UNITED STATES PATENT AND TRADEMARK OFFICE

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BEFORE THE PATENT TRIAL AND APPEAL BOARD

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NATIONAL BEEF PACKING COMPANY, LLC,
Petitioner,

v.

INSTITUTE FOR ENVIRONMENTAL HEALTH, INC.,
Patent Owner.

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Case IPR2024-00183
Patent 7,534,584

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**PETITIONER'S UPDATED EXHIBIT LIST**

Pursuant to 37 C.F.R. § 42.63(e), Petitioner National Beef Packing Company, LLC hereby submits a current listing of Petitioner's exhibits. New Exhibit 1064 is being filed and served today.

| Exhibit | Description |
|---|---|
| 1001 | U.S. Patent No. 7,534,584 B2 ("the '584 Patent") to Samadpour, titled "Modular Compositing-Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents" and U.S. Patent No. 7,534,584 C1 ("Reexamination Certificate") |
| 1002 | U.S. Patent No. 8,822,143 ("the '143 Patent") to Samadpour, titled "Modular Compositing-Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents" |
| 1003 | U.S. Patent No. 9,637,771 ("the '771 Patent") to Samadpour, titled "Modular Compositing-Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents" |
| 1004 | Complaint for Patent Infringement, *Inst. for Envtl. Health, Inc. v. Nat'l Beef Packing Co., LLC*, No. 1:23-cv-00826 (D. Del. Aug. 1, 2023) |
| 1005 | Prosecution History for U.S. Provisional Patent Appl. No. 60/599,473 |
| 1006 | Prosecution History for U.S. Patent Appl. No. 11/199,871 (Pat. No. 7,534,584) |
| 1007 | Prosecution History for Reexamination Control No. 95/001,294 (Six Parts) |

| Exhibit | Description |
|---|---|
| 1008 | U.S. Patent No. 8,389,233 ("the '233 Patent") to Samadpour, titled "Modular Compositing-Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents" |
| 1009 | Prosecution History for U.S. Patent Appl. No. 12/360,796 (Pat. No. 8,389,233) |
| 1010 | Prosecution History for U.S. Patent Appl. No. 13/784,606 (Pat. No. 8,822,143) |
| 1011 | Prosecution History for U.S. Patent Appl. No. 14/472,144 (Pat. No. 9,637,771) |
| 1012 | "Microorganisms in Foods 7: Microbiological Testing in Food Safety Management," Int'l Comm'n on Microbiological Spec's for Foods (ICMSF), Kluwer Academic/Plenum Publishers, Chapters 6, 10, 12, 15–17 (2002) ("ICMSF 2002"), ("ICMSF-7"), or ("ICMSF") |
| 1013 | "Microorganisms in Foods 2: Sampling for Microbiological Analysis: Principles and Specific Applications," Int'l Comm'n on Microbiological Spec's for Foods, Univ. Toronto Press, Glossary (2nd ed. 1986) ("ICMSF 1986") or ("ICMSF-2") |
| 1014 | David Gombas et al., "Survey of *Listeria monocytogenes* in Ready-to-Eat Foods," J. Food Prot., vol. 66, no. 4, pages 559–569 (Apr. 2003) ("Gombas") |
| 1015 | Denise Hughes et al., "*Salmonella* in Foods—A New Enrichment Procedure for Use with the TECRA *Salmonella* Visual Immunoassay: Collaborative Study," J. AOAC Int'l, vol. 82, no. 3, pages 634–647 (May/June 1999) ("Hughes 1999") or ("Hughes") |

| Exhibit | Description |
|---|---|
| 1016 | Denise Hughes et al., "*Salmonella* in Foods: New Enrichment Procedure for TECRA Salmonella Visual Immunoassay Using a Single RV(R10) Only, TT Only, or Dual RV(R10) and TT Selective Enrichment Broths (AOAC Official Method 998.09): Collaborative Study," J. AOAC Int'l, vol. 86, no. 4, pages 775–790 (July/Aug. 2003) ("Hughes 2003") |
| 1017 | W.R. Price et al., "*Salmonella* Testing of Pooled Pre-Enrichment Broth Cultures for Screening Multiple Food Samples," Appl. Microbiol., vol. 23, no. 4, pages 679–682 (Apr. 1972) ("Price") |
| 1018 | Diana Stewart et al., "Comparison of Assurance Gold Salmonella EIA, BAX for Screening/Salmonella, and GENE-TRAK Salmonella DLP Rapid Assays for Detection of *Salmonella* in Alfalfa Sprouts and Sprout Irrigation Water," J. AOAC Int'l, vol. 85, no. 2, pages 395–403 (Mar./Apr. 2002) ("Stewart") |
| 1019 | Pina Fratamico et al., "Rapid isolation of *Escherichia coli* O157:H7 from enrichment cultures of foods using an immunomagnetic separation method," Food Microbiol., vol. 9, no. 2, pages 105–113 (June 1992) ("Fratamico") |
| 1020 | Eva D'Haese & Hans Nelis, "Rapid Detection of Single Cell Bacteria as a Novel Approach in Food Microbiology," J. AOAC Int'l, vol. 85, no. 4, pages 979–983 (July/Aug. 2002) ("D'Haese") |
| 1021 | Jean-Yves D'Aoust, "Update on Preenrichment and Selective Enrichment Conditions for Detection of *Salmonella* in Foods," J. Food Prot., vol. 44, no. 5, pages 369–374, 393 (May 1981) ("D'Aoust") |
| 1022 | U.S. Food & Drug Admin., "Bacteriological Analytical Manual," Table of Contents, Introduction, About the Bacteriological Analytical Manual, Chapters 1, 5, 10 (June 2003) ("BAM 2003") |

| Exhibit | Description |
|---|---|
| 1023 | U.S. Dept. of Agric. Food Safety and Inspection Service (FSIS), "Microbiological Testing Program and Other Verification Activities for *Escherichia coli* O157:H7 in Raw Ground Beef Products and Raw Ground Beef Components and Beef Patty Components," Directive 10.010.1, Rev. 1 (Mar. 31, 2004) ("FSIS Directive") |
| 1024 | Thaddeus Midura & Raymond Bryant, "Sampling Plans, Sample Collection, Shipment, and Preparation for Analysis," Chapter 2 in Compendium of Methods for the Microbiological Examination of Foods, American Public Health Association, pages 13–23 (4th ed. 2001) ("Midura") |
| 1025 | J.H. Silliker & D.A. Gabis, "ICMSF methods studies. I. Comparison of analytical schemes for detection of *Salmonella* in dried foods," Can. J. Microbiol., vol. 19, no. 4, pages 475–479 (1973) ("Silliker") |
| 1026 | D.A. Gabis & J.H. Silliker, "ICMSF methods studies. II. Comparison of analytical schemes for detection of *Salmonella* in high-moisture foods," Can. J. Microbiol., vol. 20, no. 5, pages 663–669 (1974) ("Gabis") |
| 1027 | Basil Jarvis, "Errors Associated with Dilution Count and Presence/Absence Methods," Chapter 8 in Statistical Aspects of the Microbiological Analysis of Foods, Elsevier Science Publishers, pages 117–146 (1989) ("Jarvis") |
| 1028 | U.S. Dept. of Agric. Food Safety and Inspection Service (FSIS), "Microbiology Laboratory Guidebook,", Table of Contents, Cover, Foreword, General Considerations, Chapters 4.02, 5.03, 8.03 (July 2003) ("MLG 2003") or ("MLG") |
| 1029 | U.S. Dept. of Agric. Food Safety and Inspection Service (FSIS), "Microbiology Laboratory Guidebook," Chapter 8 (3rd ed. 1998) ("MLG 1998") |

| Exhibit | Description |
|---|---|
| 1030 | Madhu Badoni et al., "Development and testing of a prototype automatic trim sampler," Food Control, vol. 77, pages 82–87 (July 2017) ("Badoni") |
| 1031 | Tommy Wheeler & Terrance Arthur, "Novel Continuous and Manual Sampling Methods for Beef Trim Microbiological Testing," J. Food Prot., vol. 81, no. 10, pages 1605–1613 (Oct. 2018) ("Wheeler") |
| 1032 | U.S. Food & Drug Admin., "Bacteriological Analytical Manual," Chapter 10, § 10.04 (Jan. 1969) ("BAM 1969") |
| 1033 | "37. Microbiological Methods," in Changes in Official Methods of Analysis Made at the Eightieth Annual Meeting, October 10–13, 1966, J. of the A.O.A.C., vol. 50, no. 1, pages 231–239 (Feb. 1967) |
| 1034 | Prosecution History for U.S. Patent Appl. No. 15/499,719 (Expressly Abandoned) |
| 1035 | Complaint for Declaratory Judgment of Patent Invalidity and Patent Non-Infringement, *Primus Grp., Inc. v. Inst. for Envtl. Health, Inc.*, No. 3-18-cv-00005 (N.D. Cal. Jan. 2, 2018) |
| 1036 | Patent Local Rule 4-3 Joint Claim Construction and Prehearing Statement, *Primus Grp., Inc. v. Inst. for Envtl. Health, Inc.*, No. 3-18-cv-00005 (N.D. Cal. July 31, 2018) |
| 1037 | Institute for Environmental Health, Inc.'s Opening Claim Construction Brief, *Primus Grp., Inc. v. Inst. for Envtl. Health, Inc.*, No. 3-18-cv-00005 (N.D. Cal. Sept. 14, 2018) |
| 1038 | Claim Construction Order, *Primus Grp., Inc. v. Inst. for Envtl. Health, Inc.*, No. 3-18-cv-00005 (N.D. Cal. Jan. 22, 2019) |
| 1039 | Federal Court Management Statistics, District of Delaware (Reporting Period End Date: Dec. 31, 2023), available at https://www.uscourts.gov/statistics/table/na/federal-court-management-statistics/2023/12/31-1, (last visited June 19, 2024) |

| Exhibit | Description |
|---|---|
| 1040 | Declaration of Kevin B. Laurence |
| 1041 | Expert Declaration of James S. Dickson, Ph.D. |
| 1042 | Curriculum Vitae of James S. Dickson, Ph.D. |
| 1043 | Expert Declaration of James L. Mullins, Ph.D. ("Mullins Decl.") |
| 1044 | Mullins Decl. Appendix A - Curriculum Vitae of James L. Mullins, Ph.D. |
| 1045 | Mullins Decl. Appendices A-1, A-2, A-3, and A-4 |
| 1046 | Mullins Decl. Appendices B-1, B-2, and B-3 |
| 1047 | Mullins Decl. Appendices C-1, C-2, C-3, and C-4 |
| 1048 | Mullins Decl. Appendices D-1, D-2, D-3, and D-4 |
| 1049 | Mullins Decl. Appendices E-1, E-2, E-3, and E-4 |
| 1050 | Mullins Decl. Appendices F-1, F-2, F-3, and F-4 |
| 1051 | Mullins Decl. Appendix G-1, G-2, G-3, and G-4 |
| 1052 | Mullins Decl. Appendix H-1, H-2, H-3, and H-4 |
| 1053 | Mullins Decl. Appendix I-1, I-2, I-3, and I-4 |
| 1054 | Mullins Decl. Appendix J-1, J-2, J-3, J-4, and J-5 |
| 1055 | Mullins Decl. Appendix K-1, K-2, K-3, K-4, and K-5 |
| 1056 | Mullins Decl. Appendix L-1 and L-2 |
| 1057 | Mullins Decl. Appendix M-1, M-2, M-3, and M-4 |
| 1058 | Mullins Decl. Appendix N-1, N-2, N-3, N-4, and N-5 |
| 1059 | Mullins Decl. Appendix O-1, O-2, and O-3 |
| 1060 | Mullins Decl. Appendix P-1, P-2, and P-3 |

| Exhibit | Description |
|---|---|
| 1061 | Mullins Decl. Appendix Q-1, Q-2, Q-3, and Q-4 |
| 1062 | Proposed Scheduling Order, *Inst. for Envtl. Health, Inc. v. Nat'l Beef Packing Co., LLC*, No. 1:23-cv-00826 (D. Del. May 16, 2024) |
| 1063 | Assurance® GDS Salmonella Tq (2024) |
| 1064 | Email to IEH presenting *Sotera* stipulation on Nov. 18, 2024 |

2024 Nov. 26 /Kevin B. Laurence/

Kevin B. Laurence
Registration No. 38,219

## CERTIFICATE OF SERVICE

I certify that on November 26, 2024, copies of the foregoing PETITIONER'S UPDATED EXHIBIT LIST and all documents filed with it were served via email to counsel for the Patent Owner, as agreed to by counsel, upon the following counsel for the Patent Owner:

| | |
|---|---|
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/Kevin B. Laurence/
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