

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

ANCESTRY.COM DNA, LLC,
Petitioner,

v.

DNA GENOTEK INC.,
Patent Owner.

Case IPR2016-01152
Patent 8,221,381 B2

Before WILLIAM V. SAINDON, HYUN J. JUNG, and
MICHELLE N. WORMMEESTER, *Administrative Patent Judges*.

WORMMEESTER, *Administrative Patent Judge*.

DECISION

Denying Institution of *Inter Partes* Review
37 C.F.R. § 42.108

Ancestry.com DNA, LLC (“Petitioner”) filed a Petition (Paper 1, “Pet.”) requesting *inter partes* review of claims 3, 6, 9, 10, 13, 14, 18, 19, 39, 40, 43, and 45–47 of U.S. Patent No. 8,221,381 B2 (Ex. 1001, “the ’381 patent”). DNA Genotek Inc. (“Patent Owner”) filed a Preliminary Response (Paper 6, “Prelim. Resp.”). We have jurisdiction under 35 U.S.C. § 314 and 37 C.F.R. § 42.4(a). Under 35 U.S.C. § 314(a), an *inter partes* review may not be instituted “unless . . . there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.” For the reasons that follow, we deny institution of an *inter partes* review.

I. BACKGROUND

A. *Related Proceedings*

The parties identify three cases involving the ’381 patent: (1) *DNA Genotek, Inc. v. Ancestry.com DNA LLC*, Case No. 15-00355-SLR (D. Del.); (2) *DNA Genotek, Inc. v. Spectrum DNA*, Case No. 15-cv-00661-SLR (D. Del.); and (3) *DNA Genotek, Inc. v. Spectrum DNA*, Case No. 16-cv-1544-MMA-NLS (S.D. Cal.). Pet. 2; Paper 5, 2.

The parties also identify the following petition for *inter partes* review involving the ’381 patent: IPR2016-00060. Pet. 2; Paper 5, 3.

B. *The ’381 Patent*

The ’381 patent is titled “Container System for Releasably Storing a Substance.” According to the ’381 patent, there is often a need to store a substance in a container before mixing the substance with another substance. Ex. 1001, 1:19–21. For example, there is a need in certain applications to

store or ship diagnostic compositions before combining them with biological samples. *Id.* at 1:30–32. The '381 patent addresses this need, describing a container system that releasably and reliably stores a substance. *Id.* at 2:5–6, 15–16.

The container system of the '381 patent comprises a vial and a lid that may be screwed onto the vial. *Id.* at 4:6–7, 5:7–10. The lid defines a reservoir for holding a substance, such as a nucleic acid preservative. *Id.* at 4:27–31, 5:17–18. A pierceable membrane that attaches to the lid serves as a physical barrier to releasably store the substance within the reservoir. *Id.* at 4:34–36.

The vial comprises a chamber for receiving a sample, such as saliva. *Id.* at 5:53–55. The vial also comprises at least one piercing member, which extends from a base surface within the vial. *Id.* at 6:14–23. Figure 3, which is reproduced below, illustrates a piercing member.

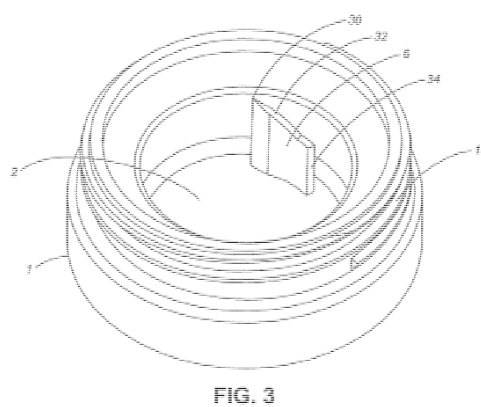


Figure 3 is a perspective view of the interior of the vial. *Id.* at 3:3–4. As shown in the figure, piercing member 6 is shaped like a trapezoid. In particular, piercing member 6 includes cutting edge 32 with first pointed end

30 at a first corner of the trapezoid and a second end at a second corner of the trapezoid where cutting edge 32 intersects side wall 34. *Id.* at 6:33–37.

When a user begins to screw (or twist) the lid onto the vial, the lid and vial are moved to a piercing position. *Id.* at 7:12–13. At the piercing position, the first pointed end of the piercing member pierces the pierceable membrane. *Id.* at 7:18–20. As the user continues to twist the lid, the cutting edge of the piercing member moves through the pierceable membrane, creating an opening in the membrane that allows for the substance stored in the lid to enter the vial and mix with the sample stored in the vial. *Id.* at 7:21–24, 11:37–39. With the lid on, the vial is sealed against leakage of its contents. *Id.* at 7:1–9.

C. Illustrative Claim

Petitioner challenges claims 3, 6, 9, 10, 13, 14, 18, 19, 39, 40, 43, and 45–47, each of which depends from independent claim 1. We resolve issues raised by Petitioner’s challenges based on claim 1, as we will explain in our discussion section below. Claim 1 recites:

1. A container system for releasably storing a substance, comprising:
 - a) a vial comprising a first open end for receiving a sample, a second end comprising a sample storage chamber and a piercing member, wherein said piercing member comprises a side wall, a first cutting edge extending from a first pointed corner to a second corner that defines the intersection between said cutting edge and said side wall; and
 - b) a lid configured to removably engage said vial, said lid comprising a reservoir for holding the substance, and a pierceable membrane sealing the substance within said reservoir,

wherein, when said system is closed by removable engagement of said vial with said lid, said vial and said lid are movable to a piercing position in which the piercing member disrupts the pierceable membrane to allow fluid communication between said reservoir and said chamber, wherein the chamber is sealed against leakage to the outside of the container system in the piercing position.

D. Asserted Grounds of Unpatentability

Petitioner challenges claims 3, 6, 9, 10, 13, 14, 18, 19, 39, 40, 43, and 45–47 of the '381 patent on the following grounds. Pet. 26–72.

References	Basis	Claims Challenged
Birnboim ¹ and O'Donovan ²	§ 103	3, 6, 9, 10, 39, 40, 43, and 45–47
Birnboim, O'Donovan, Chelles ³	§ 103	18 and 19
Birnboim, O'Donovan, and Clarkson ⁴	§ 103	13 and 14

In support of its arguments, Petitioner proffers the Declaration of Dr. Terry N. Layton, Ph.D. (Ex. 1003). *See id.*

E. Claim Construction

We construe claims in an unexpired patent by applying the broadest reasonable interpretation in light of the specification of the patent in which they appear. *See* 37 C.F.R. § 42.100(b); *Cuozzo Speed Techs. LLC v. Lee*,

¹ Birnboim, Int'l Publ'n No. WO 03/104251 A2, published Dec. 18, 2003 (Ex. 1008).

² O'Donovan, U.S. Patent No. 7,645,424 B2, issued Jan. 12, 2010 (Ex. 1007).

³ Chelles, U.S. Publ'n No. US 2003/0089627 A1, published May 15, 2003 (Ex. 1020).

⁴ Clarkson, Int'l Publ'n No. WO 2005/023667 A1, published Mar. 17, 2005 (Ex. 1021).

136 S. Ct. 2131, 2144–46 (2016) (upholding the use of the broadest reasonable interpretation standard). Under this standard, claim terms generally are given their ordinary and customary meaning, as would be understood by one of ordinary skill in the art in the context of the entire disclosure. *See In re Translogic Tech., Inc.*, 504 F.3d 1249, 1257 (Fed. Cir. 2007). A “claim term will not receive its ordinary meaning if the patentee acted as his own lexicographer,” however, and clearly set forth a definition of the claim term in the specification. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002).

Petitioner provides proposed interpretations for various limitations of the claims. *See* Pet. 16–26. Patent Owner responds. Prelim. Resp. 6. For purposes of this Decision, we conclude that no term requires express interpretation at this time to resolve any controversy in this proceeding. *See Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999) (“only those terms need be construed that are in controversy, and only to the extent necessary to resolve the controversy”).

II. DISCUSSION

A. *Obviousness over Birnboim and O’Donovan*

Petitioner argues that claims 3, 6, 9, 10, 39, 40, 43, and 45–47 of the ’381 patent would have been obvious over Birnboim and O’Donovan under 35 U.S.C. § 103. Pet. 26–51. For the reasons explained below, we are not persuaded that Petitioner has demonstrated a reasonable likelihood of prevailing on its asserted ground.

1. *Birnboim*

Birnboim describes “a novel collection device useful for collecting a biological sample from a subject, and subsequently mixing the collected sample with a composition intended to stabilize, preserve, or facilitate the recovery of components of the sample.” Ex. 1008, 22:23–26. The collection device comprises a container and a cap that may be screwed onto the container. *Id.* at 24:11–15, Fig. 10. The container includes a plunger and a sealing disc. *Id.* at 24:11–13, 17–18, Figs. 10, 11. The sealing disc divides the container into two regions, a first region above the disc and a second region below the disc. *Id.* at Fig. 11. A biological sample is added to the first region of the container, while a nucleic acid-preserving composition is added to the second region of the container. *Id.* at 11:15, 24:12–13, 22–23, Fig. 11.

When the cap is screwed onto the container, the plunger is forced downward and, in turn, causes the sealing disc to pivot. *Id.* at 24:15–20. As a result, the barrier between the two regions of the container is removed, and the composition and the sample become mixed together. *Id.* at 24:20–23.

2. *O'Donovan*

O'Donovan describes a reagent cuvette for sample analysis. Ex. 1007, 1:9–10. The cuvette comprises a starter reagent chamber and an inspection chamber. *Id.* at 2:39–43, 3:36 (“inspection chamber”), 3:53 (“starter reagent chamber”). The starter reagent chamber contains a starter reagent that is sealed inside the chamber with a foil membrane. *Id.* at 3:1–5. The inspection chamber includes an inspection part with a square cross-

section and a socket for receiving the starter reagent chamber. *Id.* at 2:46–49. There are four spikes at the base of the socket. *Id.* at 2:60–63.

In use, a sample (such as blood) is added to the inspection chamber. *Id.* at 3:11–13. The starter reagent chamber is then inserted into the socket. *Id.* at 3:17–19. As the starter reagent chamber is pressed down, the spikes in the socket pierce and tear the foil membrane such that all of the starter reagent drops into the inspection part of the inspection chamber. *Id.* at 3:17–24. The combined chambers effectively form a single chamber, where there is a friction fit between the starter reagent chamber and the socket of the inspection chamber. *Id.* at 3:28–30. The inspection part is finally placed into an optical inspection instrument for analysis of the sample/reagent mixture. *Id.* at 3:30–32.

3. Analysis

Each of claims 3, 6, 9, 10, 39, 40, 43, and 45–47 depends from claim 1, and, therefore, includes all the limitations of claim 1. With respect to claim 1, Petitioner relies primarily on Birnboim. *See* Pet. 29 (“Birnboim discloses all elements of ’381 claim 1 except [1.5], which limits the shape of the piercing member, and the positioning of reservoir [1.7] within lid [1.6].”). Petitioner additionally relies on O’Donovan for certain of the limitations recited in claim 1, including a “lid comprising a reservoir for holding the substance.” *Id.* at 29, 41. In particular, Petitioner identifies O’Donovan’s chamber 3 as a “lid,” and points out that “O’Donovan discloses that starter reagent is injected into the chamber 3.” *Id.* at 41.

It is not sufficient, however, for Petitioner to demonstrate that each of the claim elements is known. *See KSR Int’l Co. v. Teleflex Inc.*, 550 U.S.

398, 418 (2007). Petitioner must also provide “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006). In that regard, Petitioner directs us to where Birnboim describes a container with a barrier, which may be a septum that separates a composition from a fluid until the septum is pierced or punctured. Pet. 36 (citing Ex. 1008, 9:11, 23:29–31). Petitioner also directs us to where Birnboim teaches that “the means for closing the container may be coupled to the disestablishment of the barrier.” *Id.* (citing Ex. 1008, 24:8–9). According to Petitioner, however, “Birnboim does not disclose how, in such embodiment, the ‘means for closing the container may be coupled to the disestablishment of the barrier.’” *Id.* Thus, Petitioner argues, a POSITA would have looked to analogous art “for a solution that would complete” Birnboim’s embodiment, and would have “recognized [O’Donovan] as providing a particularly relevant solution to the identified problem because, like Birnboim, O’Donovan is explicitly directed to a container system for use in analyzing biological samples.” *Id.* at 36–37 (citing Ex. 1003 ¶ 111).

We are unpersuaded by Petitioner’s argument. As Patent Owner points out, Petitioner does not explain sufficiently why one of ordinary skill in the art would have considered combining the container of Birnboim with certain features of the container of O’Donovan to arrive at the claimed invention. Prelim. Resp. 35. The mere fact that both Birnboim and O’Donovan are in the same field of endeavor falls short of an adequate rationale. The same field of endeavor analysis is merely the jumping-off point in reaching the determination of whether a claimed invention is obvious. *See K-TEC, Inc. v. Vita-Mix Corp.*, 696 F.3d 1364, 1375 (Fed. Cir.

2012) (to qualify as prior art in an obviousness analysis, references must be analogous art—either from the same field of endeavor, or reasonably pertinent to the problem with which the inventor is involved).

Petitioner further argues that combining the teachings of Birnboim and O'Donovan “would have required no more than ‘[a]pplying a known technique to a known device (method, or product) ready for improvement to yield predictable results,’” noting that “[a] person with ordinary skill in the art is a person of ordinary creativity, not an automaton, and in many cases . . . will be able to fit the teachings of multiple patents together like pieces of a puzzle.” Pet. 37 (citing Ex. 1003 ¶ 112). We also are unpersuaded by this argument. Petitioner’s conclusory statements are nothing more than a restatement of basic tests identified by the Supreme Court for determining whether an invention would have been obvious. *See KSR*, 550 U.S. at 417 (“whether the improvement is more than the predictable use of prior art elements according to their established functions”); *id.* (whether “the claimed subject matter may involve more than . . . the mere application of a known technique to a piece of prior art ready for the improvement”); *see also id.* at 421 (“A person of ordinary skill is also a person of ordinary creativity, not an automaton.”). General principles on what may constitute a supporting rationale cannot substitute for specific application of those principles to the facts. Petitioner does not provide a persuasive, fact-based analysis to support the proposed combination of Birnboim and O'Donovan. Notably, it is not clear which features of O'Donovan’s container are to be incorporated into Birnboim’s container, or how, or why.

In view of the foregoing, we are not persuaded that Petitioner has provided adequately articulated reasoning with some rational underpinning

to support the legal conclusion of obviousness with respect to claim 1. *See Kahn*, 441 F.3d at 988. As each of claims 3, 6, 9, 10, 39, 40, 43, and 45–47 depends from claim 1, we determine, based on the record before us, that Petitioner has not demonstrated a reasonable likelihood of prevailing in showing that these dependent claims would have been obvious over Birnboim and O’Donovan.

B. Obviousness over Birnboim, O’Donovan, and Chelles

Petitioner argues that claims 18 and 19 of the ’381 patent would have been obvious over Birnboim, O’Donovan, and Chelles. Pet. 51–60. Claims 18 and 19 depend from claim 1. Petitioner’s arguments and evidence regarding these dependent claims do not remedy the deficiencies discussed above with respect to claim 1 in relation to Birnboim and O’Donovan. *See* Pet. 58–60 (relying on Chelles only for claims 18 and 19); *see also id.* at 58 (for claim 1, referring to “Reasons Birnboim and O’Donovan Render Obvious Claim 1 above under Ground 1,” which is based on Birnboim and O’Donovan). On this record, and for the reasons discussed above, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claims 18 and 19 would have been obvious over Birnboim, O’Donovan, and Chelles.

C. Obviousness over Birnboim, O’Donovan, and Clarkson

Petitioner argues that claims 13 and 14 of the ’381 patent would have been obvious over Birnboim, O’Donovan, and Clarkson. Pet. 60–72. Claims 13 and 14 depend from claim 1. Petitioner’s arguments and evidence regarding these dependent claims do not remedy the deficiencies discussed

above with respect to claim 1 in relation to Birnboim and O'Donovan. *See* Pet. 70–72 (relying on Clarkson only for claims 13 and 14); *see also id.* at 70 (for claim 1, referring to “Ground 1 re claim 1,” where Ground 1 is based on Birnboim and O'Donovan). On this record, and for the reasons discussed above, we determine that Petitioner has not demonstrated a reasonable likelihood of prevailing on its assertion that claims 13 and 14 would have been obvious over Birnboim, O'Donovan, and Clarkson.

III. CONCLUSION

For the foregoing reasons, we are not persuaded that Petitioner has demonstrated a reasonable likelihood that it would prevail on any of the asserted grounds as to any of the challenged claims of the '381 patent.

IV. ORDER

For the reasons given, it is

ORDERED that the Petition is *denied* as to all challenged claims, and no trial is instituted.

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