

EXHIBIT 2003

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

INSTITUTE FOR ENVIRONMENTAL
HEALTH, INC.,

Plaintiff,

v.

NATIONAL BEEF PACKING COMPANY,
LLC,

Defendant.

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C.A. No. 23-826-JHS

**DEFENDANT NATIONAL BEEF PACKING COMPANY, LLC'S
FIRST AMENDED ANSWER AND COUNTERCLAIMS**

National Beef Packing Company, LLC (“National Beef”) answers Institute for Environmental Health, Inc.’s (“IEH”) Complaint for Patent Infringement (“Complaint”) as follows.

1. National Beef lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 1 and therefore denies them.

2. National Beef admits that the Complaint purports to bring claims for patent infringement against National Beef. National Beef denies that the Complaint states a proper claim for infringement of any patent and that such claim has any merit. National Beef denies any remaining allegations in Paragraph 2.

PARTIES

3. On information and belief, National Beef admits that Plaintiff IEH is a Washington corporation with its principal place of business located in Lake Forest Park, Washington.

4. National Beef admits that it is a limited liability company formed under the laws of Delaware with its headquarters located in Kansas City, Missouri. National Beef denies any remaining allegations in Paragraph 4.

JURISDICTION AND VENUE

5. Paragraph 5 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, National Beef admits that the claims in the Complaint purport to state a claim for infringement under the patent laws of the United States, 35 U.S.C. § 1 *et seq.* National Beef denies that the Complaint states a proper claim for infringement of any patent and that such claim has any merit. National Beef denies any remaining allegations in Paragraph 5.

6. Paragraph 6 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, National Beef admits that this Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. Paragraph 7 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, National Beef does not contest whether personal jurisdiction over it properly lies in this district in this case. National Beef denies any remaining allegations in Paragraph 7.

8. Paragraph 8 states legal conclusions and allegations to which no answer is required. To the extent an answer is deemed required, National Beef admits venue is proper in this Court for purposes of this action only pursuant to this Court's opinion and order dated May 16, 2024 (D.I. 25, 27). National Beef denies any remaining allegations.

IEH'S ASSERTED PATENTS

9. National Beef admits that IEH purports to attach a copy of U.S. Patent No. 7,534,584 ("the '584 Patent") to the Complaint as Exhibit A. National Beef further admits that the face of Exhibit A indicates that the '584 Patent was issued on May 19, 2009 and is titled "Modular

Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents.” National Beef lacks knowledge or information sufficient to admit or deny if IEH is the owner by assignment of all rights, title, and interest in the ’584 Patent, and therefore denies the same. National Beef admits that IEH purports to attach to the Complaint, as part of Exhibit A, a copy of a reexamination certificate for the ’584 Patent that indicates on its face that the reexamination certificate was issued by the USPTO on March 6, 2019. National Beef denies any remaining allegations in Paragraph 9, including any suggestion or implication that the ’584 Patent was duly and legally issued or is valid and enforceable.

10. National Beef admits that IEH purports to attach a copy of U.S. Patent No. 8,822,143 (“the ’143 Patent”) to the Complaint as Exhibit B. National Beef further admits that the face of Exhibit B indicates that the ’143 Patent was issued on September 2, 2014 and is titled “Modular Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents.” National Beef lacks knowledge or information sufficient to admit or deny if IEH is the owner by assignment of all rights, title, and interest in the ’143 Patent, and therefore denies the same. National Beef denies any remaining allegations in Paragraph 10, including any suggestion or implication that the ’143 Patent was duly and legally issued or is valid and enforceable.

11. National Beef admits that IEH purports to attach a copy of U.S. Patent No. 9,637,771 (“the ’771 Patent”) to the Complaint as Exhibit C. National Beef further admits that the face of Exhibit C indicates that the ’771 Patent was issued on May 2, 2017 and is titled “Modular Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents.” National Beef lacks knowledge or information sufficient to admit or deny if IEH is the owner by assignment of all rights, title, and interest in the ’771 Patent,

and therefore denies the same. National Beef denies any remaining allegations in Paragraph 11, including any suggestion or implication that the '771 Patent was duly and legally issued or is valid and enforceable.

12. National Beef admits that IEH purports to attach a copy of U.S. Patent No. 9,845,486 (“the '486 Patent”)¹ to the Complaint as Exhibit D. National Beef further admits that the face of Exhibit D indicates that the '486 Patent was issued on December 19, 2017 and is titled “Enrichment Methods for the Detection of Pathogens and Other Microbes.” National Beef lacks knowledge or information sufficient to admit or deny if IEH is the owner by assignment of all rights, title, and interest in the '486 Patent, and therefore denies the same. National Beef denies any remaining allegations in Paragraph 12, including any suggestion or implication that the '486 Patent was duly and legally issued or is valid and enforceable

THE INVENTIONS DESCRIBED IN THE '584, '143, AND '771 PATENTS

13. National Beef admits that it strives to improve the safety and quality of its food products by safeguarding against harmful microbiological contamination such as *E. coli*, *Listeria*, and *Salmonella*. National Beef lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 13 and therefore denies them.

14. National Beef lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 14 and therefore denies them.

15. The '584, '143, and '771 patents (collectively, the “Asserted Pooling Patents”) speak for themselves. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 15 and therefore denies them.

¹ Collectively the '584, '143, '771, and '486 Patents are referred to herein as “the Asserted Patents.”

16. The Asserted Pooling Patents speak for themselves. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 16 and therefore denies them.

17. The Asserted Pooling Patents speak for themselves. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 17 and therefore denies them

18. The Asserted Pooling Patents speak for themselves. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 18 and therefore denies them.

19. The Asserted Pooling Patents speak for themselves. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 19 and therefore denies them.

20. The Asserted Pooling Patents speak for themselves. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 20 and therefore denies them.

21. The Asserted Pooling Patents speak for themselves. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 21 and therefore denies them.

22. The Asserted Pooling Patents speak for themselves. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 22 and therefore denies them.

23. The Asserted Pooling Patents speak for themselves. National Beef lacks knowledge or information sufficient to form a belief as to the truth of the remaining allegations in Paragraph 23 and therefore denies them.

24. The Asserted Pooling Patents speak for themselves. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 24 and therefore denies them.

25. The Asserted Pooling Patents speak for themselves. National Beef admits that the language of claim 1 of the '143 Patent is as it appears in the '143 Patent. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 25 and therefore denies them.

THE INVENTIONS DESCRIBED IN THE '486 PATENT

26. The '486 Patent speaks for itself. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 26 and therefore denies them.

27. The '486 Patent speaks for itself. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 27 and therefore denies them.

28. The '486 Patent speaks for itself. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 28 and therefore denies them.

29. The '486 Patent speaks for itself. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 29 and therefore denies them.

30. The '486 Patent speaks for itself. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 30 and therefore denies them.

31. The '486 Patent speaks for itself. National Beef admits that the language of claim 1 of the '486 Patent is as it appears in the '486 Patent. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 31 and therefore denies them.

32. The '486 Patent speaks for itself. National Beef admits that the language of claim 9 of the '486 Patent is as it appears in the '486 Patent. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 32 and therefore denies them.

33. The '486 Patent speaks for itself. National Beef admits that the language of claim 10 of the '486 Patent is as it appears in the '486 Patent. National Beef lacks knowledge or information sufficient to form a belief as to the truth of any remaining allegations in Paragraph 33 and therefore denies them.

NATIONAL BEEF'S ALLEGED INFRINGEMENT

34. National Beef admits that part of its business involves processing beef and beef by-products. National Beef denies the remaining allegations in Paragraph 34.

35. National Beef admits that it performs microbiological testing using labs located at its facilities. National Beef admits that its labs are IL2A accredited and that it uses AOAC testing methods. National Beef denies the remaining allegations contained in Paragraph 35, including that its processes fall within the scope of the Asserted Patents.

36. National Beef admits that it performs microbiological testing to detect pathogens and other microbes. National Beef denies the remaining allegations of Paragraph 36, including that its processes fall within the scope of the '486 Patent.

37. National Beef admits that IEH sent National Beef a letter dated April 18, 2023. The correspondence speaks for itself. National Beef denies any remaining allegations of Paragraph 37.

38. National Beef admits that IEH sent National Beef a letter dated April 18, 2023. The correspondence speaks for itself. National Beef denies any remaining allegations of Paragraph 38.

39. National Beef admits that it responded to IEH on May 9, 2023. The correspondence speaks for itself. National Beef denies any remaining allegations of Paragraph 39.

40. National Beef admits that IEH communicated with it on June 13, 2023. The referenced correspondence speaks for itself. National Beef denies any remaining allegations of Paragraph 40.

41. National Beef admits that it communicated with IEH on June 20, 2023. The referenced correspondence speaks for itself. National Beef denies any remaining allegations of Paragraph 41.

42. National Beef admits that IEH communicated with it on June 23, 2023. The referenced correspondence speaks for itself. National Beef denies any remaining allegations of Paragraph 42.

43. National Beef admits that it communicated with IEH on July 7, 2023. The referenced correspondence speaks for itself. National Beef denies any remaining allegations of Paragraph 43.

44. National Beef admits that IEH purports to attach alleged claim charts as Exhibits E–G to the Complaint. National Beef denies the remaining allegations in Paragraph 44.

45. National Beef admits that IEH purports to attach an alleged claim chart as Exhibit H to the Complaint. National Beef denies the remaining allegations in Paragraph 45.

46. National Beef admits that IEH sent National Beef a letter dated April 18, 2023. The correspondence speaks for itself. National Beef denies the remaining allegations of Paragraph 46.

47. National Beef denies the allegations of Paragraph 47.

48. National Beef denies the allegations of Paragraph 48.

49. National Beef denies the allegations of Paragraph 49.

50. National Beef denies the allegations of Paragraph 50.

COUNT I: INFRINGEMENT OF THE '584 PATENT

51. National Beef incorporates by reference the preceding paragraphs of this Answer.

52. National Beef lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 52 and therefore denies them.

53. National Beef denies the allegations in Paragraph 53.

54. National Beef admits that IEH sent National Beef a letter dated April 18, 2023. The correspondence speaks for itself. National Beef denies the remaining allegations of Paragraph 54.

55. National Beef denies the allegations in Paragraph 55.

56. National Beef denies the allegations in Paragraph 56.

57. National Beef denies the allegations in Paragraph 57.

58. National Beef denies the allegations in Paragraph 58.

59. National Beef denies the allegations in Paragraph 59.

60. National Beef denies the allegations in Paragraph 60.

COUNT II: INFRINGEMENT OF THE '143 PATENT

61. National Beef incorporates by reference the preceding paragraphs of this Answer.

62. National Beef lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 62 and therefore denies them.

63. National Beef denies the allegations in Paragraph 63.

64. National Beef admits that IEH sent National Beef a letter dated April 18, 2023. The correspondence speaks for itself. National Beef denies the remaining allegations of Paragraph 64.

65. National Beef denies the allegations of Paragraph 65.

66. National Beef denies the allegations of Paragraph 66.

67. National Beef denies the allegations of Paragraph 67.

68. National Beef denies the allegations of Paragraph 68.

69. National Beef denies the allegations of Paragraph 69.

70. National Beef denies the allegations of Paragraph 70.

COUNT III: INFRINGEMENT OF THE '771 PATENT

71. National Beef incorporates by reference the preceding paragraphs of this Answer.

72. National Beef lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 72 and therefore denies them.

73. National Beef denies the allegations in Paragraph 73.

74. National Beef admits that IEH sent National Beef a letter dated April 18, 2023. The correspondence speaks for itself. National Beef denies the remaining allegations in Paragraph 74.

75. National Beef denies the allegations of Paragraph 75.

76. National Beef denies the allegations of Paragraph 76.

77. National Beef denies the allegations of Paragraph 77.

78. National Beef denies the allegations of Paragraph 78.

79. National Beef denies the allegations of Paragraph 79.

80. National Beef denies the allegations of Paragraph 80.

COUNT IV: INFRINGEMENT OF THE '486 PATENT

81. National Beef incorporates by reference the preceding paragraphs of this Answer.

82. National Beef lacks knowledge or information sufficient to form a belief as to the truth of the allegations in Paragraph 82 and therefore denies them.

83. National Beef denies the allegations in Paragraph 83.

84. National Beef admits that IEH sent National Beef a letter dated April 18, 2023. The correspondence speaks for itself. National Beef denies the remaining allegations of Paragraph 84.

85. National Beef denies the allegations in Paragraph 85.

86. National Beef denies the allegations in Paragraph 86.

87. National Beef denies the allegations in Paragraph 87.

88. National Beef denies the allegations in Paragraph 88.

89. National Beef denies the allegations in Paragraph 89.

90. National Beef denies the allegations in Paragraph 90.

REQUEST FOR RELIEF

WHEREFORE, National Beef denies that IEH is entitled to any of the relief requested in its prayer for relief, or any relief whatsoever. National Beef respectfully requests that the Court (a) enter judgment in favor of National Beef, (b) dismiss IEH's claims against National Beef with prejudice, (c) declare this case as exceptional and award National Beef its attorney fees, costs, and expenses pursuant to 35 U.S.C. § 285, and (d) grant any such other relief that this Court may deem just and proper.

JURY DEMAND

No response is required to the section entitled "Jury Demand." To the extent a response is required, National Beef demands a trial by jury on all issues so triable.

AFFIRMATIVE DEFENSES

In addition to the defenses set forth herein, National Beef expressly reserves the right to assert any defenses or affirmative defenses under the Federal Rules of Civil Procedure, the patent laws of the United States, and any other defense, at law or in equity, that may now exist or in the future become known or available based upon discovery and further investigation in this case. Without altering any applicable burden of proof, National Beef asserts the following defenses:

FIRST AFFIRMATIVE DEFENSE (Failure to State a Claim)

IEH fails to state a claim upon which relief may be granted.

SECOND AFFIRMATIVE DEFENSE (Non-infringement)

National Beef does not and has not directly or indirectly infringed, literally or under the doctrine of equivalents, any asserted claim of the Asserted Patents.

THIRD AFFIRMATIVE DEFENSE (Invalidity)

Each asserted claim of the Asserted Patents is invalid and/or unenforceable for failing to comply with one or more of the requirements for patentability under the patent laws of the United States, including but not limited to 35 U.S.C. §§ 101, 102, 103, and/or 112.

FOURTH AFFIRMATIVE DEFENSE (Limitation of Damages)

IEH's claims for alleged damages and costs are limited by Title 35 of the United States Code, including, without limitation, 35 U.S.C. §§ 287 and 288.

**FIFTH AFFIRMATIVE DEFENSE
(Prosecution History)**

IEH's claims are barred, in whole or in part, as a result of prosecution history estoppel, prosecution disclaimer, and/or statements or amendments made with respect to the Asserted Patents during prosecution or any other proceedings before for the United States Patent Office.

**SIXTH AFFIRMATIVE DEFENSE
(Adequacy of Legal Remedy)**

IEH is not entitled to injunctive relief because, among other things, any alleged injury to IEH is not immediate or irreparable and IEH has an adequate remedy, if any, at law

**SEVENTH AFFIRMATIVE DEFENSE
(Waiver)**

IEH's claim for relief is barred in whole or in part by the doctrine of waiver.

**EIGHTH AFFIRMATIVE DEFENSE
(Inequitable Conduct, etc.)**

Any additional defenses revealed through discovery, such as inequitable conduct. For example and without limitation, U.S. Patent Nos. 8,822,143 and 9,637,771 are unenforceable due to IEH's inequitable conduct before the USPTO as is more fully set forth in National Beef's counterclaims, *infra*, which are incorporated herein.

JURY TRIAL DEMANDED

National Beef demands a trial by jury on all issues so triable.

**NATIONAL BEEF PACKING COMPANY, LLC'S FIRST AMENDED
COUNTERCLAIMS**

Defendant and counterclaimant National Beef Packing Company, LLC ("National Beef"), by and through its undersigned counsel, brings the following counterclaims against Plaintiff and counterdefendant Institute for Environmental Health, Inc. ("IEH"):

PARTIES

1. National Beef is a Delaware limited liability company with its headquarters located in Kansas City, Missouri.

2. On information and belief, IEH is a Washington corporation with its principal place of business located in Lake Forest Park, Washington.

JURISDICTION AND VENUE

3. This action arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*

4. This Court has subject matter jurisdiction over this action pursuant to at least 28 U.S.C. §§ 1331, 1338, and 2201.

5. IEH has consented to the personal jurisdiction of this Court at least by commencing its action in this District, as set forth in its Complaint.

6. Venue is proper in this Court for purposes of this action only pursuant to this Court's opinion and order dated May 16, 2024 (D.I. 25, 27).

BACKGROUND

7. National Beef is one of the largest beef processing companies in the United States. It processes, markets, and sells beef and beef by-products both domestically and internationally.

8. National Beef and its predecessors have continuously processed, marketed, and sold beef products in interstate commerce for over 30 years.

9. National Beef has three primary beef processing facilities, which are located in Dodge City, Kansas, Liberal, Kansas, and Tama, Iowa. The two beef processing plants that are located in Kansas are some of the largest in the world.

10. National Beef also has case ready operations in Hummels Wharf, Pennsylvania and Moultrie, Georgia, further processing facilities in Kansas City, Kansas and North Baltimore, Ohio, a direct-to-consumer distribution center in Kansas City, Kansas, and a leather processing facility in Saint Joseph, Missouri.

11. National Beef maintains functioning labs for pathogen testing in its primary beef processing facilities in Kansas.

12. National Beef outsources pathogen testing of the products processed at its Iowa facility to a third-party laboratory located in Des Moines, Iowa.

13. On August 1, 2023, IEH filed a Complaint for Patent Infringement against National Beef, asserting that National Beef infringes claims in U.S. Patent Nos. 7,534,584 (“the ’584 Patent”), 8,822,143 (“the ’143 Patent”), 9,637,771 (“the ’771 Patent”), and 9,845,486 (“the ’486 Patent”) (collectively, “the Asserted Patents”).

14. On April 5, 2010, the United States Patent and Trademark Office (“USPTO”) granted a request for *inter partes* reexamination of all 33 claims of the ’584 Patent (“the ’584 Reexamination”).

15. On March 6, 2019, the USPTO issued a reexamination certificate which amended and cancelled certain claims in the ’584 Patent.

16. During the nearly nine year period that the ’584 Patent was subject to reexamination, IEH filed continuation applications for what are now the ’143 Patent and the ’771 Patent.

17. During the prosecution of the ’143 and ’771 Patents, IEH failed to abide by its duty of disclosure owed to the USPTO by failing to fully apprise the examiner with relevant information

from the '584 Reexamination that was material to the patentability of the claims of the '143 and '771 Patents.

18. IEH withheld and failed to disclose material information to the examiner which would impact the patentability of the claims of the '143 and '771 Patents.

COUNT I
(Declaratory Judgment of Invalidity of the Asserted Patents)

19. National Beef realleges and incorporates herein the allegations set forth in the preceding paragraphs.

20. An actual and substantial case or controversy exists between National Beef and IEH as to the invalidity of the Asserted Patents, as evidenced by IEH's Complaint alleging that the Asserted Patents are valid and that National Beef infringes the Asserted Patents.

21. The Asserted Patents are invalid for failure to comply with the conditions of patentability set forth in the patent statutes, including without limitation 35 U.S.C. §§ 102, 103, and/or 112.

22. For example, the claims of the '584, '143, and '771 Patents, are invalid under 35 U.S.C. §§ 102 and/or 103 pursuant to at least the following prior art references, either alone or in combination: "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 (2002); 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); 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); and/or 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).

23. The claims of the '486 Patent are invalid under 35 U.S.C. §§ 102 and/or 103 pursuant to at least the following prior art references, either alone or in combination: Rayman, M.K., et al., "ICMSF methods studies. XIII. An international comparative study of the MPN procedure of the Anderson-Baird-Parker direct plating method for the enumeration of *Escherichia coli* biotype I in raw meats," Can. J. Microbiol. 25:1322-1327 (1979); Nagar, et al., EP 1253203A1, "Rapid Resuscitation, Growth and Detection of Microorganisms"; "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 (2002); and/or Anderson, J., et al., "A Rapid and Direct Plate Method for Enumerating *Escherichia coli* biotype I in Food," J. Appl. Bact., 39:111-117 (1975).

24. Additionally, the Asserted Patents are invalid under 35 U.S.C. § 112. For example, at least the terms "plurality" and "uniform or substantially uniform" contained in claims 1 and 17 of the '584, Patent are indefinite because the terms fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention. Furthermore, at least the term "multiple independent samples" in claim 1 of the '143 Patent is indefinite because the term fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. Moreover, the phrase "multiple independent samples" found in claim 1 of the '771 Patent is indefinite because the term fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention. Also, at least the terms "semi-solid" and "diluting . . . between about 1:0.1 to about 1:5 (wt./vol.) or lesser dilution" found in claim 1 of the '486 Patent are indefinite because the terms fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention. Likewise, at least the term "diluting . . . between about 1:0.1 to about 1:5 (vol./vol.) or lesser dilution, or not diluting the sample" found in claim 11 of the '486 Patent is indefinite because the

term fails to inform, with reasonable certainty, those skilled in the art about the scope of the invention.

25. As such, National Beef is entitled to a judgment finding that the Asserted Patents are invalid.

26. Pursuant to the Federal Declaratory Judgement Act, 28 U.S.C. § 2201 *et seq.*, National Beef requests a declaration that the asserted claims of the Asserted Patents are invalid for failure to comply with one or more requirements of Title 35, United States Code, including but not limited to §§ 102, 103, and/or 112 thereof.

COUNT II
(Declaratory Judgment of Noninfringement of the Asserted Patents)

27. National Beef realleges and incorporates herein the allegations set forth in the preceding paragraphs.

28. An actual and substantial case or controversy exists between National Beef and IEH as to National Beef's non-infringement of the Asserted Patents, as evidenced by IEH's Complaint alleging that National Beef infringes the Asserted Patents.

29. National Beef has not infringed and does not infringe any asserted claim of the Asserted Patents because National Beef does not perform each required element set forth in the asserted claims of the Asserted Patents.

30. As one example of National Beef's noninfringement, National Beef employs pathogen testing methods that do not include compositing separate testing lots.

31. At least because of this, National Beef does not infringe at least claims 1 and 17 of the '584 Patent, at least claim 1 of the '143 Patent, and at least claim 1 of the '771 Patent.

32. Furthermore, as an example, National Beef's pathogen testing methods do not dilute samples with liquid enrichment medium at a ratio of sample to diluent between 1:0.1 to about 1:5 (wt/vol.) or lesser.

33. At least because of this, National Beef does not infringe at least claims 1, 9 and 10 of the '486 Patent.

34. IEH's allegations against National Beef in its Complaint warrant issuance of a declaratory judgment that National Beef does not infringe the Asserted Patents. A judicial determination of non-infringement is necessary and appropriate so that National Beef may ascertain its rights regarding the Asserted Patents.

35. Pursuant to the Federal Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq.*, National Beef requests a declaration that National Beef is not infringing and has not infringed any valid asserted claim of the Asserted Patents, either directly or indirectly, willfully, jointly or individually, or literally or under the doctrine of equivalents.

COUNT III
(Declaration of Unenforceability of the '143 and '771 Patents)

36. National Beef realleges and incorporates herein the allegations set forth in the preceding paragraphs.

37. As a result of the acts described herein, there exists a substantial controversy of sufficient immediacy between National Beef and IEH to warrant the issuance of a declaratory judgment of unenforceability of the '143 and '771 Patents.

38. During the prosecution of the '143 Patent, IEH failed to disclose relevant and material documents, such as office actions, responses, and third-party comments from the '584 Reexamination proceeding that would have impacted the patentability of the '143 Patent's claims. Also, the interview summaries from three interviews conducted do not indicate that any documents

or references from the '584 Reexamination were considered during the prosecution of the '143 Patent. When the issue fee was paid for the '143 Patent, claims of the '584 Patent—that were found not patentably distinct from those that issued in the '143 Patent—had been deemed not patentable on multiple occasions by the Central Reexamination Unit (“CRU”) involved in the '584 Reexamination. These rulings by the CRU were not provided to the examiner of the '143 Patent.

39. During the prosecution of the '771 Patent, IEH failed to disclose relevant and material documents, such as office actions, responses, and third-party comments from the '584 Reexamination proceeding that would have impacted the patentability '771 Patent claims. Also, the interview summary from an interview does not indicate that any documents from the '584 Reexamination were considered during the prosecution of the '771 Patent. When the issue fee was paid for the '771 Patent, the '584 Reexamination had issued its first decision concluding that the claims of the '584 Patent were not patentable and a CRU examiner had reached the same conclusion. The examiner of the '771 Patent was not informed about these adverse findings regarding claims that he considered to be not patentably distinct from the claims of the '584 Patent.

40. The same attorneys that were conducting the '584 Reexamination were also prosecution the applications that became the '143 and '771 Patents. As such, at least IEH's attorneys had knowledge of the adverse rulings and other material documents in the '584 Reexamination proceedings and that the examiner for the '143 and '771 Patents had determined that the proposed claims for those patents were patentably indistinct from the claims in the '584 Reexamination. IEH and its attorneys had a duty to disclose these documents and findings in the '143 and '771 Patent prosecution proceedings. They did not do so in violation of their duty of candor under 37 CFR § 1.56. This failure of disclosure constitutes inequitable conduct.

41. A judicial declaration is necessary and appropriate so that National Beef may ascertain its rights regarding the enforceability of the '143 and '771 Patents.

42. National Beef is entitled to a declaratory judgment that the '143 and '771 Patents are unenforceable due to inequitable conduct before the USPTO as described with particularity in the foregoing paragraphs.

PRAYER FOR RELIEF

WHEREFORE, National Beef respectfully requests that this Court grant the following relief in its favor and against IEH:

- a. Judgment that National Beef has not infringed and does not infringe any asserted claim of the Asserted Patents either directly or indirectly, willfully, jointly or individually, or literally or under the doctrine of equivalents;
- b. A declaration that the Asserted Patents are invalid;
- c. A declaration that the '143 and '771 Patents are unenforceable due to inequitable conduct;
- d. A declaration that this case is exceptional and award National Beef its attorney fees, costs, and expenses pursuant to 35 U.S.C. § 285;
- e. Such other relief as this Court deems just and proper.

JURY DEMAND

National Beef hereby demands a trial by jury on all issues so triable.

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