NOTE: This disposition is nonprecedential.

United States Court of Appeals for the Federal Circuit

DNA GENOTEK INC.,
Plaintiff-Appellant

v.

SPECTRUM SOLUTIONS LLC,
Defendant-Appellee

2023-2017

Appeal from the United States District Court for the Southern District of California in No. 3:21-cv-00516-RSH-DDL, Judge Robert S. Huie.

Decided: February 14, 2025

BRIAN ROBERT MATSUI, Morrison & Foerster LLP, Washington, DC, argued for plaintiff-appellant. Also represented by SETH W. LLOYD; ALEXANDRA M. AVVOCATO, New York, NY; DREW ALAN HILLIER, BRIAN M. KRAMER, San Diego, CA.

ALI S. RAZAI, Knobbe, Martens, Olson & Bear, LLP, Irvine, CA, argued for defendant-appellee. Also represented by JEREMIAH HELM, JOSEPH F. JENNINGS; BENJAMIN BRUCE

ANGER, San Diego, CA; BRANDON G. SMITH, Morgan, Lewis & Bockius LLP, Costa Mesa, CA.

Before LOURIE and HUGHES, *Circuit Judges*, and GILSTRAP, *Chief District Judge*.[1]

GILSTRAP, *Chief District Judge*.

DNA Genotek Inc. ("Genotek") owns U.S. Patent No. 10,619,187 ("the '187 patent"), which is directed to compositions and methods for preserving nucleic acids at room temperature for extended periods of time and for simplifying the isolation of nucleic acids. Genotek accused Spectrum Solutions LLC ("Spectrum") of infringing its '187 patent. After claim construction, the district court granted summary judgment that the '187 patent was not infringed. Genotek appeals, arguing that the district court erred in its construction of the "reagent compartment" term in claim 1 of the '187 patent. We *affirm*.

BACKGROUND

The '187 patent is entitled "Compositions and Methods for Obtaining Nucleic Acids From Sputum." One aspect of the invention is a device for collecting and preserving biological samples, such as DNA in saliva. '187 patent col. 6 ll. 26–39. Claim 1, the only independent claim, recites:

> A device for receiving and preserving nucleic acid in a biological sample, said device comprising:
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> one or more walls defining a containment vessel having a top having an opening, and a closed bottom having a sample receiving area for holding said biological sample, said opening for receiving a

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[1] Honorable Rodney Gilstrap, Chief Judge, United States District Court for the Eastern District of Texas, sitting by designation.

> liquid sample and for sealably receiving a sealing cap, said top having an opening for receiving a biological sample from the mouth of a user and further comprising at least one marking on said one or more walls which corresponds to a fluid volume in the sample receiving area;
>
> a *reagent compartment* having a barrier, said barrier sealing and containing reagents in said reagent compartment and capable of disestablishment to release said reagents into the sample receiving area;
>
> reagents in the reagent compartment for preserving nucleic acids potentially present in the sample wherein said reagents comprise a denaturing agent, a chelator and a buffer agent; and,
>
> the sealing cap, whereby the device is configured such that, when sealably closing said opening with said sealing cap, the barrier mechanically disestablishes to release said reagents to form a mixture of reagents and said biological sample wherein said buffering agent maintains a pH of said mixture equal to or above 5.0 to preserve nucleic acids potentially present in the sample.

'187 patent col. 19 ll. 34–59 (emphasis added).

The specification explains that the device includes "a container that has a first region for collecting a biological sample and a second region containing a composition for preserving a nucleic acid, a barrier between a first region and a second region that keeps the sample and composition separate, a means for closing the container, and a means for disturbing the integrity of the barrier, such that the composition is capable of contacting the bodily sample." '187 patent col. 6 ll. 28–36. When the biological sample is mixed with the reagent composition, cells are disrupted, nucleic acids are liberated from the cells, membranous

material is solubilized, proteins are stripped from the nucleic acids, and protein digestion begins. '187 patent col. 13 ll. 38–42.

Genotek filed suit against Spectrum in 2021. Spectrum's accused device is an SDNA home saliva-collection kit for COVID-19 PCR testing. The district court held a *Markman* hearing and construed various disputed terms in the '187 patent. *DNA Genotek Inc. v. Spectrum Sols. LLC.*, No. 3:21-cv-00516-RSH-DDL, 2022 WL 17331255 (S.D. Cal. Nov. 29, 2022) ("*Order*"). In May 2023, the court granted Spectrum's motion for summary judgment of non-infringement substantially relying on its construction of "reagent compartment." *DNA Genotek Inc. v. Spectrum Sols. L.L.C.*, 671 F. Supp. 3d 1105 (S.D. Cal. 2023). Genotek timely appealed. We have jurisdiction pursuant to 28 U.S.C. § 1295(a)(1).

DISCUSSION

We review claim construction de novo. We also review underlying factual determinations based on intrinsic evidence de novo and any findings of fact regarding extrinsic evidence for clear error. *SpeedTrack, Inc. v. Amazon.com*, 998 F.3d 1373, 1378 (Fed. Cir. 2021).

As a threshold matter, Spectrum argues that Genotek's appeal is moot because the district court's summary judgment of non-infringement was not based on the "reagent compartment" limitation, but rather the "a containment vessel having a top having an opening" limitation. Spectrum Br. 27–29. We disagree. The district court's grant of summary judgment followed directly from its construction of "reagent compartment," which required Genotek to change its theory of infringement. *DNA Genotek Inc.*, 671 F. Supp. 3d at 1118; Genotek Br. 16. Accordingly, the district court's claim construction is not moot.

We next turn to whether the district court correctly construed "reagent compartment" as a "region or section of

the containment vessel." The district court concluded that "the specification of the '187 patent provides clear guidance as to the location of the reagent compartment." *Order* at *17. In particular, the district court noted that the specification discloses "a container that has a first region for collecting a biological sample and a second region containing a composition for preserving a nucleic acid." *Id.* In the district court's view, that portion of the specification, which describes the invention as a whole, "expressly and clearly states that the region containing the composition for preserving a nucleic acid (*i.e.*, the reagent compartment) is located within the container (*i.e.*, the containment vessel)." *Id.*

The district court further found that the prosecution history and statements made during IPR proceedings supported its construction. Genotek's intentional deletion of "any explicit disclosure of the reagent compartment being in the cap/lid" when it filed its non-provisional application "evidence[s] a clear intent to limit the final scope of the invention to a device with the reagent compartment in the containment vessel." *Id.* at *20 (citing *MPHJ Tech. Invs., LLC v. Ricoh Ams. Corp.*, 847 F.3d 1363, 1369 (Fed. Cir. 2017)). In addition, during IPR proceedings for another Genotek patent, counsel for Genotek explained that the '187 patent was "very different" from a device where the reagent is in a lid. *Id.* at *21.

On appeal, Genotek argues that the district court improperly imported limitations from embodiments and that the claims do not place any limit on the location of the "reagent compartment." Genotek emphasizes that the portions of the specification relied upon by the district court do not use the term "reagent compartment" at all and merely describe various embodiments of the invention.

We agree with the district court that the specification provides intrinsic support for the adopted construction. Under the "Summary of the Invention" section, the

specification describes the invention as "a container that has a first region for collecting a biological sample and a second region containing a composition for preserving a nucleic acid." '187 patent, col. 6, ll. 26–31. The specification also contains identical language under the "Detailed Description" section. '187 patent, col. 14, ll. 49–58. We agree with the district court that those portions of the specification expressly state that the reagent compartment (the second region) is located within the container. We also agree with the district court that these portions of the specification describe the invention as a whole, not merely a preferred embodiment. *Regents of Univ. of Minnesota v. AGA Med. Corp.*, 717 F.3d 929, 936 (Fed. Cir. 2013) ("When a patent thus describes the features of the 'present invention' as a whole, this description limits the scope of the invention.")

Genotek next argues that the district court erred in finding that the specification's omission of an embodiment from the '398 provisional supported its construction. Genotek points out that the '187 patent incorporated by reference the '398 provisional, which contains an embodiment where the reagent compartment is in the cap. According to Genotek, under the district court's reasoning, anything from the provisional application that was omitted from the issued patent would be disclaimed.

We find that the prosecution history supports the district court's construction. The '187 patent claims priority from the '398 provisional, which includes an embodiment with a reagent compartment in the cap. J.A. 3190. When Genotek filed its non-provisional application, it intentionally deleted all references to that embodiment and included only embodiments with the reagent compartment in the container. This Court has previously explained that "deletion from the [] provisional application [] contributes understanding of the intended scope of the final application." *MPHJ Tech.*, 847 F.3d at 1369. Accordingly, we agree with the district court that Genotek's deletion of an embodiment

with the reagent compartment in the cap evidences an intent to limit the '187 patent to a device with a reagent compartment in the containment vessel.

Finally, Genotek argues that the district court erred in relying on statements Genotek's counsel made during IPR proceedings for a different, unrelated patent. Genotek also contends that its counsel was merely describing the preferred embodiments of the '187 patent, not the '187 patent as a whole.

During the IPR of another Genotek patent, Genotek's counsel distinguished the '187 patent from another piece of prior art that had a reagent compartment in a lid. *Order* at *21. Genotek's counsel explained that the two devices are "very different" because "O'Donovan is a pushed friction fit engagement with spikes in a vial and a *reagent in a lid*," whereas the '187 patent "is a rotated screw cap with a ram in the cap and a *reagent below a plastic cover in a container*." *Id.* (emphasis added). As the district court reasoned, Genotek "described the scope of its own invention as being a device where the reagent is contained in the container," which is "very different from a device where the reagent is in a lid." *Id.* While we agree that the statements made during IPR proceedings by Genotek counsel are not themselves dispositive, they do inform the district court's construction.

CONCLUSION

We have considered Genotek's remaining arguments and find them unpersuasive. For the foregoing reasons, we conclude that the district court properly construed "reagent compartment" as a "region or section of the containment vessel." We accordingly *affirm* the district court's claim construction and grant of summary judgment of non-infringement.

AFFIRMED