

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPECTRUM SOLUTIONS LLC,
Petitioner,

v.

DNA GENOTEK INC.,
Patent Owner.

IPR2022-00774
Patent 10,000,795 B2

Before ERICA A. FRANKLIN, DAVID COTTA, and JAMIE T. WISZ,
Administrative Patent Judges.

FRANKLIN, *Administrative Patent Judge.*

DECISION
Granting Institution of *Inter Partes* Review
35 U.S.C. § 314

I. INTRODUCTION

Spectrum Solutions LLC (“Petitioner”) filed a Petition requesting an *inter partes* review of claims 1–18 of U.S. Patent No. 10,000,795 B2 (Ex. 1001, “the ’795 patent”). Paper 1 (“Pet.”). DNA Genotek Inc. (“Patent Owner”) has elected not to file a Preliminary Response.

We have authority under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless there is a reasonable likelihood that the petitioner would prevail with respect to at least one of the claims challenged in the petition. 35 U.S.C. § 314(a). Upon considering the argument and evidence presented in the Petition, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of at least one claim challenged in the Petition. Accordingly, we institute an *inter partes* review.

A. *Real Parties-in-Interest*

Petitioner identifies itself as the real party-in-interest. Pet. 1. In addition, Petitioner notes that Spectrum Holdco LLC is its parent company and that Spectrum Holdco LLC and Spectrum Intermediate LLC have “a financial interest in, or could be substantially affected by the outcome of, this proceeding.” *Id.* Patent Owner identifies itself as the real party-in-interest and notes that it is a wholly owned subsidiary of OraSure Technologies, Inc. Paper 4, 1.

B. *Related Matters*

The parties indicate that they are involved in a district court litigation in *DNA Genotek Inc. v. Spectrum Solutions LLC*, C.A. No. 21-cv-0516 (S.D.Cal.). Pet. 1; Paper 4, 1. Petitioner notes that the ’795 patent has not been asserted in that proceeding. Pet. 1.

The parties also identify an *inter partes* review (IPR2022-00134) of US Patent No. 10,767,215 (“the ’215 patent”), a continuation of the ’795 application. Pet. 1; Paper 4, 2.

Patent Owner identifies also pending U.S. Patent Application No. 17/014,688 (which claims priority from the application that issued as the ’215 patent). Paper 4, 2. Patent Owner further identifies a district court litigation between itself and a third party, Longhorn Vaccines & Diagnostic Inc. (“Longhorn”), and several *inter partes* review proceedings filed by Patent Owner that challenged patents assigned on their face to Longhorn. *Id.* at 1–2.

C. The ’795 Patent

The ’795 patent is directed to “compositions and methods for storage and/or isolation of ribonucleic acids [“RNA”] from bodily fluid(s), and/or secretion(s), (e.g., saliva, mucous), and/or tissue(s).” Ex. 1001, 1:19–22. According to the Specification,

a large number of pathogenic mammalian viruses (e.g. SARS-CoA, Influenza virus, Measles virus, Rabies virus, Dengue fever virus, Respiratory Syncytial Virus (RSV) HIV and Hepatitis A, C-E virus) have genomes based on RNA rather than DNA. Detection and/or analysis of such RNA are potentially of great importance, yet an accepted method that is optimal for collecting, preserving/stabilizing, transporting and extracting RNA has not yet been developed.

Id. at 1:28–36.

The Specification explains that “routine use of RNA as an analyte in detection of analysis or RNA has been limited because of its labile nature.” *Id.* at 1:38–40. For example, its sugar-phosphate backbone “is particularly sensitive to breakdown (degradation, hydrolysis) by alkaline solutions,” as well as by acidic solutions. *Id.* at 1:40–43. Additionally, RNA may be

degraded enzymatically by endoribonucleases. *Id.* at 1:46–47. Due, in part, to this instability, “RNA is often considered as an unsuitable analyte for diagnosis or detection.” *Id.* at 1:54–56.

The ’795 patent explains that “RNA can be extracted from most, if not all, cell types in the human body (except erythrocytes) and from a variety of cell-containing bodily fluids and/or secretions as well as tissues.” *Id.* at 2:13–16. That RNA sample, however, “must be either frozen (e.g., with liquid nitrogen) or quickly transported in the unfrozen state at 4° C to a laboratory for extraction of RNA.” *Id.* at 2:21–24. The need for immediate freezing or rapid analysis is “problematic in terms of cost and storage space.” *Id.* at 2:24–26.

According to the ’795 patent, “[a] simpler procedure for collecting RNA in a form that would not require the sample be frozen or transported immediately to a laboratory including equipment such as freezers, refrigerators, centrifuges, etc., would be desirable,” particularly given the “increasing use of nucleic acid-based testing in human and veterinary medicine and in research.” *Id.* at 2:32–51. “In addition, it would be desirable for the amount of RNA in the collected sample to be sufficiently large to allow for the detection of low copy number RNA species such as messenger RNA and some viruses.” *Id.* at 3:4–7.

Accordingly, an object of the invention is to provide a “a composition and method for prolonged storage of RNA from bodily fluids and/or tissues at room temperature, which compositions and methods further facilitate extraction of the RNA in as high a yield and as nearly intact state as is possible.” *Id.* at 3:18–23. In particular, the ’795 patent provides a method for preserving ribonucleic acid from a biological sample.

D. Illustrative Claim

Petitioner challenges claims 1–18 in the ’795 patent. Claim 1, the only independent claim, is illustrative of the challenged claims and reads as follows:

1. A phenol-free method for preserving ribonucleic acid from a biological sample comprising the steps of:
 - a. obtaining the sample from a subject;
 - b. contacting the sample with a composition comprising an anionic detergent, wherein the anionic detergent is at a concentration of 1 % to 8%, and a buffering agent at a pH of about 5 to about 8.2 to form a mixture;
 - c. storing the mixture at room temperature; and
 - d. heating the mixture, wherein the mixture is heated at a temperature of greater than 50°C., wherein the composition stabilizes the ribonucleic acid at room temperature.

Ex. 1001, 35:34–45.

E. Asserted Grounds of Unpatentability

Petitioner asserts three grounds of unpatentability in this Petition (Pet. 14), which are provided in the table below:

Claims Challenged	35 U.S.C. § ¹	Reference(s)/Basis
1–3, 5–18	103(a)	Birnboim, ² Stefan ³

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §103, effective March 16, 2013.

Because the application from which the ’795 patent issued has an effective filing date prior to March 16, 2013, the pre-AIA version of §103 applies.

² Birnboim, WO 2003/104251 A2, published Dec. 18, 2003 (Ex. 1003, “Birnboim”).

³ Stefan et al., DE 102 19 117 C1, published Oct. 30, 2003 (Ex. 1005, “Stefan”). Stefan is a German language document. All references to Stefan herein are to the English language translation provided by Petitioner (Ex. 1005) rather than the German language original (Ex. 1004).

Claims Challenged	35 U.S.C. § ¹	Reference(s)/Basis
4	103(a)	Birnboim, Stefan, Tuggle ⁴
10	103(a)	Birnboim, Stefan, Heath ⁵

Petitioner relies on the declaration of Dr. Vincent A. Fischetti, among other evidence. Ex. 1002.

II. ANALYSIS

A. *Person of Ordinary Skill in the Art*

The level of skill in the art is a factual determination that provides a primary guarantee of objectivity in an obviousness analysis. *Al-Site Corp. v. VSI Int’l Inc.*, 174 F.3d 1308, 1323 (Fed. Cir. 1999) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966)); *Ryko Mfg. Co. v. Nu-Star, Inc.*, 950 F.2d 714, 718 (Fed. Cir. 1991)).

Petitioner contends that a person of ordinary skill in the art (“POSA”) would have had:

(1) a Ph.D. in microbiology, molecular biology, biochemistry, or related discipline; (2) at least two years of post-graduate experience in the area of nucleic acid extraction, preservation, and analysis; and (3) experience with the development or use of nucleic acid extraction formulations, and the literature concerning nucleic acid extraction, preservation, and analysis.

Pet. 11–12 (citing Ex. 1002 ¶¶ 19–20).

Petitioner’s definition of one of ordinary skill in the art is uncontested on the current record. Because we find Petitioner’s definition to be

⁴ Tuggle et al., U.S. Patent Publication No. 2003/0104424 A1, published Jun. 5, 2003 (Ex. 1006, “Tuggle”).

⁵ Heath, U.S. Patent No. 5,973,137, issued Oct. 26, 1999 (Ex. 1009, “Heath”).

reasonable and consistent with the '795 patent and the cited art, we adopt it for purposes of this Decision.

B. Claim Construction

The Board applies the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. § 282(b).

37 C.F.R. § 100(b) (2019). Under that standard, claim terms “are generally given their ordinary and customary meaning” as understood by a person of ordinary skill in the art at the time of the invention. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). “In determining the meaning of the disputed claim limitation, we look principally to the intrinsic evidence of record, examining the claim language itself, the written description, and the prosecution history, if in evidence.” *DePuy Spine, Inc. v. Medtronic Sofamor Danek, Inc.*, 469 F.3d 1005, 1014 (Fed. Cir. 2006) (citing *Phillips*, 415 F.3d at 1312–17).

Petitioner does not propose a construction for any claim term. *See generally*, Pet. At this stage in the proceeding, we determine that no explicit construction of any claim term is necessary to determine whether to institute review. *See Nidec Motor Corp. v. Zhongshan Broad Ocean Motor Co. Ltd.*, 868 F.3d 1013, 1017 (Fed. Cir. 2017) (“[W]e need only construe terms ‘that are in controversy, and only to the extent necessary to resolve the controversy’” (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999))); *Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (“[C]laim terms need only be construed ‘to the extent necessary to resolve the controversy’”).

C. Obviousness over Birnboim and Stefan

Petitioner asserts that claims 1–3 and 5–18 would have been obvious over the combined teachings of Birnboim and Stephan. Pet. 14–38.

A patent claim is unpatentable under 35 U.S.C. § 103(a) if the differences between the claimed subject matter and the prior art are such that the subject matter, as a whole, would have been obvious at the time the invention was made to a person having ordinary skill in the art to which the subject matter pertains. *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 406 (2007). “An obviousness determination requires finding both ‘that a skilled artisan would have been motivated to combine the teachings of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success in doing so.’” *CRFD Research, Inc. v. Matal*, 876 F.3d 1330, 1340 (Fed. Cir. 2017) (quoting *Intelligent Bio-Sys., Inc. v. Illumina Cambridge Ltd.*, 821 F.3d 1359, 1367–1368 (Fed. Cir. 2016)).

Notwithstanding what the teachings of the prior art would have suggested to one with ordinary skill in the art at the time of the patent’s invention, the totality of the evidence submitted, including objective evidence of nonobviousness, may lead to a conclusion that the challenged claims would not have been obvious to one with ordinary skill in the art. *In re Piasecki*, 745 F.2d 1468, 1471–72 (Fed. Cir. 1984); *see also Graham v. John Deere Co.*, 383 U.S. 1, 17–18 (1966); *Leapfrog Enters., Inc. v. Fisher–Price, Inc.*, 485 F.3d 1157, 1162 (Fed. Cir. 2007).⁶

⁶ At this stage of the proceeding, Patent Owner does not assert evidence of objective indicia supporting nonobviousness of the challenged claim.

1. Birnboim

Birnboim discloses “methods for preserving nucleic acids.” Ex. 1003, 1:5–7. In Birnboim’s method, “a composition, which, when mixed with mucin-containing bodily fluid, preserves the nucleic acids at room temperature under ambient conditions for extended periods of time.” *Id.* at 5:2–4. “The nucleic acid to be preserved by the composition can be DNA or RNA, including mRNA or viral RNA.” *Id.* at 6:22–23; *see also, id.* at 8:29–30 (“In yet another embodiment, the nucleic acid is DNA or RNA. If the nucleic acid is RNA, desirably it is mRNA or viral RNA.”), 11:12–14 (defining “nucleic acid” as “a chain of the nucleotides, including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), typically found in chromosomes, mitochon[dria], ribosomes, bacteria, or viruses.”).

In Birnboim’s Example 7, Birnboim discloses specific nucleic acid-preserving compositions that include “0.2M TRIS^[7]-HCL” and “1% SDS^[8].” *Id.* at 28, Table 3 (Lanes 1–3). The compositions of Example 7 include DNA and have a pH of 9.5. *Id.* at 27–28. Birnboim discloses that “RNA is most stable in the pH range of 5.0 to 7.0, desirably a pH of from 6.5 to 6.8” and that to achieve the desired pH, “the pH of the composition may be adjusted using pH buffers.” *Id.* at 14:29–31.

Birnboim explains,

Incubation [of mixtures of saliva samples and compositions] can be at room temperature over a relatively long period of time (days or weeks) while samples are being shipped to a laboratory for analysis. If transferred to a laboratory soon after collection, incubation at 55°C for 4 to 16 hours is sufficient to allow the activated protease to digest the majority of protein to small

⁷ Tris(hydroxymethyl)-aminomethane.

⁸ Sodium dodecyl sulfate.

peptides or amino acids. Under such conditions, nucleic acids and polysaccharides remain relatively intact.

Id. at 21:7–12.

2. *Stefan*

Stefan's objective is "to provide an improved stabilization method for ribonucleic acids" using lithium dodecyl sulfate. Ex. 1005 ¶¶ 8–9. Stefan explains that, "surprisingly . . . RNA is stabilised by adding lithium dodecyl sulfate for many hours to days, although RNases were present in the respective solution." *Id.* ¶ 10.

Stefan provides a working example of "carrying out an RNA stabilisation" using an "RNA-stabilising buffer." *Id.* ¶ 15, 18. Stefan's "RNA-stabilising buffer" is a composition comprising, among other things, 150 mmol/l Tris-HCL pH 7.5 and 2% (weight/volume) lithium dodecyl sulfate. *Id.* ¶ 18. In Stefan's working example, the solution was incubated with RNA "for various times (0, 3, 24 and 48 hours) at room temperature." *Id.* Following cDNA synthesis and PCR amplification, Stefan concluded that "the RNA in the stabilising solution is not degraded or is extremely slowly degraded over at least 1 day and, if the RNA concentration is appropriate, for 2 days." *Id.* ¶¶ 18–24.

3. *Discussion*

Petitioner contends that the phenol-free method of preserving RNA from a biological sample, as recited in claim 1, would have been obvious over the combined teachings of Birnboim and Stefan. Pet. 29. To begin, Petitioner asserts that both Birnboim and Stefan disclose a phenol-free method for preserving RNA from a biological sample obtained from a subject. *Id.* at 20–22. Petitioner asserts that Birnboim's Example 7

discloses the step of contacting the sample with a composition including 1% SDS (anionic detergent). *Id.* at 22 (citing Ex. 1003, 25:27–28:4 (Table 3)).

Petitioner acknowledges that Birnboim’s compositions have a pH of 9.5, but notes that Birnboim explicitly discloses using a pH of 5–7, as recited by claim 1. *Id.* at 22 (citing Ex. 1003, 6:30–7:2, 14:29–30). For the buffering agent, Petitioner turns to Stefan’s working example which uses an “RNA-stabilising buffer” containing, among other items, 150 mmol/l Tris-HCl pH 7.5 and 2% (weight/volume) LDS. *Id.* (citing Ex. 1005 ¶ 18). According to Petitioner, “Stefan’s disclosure confirms the motivation provided by Birnboim for using a composition containing an anionic detergent at an appropriate pH for storing RNA, and Stefan’s working example validates the reasonable expectation of success in doing so.” *Id.* at 23 (citing Ex. 1002 ¶ 48).

Petitioner asserts that Birnboim and Stefan each disclose storing the nucleic acid-containing mixture at room temperature. *Id.* at 24. Further, Petitioner asserts that Birnboim explains that its composition “preserves the nucleic acids at *room temperature* under ambient conditions for extended periods of time.” *Id.* at 26 (quoting Ex. 1003, 5:2–4) (emphasis added by Petitioner). Petitioner asserts that Stefan similarly explains that its composition stabilizes the RNA in solution at room temperature. *Id.* at 27.

For the limitation requiring the mixture to be “heated at a temperature of greater than or about equal to 50°C.,” Petitioner relies on Birnboim’s disclosure of an optional step of adding a protease to the mixture and heating the mixture to 55°C to allow the activated protease to digest the majority of protein to small peptides or amino acids. *Id.* at 25–26 (citing Ex. 1003, 8:22–26, 21:9–12; Ex. 1002 ¶ 56).

According to Petitioner, a POSA would have been motivated to combine Birnboim's method for preserving nucleic acids at room temperature with Stefan's exemplary use of an anionic detergent and a buffering agent at a pH of 7.5 because both references describe closely related subject matter directed to preserving nucleic acids at room temperature using compositions comprising an anionic detergent and a buffering agent. *Id.* at 28. Additionally, Petitioner asserts that the POSA would have expected that combination to yield predictable results, as it involved using known reagents for their known functions. *Id.* at 28–29; Ex. 1002 ¶¶ 63–64.

Petitioner contends that the combination of Birnboim and Stefan also teaches each limitation of the dependent claims. In particular, Petitioner asserts that Birnboim discloses contacting the mixture with a protease, as required by claim 2, and further suggests the use of proteinase K as the protease, as required by claim 3. Pet. 29 (citing Ex. 1003, 8:22–26, 21:9–12, 20:19). Petitioner asserts that Birnboim discloses using sodium dodecyl sulfate (SDS), which satisfies the limitations of claims 5 and 6. Petitioner asserts that Birnboim teaches the pH ranges recited in claims 7, 16, and 17, and the specific pH limitation recited in claim 18 by disclosing the use of pH ranges from about 5.0 to about 7.0, and desirably from about 6.5 to about 6.8. *Id.* at 32 (citing Ex. 1003, 6:30–7:1, 33:25–29).

Petitioner asserts that Birnboim discloses specific buffering agents, i.e., 4-(2-hydroxyethyl)piperazine-1-ethanesulfonic acid (HEPES), TRIS, and carbonate, that meet the limitations of claims 8 and 9. *Id.* at 33–34 (citing Ex. 1003, 6:28–30, 15:1–3). For the buffering agent required by claim 10, “CDTA or citric acid,” Petitioner asserts that a POSA would have been motivated to use CDTA as a buffering agent in the proposed

combination because: (a) Birnboim discloses the use of CDTA, albeit as a chelating agent; and (b) use of CDTA as a buffering agent in nucleic acid preservation solutions was well known in the art prior to the time of the invention. *Id.* at 35 (citing Ex. 1003, 6:4–12, 15:12–15; Ex. 1002 ¶ 85).

For the additional requirements in claims 11–13 directed to the type and source of the sample, Petitioner asserts that Birnboim and Stefan meet those limitations by disclosing the use of saliva and/or blood samples from a human. *Id.* at 36 (citing Ex. 1003, 11:1–3, 10:27–29, 8:28–29; Ex. 1005 ¶ 17). For claim 14, which requires the composition to stabilize RNA at room temperature for one or more time periods between “at least one day” and “greater than about eight weeks,” and claim 15, which requires such stabilization “for about one day to about eight weeks,” Petitioner relies on Birnboim’s description of the invention as relating to “compositions and methods for preserving nucleic acids at room temperature for extended periods of time” and Examples 3–6 disclosing such stabilization. *Id.* at 37 (citing Ex. 1003, 1:5–7, 26:1–27:23). Petitioner also relies on Stefan’s disclosure that its composition stabilizes RNA “for many hours to days.” *Id.* (quoting Ex. 1005, 1).

Based on our review of the current record, we determine that Petitioner’s foregoing assertions are supported by the cited references and the currently unrebutted testimony of Petitioner’s declarant, Dr. Fischetti. In particular, based on the current record, we determine that Petitioner has shown sufficiently for institution that Petitioner’s proposed combination of Birnboim and Stefan teaches or suggests a phenol-free method for preserving RNA from a biological sample comprising each step recited in claims 1–3 and 5–8. Petitioner has demonstrated persuasively, at this stage in the proceeding, that a POSA would have been motivated to combine the

teachings of Birnboim and Stefan, as Petitioner proposes, with a reasonable expectation of providing a method of using the recited composition comprising an anionic detergent at a concentration of 1% to 8%, and a buffering agent at a pH of about 5 to 8.2 to stabilize RNA at room temperature.

Accordingly, based on the information presented at this stage of the proceeding, we determine that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing that claims 1–3 and 5–18 are rendered obvious by the combination of Birnboim and Stefan.

D. Obviousness over Birnboim, Stefan, and Tuggle

Petitioner asserts that claim 4 would have been obvious over Birnboim, Stefan, and Tuggle. Pet. 38–39.

We incorporate our description and discussion of Birnboim and Stefan in Section II.C. here.

1. Tuggle

Tuggle discloses a “method for screening pigs to determine those more likely to have the improved trait of superior disease resistance” by “analyzing . . . mRNA or genomic DNA” in a sample. Ex. 1006 ¶ 17. In Tuggle’s method, cells are suspended in a buffer “supplemented with 100 µl/ml of proteinase K.” *Id.* ¶ 73. After incubating, “the cells are heated to 95° C for 10 min to inactivate the proteinase K.” *Id.*

2. Discussion

Claim 4 depends from claim 1 and further requires the mixture to be “heated at a temperature of greater than or equal to about 90° C.” Ex. 1001, 35:50–53. We understand Petitioner relies on the combination of Birnboim and Stefan for the limitations recited in claim 1, as set forth in Ground 1, and relies on Tuggle to teach the additional limitation of claim 4. *See* Pet. 38–

39. In particular, Petitioner directs us to Tuggle’s method of extracting nucleic acid from cells by suspending the cells in a solution containing a buffer and a detergent. *Id.* (citing Ex. 1006 ¶¶ 3, 17). Petitioner asserts that Tuggle discloses adding proteinase K to the mixture and heating the mixture to a temperature of greater than 50° C, as disclosed in Birnboim. *Id.* at 39 (citing Ex. 1006 ¶ 73). Petitioner notes that Tuggle additionally discloses that “[a]fter incubating at 56° C. for 2 hr. the cells are heated to 95° C. for 10 min to inactivate the proteinase K.” *Id.* (quoting Ex. 1006 73). According to Petitioner,

A POSA would have been motivated with a reasonable expectation of success to increase the temperature from 55° C as disclosed in Birnboim, to greater than 90° C as disclosed in Tuggle, to inactivate the protease (e.g., proteinase K) prior to amplification, because proteases were known to interfere with diagnostic protocols.

Id.; Ex. 1002 ¶ 99.

Based on our review of the current record, we determine that Petitioner’s foregoing assertions are supported by the cited references and the currently unrebutted testimony of Petitioner’s declarant, Dr. Fischetti.

Accordingly, based on the information presented at this stage of the proceeding, we determine that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing that claim 4 is rendered obvious by the combination of Birnboim, Stefan, and Tuggle.

E. Obviousness over Birnboim, Stefan, and Heath

Petitioner asserts that claim 10 would have been obvious over Birnboim, Stefan, and Tuggle. Pet. 40.

We incorporate our description and discussion of Birnboim and Stefan in Section II.C. here.

1. Heath

Heath discloses “an RNA isolation process which utilizes low pH reagents.” Ex. 1009, code (57). Heath’s process uses “a ‘Cell Lysis Reagent,’ [which] includes an anionic detergent dissolved in water.” *Id.* at 5:61–52. “The pH of the Cell Lysis Reagent is maintained at less than about 6 using a buffer, such as a citrate buffer.” *Id.* at 6:21–22. Heath teaches that the concentration of sodium citrate and citric acid can be adjusted to obtain the desired pH. *Id.* at 6:28–37.

2. Discussion

Claim 10 depends from claim 1 and further recites that the “buffering agent is CDTA or citric acid.” Ex. 1001, 35:25–26. We understand that Petitioner relies on the combination of Birnboim and Stefan for the limitations recited in claim 1, as set forth in Ground 1, and relies on Heath for the additional limitation of claim 10. *See* Pet. 40. In particular, Petitioner asserts that Heath discloses using citric acid as a buffer in its composition used for RNA extraction. *Id.* (Ex. 1009, 6:21–28). Petitioner also notes that Heath explains that the molar ratio of sodium citrate to citric acid can be adjusted to obtain the desired pH. *Id.* (citing Ex. 1009, 6:28–37). According to Petitioner, “a POSA would have been motivated with a reasonable expectation of success to adjust the sodium citrate/citric acid molar ratio to establish the desired pH as disclosed in Stefan to successfully preserve RNA.” *Id.*; Ex. 1002 ¶¶ 102–103.

Based on our review of the current record, we determine that Petitioner’s foregoing assertions are supported by the cited references and the currently unrebutted testimony of Petitioner’s declarant, Dr. Fischetti.

Accordingly, based on the information presented at this stage of the proceeding, we determine that Petitioner has shown sufficiently that there is a reasonable likelihood that it would prevail in showing that claim 10 is rendered obvious by the combination of Birnboim, Stefan, and Heath.

III. CONCLUSION

For the foregoing reasons, we conclude that Petitioner has established a reasonable likelihood of prevailing in its assertion that claims 1–18 of the ’795 patent are unpatentable. Accordingly, we institute an *inter partes* review of all of the challenged claims on all of the asserted grounds.

Our determination in this Decision is not a final determination on either the patentability of any challenged claims or the construction of any claim.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314(a), an *inter partes* review of claims 1–18 of the ’795 patent on all grounds set forth in the Petition is instituted, commencing on the entry date of this decision; and

FURTHER ORDERED that pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4, notice is hereby given of the institution of review.

IPR2022-00774
Patent 10,000,795 B2

FOR PETITIONER:

Joseph F. Jennings
Ali S. Razai
Paul N. Conover
Benjamin B. Anger
KNOBEE, MARTENS, OLSEN, & BEAR, LLP
2JFJ@knobbe.com
2AZR@knobbe.com
2PNC@knobbe.com
2BBA@knobbe.com

FOR PATENT OWNER:

Brian M. Kramer
Desmond P. O'Sullivan
MORRISON & FOERSTER LLP
BMKramer@mofo.com
DOSullivan@mofo.com