potentially covers very many—perhaps 10,000—euryhaline organisms, while the patent discloses only one such organism in a working example. J.A. at 7615. Dr. Ward also stated that

the technology at issue here "involves a lot of unpredictability." J.A. at 7616. When asked to estimate "the quantity of experimentation that would be required to find a euryhaline microorganism that would meet the claim limitations of Claim 1," Dr. Ward replied, "an enormous amount of research." J.A. at 7615. Based on Dr. Ward's testimony, and in light of the fact that Martek presented no contradictory testimony, the district court granted Lonza's motion for JMOL and held the '567 patent claims invalid.

The district court's grant of JMOL was inappropriate because Lonza failed to present any evidence—much less clear and convincing evidence—that one of ordinary skill in the art must perform undue experimentation to practice claims 4 and 5. As Martek correctly notes, dependent claims 4 and 5 are narrower than claim 1: claim 4 is limited to euryhaline organisms in the order Thraustochytriales; claim 5 is limited to euryhaline organisms of the Thraustochytrium or Schizochytrium genus. Lonza presented no evidence of undue experimentation regarding those additional limitations. Regarding claim 4's additional limitation, the evidence indicated only that the Thraustochytriales order contains at least all organisms of the Thraustochytrium and Schizochytrium genera. J.A. at 7357–58. Regarding claim 5's additional limitation, another expert witness for Lonza, Dr. Porter, testified that the Thraustochytrium and Schizochytrium genera together encompass only 22 known species. J.A. at 7549. Thus, the evidence presented to the jury supports an inference that there are relatively few potential species that may meet the limitations of claims 4 and 5, as compared to the large number of potential species that may meet the limitations of claim 1. Dr. Ward's testimony—regarding the amount of experimentation necessary to select a qualifying species from 10,000 possibilities—is far less relevant and persuasive when

considering the selection of a qualifying species from only 22 possibilities. Thus, the evidence supports the jury's implicit finding that one need not perform undue experimentation to practice claims 4 and 5, as well as the jury's ultimate conclusion that Lonza failed to prove invalidity of those claims by clear and convincing evidence. For these reasons, we reverse the district court's grant of JMOL as to claims 4 and 5 of the '567 patent.

VI. Claim Construction of "Animal"

All asserted claims of the '244 patent are directed to methods for achieving high concentrations of omega-3 HUFA in an "animal." '244 Patent col.1 ll.21–24, col.2 ll.17–19, col.9 l.44–col.10 l.58. The district court construed the claim term "animal" to mean "any member of the kingdom Animalia, except humans." Claim Construction Order at 2. Based on the court's construction, Martek stipulated that Lonza does not infringe the '244 patent claims, because neither Lonza nor its customers use the claimed methods to provide omega-3 HUFA to non-human animals. See Stipulated Order Of Non-Infringement at 1, Martek Biosciences Corp. v. Nutrinova Inc., No. 03-896 (D. Del. Apr. 21, 2006); Cross Appellant's Br. at 9. Martek now appeals the district court's claim construction, arguing it is erroneous in light of the patent's stated definition of "animal." We review such issues of claim construction without deference. See Cybor Corp., 138 F.3d at 1456. For the following reasons, we agree with Martek.

When a patentee explicitly defines a claim term in the patent specification, the patentee's definition controls. See Phillips v. AWH Corp., 415 F.3d 1303, 1321 (Fed. Cir. 2005) (en banc) ("[T]he specification 'acts as a dictionary when it expressly defines terms used in the claims . . . .'" (quoting Vitronics Corp. v. Conceptronic, Inc., 90 F.3d

1576, 1582 (Fed. Cir. 1996)); id. at 1316 ("[O]ur cases recognize that the specification may reveal a special definition given to a claim term by the patentee that differs from the meaning it would otherwise possess. In such cases, the inventor's lexicography governs."); see also Honeywell Int'l, Inc. v. Universal Avionics Sys. Corp., 493 F.3d 1358, 1361 (Fed. Cir. 2007) ("When a patentee defines a claim term, the patentee's definition governs, even if it is contrary to the conventional meaning of the term."); 3M Innovative Props. Co. v. Avery Dennison Corp., 350 F.3d 1365, 1374 (Fed. Cir. 2003) ("Because 3M expressly acted as its own lexicographer by providing a definition of embossed in the specification, the definition in the specification controls the meaning of embossed, regardless of any potential conflict with the term's ordinary meaning as reflected in technical dictionaries."). Here, Martek explicitly defined the term "animal" in the '244 patent: "The term 'animal' means any organism belonging to the kingdom Animalia." '244 Patent col.5 ll.11–12. That definition controls. Thus, because it is undisputed that humans are members of the kingdom Animalia,[5] it was error for the district court to limit the claim term "animal" to exclude humans.

Lonza, however, argues that when the '244 patent specification is considered in its entirety, it clearly limits the claim term "animal" to non-human animals. See Phillips, 415 F.3d at 1313 ("Importantly, the person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term

[5] Lonza does not dispute that humans are members of the kingdom Animalia. Indeed, the record contains evidence detailing the full hierarchical classification of a human as follows—Kingdom: Animalia, Phylum: Chordata, Subphylum: Vertebrata, Superclass: Tetrapoda, Class: Mammalia, Order: Primates, Family: Hominidae, Genus: Homo, Species: Homo sapiens. Helena Curtis & N. Sue Barnes, Invitation to Biology 240 (4th ed. 1985); see also Neil A. Campbell et al., Biology 723 (8th ed. 2008) (explaining that humans are mammalian primates in the kingdom Animalia).

appears, but in the context of the entire patent, including the specification."). For the following reasons, Lonza's arguments are unpersuasive.

First, the disclosure and enumeration of preferred non-human animals does not constitute a clear and manifest disavowal of human animals. The '244 patent states:

> The term "animal" means any organism belonging to the kingdom Animalia. Preferred animals from which to produce a food product include any economic food animal. More preferred animals include animals from which eggs, milk products, poultry meat, seafood, beef, pork or lamb is derived. Milk products include, for example, milk, cheese and butter.

'244 Patent col.5 ll.11–17. Although the patent contemplates that certain animals are "[p]referred animals from which to produce a food product," that statement does not disavow human animals because it relates to preferred embodiments only; it does not state that all animals covered by the claims must produce a food product. As we have explained:

> [P]articular embodiments appearing in the written description will not be used to limit claim language that has broader effect. And, even where a patent describes only a single embodiment, claims will not be read restrictively unless the patentee has demonstrated a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction.

Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc., 381 F.3d 1111, 1117 (Fed. Cir. 2004) (citations and internal quotation marks omitted). Here, the patentee has used no words or expressions that manifestly exclude coverage of humans, and thus, it would be improper to override the patentee's express definition of "animal" to limit the scope of the claims. Moreover, the patentee's use of modifying language to specify "[p]referred animals" as "economic food animal[s]" ultimately supports a broad construction of the

unmodified term "animal" that includes non-food animals, such as humans.[6] In summary, absent a clear intention to restrict the invention to particular members of the kingdom Animalia, we cannot limit the claims to the listed preferred embodiments. See id.

Second, contrary to Lonza's assertions, the '244 patent does not otherwise contain language that can be fairly interpreted as a clear intention to disclaim coverage of humans. See id.; Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352, 1358 (Fed. Cir. 2004) ("Absent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language."). For example, the fact that the claims refer to "raising" and "feeding" animals does not clearly disclaim humans. Lonza cites no persuasive reason, and we can think of no reason, why those two generic terms do not apply to human animals. Likewise, the fact that some dependent claims are directed to certain types of animals—such as cows, sheep, and goats—does not limit the scope of broader claims directed more generally to "an animal." In fact, the patent plainly contemplates that the invention is applicable to

[6] The dissent focuses on statements in the patent that allegedly distinguish between humans and other animals. See, e.g., '244 Patent col.7 ll.51–54 ("[T]he whole-cell biomass can be used directly as a food additive to enhance the omega-3 highly unsaturated fatty acid content and nutritional value of processed foods for human intake or for animal feed." (emphasis added)). The dissent asserts that if the term "animal" includes human animals, "[t]here would have been no need to distinguish between what will be eaten by humans and what will be eaten by animals." See Dissenting Op. at 4. However, as noted here, if the general term "animal" encompasses only non-human food animals, there would have been no need for the patentee to describe preferred animals as "food animal[s]." The fact that the patentee chose to distinguish food animals from other animals indicates that the general term "animal" encompasses non-food animals, such as humans. And certainly, the isolated statements cited by the dissent do not rise to the level of "a clear intention to limit the claim scope using words or expressions of manifest exclusion or restriction," Innova/Pure Water, 381 F.3d at 1117 (internal quotation marks omitted), as would be necessary to override the patentee's explicit lexicography.

humans. See, e.g., '244 Patent col.7 ll.8–11 ("The purified omega-3 highly unsaturated fatty acids can then be used as a nutritional supplement for humans, as a food additive, or for pharmaceutical applications."); id. at col.7 ll.42–45 ("As discussed in detail above, the whole-cell biomass can be used directly as a food additive to enhance the omega-3 highly unsaturated fatty acid content and nutritional value of processed foods for human intake or for animal feed."); id. at col.7 ll.51–54 ("A further aspect of the present invention includes introducing omega-3 HUFAs from the foregoing sources into humans for the treatment of various diseases."). Thus, we are "governed by the principle that '[a]bsent a clear disclaimer of particular subject matter, the fact that the inventor may have anticipated that the invention would be used in a particular way does not mean that the scope of the invention is limited to that context.'" Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 909 (Fed. Cir. 2004) (quoting Northrop Grumman Corp. v. Intel Corp., 325 F.3d 1346, 1355 (Fed. Cir. 2003)). Under our precedent, because the patent does not clearly disclaim coverage of humans, it would be erroneous to limit the claims to certain types of animals that the inventor anticipated would prove useful in the invention. That is especially true in the present case because the patent expressly defines the claim term "animal" broadly enough to encompass humans and discloses uses of the claimed invention applicable to humans.

Finally, Lonza asserts that the extrinsic evidence of record demonstrates that the ordinary meaning of "animal" is a non-human animal. Appellant's Reply Br. at 57. In this case, because the patentee explicitly defined "animal," Lonza's extrinsic evidence is simply irrelevant. See, e.g., Honeywell Int'l, 493 F.3d at 1361 ("When a patentee

defines a claim term, the patentee's definition governs, even if it is contrary to the conventional meaning of the term.").

For the foregoing reasons, we hold that the district court's claim construction is erroneous. The proper construction for the claim term "animal" is the one explicitly provided by the patentee: "any organism belonging to the kingdom Animalia," which includes humans. Thus, we reverse and remand for further proceedings under the correct construction.

We have considered the parties' remaining arguments, and we find them unpersuasive.

Conclusion

We affirm the denial of Lonza's JMOL motions asserting invalidity of the '594 patent claims and noninfringement of the '281 patent claims, the exclusion of Lonza's prior inventorship evidence, and the construction of the claim term "non-chloride sodium salt." We reverse the grant of JMOL of invalidity of claims 4 and 5 of the '567 patent and the court's construction of the claim term "animal," and we remand for further proceedings consistent with this opinion.

AFFIRMED-IN-PART, REVERSED-IN-PART, and REMANDED

Costs

No costs.

United States Court of Appeals for the Federal Circuit

2008-1459, -1476

MARTEK BIOSCIENCES CORPORATION,

Plaintiff-Cross Appellant,

v.

NUTRINOVA, INC.,
NUTRINOVA NUTRITION SPECIALTIES AND FOOD INGREDIENTS GMBH,
and LONZA, LTD.,

Defendants-Appellants.

Appeals from the United States District Court for the District of Delaware
in Case No. 03-CV-896, Chief Judge Gregory M. Sleet.

LOURIE, Circuit Judge, with whom Circuit Judge RADER joins, dissenting in part.

I respectfully dissent from the majority's conclusion that the district court erred in construing the term "animal" in U.S. Patent 5,698,244 ("the '244 patent"). I believe that the district court properly construed the word "animal" in claim 1 to mean "any member of the kingdom Animalia, except humans." Martek Biosciences Corp. v. Nutrinova Inc., No. 03-896 (D. Del. Dec. 12, 2005).

Our precedents make clear that a patentee is free to be his own lexicographer. See Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996). To that end, Martek argues, and the majority agrees, that it defined "animal" in a single line in the '244 patent: "The term 'animal' means any organism belonging to the kingdom Animalia." '244 patent col.5 ll.11-12. Because humans are members of the Animalia

kingdom, Martek contends that the district court's exclusion of humans from its claim construction was in error.

This case illustrates the unusual situation in which a purported definition of a claim term in the written description is totally negated by the remainder of the text of the patent. Martek's attempt at lexicography does not conform to the way in which it otherwise describes its invention.

It is fundamental that we must read a claim term in a manner that comports with the written description of the patent as a whole, see Markman v. Westview Instruments, Inc., 517 U.S. 370, 389 (1996), and not simply with a single sentence, even one purporting to be a definition, that is inconsistent with the remainder of the specification. We have stated many times that the specification of a patent is the "single best guide to the meaning of a disputed term," and that the specification is to be viewed in its totality. Vitronics, 90 F.3d at 1582; see Phillips v. AWH Corp., 415 F.3d 1303, 1313 (Fed. Cir. 2005) (en banc) ("[T]he person of ordinary skill in the art is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification."); id. at 1315 ("The specification is, thus, the primary basis for construing the claims.") (quotation marks omitted). Thus, rather than reading in isolation the single line in the specification that Martek argues provides a definition of "animal," one should review the entire patent to determine the proper construction of the term. Having done so, it is clear that humans should be excluded from the construction of the term "animal" in the '244 patent.

Starting with the claims, claim 1, which is the only independent claim in the '244 patent, reads, "A method of raising an animal, comprising feeding said animal material"

that contains omega-3 highly unsaturated fatty acids "in an amount effective to increase the content of omega-3 highly unsaturated fatty acids in said animal." Martek argues that this language applies to humans, since children are "raised" in the sense that they are "reared." But, as demonstrated by the discussion below, the specification is not directed to raising children; it is directed to raising non-human animals.

The Field of the Invention portion of the patent reads, "[t]he present invention concerns a method for raising an animal having [ ] high concentrations of omega-3 highly unsaturated fatty acids (HUFA) and food products derived from such animals." '244 patent col.1 ll.21-24 (emphasis added). We have found that the use of the words "the present invention" can be read to limit the invention to what is described as such. See Honeywell Int'l, Inc. v. ITT Indus., Inc., 452 F.3d 1312, 1318 (Fed. Cir. 2006) (discussing the patentee's use of "this invention" and "the present invention" in the specification). Food products are not derived from humans. Thus, because "the present invention" concerns "food products" that come from "such animals," the '244 patent is directed to raising only those animals from which one can derive food products. Accordingly, the Brief Summary of the Invention states that "[a]nimals raised by the method of the present invention include poultry, cattle, swine and seafood, which includes fish, shrimp and shellfish. The omega-3 HUFAs are incorporated into the flesh, eggs and milk products." '244 patent col.2 ll.19-23.

It is true that the specification states, in one sentence, "The term 'animal' means any organism belonging to the kingdom Animalia." Id. col.5 ll.11-12. It is also true that humans belong to the kingdom Animalia. However, the lines in the specification directly

following that sentence list a host of non-human animals from which one derives food or milk:

> Preferred animals from which to produce a food product include any economic food animal. More preferred animals include animals from which eggs, milk products, poultry meat, seafood, beef, pork or lamb is derived. Milk products include, for example, milk, cheese and butter. . . . Preferred animals for milk product production include milk-producing animal, in particular cows, sheep, goats, bison, buffalo, antelope, deer and camels. More preferred animals for milk product include cows, sheep and goats.

Id. col.5 ll.12-29 (emphasis added). Humans are not economic food animals. Although particular embodiments of a specification are generally not to be read into the claims, see Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988), the listing of particular "food animal[s]" here strongly supports a conclusion that the term "animal" encompasses only those animals raised for production of food and milk products, thereby not including humans.

The next portion of the specification discusses how to incorporate materials containing omega-3 HUFAs into animal feed. In contrast to the addition of those materials to animal feed, the patent goes into detail about purifying omega-3 HUFAs from microorganisms that "can then be used as a nutritional supplement for humans, as a food additive, or for pharmaceutical applications." '244 patent col.7 ll.8-11. An even more explicit distinction between humans and animals is made later in the specification: "As discussed in detail above, the whole-cell biomass can be used directly as a food additive to enhance the omega-3 highly unsaturated fatty acid content and nutritional value of processed foods for human intake or for animal feed." Id. col.7 ll.42-45 (emphasis added). There would have been no need to distinguish between what will be eaten by humans and what will be eaten by animals if humans were included in the term

"animal." Furthermore, in the same paragraph, the patent discusses the treatment of "human" diseases, such as "cardiovascular diseases, inflammatory and/or immunological diseases and cancer." Id. col.7 ll.59-60. Again, if humans were included in the term "animals," there would be no reason to specify the treatment of humans, since non-human animals also suffer from the same diseases.

Importantly, the fact that the milk or meat products of the animals subjected to the method of the patent can be fed to humans does not mean that humans are among the animals that are raised, according to claim 1, to yield milk or meat with high omega-3 HUFA content. In other words, the majority fails to make a distinction between using omega-3 HUFAs as a nutritional supplement for humans and animals, which is clearly contemplated in the patent, and raising humans to be the source of such a nutritional supplement, as human milk and meat with high concentrations of omega-3 HUFAs are not used as nutritional supplements. Although women may produce milk, they are not "raised" for that purpose.

We are bound to read a claim term in a manner that is consistent with the specification as a whole. Having examined the use of the term "animal" in the claims and the specification of the '244 patent, I believe it is clear that one of ordinary skill in the art would conclude that, despite the purported definition in the specification, the term "animal" in the claims cannot include humans.

For the foregoing reasons, I respectfully dissent from the majority's reversal of the district court's claim construction of "animal" in the '244 patent. I otherwise join the majority opinion.