

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

SPECTRUM SOLUTIONS LLC,
Petitioner,

v.

LONGHORN VACCINES & DIAGNOSTICS, LLC,
Patent Owner.

IPR2021-00850
Patent 8,293,467 B2

Before GEORGIANNA W. BRADEN, ZHENYU YANG, and
WESLEY B. DERRICK, *Administrative Patent Judges*.

YANG, Administrative Patent Judge.

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

I. INTRODUCTION

Spectrum Solutions LLC (“Petitioner”) filed a Petition (Paper 1 (“Pet.”)), seeking an *inter partes* review of claims 1–42 of U.S. Patent No. 8,293,467 B2 (Ex. 1001, “the ’467 patent”). Longhorn Vaccines & Diagnostics, LLC (“Patent Owner”) filed a Preliminary Response (Paper 7 (“Prelim. Resp.”)). With our authorization (Ex. 3001), Petitioner filed a Reply to the Preliminary Response (Paper 8, “Reply”), and Patent Owner filed a Sur-reply (Paper 11).

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 1 of the claims challenged in the petition.” 35 U.S.C. § 314(a). The Federal Circuit has interpreted the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition.” *PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018).

For the reasons provided below, we determine Petitioner has satisfied the threshold requirement set forth in 35 U.S.C. § 314(a). Thus, based on the information presented, we institute an *inter partes* review of claims 1–42 of the ’467 patent on all grounds.

A. Related Matters

According to the parties, Patent Owner asserted the ’467 patent against Petitioner in *Longhorn Vaccines & Diagnostics, LLC v. Spectrum Solutions LLC*, C.A. No. 2:20-cv-00827 (D. Utah). Pet. 1; Paper 4.

Petitioner also filed IPR2021-00847, -00851, -00854, -00857, and -00860, challenging claims of related U.S. Patents Nos. 8,084,443; 8,415,330; 8,669,240; 9,212,399; and 9,683,256, respectively.

B. The '467 Patent

The '467 patent relates to “aqueous compositions for collection, transport, and storage of a biological specimen containing a population of nucleic acids in a single reaction vessel, which can then be purified and/or analyzed using conventional molecular biology methods.” Ex. 1001, 1:27–31. Petitioner and its declarant, Dr. Taylor, note that, as of the earliest possible priority date of the '467 patent, aqueous reagents for extracting, “stabilizing and preserving nucleic acids were wide-spread in the prior art.” *See generally*, Pet. 4–7; Ex. 1002 ¶¶ 48–62 (citations omitted). Petitioner and its declarant point to, for example, the 1982 Maniatis Laboratory Manual as disclosing the isolation of RNA using a buffered, nuclease-free, aqueous solution of guanidinium isothiocyanate (a potent chaotropic agent), sodium lauryl sarkosinate (a detergent), β -mercaptoethanol (a reducing agent), and EDTA (a chelator). Pet. 4–5; Ex. 1002 ¶¶ 48–50; Ex. 1004, 189–90.

The '467 patent, however, states that prior art methods could result in the degradation of nucleic acids, even when stored under freezing temperatures, and had the potential for exposure to infectious agents during collection, transfer, and testing. Ex. 1001, 1:49–2:28. The '467 patent also states that “clinical laboratory methods for pathogen detection were

labor-intensive, expensive processes that required highly knowledgeable and expert scientists with specific experience.” *Id.* at 2:29–32.

Against this background, the ’467 patent purports to disclose “new and useful compositions . . . that may advantageously improve conventional collection, lysis, transport and storage methods for the preparation of nucleic acids from one or more biological sources.” *Id.* at 3:14–18. In particular, the ’467 patent discloses a one-step, aqueous composition that:

- a) inactivates viruses or microbes in the sample, b) lyses the biological cells or tissues to free the nucleic acids from cellular debris and extraneous biomolecules, c) protects the nucleic acids from degradation by endonuclease activity, and
- d) preserves the nucleic acids for subsequent isolation, detection, amplification, and/or molecular analysis.

Id. at 1:31–38; *see id.* at 6:35–43. The Specification further discloses exemplary compositions comprising a buffered solution of nuclease-free water containing:

- a chaotrope, e.g., guanidine thiocyanate, guanidine hydrochloride, or guanidine isocyanate;
- a detergent, e.g., sodium dodecyl sulfate (SDS), lithium dodecyl sulfate (LDS), sodium taurodeoxycholate (NaTDC), sodium taurocholate (NaTC), sodium glycocholate (NaGC), sodium deoxycholate (NaDC), sodium cholate, sodium alkybenzene sulfonate (NaABS), or N-lauroyl sarcosine (NLS);
- a reducing agent, e.g., β -mercaptoethanol (β -ME), dithiothreitol (DTT), dimethylsulfoxide (DMSO), formamide, or phosphine (TCEP);
- a chelator, e.g., EGTA, HEDTA, DTPA, NTA, EDTA, citrate anhydrous, sodium citrate, calcium citrate, ammonium citrate,

ammonium bicitrate, citric acid, diammonium citrate, ferric ammonium citrate, or lithium citrate);

a surfactant/defoaming agent, e.g., a silicone polymer such as Antifoam A®, or a polysorbate such as Tween®; and

a short chain alkanol, e.g., methanol, ethanol, propanol, butanol, pentanol, hexanol.

Id. at 4:23–7:40.

According to the Specification:

In certain embodiments, the composition containing the sample suspected of containing nucleic acids will stabilize the nucleic acids to the extent that they either remain at least substantially non-degraded (i.e., at least substantially stable) even upon prolonged storage of the composition at ambient, refrigerator, or sub-zero temperatures. It will be desirable that this stability provides that at least about 70%, at least about 85%, more preferably at least about 90%, more preferably at least about 95%, or even more preferably, at least about 98% of the polynucleotides contained within the stored sample will not be degraded upon prolonged storage of the sample. In certain embodiments, substantially all of the polynucleotides contained within the sample will be stabilized such that the original integrity of the polynucleotides is preserved during the collection, lysis, storage, and transport of the processed sample.

Id. at 9:57–10:5.

C. Illustrative Claims

Claims 1, 24, 29 and 31 of the '467 patent are independent. They are reproduced below:

1. A method for denaturing proteins, inactivating nucleases and killing pathogens in one step without degrading nucleic acid of a biological sample containing proteins, nucleases, and nucleic acid, and suspected to contain pathogens, comprising:

providing a mixture containing one or more chaotropes, one or more detergents, one or more reducing agents, one or more chelators, and one or more buffers, together present in an amount sufficient to denature proteins, inactivate nucleases, kill pathogens, and not degrade nucleic acid;

contacting the biological sample with the mixture which denatures proteins, inactivate nucleases, kill pathogens, and does not degrade nucleic acid of the biological sample; and

detecting the presence and identity of or absence of the pathogens in the biological sample.

Ex. 1001, 32:56–33:6.

24. A method for denaturing proteins, inactivating nucleases and killing pathogens in one step without degrading nucleic acid of a biological sample containing proteins, nucleases, and nucleic acid, and suspected to contain pathogens, comprising:

providing a mixture containing one or more chaotropes, one or more detergents, one or more reducing agents, one or more chelators, one or more buffers, one or more short-chain alkanols, and one or more surfactants, together present in an amount sufficient to denature proteins, inactivate nucleases, kill pathogens, and not degrade nucleic acid;

contacting the biological sample with the mixture which denatures proteins, inactivate nucleases, kill pathogens, and does not degrade nucleic acid of the biological sample, and

detecting the presence and identity of or absence of the pathogens in the biological sample, wherein,

said one or more chaotropes are selected from the group consisting of guanidine thiocyanate, guanidine isocyanate, guanidine hydrochloride, and any combination thereof;

said one or more detergents are selected from the group consisting of sodium dodecyl sulfate, lithium dodecyl sulfate, sodium taurodeoxycholate, sodium taurocholate, sodium glycocholate, sodium deoxycholate, sodium cholate,

sodium alkylbenzene sulfonate, N-lauroyl sarcosine, and any combination thereof;

said one or more chelators are selected from the group consisting of ethylene glycol tetra acetic acid, hydroxyethylethylenediaminetriacetic acid, diethylene triamine penta acetic acid, N,N-bis(carboxymethyl)glycine, ethylenediaminetetraacetic, citrate anhydrous, sodium citrate, calcium citrate, ammonium citrate, ammonium bicitrate, citric acid, diammonium citrate, ferric ammonium citrate, lithium citrate, and any combination thereof; and

said one or more buffers are selected from the group consisting of tris(hydroxymethyl)aminomethane, citrate, 2-(N-morpholino)ethanesulfonic acid, N,N-Bis(2-hydroxyethyl)-2-aminoethanesulfonic acid, 1,3-bis(tris(hydroxymethyl)methyl amino)propane, 4-(2-hydroxyethyl)-1-piperazine ethanesulfonic acid, 3-(N-morpholino) propanesulfonic acid, bicarbonate, phosphate, and any combination thereof; and

said one or more short-chain alkanols are selected from the group consisting of methanol, ethanol, propanol, butanol, pentanol, or hexanol, and any combination thereof;

which are together present in an amount sufficient to denature proteins, inactivate nucleases; kill pathogens, and not substantially degrade nucleic acid of the biological sample upon contacting the mixture.

Id. at 34:28–35:12.

29. A method for denaturing proteins, inactivating nucleases and killing pathogens in one step without degrading nucleic acid of a biological sample containing proteins, nucleases, and nucleic acid comprising:

providing a mixture containing one or more chaotropes, one or more detergents, one or more reducing agents, one or more chelators, and one or more buffers, together present in an

amount sufficient to denature proteins, inactivate nucleases, kill pathogens, and not degrade nucleic acid;
providing the biological sample suspected to contain pathogens;
contacting the biological sample with the mixture which liberates nucleic acid of the pathogens for PCR analysis;
PCR amplifying the nucleic acid, if present; and
determining the presence or absence of the pathogens in the biological sample.

Id. at 35:45–61.

31. A method for denaturing proteins, inactivating nucleases and killing pathogens in one step without degrading nucleic acid of a biological sample containing proteins, nucleases, and nucleic acid, and suspected to contain pathogens, comprising:
providing a mixture containing one or more chaotropes, one or more detergents, one or more reducing agents, one or more chelators, and one or more buffers, together present in an amount sufficient to denature proteins, inactivate nucleases, kill pathogens, and not degrade nucleic acid, wherein the one or more chaotropes are present in an amount from about 0.5 M to about 6 M, the one or more detergents are present in an amount from about 0.1% to about 1% (wt./vol.); the one or more reducing agents are present in an amount from about 0.5 mM to about 0.3 M; the one or more chelators are present in an amount from about 0.01 mM to about 1 mM; and the one or more buffers are present in an amount from about 1 mM to about 1M.

Id. at 36:4–23.

A. Asserted Challenges to Patentability

Petitioner asserts the following challenges to patentability:

Claim(s) Challenged	35 U.S.C. §¹	Reference(s)
1, 2, 4, 7, 17–20, 22, 23, 29, 31, 34–39	102(b)	Birnboim ²
1–9, 15–23, 29–39	103(a)	Birnboim
10, 11, 24, 25, 28	103(a)	Birnboim, Mori ³
12	103(a)	Birnboim, Das ⁴
27	103(a)	Birnboim, Mori, Das
13, 14	103(a)	Birnboim, Helftenbein, ⁵ Birnboim 2006 ⁶
26	103(a)	Birnboim, Mori, Helftenbein
40–42	103(a)	Birnboim, Mori, Helftenbein, Birnboim 2006

In support of their respective positions, Petitioner relies on the Declaration of Richard F. Taylor, Ph.D. (Ex. 1002), and Patent Owner relies on the Declaration of Louis DeFilippi, Ph.D. (Ex. 2001).

¹ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112-29, 125 Stat. 284, 287–88 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. The ’467 patent issued before the effective date of the AIA. Ex. 1001, code (45). Thus, pre-AIA version of §§ 102 and 103 applies.

² US 2004/0038269 A1, published Feb. 26, 2004 (Ex. 1003).

³ WO 2005/111210 A1, published Nov. 24, 2005 (Ex. 1011).

⁴ US 2005/0123928 A1, published Jun. 9, 2005 (Ex. 1008).

⁵ US 6,776,959 B1, issued Aug. 17, 2004 (Ex. 1019).

⁶ WO 2006/096973 A1, published Sept. 21, 2006 (Ex. 1023).

II. ANALYSIS

A. Claim Construction

In an *inter partes* review, we construe a claim term “using 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. § 42.100(b) (2020). Under that standard, the words of a claim “are generally given their ordinary and customary meaning,” which is “the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

The parties do not propose any claim construction. *See* Prelim. Resp. 5. On this record and for purposes of this Decision, we see no need to construe any term expressly.⁷ *See Wellman, Inc. v. Eastman Chem. Co.*, 642 F.3d 1355, 1361 (Fed. Cir. 2011) (stating that claim terms need only be construed to the extent necessary to resolve the controversy).

B. Alleged Anticipation by Birnboim

Petitioner asserts that Birnboim anticipates challenged claims 1, 2, 4, 7, 17–20, 22, 23, 29, 31, and 34–39. Pet. 9–32. Patent Owner disputes Petitioner’s challenge. Prelim. Resp. 5–34. Based on this record, we

⁷ As explained below in Section II.B.2, in its arguments, Patent Owner implicitly relies on narrow constructions of “kill pathogens” and “not degrade nucleic acids.” Patent Owner, however, has not proposed the constructions of these terms. On this record and for purposes of this Decision, we provisionally apply their plain and ordinary meaning.

determine Petitioner has established a reasonable likelihood that it would prevail in this assertion, at least with regard to independent claim 1.

1. Birnboim

Birnboim discloses “compositions and methods for preserving nucleic acids at room temperature for extended periods of time and for simplifying the isolation of nucleic acids,” most particularly, DNA or RNA from sputum or saliva. Ex. 1003 ¶¶ 2, 27. According to Birnboim, nucleic acid isolated can be that of the sputum or saliva donor or “from a bacterium or a virus that is residing in the buccal, nasal, or respiratory passages of the subject.” *Id.* ¶ 27; *see id.* ¶ 43 (defining “nucleic acid” as meaning “a chain of the nucleotides, including deoxyribonucleic acid (DNA) or ribonucleic acid (RNA), typically found in chromosomes, mitocho[n]dria, ribosomes, bacteria, or viruses”); ¶ 18 (“The nucleic acid to be preserved can be . . . viral RNA.”); ¶ 27 (“If the nucleic acid is RNA, desirably it is mRNA or viral RNA.”); ¶ 45 (discussing quantitation of “high molecular weight nucleic acid (DNA, RNA, mRNA, or viral RNA)”); claims 7, 16.

Birnboim discloses “nucleic acid preserving compositions” for use in a one-step method to lyse nucleic acid-containing cells or viruses, release the nucleic acids into the composition, inactivate nucleases in the sample, and stabilize the extracted nucleic acid for future analysis. *See generally id.* ¶¶ 11, 22, 27, 64, 114–122. Birnboim further discloses “inclusion of an inhibitor of ribonuclease in the composition of the invention . . . when the nucleic acid to be preserved is RNA, desirably mRNA, or when the nucleic acid to be preserved is from a virus or a bacterium.” *Id.* ¶ 22; *see also id.*

¶ 68 (stating that in addition to the use of various denaturing agents, “reagents such as heparin, heparan sulfate, or oligo(vinylsulfonic acid) . . . are known to inhibit the action of deoxynucleases and /or ribonucleases”).

Birnboim explains:

When sputum is mixed with a composition of the present invention, 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 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 peptides or amino acids. Under such conditions, nucleic acids and polysaccharides remain relatively intact.

Once digestion is complete, nucleic acid isolation can be performed using any technique known in the art.

Id. ¶¶ 84–85.

In Example 1, Birnboim discloses an embodiment wherein a subject spits saliva into a collection tube which is mixed with an equal volume of the nucleic acid-preserving composition. *Id.* ¶¶ 107–109. Once the container is capped and the contents shaken, the nucleic acid is “in an intermediate preserved state” and “can be maintained in a frozen state or at any temperature up to about 60° C.” *Id.* ¶ 110. Alternatively, “[t]he container can be mailed back to the testing lab at room temperature.” *Id.* ¶ 111.

In Example 3, Birnboim discloses the collection and extraction of DNA using a nucleic acid-preserving composition comprising “33 mM TRIS-HCl, 0.67 M urea, 0.67 M LiCl, 0.6% sodium dodecyl sulfate, 3.3 mM CDTA, 30% ethanol, and 0.25 M sodium ascorbate, all adjusted to a final

pH of 8.0.” *Id.* ¶¶ 114–122. In Example 4, Birnboim subjects the DNA extracted from saliva collected in the composition of Example 3 and stored for 14 days to agarose gel electrophoresis and ethidium bromide staining, noting “the characteristic band of chromosomal DNA present in all samples.” *Id.* ¶ 117, Fig. 1. In Examples 5 and 6, Birnboim subjects the DNA extracted after 62 and 30 days, respectively, to real time PCR. *Id.* ¶¶ 118–121. According to Birnboim, the results using real time PCR demonstrate the suitability of the DNA for PCR analysis. *Id.* ¶ 119.

2. Analysis

a. *Claim 1*

For purposes of this Decision, we focus on independent claim 1. Petitioner provides a detailed analysis of where each element of challenged claim 1 is found in Birnboim. Pet. 14–20, 23–24. Specifically, Petitioner argues that Birnboim discloses contacting a sputum sample, which contains proteins, nucleases, and nucleic acid, with Birnboim’s aqueous compositions to preserve nucleic acid in one step. Pet. 14 (citing Ex. 1003 ¶¶ 11, 77, 78, 84, 91, 114–122). Petitioner contends the aqueous compositions used in Birnboim’s method “provide the advantageous properties of chemical stabilization of nucleic acids and the inhibition of nucleases, including deoxyribonucleases, and microbial growth.” *Id.* (quoting Ex. 1003 ¶ 64).

Petitioner also refers to Birnboim for disclosing “the nucleic acid can be from a bacterium or a virus that is residing in the buccal, nasal, or respiratory passages of the subject.” *Id.* at 15 (quoting Ex. 1003 ¶ 27). Thus,

according to Petitioner, “Birnboim discloses performing the method on a sample ‘suspected to contain pathogens.’” *Id.*

Petitioner further asserts that Birnboim discloses the step of “providing a mixture.” *Id.* at 15–20. Petitioner points out that Example 3 of Birnboim discloses an aqueous composition comprising the chaotrope, detergent, reducing agent, chelator, and buffer, as recited in challenged claim 1. *Id.* at 16–19. Petitioner argues that Birnboim’s “Reagents Are Present in an Amount Sufficient to Perform the Claimed Functions.” *Id.* at 19–20.

In addition, Petitioner asserts that Birnboim discloses the contacting step of claim 1. *Id.* at 23. Lastly, Petitioner relies on Birnboim’s Examples 4–6 to show analyzing saliva samples “using either gel electrophoresis or PCR to detect the presence and identity of DNA in the samples. *Id.* at 24 (citing Ex. 1003 ¶¶ 116–122). According to Petitioner, an ordinarily skilled artisan would understand that “by analyzing the nucleic acids of, for example, the bacteria or virus in the sputum as disclosed in Birnboim, one would ‘detect[] the presence and identity of or absence of the pathogens in the biological sample,’ as recited in claim 1 of the ’467 patent.” *Id.* (citing Ex. 1002 ¶¶ 121–122).

Patent Owner counters that Birnboim does not disclose the compositions of the claimed methods, because it does not teach “the use of chaotropes and detergents as individual and separate components.” Prelim. Resp. 8–9. Patent Owner also contends Birnboim does not expressly disclose

killing pathogens with its composition.”⁸ *Id.* at 11–19. Patent Owner further asserts Birnboim does not disclose “a Method as-Claimed with Reagents ‘Together Present in an Amount Sufficient to Perform’ the Functional Limitations of Claim 1.” *Id.* at 19–32. Lastly, Patent Owner argues Birnboim does not disclose the step of “detecting the presence and identity of or absence of the pathogens.” *Id.* at 32–33.

On this record, and at this stage of the proceeding, Petitioner has shown sufficiently Birnboim discloses each limitation of claim 1. *See* Pet. 14–15 (showing Birnboim discloses the preamble); 18–19 (table showing “Birnboim Example 3 discloses using each of claim 1’s recited ingredients together in an aqueous composition”), 19–20, 23, 24 (relying on Birnboim’s Examples 4–6 for confirming the amounts of the compounds used in the composition in Example 3 perform the claimed functions, and disclosing the “contacting” and “detecting” steps). We address below Patent Owner’s counterarguments, which do not undermine the adequacy of Petitioner’s showing for purposes of trial institution.

Patent Owner argues that Birnboim neither teaches “the use of chaotropes and detergents as individual and separate components” nor explains why denaturing agents urea and SDS were selected for the

⁸ Patent Owner also argues Petitioner has not shown that Birnboim inherently kills pathogens with its composition. Prelim. Resp. 18–19. But, as Patent Owner acknowledges, “Petitioner has not argued inherency in the Petition.” *Id.* at 18. We, thus, do not address the inherency argument.

exemplary composition in Example 3. Prelim. Resp. 9–10. Patent Owner’s argument is unavailing.

As Patent Owner acknowledges, the exemplary composition in Example 3 of Birnboim includes “a denaturing agent that works as a chaotrope (urea) and a second denaturing agent that works as a detergent (SDS).” Prelim. Resp. 10. It matters not that Birnboim refers to these reagents generally as “denaturing agents” (Ex. 1003 ¶¶ 20, 68), because an ordinarily skilled artisan would understand the use and identity of chaotropes and detergents for isolating nucleic acid.

For example, as Dr. Taylor points out, Koller (Ex. 1016) teaches “nucleic acid releasing compositions containing a chaotrope, detergent, reducing agent, and chelator salt that could keep nucleic acids stable for months.” Ex. 1002 ¶ 52 (citing Ex. 1016, 7:1–5). According to Koller, “[t]he chaotropic component of the nucleic acid releasing composition is both an effective protein denaturant and a strong inhibitor of nucleases. The effect of a chaotropic agent on growing cells is an almost instantaneous dissolution of the cells.” Ex. 1016, 7:19–23. Koller teaches urea is a useful chaotropic agent. *Id.* at 7:23–25. Koller also teaches that for the nucleic acid releasing composition, it is “beneficial to incorporate a surface-active anionic detergent to further aid in lysis and disruption of the cells,” and SDS is such a detergent. *Id.* at 8:8–15. Thus, we are persuaded that an ordinarily skilled artisan would have understood the individual properties and uses of urea as a chaotrope and SDS as a detergent for isolating nucleic acid.

Patent Owner points out that the exemplary composition of Birnboim's Example 3 includes ethanol and other "unexplained components . . . not claimed in the composition of claim 1, including LiCl and NaOAc." Prelim. Resp. 11. Patent Owner is correct; but that does not undercut Petitioner's anticipation argument. Challenged claim 1 recites a mixture "containing" five categories of reagents. Thus, we agree with Petitioner that "[t]he claimed composition includes the listed reagents but does not exclude others." Reply 4. Indeed, just like the exemplary composition in Example 3 of Birnboim, challenged claim 9, which indirectly depends from claim 1, recites ethanol.

Patent Owner argues that although Birnboim teaches the use of antimicrobial agents, and preferably ethanol, the composition of Example 3 includes only 30% ethanol, which, Patent Owner asserts, "is not sufficient to have a bactericidal effect, much less kill viruses or vegetative bacteria." Prelim. Resp. 13–14 (citing Ex. 2001 ¶¶ 21, 25–26). In addition, Patent Owner argues that SDS in Birnboim's Example 3 "would not *necessarily* be expected to be bactericidal." *Id.* at 29–30 (citing Ex. 2001 ¶¶ 29, 31, 33–35). Dr. DeFilippi testifies that SDS "is quite poor as a lysis agent," because "[d]uring prolonged SDS interaction" only "25% of the ribonucleic acid and 40% of the deoxyribonucleic acid were released from the cells." Ex. 2001 ¶¶ 29–30 (citing Ex. 2007⁹). Thus, according to Dr. DeFilippi, an ordinarily

⁹ Woldringh et al., Effects of treatment with sodium dodecyl sulfate on the ultrastructure of *Escherichia coli*, 111 J. Bacteriol. 801–13 (1972)

skilled artisan “would not rely on SDS in [an] aqueous composition to ‘kill pathogens’ in a sample.” *Id.* ¶ 30. We disagree.

Exhibit 2007 shows “the structural alterations . . . occur[red] in *E. coli* during its interaction with a comparatively low concentration of detergent, i.e. with 0.05% SDS.” Ex. 2007, 5. This concentration is substantially lower than the 0.6% SDS used in Birnboim’s Example 3. Ex. 1003 ¶ 115.

Nevertheless, as Petitioner argues, even at this low concentration of SDS, there was reported dissolution of bacterial plasma membranes and release of nucleic acids, reasonably indicating that, “the cells are, of course, dead.” Reply 3 (citing Ex. 2007, 5, 11, 13, Figs. 2, 12).

We also are persuaded by Petitioner’s argument and evidence that “[l]ater publications citing to Ex. 2007 . . . reiterat[e] that SDS kills pathogens by lysing cells and releasing vital cellular components, just as Birnboim discloses.” *Id.* at 3. For example, citing Exhibit 2007, Exhibit 1044 states that “SDS has been shown more than 40 years ago to cause ***significant bacterial membrane damage*** with subsequent ***release of DNA, RNA and protein.***” *Id.* at 4 (quoting Ex. 1044¹⁰). Thus, on this record,

(Ex. 2007). Petitioner cites to the exhibit page number Patent Owner provides. For consistency, we do the same.

¹⁰ McDaniel et al., A Putative ABC Transporter Permease is Necessary for Resistance to Acidified Nitrite and EDTA in *Pseudomonas aeruginosa* under Aerobic and Anaerobic Planktonic and Biofilm Conditions, 7 *Frontiers in Microbiol.* 1–14 (2016) (Ex. 1044).

we find SDS in Birnboim’s Example 3 would “kill pathogens,” as required in challenged claim 1.

Patent Owner also argues that “Birnboim is focused on collection and preservation of nucleic acids from native human cells, not pathogens.”

Prelim. Resp. 12.¹¹ According to Patent Owner, “[t]he amount of extracted nucleic acid needed for analysis [in Birnboim] is small and does not require lysing all or even most of the cells in the sample.” *Id.* at 11. Acknowledging Birnboim’s express teaching to isolate nucleic acid “from a bacterium or a virus,” Patent Owner argues this “off-hand reference . . . fails to expressly teach killing pathogens because extracting the small amount of DNA necessary for testing does not ‘kill pathogens’ in the meaning of the ’476 Patent—to prevent ‘dissemination of live infectio[u]s pathogens.’” *Id.* at 15. Patent Owner’s argument, again, is unavailing.

As an initial matter, a reference is prior art for all that it teaches. *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547, 1551 (Fed. Cir. 1989). Thus, we decline to dismiss the express teachings of Birnboim merely because they are not the main focus of its disclosure.

Patent Owner equates the claim language “kill pathogens” with complete sterilization of a sample “to prevent ‘dissemination of live infection[u]s pathogens.” Prelim. Resp. 15 (citing Ex. 1001, 2:15–17, 6:35–

¹¹ In this context, we understand Patent Owner’s reference to “nucleases” “human nuclease material” and “human cell nucleases” as indicating “nucleuses” or, more commonly, “nuclei,” as opposed to enzymes capable of cleaving the phosphodiester bonds between nucleotides of nucleic acids.

43; Ex. 2001 ¶ 7). On their face, however, the claims do not require killing every potential pathogen in a sample. *See In re Self*, 671 F.2d 1344, 1348 (CCPA 1982) (holding similar arguments fail because “they are not based on limitations appearing in the claims”). Birnboim expressly discloses isolating nucleic acid from bacteria and viruses. Ex. 1003 ¶¶ 18, 22, 27. It does not suggest such isolation as non-destructive, and we presume that at least some pathogens are “killed” in the extraction process according to the plain and ordinary meaning of the term.

Dr. DeFilippi testifies that Birnboim fails to kill pathogens because it only references “bacteriostatic” and “bactericidal,” and does not teach killing “yeast or other fungi or viruses.”¹² Ex. 2001 ¶ 18. On this record, we do not read the challenged claims as requiring the claimed composition to clear every sample of every type of pathogenic agent. *See* Ex. 1001, 27:6–29:20 (the ’467 patent itself disclosing killing bacteria only in Example 8).

To the extent Patent Owner implies that the term “kill pathogens” has a special meaning in the ’467 patent, Patent Owner has not proposed a specific construction of the term. Patent Owner argues “one of the major

¹² Petitioner contends Dr. DeFilippi admitted that “[Birnboim] does not teach killing of anything but bacteria.” Reply 1 (citing Ex. 1042 ¶ 17). Patent Owner reasonably argues that Dr. DeFilippi merely stated that “the word ‘bactericidal’ itself (not Birnboim’s composition) ‘does not teach the killing of anything but bacteria.’” Sur-reply 1 (citing Ex. 1042 ¶ 17). Birnboim, nevertheless, expressly teaches compositions comprising antimicrobial agents that “can be bacteriostatic, bactericidal or both.” Ex. 1003 ¶ 21.

objectives of the '467 Patent is to render the sample sufficiently or entirely non-pathogenic to allow safe handling and transport of the sample.” Prelim. Resp. 17 (citing Ex. 1001, 2:17–20, 6:36–40, 26:17–23; Ex. 2001 ¶ 36). Patent Owner, however, has not provided sufficient reasoned argument why we should import such description in the Specification into the challenged claims. Accordingly, on this record, we decline to do so. *See SuperGuide Corp. v. DirecTV Enters., Inc.*, 358 F.3d 870, 875 (Fed. Cir. 2004) (“Though understanding the claim language may be aided by the explanations contained in the written description, it is important not to import into a claim limitations that are not a part of the claim.”).

Considering the record as a whole, Petitioner persuades us that the exemplary composition in Birnboim’s Example 3 kills at least some bacteria and/or viruses. Thus, we find Birnboim’s instruction to isolate nucleic acid “from a bacterium or a virus that is residing in the buccal, nasal, or respiratory passages of the subject,” necessarily “kills pathogens,” under its plain and ordinary meaning. *See* Ex. 1003 ¶ 27.

Patent Owner further contends that “nothing in Birnboim teaches using the ***composition utilized in the claimed methods***, as opposed to utilizing additional unclaimed substances, to kill pathogens.” Prelim. Resp. 20. According to Patent Owner, Birnboim suggests that LiCl and NaOAc, “both outside the group of the reagents required” in challenged claim 1, “were important for one or more of the functions of denaturing proteins, inactivating nucleases, and preventing degradation of nucleic acids,” as recited in claim 1. *Id.* at 23 (citing Ex. 2001 ¶ 39). Thus, Patent

Owner argues Birnboim does not teach “the combination of the two denaturing agents in Birnboim’s Example 3 alone, without the unclaimed ethanol, (and without other unexplained components of Birnboim’s Example 3 composition that likewise are not claimed in the composition of claim 1, including LiCl and NaOAc) would be sufficient to perform the claimed functions” *Id.* at 10–11. Patent Owner’s argument is unavailing.

At the time of the ’467 patent, ordinarily skilled artisans were well versed in the methods and reagents used in isolating nucleic acids. *See* Ex. 1002 ¶¶ 48–62); *see also, e.g.*, Ex. 1004, 192, 192 (use of NaOAc to wash/precipitate nucleic acids); Ex. 1009, 1:66–68 (the same); Ex. 1013, 4.3.1, 4.5.2 (use of LiCl for selective precipitation of RNA and as buffer component); Ex. 1018, 15:55–67 (commercial RNA extraction kits comprising LiCl in combination with chaotrope); Ex. 1016, 8:26–9:2 (“Typically, the nucleic acid releasing composition will further include salt . . . The type of salt included in the nucleic acid releasing composition is not critical . . . however, optimum results are obtained with . . . [NaOAc].”). Given the extensive background knowledge in the field, we reject Patent Owner’s implication that, at the priority date of the ’467 patent, an ordinarily skilled artisan would not have understood the role of LiCl or NaOAc in Birnboim’s Example 3.

Patent Owner refers to Birnboim for “stat[ing] in Example 4 that the enzyme proteinase K is added to the solution of Example 3 to prepare the solution for precipitating DNA.” Prelim. Resp. 22 (citing Ex. 1003 ¶ 117). This, according to Patent Owner, demonstrates that the composition of

Example 3 does not “denature proteins,” because, if it did, “the composition of Example 3 would have denatured the proteinase K added in Example 4, rendering it inoperable.” *Id.* a 23 (citing Ex. 2001 ¶¶ 40–45, 47). We disagree.

Birnboim discloses that

Low specificity proteases such as proteinase K are frequently used in the purification of nucleic acids. Since proteases are themselves proteins, their action can be inhibited by denaturing agents. Thus, a balance must be struck between the concentration of denaturing agents that will, on the one hand, *inhibit deoxyribonucleases or ribonucleases and denature other proteins* in saliva and, on the other hand, not significantly inhibit the proteolytic enzymes.

Ex. 1003 ¶ 69 (emphasis added). Thus, Birnboim as a whole shows the exemplary composition in Example 3 contains denaturing agents at concentrations sufficient to denature proteins in the saliva sample without rendering the later added proteinase K inoperable. *See also* Ex. 1016, 7:19–25 (teaching chaotropic agent, such as urea used in the exemplary composition in Birnboim’s Example 3, “is both an effective protein denaturant and a strong inhibitor of nucleases”).

Patent Owner further asserts that “Birnboim does not necessarily prevent degradation of nucleic acids.” Prelim. Resp. 31 (citing Ex. 2001 ¶¶ 13, 46–50). As support, Patent Owner points out that Birnboim states DNA is stable for “desirably more than 60 days” when ascorbic acid, a reducing agent preferred in Birnboim, is present and “desirably more than 360 days” when “the composition does not contain ascorbic acid.” *Id.* (citing Ex. 1003 ¶¶ 13, 25). Patent Owner also points out that Birnboim defines

“stable” when referring to nucleic acid as retention of at least about 50% of the initial amount. *Id.* (citing Ex. 1003 ¶ 45). Thus, according to Patent Owner, it is inaccurate to equate “stabilizing nucleic acid” in Birnboim with “not degrad[ing] nucleic acid,” as recited in challenged claim 1. *Id.* Patent Owner’s argument, again, is unavailing.

Dr. DeFilippi, contrasts the disclosure of Birnboim (“at least about 50%” retention) with those of the ’467 patent (“desirable” to have “at least about 70%” to “at least about 98% of the polynucleotides contained within the stored sample will not be degraded upon prolonged storage,” such as “several days to several weeks,” or “several weeks to even several months or more”). *See* Ex. 2001 ¶¶ 9–10 (citing Ex. 1001, 9:57–10:5, 10:34–50). These disclosures in the ’467 patent Specification, however, are not the limitations of challenged claim 1; and Patent Owner does not provide sufficient reasoned argument why we should import them into the claim. In fact, Patent Owner has not proposed a construction of the term “not degrade nucleic acid.”¹³

Thus, on this record, and for purposes of this Decision, we find Petitioner has met its burden in showing that Birnboim discloses “not degrad[ing] nucleic acid of a sample” under the term’s plain and ordinary meaning.

¹³ The parties agree that the term, as recited in challenged claim 1, does not mean complete preservation of all nucleic acid. *See* Reply 5 (citing Ex. 1045, 4); Sur-reply 4.

Moreover, Patent Owner's position in the parallel district court case undercuts its various arguments on the functional limitations of claim 1 here. In the district court, Patent Owner argued that

It is common knowledge to one skilled in the art that an aqueous composition that comprises a) one or more chaotropes; b) one or more detergents and/or surfactants; c) one or more reducing agents; d) one or more chelators; and e) one or more buffers serves the purpose of denaturing proteins, inactivating nucleases, killing pathogens, and not degrading nucleic acid of a sample suspected of containing pathogens when the sample is contacted with the composition.

Ex. 1007 ¶ 17.

Petitioner contends that this statement constitutes a prior admission that "Birnboim's compositions having these five reagents perform the functions recited in claim 1 of the '467 patent." Pet. 23 n.1; *see also* Reply 4–5 (asserting Patent Owner's arguments in the Preliminary Response are inconsistent with its district court complaint). Patent Owner responds that "it does not admit anything regarding what was known in the art at the time of the invention," but refers to "what is known in the art *today* because of PO's disclosures." Sur-reply 4.

On this record, particularly in light of Birnboim's disclosure of compositions comprising all the claimed reagents and the general skill in the art regarding methods and reagents for isolating nucleic acids, we provisionally find that the "common knowledge [of] one skilled in the art" referred to in the district court complaint encompasses the knowledge as of the priority date of the '467 patent. Thus, Patent Owner's statement in the district court complaint demonstrates the exemplary composition in

Birnboim's Example 3, having the five reagents recited in challenged claim 1, performs the functions recited therein.

Patent Owner further contends that Birnboim does not teach the “detecting” step of challenged claim 1. Prelim. Resp. 32. According to Patent Owner, because “Birnboim’s reference to nucleic material ‘from a virus or a bacterium’ is prophetic,” “a POSA would not think to utilize the Birnboim compositions in methods that include samples suspected to contain pathogens.” *Id.* at 32–33. We disagree.

As explained above, we decline to dismiss the express teachings of Birnboim. *See Beckman Instruments*, 892 F.2d at 1551. Birnboim explicitly discloses isolating nucleic acid “from a bacterium or a virus that is residing in the buccal, nasal, or respiratory passages of the subject.” Ex. 1003 ¶ 27. Thus, we agree with Petitioner that “Birnboim discloses practicing its method on a sample suspected of containing pathogens.” Pet. 15, 24. We also agree with Petitioner that analyzing the nucleic acids of the bacteria or virus in the sputum, using the methods disclosed in Examples 4–6 in Birnboim, would meet the limitation of “detecting the presence and identity of or absence of the pathogens in the biological sample,” as recited in challenged claim 1. *Id.* at 24.

In sum, based on the current record and for purposes of this Decision, Petitioner has met its burden in showing that Birnboim discloses each limitation of claim 1. Pet. 25–49. Because there is a reasonable likelihood that Petitioner would prevail in its challenge of claim 1 as anticipated by Birnboim, we institute an *inter partes* review as to all challenges raised in

the Petition. *See* Patent Trial and Appeal Board Consolidated Trial Practice Guide 64 (Nov. 2019)¹⁴ (“The Board will not institute on fewer than all claims or all challenges in a petition.”). We nevertheless offer the following observations on Petitioner’s challenge of the other independent claims, claims 24, 29, and 31.

b. Claim 29

Claim 29 is similar to claim 1, and further recites “contacting the biological sample with the mixture which liberates nucleic acid of the pathogens for PCR analysis,” and “PCR amplifying the nucleic acid, if present.”

For limitations of claim 29 that overlap with those of claim 1, Petitioner relies on the evidence and argument presented in its challenge of claim 1. Pet. 29. For the additional steps recited in claim 29, Petitioner refers to Birnboim for disclosing that “[w]hen sputum is mixed with a composition of the present invention, 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.” *Id.* at 28 (quoting Ex. 1003 ¶ 84). Petitioner also argues that “Example 5 of Birnboim expressly discloses detecting the presence of nucleic acids in the contacted saliva sample using PCR.” *Id.* (citing Ex. 1003 ¶¶ 118–119).

Although Patent Owner disputes that Birnboim discloses the

¹⁴ Available at <https://www.uspto.gov/sites/default/files/documents/tpgnov.pdf>

additional steps recited in claim 29 (*see* Prelim. Resp. 33 (“No such method steps are contemplated by Birnboim.”)), it does not provide any substantive analysis.

Because we institute an *inter partes* review as to all challenges raised in the Petition, the parties are encouraged to further address the relevant issues to fully develop the record during trial.

c. Claim 31

Claim 31 is similar to claim 1, and further recites concentration ranges of the compound classes recited in claim 1.

Petitioner argues that Birnboim’s Example 3 discloses a specific composition with a chaotrope, detergent, reducing agent, and buffer in amounts that fall within the claimed range of challenged claim 31. Pet. 21, 29 (citing Ex. 1003 ¶ 115). For the concentration of the chelator, Petitioner acknowledges that the concentration of the chelator (CDTA) in Birnboim’s Example 3, at 3.3 mM, is higher than the range in challenged claim 31 (0.01–1 mM). *Id.* at 21. Petitioner, however, argues that

Birnboim discloses that “concentrations in the 1–20 mM range are sufficient” and even that “other concentrations would work, and the compositions of the invention are not intending to be limited to this range.” Ex. 1003, ¶[0067]. Birnboim’s disclosed concentration range of 1–20 mM overlaps the claimed range of 0.01–1 mM, thus satisfying the limitation for anticipation purposes.

Id. at 21–22.

Patent Owner does not address this argument in its Preliminary Response.

Because we institute an *inter partes* review as to all challenges raised in the Petition, the parties are encouraged to further address the relevant issues to fully develop the record during trial.¹⁵

C. Alleged Obviousness over Birnboim and Mori

Claim 24 is similar to claim 1, and further requires that the recited mixture contain a surfactant and a short-chain alkanol. Claim 24 also lists specific compounds in each compound class, from which constituents must be selected. Petitioner asserts that independent claim 24 would have been obvious over the combination of Birnboim and Mori. Pet. 52–54. Patent Owner disputes Petitioner’s challenge. Prelim. 40–43.

1. Mori

Mori teaches isolating nucleic acids from a test sample (e.g., bodily fluids, plants, animals, bacteria, viruses, and cultured cells) by treating the sample with a “nucleic acid-solubilizing reagent,” which “dissolves cell membranes and nuclear membrane, and solubilizes nucleic acid.” Ex. 1011, 57. Exemplary nucleic acid-solubilizing reagents may include “a chaotropic salt, a surfactant, a defoaming agent, a protease and a nucleic acid stabilizing agent.” *Id.* at 58.

With respect to the surfactant, Mori teaches the use of a wide variety of compounds including an anionic surfactant, an amphoteric surfactant and, preferably, either a nonionic or cationic surfactant:

¹⁵ Patent Owner provides no additional argument with respect to claims 2, 4, 7, 17–20, 22, 23, 29, 31, and 34–39, also challenged under this ground.

Nonionic surfactants include a polyoxyethylene alkyl phenyl ether-based surfactant, a polyoxyethylene alkyl ether-based surfactant, and fatty acid alkanolamide, and the preferable one is a polyoxyethylene alkyl ether-based surfactant. Among the polyoxyethylene (POE) alkyl ether surfactant, POE decylether, POE lauryl ether, POE tridecyl ether, POE alkylendecyl ether, POE sorbitan monolaurate, POE sorbitan monooleate, POE sorbitan monostearate, tetraoleic polyoxyethylene sorbit, POE alkyl amine, and POE acetylene glycol are more preferred.

Cationic surfactants include cetyl trimethyl ammonium bromide, dodecyl trimethyl ammonium chloride, tetradecyl trimethyl ammonium chloride, cetyl pyridinium chloride.

Id. at 61–62.

2. Analysis

“[W]hen a patent simply arranges old elements with each performing the same function it had been known to perform and yields no more than one would expect from such an arrangement, the combination is obvious.” *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398, 417 (2007) (internal quotation marks omitted). But “a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art.” *Id.* at 418. In an obviousness inquiry, “it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does.” *Id.* On this record, we find Petitioner has not shown sufficiently “some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness.” *Id.*

In asserting that claim 24 would have been obvious over Birnboim and Mori, Petitioner relies on Mori for teaching the use of surfactant, and

Birnboim for teaching the use of the other compound classes.

See Pet. 50–51. We focus on Petitioner’s reliance on Birnboim.

Petitioner characterizes independent claim 24’s list of specific compounds as “a compilation of limitations found in dependent claims 3, 4, 6, 7, and 9.” *Id.* at 52. Petitioner then refers to the analyses of those corresponding claims, and summarizes its previous demonstration that Birnboim discloses each of those “different ingredients in the mixture.” *Id.* at 53.

Specifically, for chaotropes, Petitioner argues that “Birnboim explicitly discloses using either guanidine thiocyanate or guanidine hydrochloride as part of its compositions.” Pet. 35 (citing Ex. 1003 ¶¶ 20, 68). Therefore, according to Petitioner, “[a] POSA would have been motivated to use either or both of these compounds in Birnboim’s method.” *Id.* For detergents, Petitioner relies on Birnboim’s Example 3 for “using SDS as the denaturing agent (detergent) in the ‘nucleic acid-preserving composition.’” *Id.* at 25 (citing Ex. 1003 ¶ 115). For chelators, Petitioner argues that “Birnboim discloses using either EDTA or DTPA as the chelator in its method.” *Id.* at 38 (citing Ex. 1003 ¶¶ 16, 67). Thus, Petitioner argues, an ordinarily skilled artisan “would have been motivated to use either of these chelators in Birnboim’s method.” *Id.* at 38–39. For buffers, Petitioner relies on Birnboim’s Example 3 for “using Tris-HCl as the buffering agent in the ‘nucleic acid-preserving composition.’” *Id.* at 25 (citing Ex. 1003 ¶ 115). And for short-chain alkanols, Petitioner argues that “Birnboim discloses using alkanols, such as ethanol, in the aqueous compositions and

includes ethanol in composition of Example 3.” *Id.* at 40 (citing Ex. 1003 ¶ 13). According to Petitioner, “[a] POSA would have been motivated to use ethanol in Birnboim’s method.” *Id.*

Although Petitioner’s mapping of these individual compounds to Birnboim’s disclosures appears reasonable, we are not persuaded that Petitioner has shown sufficiently a reason that would have prompted an ordinarily skilled artisan to combine the discrete ingredients all at once.

What we have here is different from that of claim 1. For claim 1, Petitioner relies on the exemplary composition in Example 3, which includes all five categories of compounds recited. *See* Pet. 18–19 (table showing “Birnboim Example 3 discloses using each of claim 1’s recited ingredients *together* in an aqueous composition” (emphasis added)). In contrast, here, Petitioner appears to “use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.”¹⁶ *In re Fine*, 837 F.2d 1071, 1075 (Fed. Cir. 1988); *see* Pet. 53 (tables showing each limitation addressed separately in corresponding claims).

¹⁶ In this regard, we agree with Patent Owner that an ordinarily skilled artisan “would not have used the Birnboim Example 3 composition as a starting point and arrived at the composition utilized by the method of claim 24,” because “doing so would have required substituting the chaotrope . . . the reducing agent and the chelator.” Prelim. Resp. 42.

D. Other Asserted Challenges

Petitioner challenges claims 1–9, 15–23, and 29–39 as obvious over Birnboim. Pet. 32–48. Patent Owner only addresses the challenge as applied to claim 1. Prelim. Resp. 34–39. Because we determine Petitioner has met its burden in showing that Birnboim anticipates claim 1, we do not address this challenge.

Petitioner also challenges other claims as obvious over Birnboim and certain other prior art references. Pet. 48–68. Patent Owner does not address those challenges on the merits. Prelim. Resp. 43–44.

Because we institute an *inter partes* review as to all challenges raised in the Petition, the parties are encouraged to further address the relevant issues of all challenges, including these other grounds, to fully develop the record during trial.

Any argument not raised in a timely Patent Owner Response to the Petition, or as permitted in another manner during trial, shall be deemed waived even if asserted in the Preliminary Response. In addition, nothing in this Decision authorizes Petitioner to supplement information advanced in the Petition in a manner not permitted by the Board's Rules.

III. CONCLUSION

Based on the current record, we find Petitioner has demonstrated a reasonable likelihood that it would prevail with respect to at least one claim challenged in the Petition.

At this stage of the proceeding, the Board has not made a final determination as to the construction of any claim term or the patentability of

any challenged claim. Our view with regard to any conclusion reached in the foregoing could change upon further development of the record during trial.

IV. ORDER

In consideration of the foregoing, it is hereby:

ORDERED that pursuant to 35 U.S.C. § 314, an *inter partes* review is hereby instituted on all challenged claims of the '467 patent based on all the asserted grounds set forth in the Petition; 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 a trial commencing on the entry date of this decision.

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Patent 8,293,467 B2

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