

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

NATIONAL BEEF PACKING COMPANY, LLC,
Petitioner,

v.

INSTITUTE FOR ENVIRONMENTAL HEALTH, INC.,
Patent Owner.

IPR2024-01156
Patent 9,845,486 B2

Before JEFFREY N. FREDMAN, ROBERT A. POLLOCK, and
RYAN H. FLAX, *Administrative Patent Judges*.

FREDMAN, *Administrative Patent Judge*.

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

I. INTRODUCTION

National Beef Packing Company, LLC (“Petitioner”) filed a Petition (Paper 2, “Pet.”) requesting *inter partes* review of claims 1–30 (the “challenged claims”) of U.S. Patent No. 9,845,486 B2 (Ex. 1001, “the ’486 patent”). The Institute for Environmental Health (“Patent Owner”) expressly waived filing a Preliminary Response. Paper 7, 1.

We have jurisdiction under 35 U.S.C. § 314, which provides that an *inter partes* review may not be instituted unless the information presented in the Petition “shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition.”

A decision to institute under § 314 may not institute on fewer than all claims challenged in the petition. *SAS Inst., Inc. v. Iancu*, 138 S. Ct. 1348, 1359–60 (2018). In addition, if the Board institutes trial, it will “institute on all grounds in the petition.” PTAB Consolidated Trial Practice Guide, 5–6 (Nov. 2019); *see also PGS Geophysical AS v. Iancu*, 891 F.3d 1354, 1360 (Fed. Cir. 2018) (interpreting the statute to require “a simple yes-or-no institution choice respecting a petition, embracing all challenges included in the petition”).

Having considered the arguments and evidence presented in the Petition and the Preliminary Response, for the reasons described below, we institute *inter partes* review.

II. REAL PARTIES-IN-INTEREST

Petitioner identifies the National Beef Packing Company, LLC as the real party-in-interest. Pet. 65. Patent Owner identifies the real party-in-interest as the Institute for Environmental Health, Inc. Paper 4, 2.

III. RELATED MATTERS

Petitioner identifies the '486 patent as the subject of a district court proceeding: *Inst. for Env'tl. Health, Inc. v. Nat'l Beef Packing Co.*, No. 1:23-cv-00826 (D. Del. Aug. 1, 2023). Pet. 66 (*cf.* Ex. 1002). Patent Owner further notes the '486 Patent is subject to an additional civil action, in *Institute for Environmental Health, Inc. v. Genista Biosciences Inc.*, 5-23-cv-06471 (D. Ca. 2023), filed December 15, 2023. Paper 4, 2.

IV. THE '486 PATENT

The '486 patent issued on December 19, 2017, from U.S. application 12/360,646, which was filed on January 27, 2009. Ex. 1001, codes (45), (21), (22). The '486 patent indicates it is a continuation application of U.S. application 10/848,253, which was filed on May 17, 2004, and issued as U.S. Patent 7,531,163. *Id.* at code (63). Further, the '486 patent indicates relation to U.S. provisional application 60/470,975, filed on May 16, 2003. *Id.* at code (60).¹

The '486 patent states “the present invention provides novel enrichment, testing and detection methods for detection of pathogens or other microbes in food, water, wastewater, sludge, pharmaceutical, industrial samples and the link.” Ex. 1001, 6:24–27. The '486 patent states that “[p]rior to the present invention, low-dilution enrichment, transit incubation methods were not known or appreciated in the relevant art. Prior art methods . . . are based on 1:10 (wt./vol.) dilutions of the sample.” *Id.* at 8:22–26.

¹ Petitioner asserts “the priority date for claims 11, 12, 20, 24-26 is the filing date of the Provisional Application No. 60/470,975 on May 16, 2003, while the priority date for the other claims is the filing date of Application No. 10/848,253 on May 17, 2004.” Pet. 4.

The '486 patent states

a sample is obtained at a first location and is enriched, based on its intrinsic properties (if water activity and nutrition, pH, are sufficient/proper to support the growth of the target organism), either with no addition of other compounds, or by the addition of minimal amounts of enrichment appropriate media, ranging from 0.1 volume to 1 volume (per wt sample). The samples are then incubated at the appropriate temperature which is selected on the basis of the temperature that allows for the optimal growth of the target organism (s) over the background flora. The samples, after sufficient incubation, are then analyzed for the presence of the pathogen using any number of available methods.

Id. at 6:36–47.

The '486 patent describes that the samples are preferably subjected to “diluting is at a ratio of 1:1 (wt./vol.) or greater. More preferably, diluting is at a ratio of 1:0.5 (wt./vol.) or greater. Alternatively, diluting is at a ratio of 1:0.3 (wt./vol.) or greater, or at a ratio of 1:01 (wt./vol.) or greater (i.e., non-diluted).” *Id.* at 10:51–55. The '486 patent explains that the use of reduced dilution

allows, inter alia, for: (i) savings in the cost of enrichment media/buffers; (ii) the ability to ship the samples economically (with up to 90% less weight), and with far less chances of spills (e.g., because of 90% less liquids in enriched samples), in specially designed dry/semi-dry shipping incubators, to remote/distant laboratories; (iii) increased sensitivity in the detection of the target organisms, due to smaller dilution factor; and (iv) the ability to form centralized laboratories (that may be remote from the sampling sites) that use the enrichment/incubation-in shipping concept to provide testing services to distant clients with the ability to report as fast as a local laboratory, and at similar or reduced costs relative to local laboratories.

Id. at 8:43–55.

Example 1 of the '486 compared “the effectiveness of dry (1:0.5 meat to media) to standard (1:10) enrichment methods on the growth of *Escherichia coli* O157:H7 and *Salmonella* spp. on experimentally inoculated meat samples incubated for 6, 7, 8, and 24 h.” *Id.* at 16:66–17:3.

Example 1 of the '486 patent stated

the results show that enrichment of meat trimmings with the inventive ‘dry’ method (e.g., 1:0.5 wt./vol. dilution) gave results comparable to those obtained using standard (USDA) methods employing the art-recognized 1:10 dilution factor. This experiment showed that enrichment of meat trimming with ‘dry’ method (1:0.5 dilution) showed similar results to the standard FDA (1:10 dilution) method.

Id. at 20:39–46.

V. ILLUSTRATIVE CLAIMS

Petitioner challenges claims 1–30 (all claims) of the '486 patent, of which claims 1 and 11 are independent. Claim 1 is representative and reproduced below:

1. A method for detection of a particular bacterial pathogen or bacterial microbe, comprising:
obtaining a test sample, the sample being solid or semi-solid;
diluting the sample with liquid enrichment medium at a ratio of sample to diluent between about 1:0.1 to about 1:5 (wt./vol.) or lesser dilution;
incubating, in an incubator, the diluted sample at an optimal temperature for the particular bacterial pathogen or bacterial microbe to be detected for a time period sufficient to allow levels of the particular bacterial pathogen or microbe to reach levels detectable by use of an assay suitable to detect the particular bacterial pathogen or bacterial microbe; and
determining, by assaying the diluted incubated test sample, or a portion thereof, with the assay suitable to detect the

particular bacterial pathogen or bacterial microbe, whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe.

Ex. 1001, 21:13–32.

VI. ASSERTED GROUNDS

Petitioner contends that the challenged claims are unpatentable based on the following grounds. Pet. 6–7.

Ground	Reference	Basis	Claims Challenged
1	Rayman, ²	§ 102 ³	1, 4–8, 17, 19
2	Rayman, PR/HACCP ⁴	§ 103	1–8, 17, 19, 27
3	Nagar, ⁵ Rayman	§ 103	1, 4–8, 11–26
4	Nagar, Karlsen ⁶	§ 103	1, 4–8, 11–28
5	Nagar, PR/HACCP	§ 103	1–8, 11–30
6	Rayman, ICMSF ⁷	§ 103	9, 10

² Rayman et al., *ICMSF methods studies. XIII. An international comparative study of the MPN procedure and the Anderson–Baird–Parker direct plating method for the enumeration of Escherichia coli biotype I in raw meats*, 25 Can. J. Microbiol. 1321–1327 (1979) (“Rayman”). Ex. 1010.

³ The Leahy-Smith America Invents Act (“AIA”), Pub. L. No. 112–29, 125 Stat. 284 (2011), amended 35 U.S.C. §§ 102 and 103, effective March 16, 2013. Because the application from which the ’771 patent issued has an effective filing date of August 8, 2005, the pre-AIA versions of § 103 apply.

⁴ *Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems*; Final Rule, 61 Fed. Reg. 38805 (July 25, 1996) (codified at 9 CFR Part 304, et al.) (“PR/HACCP”). Ex. 1017.

⁵ Nagar et al., EP 1,253,203 A1, pub. Oct. 30, 2002 (“Nagar”). Ex. 1012.

⁶ Karlsen, F., WO 01/12853 A1, pub. Feb. 22, 2001 (“Karlsen”). Ex. 1016.

⁷ *Microorganisms in Foods 7: Microbiological Testing in Food Safety Management*, Int’l Comm’n on Microbiological Spec’s for Foods, Kluwer

7	Rayman, AAPA	§ 103	9, 10
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Petitioner relies on the Declaration of James S. Dickson, Ph.D. *See* Ex. 1020.

VII. CLAIM INTERPRETATION

The Board interprets claim terms in an *inter partes* review using the same claim construction standard that is used to construe claims in a civil action in federal district court. *See* 37 C.F.R. § 42.100(b)). In construing claims, district courts give claims 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.” *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312–13 (Fed. Cir. 2005) (en banc).

On the current record, there is no controversy over the meaning of any of the claim terms and neither party identifies a claim construction that would impact our analysis. We therefore find that, at this stage of the proceeding, there are no terms that need claim construction. *See, e.g., 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.’”) (quoting *Vivid Techs., Inc. v. Am. Sci. & Eng’g, Inc.*, 200 F.3d 795, 803 (Fed. Cir. 1999)).

Should either party argue at trial that any claim term requires express interpretation, they should do so in a designated section of briefing under the heading “Claim Construction.” Claim construction arguments should not be mingled with arguments over the merits of Petitioner’s challenges.

Academic/Plenum Publishers, Chapters 6, 10, 12, 15–17 (2002) (“ICMSF”). Ex. 1014.

VIII. LEVEL OF ORDINARY SKILL IN THE ART

Petitioner asserts (without opposition):

A person of ordinary skill in the art (“POSA”) at the time of invention would have a working knowledge of microbiology and would have been involved in developing testing methodologies for analysis of samples such as food products (“validation methodologies”). The POSA would most likely have an advanced degree in microbiology, food science, or animal science and at least two years of work experience but may alternatively have a bachelor’s degree in those areas and at least four years of experience with validation methodologies. The POSA would have been familiar with relevant scientific literature and industry regulations, directives, and guidelines relating to validation methodologies.

Pet. 9 (citing Ex. 1020 ¶¶ 22–24).

At this stage in the proceeding, we find that Petitioner’s uncontested analysis reasonably identifies the level of ordinary skill in the art as of the invention date as it directly relates to those involved in food analysis testing based on the prior art references. *See, e.g.*, Ex. 1013, xxi. The level of ordinary skill in the art usually is evidenced by the prior art references themselves. *See Okajima v. Bourdeau*, 261 F.3d 1350, 1355 (Fed. Cir. 2001); *In re GPAC Inc.*, 57 F.3d 1573, 1579 (Fed. Cir. 1995).

IX. ANTICIPATION GROUND

A. Principles of Law

In an *inter partes* review, “the petitioner has the burden from the onset to show with particularity why the patent it challenges is unpatentable.” *See Harmonic Inc. v. Avid Tech., Inc.*, 815 F.3d 1356, 1363 (Fed. Cir. 2016). This burden of persuasion never shifts to Patent Owner. *See Dynamic Drinkware, LLC v. Nat’l Graphics, Inc.*, 800 F.3d 1375, 1378 (Fed. Cir. 2015).

“Determining whether claims are anticipated involves a two-step analysis. The first step involves construction of the claims of the patent at issue. Claim construction is a question of law reviewed de novo.” *In re Aoyama*, 656 F.3d 1293, 1296 (Fed.Cir.2011). “The second step [of an anticipation analysis] involves comparing the claims to the prior art. Anticipation is a question of fact reviewed for substantial evidence.” *In re Aoyama*, 656 F.3d at 1296. “A prior art reference anticipates a patent claim under 35 U.S.C. § 102(b) if it discloses every claim limitation.” *In re Montgomery*, 677 F.3d 1375, 1379 (Fed. Cir. 2012). A reference may anticipate inherently if a claim limitation that is not expressly disclosed “is necessarily present, or inherent, in the single anticipating reference.” *Verizon Servs. Corp. v. Cox Fibernet Va., Inc.*, 602 F.3d 1325, 1337 (Fed. Cir. 2010).

We analyze the asserted anticipation ground of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the ’486 patent is unpatentable as anticipated.

B. Prior art cited for Anticipation

Petitioner asserts that, whether the challenged claims are accorded a priority date of May 16, 2003, or May 17, 2004, “each publication was prior art as of the earliest priority date of May 16, 2003 under 35 U.S.C. § 102(b) (pre-AIA). Public availability of these references is established by the declaration of James L. Mullins, Ph.D. (Ex. 1022).” Pet. 4–5.

1. *Rayman (Ex. 1010)*

Rayman is an article published in the Canadian Journal of Microbiology in 1979 that compares two methods for the detection of *E. coli* in raw meats, “the direct plating method of Anderson and Baird-Parker (1975) and the North American MPN method (American Public Health Association 1970).” Ex. 1010, 1322.

Rayman teaches “[r]aw red meats, poultry and pork, and washings and surface swabs of carcasses thereof were examined. All samples, frozen or non-frozen, were obtained in the country of the participating laboratory and were naturally contaminated.” Ex. 1010, 1322. Rayman teaches the samples were “weighed and homogenized in 4 parts (v/w) of 0.1% peptone.” *Id.*

Rayman teaches that for the direct plating method, “[d]uplicate 1.0 mL volumes of the 1:5 and 1:10 dilutions of solid samples were evenly spread on the membranes, taking care that the inocula did not spill over the edges.” *Id.* at 1322–23. Rayman teaches that “[a]fter absorption of the inocula (usually 20–30 min), the plates were incubated in the upright position in stacks of not more than three in a $44.5 \pm 0.5^{\circ}\text{C}$ water-jacked or similarly accurate incubator for 24 h.” *Id.* at 1323. Rayman teaches that

[a]fter incubation in 44.5°C , the membranes were lifted off the TBA, placed in clean covers of the Petri dishes, and stained for 10–15 min with 2.0 ml of 5% p-dimethylaminobenzaldehyde reagent. . . . The membranes were then removed from the covers and dried under a low pressure UV lamp or in sunlight . . . The pink indole positive colonies were enumerated as *E. coli*.

Id.

C. Ground 1 – Anticipation by Rayman

1. Petitioner’s position – Ground 1

Petitioner asserts “Rayman’s meat samples meet the sampling step of claim 1.” Pet. 30. Petitioner asserts “Rayman meets the limitation of the second step of claim 1, the diluting step, because the sample is diluted with liquid enrichment medium for a 1:5 dilution, which is a ratio of sample to diluent of 1:4 (wt./vol.).” *Id.* at 31 (citing Ex. 1020 ¶¶ 139, 140). Petitioner asserts “Rayman refers to conventional incubators, such as ‘incubating plates.’ [Ex. 1001], 1323. Thus, Rayman meets the limitation of the incubating step of claim 1 because the sample is incubated in an incubator at an elevated temperature throughout the incubation period.” Pet. 32–33 (citing Ex. 1020 ¶¶ 148, 149). Petitioner asserts “Rayman meets the limitation of the fourth step of claim 1, the assaying step, because Rayman describes determining, by assaying with an assay suitable to detect *E. coli* in meat samples.” *Id.* at 34 (citing Ex. 1020 ¶¶ 156, 157).

Petitioner concludes “[b]ecause Rayman discloses a ratio of sample to diluent of 1:4 (wt./vol.) (i.e., a 1:5 dilution), as well as the other well-known steps, Rayman anticipates claim 1.” Pet. 34 (citing Dickson ¶ 163).

As to claims 4 and 5, which require incubation at optimal temperatures in a range between 25 and 45°C, Petitioner asserts that “Rayman further characterized the technique as **incubating** plates “in the upright position in stacks of not more than three in a 44.5±0.5°C water-jacketed or similarly accurate **incubator** for 24 h. [And] [i]t is important that this temperature range be maintained throughout the **incubation period**.” Pet. 49 (citing Ex. 1010, 1323; Ex. 1020 ¶ 171).

As to claim 6, which limits the assay to, among other options, classical microbiology-based assays, Petitioner asserts that

Rayman describes various options to assay for *E. coli* in food and notes “the ICMSF selected as most promising the direct plating method of Anderson and Baird-Parker (1975).” Ex. 1010, 1322; *see also id.*, 1322–23 (description of direct plating (DP) method). Dickson ¶ 173. Direct plating is an example of a “classical microbiology-based assay.” *Id.*

Pet. 50–51 (citing Ex. 1020).

As to claims 7 and 8, which limits the claims to, among other organisms, generic *E. coli*, Petitioner asserts “Rayman is titled ‘An international comparative study of the MPN procedure and the Anderson–Baird-Parker direct plating method for the enumeration of *Escherichia coli* biotype I in raw meats.’” Pet. 52 (citing Ex. 1010, 1321; Ex. 1020 ¶ 175).

As to claim 17, which limits the claims to, among other sample types, beef, poultry, and pork, Petitioner asserts that Rayman states “red meats, poultry and pork, and washings and surface-swabs of carcasses thereof were examined.” Pet. 53 (citing Ex. 101, 1322; Ex. 1020 ¶ 177).

As to claim 19, which limits the claims to, among other dilution liquids, combinations of water and proteins, Petitioner asserts that “Rayman describes diluting samples with 0.1% peptone water.” Pet. 55 (citing Ex. 1010, 1322; Ex. 1020 ¶ 179).

2. Analysis

We note that Patent Owner has not, at this time, provided arguments on the patentability of the challenged claims (nor was it required to do so, as the burden is upon Petitioner). Based on the preliminary record, Petitioner has met its institution burden and demonstrated to a reasonable likelihood that it will prevail in showing that claims 1, 4–8, 17, and 19 were anticipated

by Rayman. We find the Petition has reasonably accounted for every element of these claims as taught in the prior art, thus establishing a reasonable likelihood that Petitioner will succeed at trial on the challenge to these claims.

X. OBVIOUSNESS GROUNDS

A. Principles of Law

The Supreme Court in *KSR Int’l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), reaffirmed the framework for determining obviousness set forth in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). In *KSR*, the Court summarized the four factual inquiries set forth in *Graham* (383 U.S. at 17–18) that are applied in determining whether a claim is unpatentable as obvious under 35 U.S.C. § 103 as follows: (1) determining the scope and content of the prior art; (2) ascertaining the differences between the prior art and the claims at issue; (3) resolving the level of ordinary skill in the art; and (4) considering objective evidence indicating obviousness or non-obviousness. *KSR*, 550 U.S. at 406.

“The combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results.” *Id.* at 416. “[W]hen the question is whether a patent claiming the combination of elements of prior art is obvious,” the answer depends on “whether the improvement is more than the predictable use of prior art elements according to their established functions.” *Id.* at 417.

The motivation-to-combine analysis is a flexible one. “[A]ny need or problem known in the field of endeavor at the time of invention and addressed by the patent can provide a reason for combining the elements in the manner claimed,” [but the] “analysis ‘need not seek out precise teachings directed to the specific subject matter of the challenged claim, for a court can

take account of the inferences and creative steps that a person of ordinary skill in the art would employ.’”

Intel Corp. v. PACT XXP Schweiz AG, 61 F.4th 1373, 1379–80 (Fed. Cir. 2023) (quoting *KSR*, 550 U.S. at 418, 420 (emphasis added)). “[I]f there’s a known technique to address a known problem using ‘prior art elements according to their established functions,’ then there is a motivation to combine,” because *KSR* explains that “if a technique has been used to improve one device [or method], and a person of ordinary skill in the art would recognize that it would improve similar devices [or methods] in the same way, using the technique is obvious unless its actual application is beyond his or her skill.” *Id.* at 1380 (quoting *KSR*, 550 U.S. at 417; and *Intel Corp. v. Qualcomm Inc.*, 21 F.4th 784, 797 (Fed. Cir. 2021)). If addressing a known problem, the prior art combination need not be “the *best* option, only . . . a *suitable* option.” *Id.* (quoting *Intel*, 21 F.4th at 800 (emphasis original)).

We analyze the asserted obviousness grounds of unpatentability in accordance with these principles to determine whether Petitioner has met its burden to establish a reasonable likelihood of prevailing in showing that at least one of the challenged claims of the ’486 patent is unpatentable as obvious.

B. Prior art cited for Obviousness

Petitioner asserts that, whether the challenged claims are accorded a priority date of May 16, 2003, or May 17, 2004, “each publication was prior art as of the earliest priority date of May 16, 2003 under 35 U.S.C. § 102(b) (pre-AIA). Public availability of these references is established by the declaration of James L. Mullins, Ph.D. (Ex. 1022).” Pet. 4–5.

1. *PR/HACCP (Ex. 1017)*

PR/HACCP is a final rule from the Department of Agriculture as published in the Federal Register in 1996. Ex. 1017, title page. PR/HACCP mandates, among other requirements “regular microbial testing by slaughter establishments to verify the adequacy of the establishments’ process controls for the prevention and removal of fecal contamination and associated bacteria.” *Id.* at 38806.

PR/HACCP teaches “[s]amples are to be taken randomly at the required frequency (See section on Sampling Frequency). For example, given the frequency of testing for cattle is 1 (one) test per every 300 cattle slaughtered, then if a plant slaughters 150 head of cattle an hour, 1 (one) sample will be taken every 2 hours.” *Id.* at 38930. PR/HACCP teaches a process for sampling, with materials including a sterile sponge, 25 ml of a sterile diluent, sterile gloves, and a sterile bag where the sponge is moistened with the diluent, then the person sampling must “wipe the sponge over the enclosed sampling area (10 cm x 10 cm) for a total of approximately 10 times in the vertical and 10 times in the horizontal directions. The pressure for swabbing would be as if you were removing dried blood from the carcass.” *Id.* at 38932. PR/HACCP teaches the sponge is placed within the sterile bag. *Id.* PR/HACCP then teaches “[s]amples must be analyzed using one of the *E. coli* (Biotype I) quantitation methods,” for example:

[i]f a generic one ml plating technique is used for *E. coli* quantitation for cattle or swine carcass sponging sample analysis, the plate count would be divided by 12 to equal the count per cm². To cover the marginal and unacceptable range for *E. coli* levels (described in later section), the undiluted sample extract, a 1:10, a 1:100, a 1:1,000 and a 1:10,000 dilution should be plated, preferably in duplicate. Higher or lower dilutions may need to be plated based on the specific product.

Id. at 38933.

2. *Nagar (Ex. 1012)*

Nagar is an October 30, 2002, European patent publication titled “Rapid resuscitation, growth, capture and detection of microorganisms.” Ex. 1012, 1. Nagar discloses:

The method and system involve the use of a capture matrix throughout the resuscitation, growth and detection processes. In accordance with one embodiment of the present invention, the method and system include the steps of: placing a sample in a container containing a resuscitation/growth medium; optionally homogenizing the sample; placing a capture matrix in the sampling bag with the sample; incubating the sample in the resuscitation/growth medium for a pre-determined amount of time at an elevated temperature while optionally shaking; optionally removing the capture matrix from the container; performing detection assays to detect the presence of the target pathogens in the sample.

Ex. 1012 ¶ 22. Nagar teaches that “in testing a food sample, the rapidly growing target pathogens that could be tested for could include, but are not limited to, *Salmonella* and/or *E. coli*.” *Id.* ¶ 36. Nagar explains because “these pathogens which are often found in a variety of foods (e.g., ground beef, milk, cheese, vegetables, apple cider, etc.), they are often ‘targeted’ for testing in order to determine if they are present in a food sample.” *Id.*

3. *Karlsen (Ex. 1016)*

Karlsen is a February 22, 2001, international patent publication titled “Method for Identification of the Indicators of Contamination in Samples.”

Ex. 1016, 1. Karlsen teaches a method that

comprises the following steps: (1) providing a liquid or liquified sample (which may include treating the sample with a culture media to enrich microorganisms present in the sample); (2) recovering microorganisms from the treated sample . . .

(7) detecting the presence of the amplicon (amplified target DNA sequence) by binding the amplicon to a microtiter plate and staining with a stain such as PicoGreen, which selectively stains double stranded DNA; and (8) making a determination about the presence or absence of the microorganism in the original liquid or liquified sample based on presence or absence of the amplicon.

Id. at 10. Karlsen teaches that “[e]xamples of the liquid or liquified sample include but are not limited to drinking water, bathing water, cerebrospinal fluid, blood, juices, soft drinks, wine or other alcoholic beverages, milk, milk products, cheeses, and yogurt.” *Id.* at 14.

Karlsen teaches an example where

an approximately 10 ml portion of the liquid or liquified sample (as defined elsewhere) herein which is desired to be tested for bacteria is mixed with approximately 10 ml of an enrichment media for enhancing growth of bacteria which may be present in the sample and is incubated, preferably at about 41° to about 44°C for about three to about five hours.

Id. at 23.

4. ICMSF (Ex. 1014)

ICMSF is a 2002 publication of the International Commission on Microbiological Specifications for Foods that discusses microbiological testing in food safety management. Ex. 1014, title page. ICMSF teaches the “particular choice of sampling procedure and the decision criteria make up the *sampling plan*. Proper drawing of samples is essential if the decision making criteria of the sampling plan are to give unbiased results.” *Id.* at 115.

ICMSF teaches “[m]any different types of samples are collected and submitted to the laboratory for analysis. Some are sample units from lots or consignments of food or ingredients for lot acceptance determination.” *Id.* at 225. ICMSF teaches a “sample unit is a small portion of the lot in which the

distribution of both numbers and types of microorganisms should be representative of the whole lot.” *Id.* at 225. ICMSF

has defined a lot as follows: In the commercial sense, a lot is a quantity of food supposedly produced under identical conditions, all packages of which would normally bear a lot number that identifies the production during a particular time interval, and usually from a particular line, retort, or other critical processing unit. Statistically, a lot is considered as a collection of units of a product from which a sample is drawn to determine acceptability of the lot.

Id. at 327. ICMSF teaches that “[t]o reduce laboratory effort while maintaining the stringency of the sampling plan, it would be helpful to combine either groups of analytical units or the enrichment cultures therefrom, using plans in which the presence of a single positive rejects the consignment.” *Id.* at 187. ICMSF teaches that “considerable reductions may be made in the cost of laboratory analyses by compositing (pooling) analytical units. Such compositing offers the prospect of large increases in the number of analytical units, n , with corresponding increase in the stringency of examination, without correspondingly increasing laboratory effort.” *Id.* ICMSF teaches “[t]here is the very great technical advantage of combining many analytical units for bacteriological examination.” *Id.* at 188.

C. Obviousness Grounds

Because Patent Owner did not file a preliminary response and, therefore, does not presently address Petitioner’s asserted references nor any claim limitation specific to the dependent claims, we focus on Grounds 3–5 and the challenged independent claims (claims 1 and 11).

1. *Petitioner's position – Ground 3 – Nagar and Rayman*

In Ground 3, Petitioner challenges claims 1, 4–8 and 12–26 of the '486 patent. Pet. 38–52.

a. Claims 1 and 11

Petitioner contends that “Nagar states: ‘Target pathogens that can be detected and identified using the method and system of the present invention include Gram (-) organisms such as the *Enterobacteriaceae*, including *E. coli*.’” Pet. 37 (citing Ex. 1012 ¶ 35).

As to the “obtaining a test sample” step of claims 1 and 11, Petitioner cites Nagar as teaching

For example, in **testing a food sample**, the rapidly growing target pathogens that could be tested for could include, but are not limited to, *Salmonella* and/or *E. coli*. Since these pathogens which are often found in a variety of foods (e.g., **ground beef**, milk, **cheese**, vegetables, **apple cider**, etc.), they are often “targeted” for testing in order to determine if they are present in a food sample.

Pet. 38 (citing Ex. 1012 ¶ 36).

As to the “diluting the sample” step of claims 1 and 11, Petitioner states “Nagar discloses use of decimal dilution in a feasibility study in which ground beef was artificially inoculated with *E. coli* O157:H7 pathogen. Samples of ground beef weighing **25 g** were placed in stomacher bags and then **225 ml resuscitation/growth medium was added** to each bag.” Pet. 39 (citing Ex. 1012 ¶ 50; Ex. 1020 ¶ 142).

As to the “incubating” step of claims 1 and 11, Petitioner cites Nagar as teaching

placing a sample in a container containing a resuscitation/growth medium; optionally homogenizing the sample; placing a capture matrix in the sampling bag with the

sample; **incubating** the sample in the resuscitation/growth medium for a pre-determined amount of time **at an elevated temperature** while optionally shaking; optionally removing the capture matrix from the container; performing detection assays to **detect the presence of the target pathogens in the sample**.

Pet. 40 (citing Ex. 1012 ¶¶ 23, 44, 45; Ex. 1020 ¶¶ 151, 152).

As to the “determining” step of claims 1 and 11, Petitioner cites Nagar for “performing detection assays to **detect the presence of the target pathogens in the sample**.” Pet. 42 (citing Ex. 1012 ¶ 23; Ex. 1020 ¶¶ 160, 161). Petitioner states that Nagar describes various assays, teaching:

The presence/absence test may be run on one part of the two-part device and, if present, the other part of the two-part device can be used for culturing and **confirming target pathogen(s)** using, but not limited to, **detection methodologies**, such as enzyme-linked immunosorbent assay (ELISA), polymerase chain reaction (PCR), or manual strand displacement amplification (SDA).

Id. (citing Ex. 1012 ¶ 26).

Petitioner asserts Rayman states “the present concern about the enumeration of fecal coliforms, or more specifically *Escherichia coli* in foods, is the length of time and the amount of media and analysts’ time required to complete the analyses.” Pet. 43 (citing Ex. 1010, 1322). Petitioner asserts, “[g]iven that Nagar and Rayman were trying to solve the same problem, a POSA utilizing the method of Nagar would have looked to the teachings of Rayman, which included 1:5 dilutions in the Anderson and Baird-Parker method.” *Id.* at 44 (citing Ex. 1020 ¶ 165). Petitioner asserts

A POSA would have been motivated to replace Nagar’s decimal dilution (1:10) for any solid or liquid sample with Rayman’s more concentrated dilution (1:5) with the objective of rapid analysis. Dickson ¶ 165. The modification also reduces the amount of enrichment media that is required. *Id.*

A POSA would have been motivated to modify Nagar based on Rayman under the teaching-suggestion-motivation test so Nagar's samples are less dilute, with a reasonable expectation of success for efficient analysis. *Id.* Moreover, a POSA would have improved Nagar with the similar methods of Rayman to yield rapid and efficient analysis, which is a predictable result.

Pet. 44.

b. Analysis

As already noted, Patent Owner has not yet provided arguments on the patentability of the challenged claims. Based on the preliminary record, Petitioner has met its institution burden and demonstrated to a reasonable likelihood that it will prevail in showing that claims 1 and 11 were obvious over Nagar and Rayman. Petitioner accounts for each step/element of the independent claims as taught or suggested by the prior art combination, and reasonably shows that the person of ordinary skill in the art would have had reason to combine the prior art with a reasonable expectation of success.

2. Petitioner's Position – Ground 4 – Nagar and Karlsen

In Ground 4, Petitioner challenges claims 1, 4–8 and 12–28 of the '486 patent. Pet. 38–52.

a. Claims 1 and 11

Petitioner relies on Nagar, regarding claims 1 and 11, as discussed above in Ground 3.

Petitioner asserts that Karlsen describes “[a] method for the identification of the presence of *E. coli*. . . in a liquid or liquified sample.” Pet. 37 (citing Ex. 1016, Abstract).

As to the “obtaining a test sample” step of claims 1 and 11, Petitioner notes that Karlsen states

The term “liquid or liquified sample” may be used herein interchangeably with the term “test sample”. The liquid or liquified sample may comprise . . . **food**, feed, and water. It is therefore contemplated that the liquid or liquified sample comprise any number of sample types, both environmental and clinical. Examples of the liquid or liquified sample include but are not limited to drinking water, bathing water, cerebrospinal fluid, blood, **juices**, soft drinks, wine or other alcoholic beverages, **milk**, milk products, **cheeses**, and **yogurt**.

Pet. 38 (citing Ex. 1016, 14; 1020 ¶ 136).

As to the “diluting the sample” step of claims 1 and 11, Petitioner asserts that Karlsen teaches an example where “an approximately **10 ml portion of the liquid or liquified sample** (as defined elsewhere) herein which is desired to be tested for bacteria is mixed with approximately **10 ml of an enrichment media** for enhancing growth of bacteria which may be present in the sample.” Pet. 39 (citing Ex. 1016, 23; Ex. 1020 ¶ 143).

Petitioner asserts, “[t]hus, Karlsen discloses a 1:1 ratio of sample to diluent (i.e., a 1:2 dilution).” *Id.*

As to the “incubating” step of claims 1 and 11, Petitioner asserts that Karlsen teaches

an approximately 10 ml portion of the liquid or **liquified sample** . . . mixed with approximately 10 ml of an **enrichment media** for enhancing growth of bacteria which may be present in the sample and is **incubated**, preferably at about 41° to about 44°C for about three to about five hours.

Pet. 41 (citing Ex. 1016, 23; Ex. 1020 ¶¶ 153, 154).

As to the “determining” step of claims 1 and 11, Petitioner asserts that Karlsen teaches the “**method of detection** and identification preferably involves enrichment of the bacteria using selective culture media, recovery of bacteria from media, lysing of the bacteria to release DNA, **polymerase**

chain reaction (PCR) amplification of the target sequences using the novel oligonucleotides, and specific detection of PCR products.” Pet. 43 (citing Ex. 1016, 8; Ex. 1020 ¶ 162).

Petitioner asserts that “[g]iven that Nagar and Karlsen were trying to solve the same problem, a POSA utilizing the method of Nagar would have looked to the teachings of Karlsen, which included a 1:2 dilution.” Pet. 45 (citing Ex. 1020 ¶ 165). Petitioner states

A POSA would have been motivated to replace Nagar’s decimal dilution (1:10) for any solid or liquid sample with Karlsen’s more concentrated dilution (1:2) with the objective of reducing the time for analysis. Dickson ¶ 165. The modification also reduces the amount of enrichment media that is required. *Id.*

A POSA would have been motivated to modify Nagar based on Karlsen under the teaching-suggestion-motivation test so Nagar’s samples are less dilute, with a reasonable expectation of success for efficient analysis. *Id.* Moreover, a POSA would have improved Nagar with the similar methods of Karlsen to yield rapid and efficient analysis, which is a predictable result.

Pet. 45.

b. Analysis

Based on the preliminary record, Petitioner has met its institution burden and demonstrated to a reasonable likelihood that it will prevail in showing that claims 1 and 11 were obvious over Nagar and Karlsen.

Petitioner accounts for each step/element of the independent claims as taught or suggested by the prior art combination, and reasonably shows that the person of ordinary skill in the art would have had reason to combine the prior art with a reasonable expectation of success.

3. Petitioner’s Position – Ground 5 – Nagar and PR/HACCP

In Ground 5, Petitioner challenges claims 1–8 and 12–30. Pet. 38–52.

a. Claims 1 and 11

Petitioner relies on Nagar, regarding claims 1 and 11, as discussed above in Ground 3.

Petitioner asserts that PR/HACCP teaches “methods for detecting *E. coli*.” Pet. 37 (citing Dickson ¶¶ 124–129).

As to the “obtaining a test sample” step of claims 1 and 11, Petitioner notes that “PR/HACCP sample[s] meat.” Pet. 38.

As to the “diluting the sample” step of claims 1 and 11, Petitioner states that a “POSA utilizing the method of Nagar would have looked to the PR/HACCP requirements for swabbing, to utilize even less liquid enrichment medium than Nagar’s decimal dilution.” Pet. 46 (citing Ex. 1020 ¶ 165).

Petitioner relies upon Nagar as teaching “the other well-known steps of incubating and assaying.” Pet. 46.

Petitioner states that

A POSA would have been motivated to replace Nagar’s decimal dilution for a solid or liquid sample with the PR/HACCP’s more concentrated dilution of a ratio of sample to diluent of less than 1:0.1 with the objectives of rapid analysis and reduction in the amount of enrichment media that is required. Dickson ¶ 165.

A POSA would have been motivated to modify Nagar based on the PR/HACCP under the teaching-suggestion-motivation test so Nagar’s samples are less dilute, with a reasonable expectation of success for efficient analysis. *Id.* Moreover, a POSA would have improved Nagar with the similar methods of PR/HACCP to yield rapid and efficient analysis, which is a predictable result.

Pet. 46.

b. Analysis

Based on the preliminary record, Petitioner has met its institution burden and demonstrated to a reasonable likelihood that it will prevail in showing that claims 1 and 11 were obvious over Nagar and PR/HACCP. Petitioner accounts for each step/element of the independent claims as taught or suggested by the prior art combination, and reasonably shows that the person of ordinary skill in the art would have had reason to combine the prior art with a reasonable expectation of success.

XI. CONCLUSION

After reviewing the information presented in the Petition, as yet unopposed by Patent Owner, we determine that the evidence of record shows that Petitioner has established that it is more likely than not it will prove that claims 1–30 of the '486 patent are unpatentable.

XII. ORDER

Accordingly, it is

ORDERED that, pursuant to 35 U.S.C. § 314(a), institution of an *inter partes* review of all challenged claims on all grounds presented in the Petition is granted; and

FURTHER ORDERED that, pursuant to 35 U.S.C. § 314(c) and 37 C.F.R. § 42.4(b), notice is hereby given of the institution of a trial, which commences on the entry date of this Order.

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