

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

INSTITUTE FOR ENVIRONMENTAL)	
HEALTH, INC.,)	
)	
Plaintiff,)	
)	C.A. No. _____
v.)	
)	JURY TRIAL DEMANDED
NATIONAL BEEF PACKING COMPANY,)	
LLC,)	
)	
Defendant.)	

COMPLAINT FOR PATENT INFRINGEMENT

1. Plaintiff Institute for Environmental Health, Inc. (“Plaintiff” or “IEH”) is an industry leader in food safety and owns patents covering its innovative methods of testing for microbiological contamination. Founded in 2000, IEH is a family-owned and operated company that has become one of the nation’s leading providers of testing for microbiological contamination. IEH invests heavily in research and development to improve the efficiency and accuracy of biological testing. Patent offices around the world, including the U.S. Patent Office (“USPTO”), have granted IEH numerous patents in recognition of IEH’s innovation in this field. IEH leverages its patented technology and methods to provide its services to customers, helping to secure the safety of food resources provided to consumers throughout the United States and around the world.

2. Through this Complaint, IEH brings claims for patent infringement against National Beef Packing Company, LLC (“Defendant” or “National Beef”) based on the following:

PARTIES

3. Plaintiff IEH is a Washington corporation with its principal place of business located in Lake Forest Park, Washington.

4. On information and belief, Defendant National Beef is a Delaware limited liability company with its principal place of business located in Kansas City, Missouri.

JURISDICTION AND VENUE

5. These claims are for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 1 *et seq.*

6. This Court has original jurisdiction over IEH's claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

7. This Court has personal jurisdiction over National Beef because it is formed under the laws of Delaware.

8. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b) and 1400(b).

IEH'S ASSERTED PATENTS

9. IEH is the owner by assignment of all rights, title, and interest in U.S. Patent No. 7,534,584 (the "'584 Patent") entitled "Modular Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents." The USPTO duly and legally issued the '584 Patent on May 19, 2009. The USPTO issued a reexamination certificate for the '584 Patent on March 6, 2019. A copy of the '584 Patent is attached as **Exhibit A** to the Complaint.

10. IEH is the owner by assignment of all rights, title, and interest in U.S. Patent No. 8,822,143 (the "'143 Patent") entitled "Modular Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents." The

USPTO duly and legally issued the '143 Patent on September 2, 2014. A copy of the '143 Patent is attached as **Exhibit B** to the Complaint.

11. IEH is the owner by assignment of all rights, title, and interest in U.S. Patent No. 9,637,771 (the "'771 Patent") entitled "Modular Compositing—Multiple Lot Screening Protocols for Detection of Pathogens, Microbial Contaminants and/or Constituents." The USPTO duly and legally issued the '771 Patent on May 2, 2017. A copy of the '771 Patent is attached as **Exhibit C** to the Complaint.

12. IEH is the owner by assignment of all rights, title, and interest in U.S. Patent 9,845,486 (the "'486 Patent") entitled "Enrichment Methods for the Detection of Pathogens and Other Microbes." The USPTO duly and legally issued the '486 Patent on December 19, 2017. A copy of the '486 Patent is attached as **Exhibit D** to the Complaint.

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

13. Food producers, manufacturers, and regulators strive to improve the safety and quality of food products by safeguarding against harmful microbiological contamination, such as *E. coli*, *Listeria*, and *Salmonella*. See '143 Patent Col. 1:49-50; '771 Patent Col. 1:56-57; '584 Patent Col. 1:37-38; '486 Patent Col. 1:40-42.

14. In or around 2002, an IEH scientist invented new methods of testing for contamination that have since revolutionized the food industry and were subsequently patented through the '584 Patent, the '143 Patent, the '771 Patent, and the '486 Patent (collectively, the "Asserted Patents"). The inventor assigned each of the Asserted Patents to IEH.

15. The '584 Patent, the '143 Patent, and the '771 Patent (collectively, the "Asserted Pooling Patents") involve a method known as "wet pooling." The patented methods may be used to simultaneously test multiple lots of food for contamination. For example, in the context of

meat products, a “lot” of beef trim may consist of a combo-bin containing 2,000 pounds of beef trim. The patented methods can be used to test five such lots simultaneously, greatly improving efficiency and lowering costs, while maintaining accuracy.

16. The methods patented in the Asserted Pooling Patents begin, for example, by “separately collecting multiple independent samples” from each lot. ’584 Patent Claim 1(a); ’143 Patent Claim 1(a); ’771 Patent Claim 1(a). In the beef example, this collection step may involve gathering, for example, sixty independent samples (portions or pieces) of beef trim.

17. Those samples are combined to form a composite sample that is representative of the lot from which the samples were collected. ’584 Patent Claim 1(b); ’143 Patent Claim 1(b); ’771 Patent Claim 1(b). That composited sample is then added to an enrichment medium, often a liquid broth containing nutrients allowing the target microbe (e.g., *E. coli*) to grow. ’584 Patent Claim 1(c); ’143 Patent Claim 1(c); ’771 Patent Claim 1(c). This enriched composite allows for more accurate testing for contamination because it contains a greater volume of detectable microbes.

18. This process is performed for each lot to create multiple enriched composites, one for each lot.

19. Next, the patented methods combine a portion from each enriched composite to create a single pooled sample representing all lots from which the samples were collected. ’584 Patent Claim 1(d); ’143 Patent Claim 1(d); ’771 Patent Claim 1(d).

20. Finally, the pooled sample is tested to determine whether it contains the target microbe, such as *E. coli*. ’584 Patent Claim 1(e); ’143 Patent Claim 1(e); ’771 Patent Claim 1(e).

21. The Asserted Pooling Patents teach that, if just one of the lots is contaminated, testing the pooled sample would detect that contamination. '584 Patent Claim 1(e); '143 Patent Claim 1(e); '771 Patent Claim 1(e). Thus, if the testing assay does not detect the microbe, *all five lots* are deemed free of the target microbe. *Id.* The Asserted Pooling Patents refer to this step as “validating” the test lots. *Id.* This allows multiple lots to be analyzed and validated using a single test.

22. If the test detects contamination in the pooled sample, the remaining enriched composites are individually tested to pinpoint the contamination to a particular lot or lots, rather than requiring destruction of all lots of beef that made up the pooled sample. '584 Patent Claim 1(e); '143 Patent Claim 1(e); '771 Patent Claim 1(e).

23. The inventor of the Asserted Pooling Patents discovered that, in most instances, the contamination is restricted to a small number of lots. The invention leverages that discovery to allow for more efficient testing (by requiring fewer tests across lots) as well as the ability to pinpoint contamination (when contamination is found), thereby resulting in substantial net savings for food producers because fewer test are needed, less food is destroyed (or otherwise diverted), and food safety remains ensured.

24. The '584, '143 and '771 Patents cover this form of testing.

25. Claim 1 of the '143 Patent provides an example claim describing one of the inventive methods:

1. A method of sampling and testing products for microbes in multiple separate lots, comprising:

a) separately collecting multiple independent samples from each of multiple separate lots, wherein each separate lot is separately sampled by taking said multiple independent samples thereof;

b) separately compositing the collected multiple independent samples from each of the separate lots to provide a corresponding

set of separate composited lot samples, wherein each of the separate composited lot samples is attributed to a particular corresponding separate lot;

c) enriching each of the separate composited test lot samples to provide a set of separate composited test lot samples enriched for the target microbe(s);

d) removing portions of each separate enriched composited lot sample, and combining the removed portions to provide a pooled modular composite sample; and

e) testing of the pooled modular composite sample, using a suitable detection assay, for the target microbe(s), wherein when such testing is negative all of said samples that were composited to form the separate composited lot samples are deemed negative for the target microbe(s) and each of the multiple separate lots is validated, and wherein when such testing is positive, each of the individual separate composited lot samples that were used to form the pooled modular composite sample are individually tested to determine which of the separate composited lot samples is positive for the target microbe(s), wherein the lots corresponding to any negatively testing composited lot samples are validated.

THE INVENTIONS DESCRIBED IN THE '486 PATENT

26. The '483 Patent involves enrichment methods for testing for microbes. The patented methods may be used to test food for contamination more efficiently and cost effectively. For example, prior art enrichment methods for detecting pathogens in food involve diluting the sample with an enrichment media at a ratio of 1:10 (weight to volume). Maintaining this ratio uses substantial volumes of media. The patented methods can be used to detect pathogens in food by diluting the sample at a ratio of between about 1:0.1 to 1:5, greatly improving efficiency and lowering costs, while maintaining accuracy.

27. The patented methods begin by "obtaining a test sample, the sample being solid or semi-solid." '486 Patent Claim 1. In some embodiments, the test sample that is obtained is a standard lot-unit sample, such as a sample taken from a combo-bin containing 2,000 pounds of beef trim. '486 Patent Claim 9. In other embodiments, the test sample is a composite lot-unit

sample corresponding to a combination of samples taken from lots of raw or processed samples, such as a sample composited from multiple samples taken from a combo-bin containing 2,000 pounds of beef trim. '486 Patent Claim 10.

28. The sample is diluted with liquid enrichment medium at a ratio between about 1:0.1 to 1:5 (weight to volume) or lesser dilution. '486 Patent Claim 1. The diluted sample is incubated at an optimal temperature for a time period sufficient to allow levels of the particular bacterial pathogen or microbe to be detected by a suitable assay. '486 Claim 1. The assay is used to determine whether the sample is contaminated with the particular bacterial pathogen or bacterial microbe. '486 Claim 1.

29. For example, a 100 gram sample of meat trim could be diluted with 50 mL of a commercial media used to detect *E. coli* O157 (i.e., weight-to-volume ratio of 1:0.5). The diluted sample could be incubated at 42 degrees Celsius for 24 hours. A multiplex polymerase chain reaction (PCR) assay could be used to determine whether the sample is contaminated with *E. coli* O157.

30. The '486 Patent provides several illustrations demonstrating the effectiveness and reliability of this inventive method. For instance, Figures 13 and 14 illustrate amplification products obtained by multiplex PCR of *E. coli* O157:H7 inoculated on meat trimmings, diluted under standard (1:10) conditions and diluted under the inventive "dry" (1:0.5) conditions, respectively, and then incubated at an optimal temperature for 24 hours. The inventive "dry" enrichment method gave comparable results, as shown the figures reproduced below:

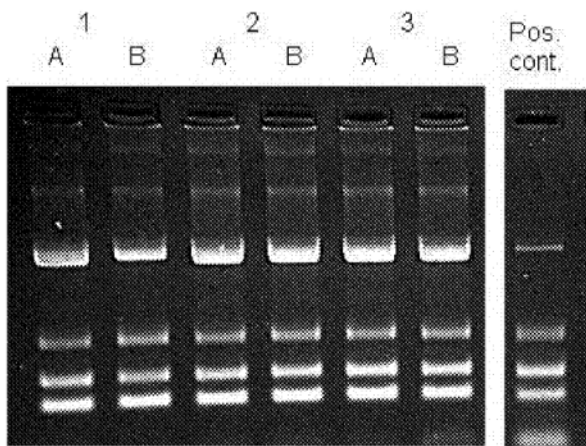


Figure 13

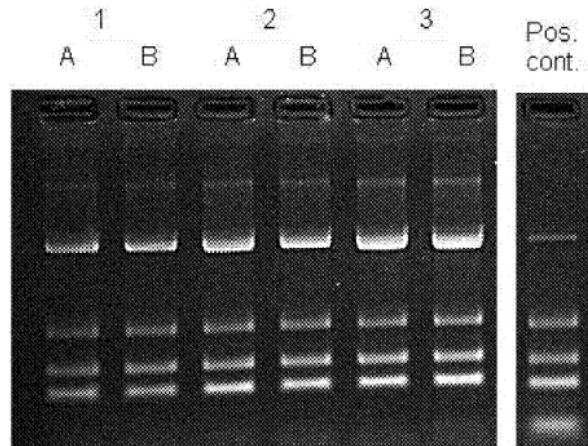


Figure 14

31. Claim 1 of the '486 Patent provides an example claim describing one of the inventive methods:

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.

32. Claim 9 of the '486 Patent provides an example claim describing another embodiment of the inventive methods:

The method of claim 1, wherein obtaining a sample is obtaining a standard Lot-unit sample.

33. Claim 10 of the '486 Patent provides an example claim describing another embodiment of the inventive methods:

The method of claim 1, wherein the sample is a composite-Lot sample, corresponding to a combination of samples selected from the group consisting of samples or subsamples taken from sublots/lots of raw or processed samples, environmental samples, industrial samples, pharmaceutical samples, bio-solid samples, samples taken by spore traps, settled dust, impingers, or filtration, and combinations thereof

NATIONAL BEEF'S INFRINGEMENT

34. National Beef is in the business of, among other things, processing beef and beef by-products.

35. On information and belief, National Beef performs microbiological testing using methods of sampling and testing for microbes, including the use of selectively enriched sample "pooling" for microbes. For instance, National Beef uses wet pooling that falls within the scope of the Asserted Pooling Patents when testing meat (specifically, beef) for bacterial pathogens (including *E. coli* O157:H7, *Salmonella*, and *Listeria*, among others) in what it describes as its "full service, on premise labs" that are "IL2A accredited for pathogen testing" and use "AOAC testing methods" as part of the "control and assessment protocol" of its Biologic Food Safety System (the "National Beef Pooling Methods"). National Beef utilizes the National Beef Pooling Methods throughout its six Food Safety Zones, including prior to grinding and throughout the production and packaging process.

36. On information and belief, National Beef performs microbiological testing using enrichment methods for the detection of pathogens and other microbes. For instance, National Beef uses enriched pathogen testing methods that fall within the scope of the '486 Patent when

testing meat (specifically, beef) for bacterial pathogens (including *E. coli* O157:H7, *Salmonella*, and *Listeria*, among others) (the “National Beef Pathogen Testing Methods”).

37. IEH has made repeated efforts to persuade National Beef to either cease its ongoing infringement or license the Asserted Patents. On April 18, 2023, IEH notified National Beef of the Asserted Patents and provided a copy of the Asserted Patents.

38. In its April 18, 2023 letter, IEH shared its understanding of the National Beef Pooling Methods and described how these methods infringed claim 1 of the ’143 Patent, claim 1 of the ’771 Patent, claims 1 and 17 of the ’584 Patent, and Claim 1 of the ’486 Patent. IEH requested that, to the extent National Beef disputed the accuracy of IEH’s description of the National Beef Pooling Methods, National Beef provide the basis for that contention, such as by providing materials that describe National Beef’s sampling, enriching, testing, and verification procedures. IEH explained it was willing to treat those materials confidentially, if appropriate. Alternatively, IEH also requested that National Beef provide the basis for any contention that its methods could be determined from publicly available information.

39. On May 9, 2023, National Beef responded to IEH’s pre-filing inquiry. National Beef did not dispute the accuracy of IEH’s understanding of the National Beef Pooling Methods or state that its methods could be determined from publicly available information. Instead, it requested information about IEH’s licensing program for the Asserted Patents.

40. On June 13, 2023, IEH provided National Beef with licensing rates for testing performed using the inventions of the Asserted Patents.

41. On June 20, 2023, National Beef requested that IEH provide claim charts illustrating how the Asserted Patents covered National Beef’s testing methods. National Beef

also requested that IEH keep its offer to license the Asserted Patents open for 30 days following National Beef's receipt of the claim charts.

42. On June 23, 2023, IEH provided exemplary claim charts to National Beef. The claim charts again described IEH's understanding of the National Beef Pooling Methods and National Beef Pathogen Testing Methods and illustrated how the methods infringed each element of claim 1 of the '143 Patent, claim 1 of the '771 Patent, claims 1 and 17 of the '584 Patent, and claim 1 of the '486 Patent. IEH noted National Beef had not disputed the facts IEH identified in its May 9, 2023 letter. IEH informed National Beef it would keep its licensing offer open until July 7, 2023.

43. On July 7, 2023, National Beef informed IEH that National Beef was evaluating IEH's infringement claims. Again, National Beef did not dispute the accuracy of IEH's understanding of the National Beef Pooling Methods or National Beef Pathogen Testing Methods.

44. On information and belief, National Beef has and continues to infringe, literally or under the doctrine of equivalents, at least one claim of the '584, '143, and '771 Patents, including claim 1 of the '143 and '771 Patents, and claims 1 and 17 of the '584 Patent, by practicing the National Beef Pooling Methods. Claim charts mapping each element of exemplary claims of the Asserted Pooling Patents to the National Beef Pooling Methods are attached as **Exhibits E-G** of the Complaint.

45. On information and belief, National Beef has and continues to infringe, literally or under the doctrine of equivalents, at least claims 1, 9, and 10 of the '486 Patent by practicing the National Beef Pathogen Testing Methods. A claim chart mapping each element of these

exemplary claims to the National Beef Pathogen Testing Methods is attached as **Exhibit H** of the Complaint.

46. National Beef is, and has been, on notice of the Asserted Patents since April 18, 2023, if not earlier, when IEH sent a letter to National Beef, alerting National Beef to the existence and its infringement of the Asserted Patents.

47. On information and belief, National Beef has continued to infringe the Asserted Patents despite an objectively high likelihood that its actions constitute infringement of these valid patents. National Beef's infringement of the Asserted Patents has therefore been willful.

48. National Beef's infringing conduct was and is without authority, consent, or license.

49. IEH has suffered irreparable harm and will continue to suffer irreparable harm unless National Beef is enjoined from infringing the Asserted Patents. IEH has no adequate remedy at law.

50. IEH is entitled to recover from National Beef the damages sustained by IEH as a result of National Beef's wrongful acts in an amount IEH will prove at trial, including, but not limited to, lost profits and/or a reasonable royalty, together with interest and costs, as well as attorneys' fees, should the Court deem the case to be exceptional.

COUNT I: INFRINGEMENT OF THE '584 PATENT

51. IEH repeats and re-alleges the allegations contained in the preceding paragraphs as if fully set forth here.

52. IEH is the assignee of the '584 Patent. IEH has all substantial rights to enforce the '584 Patent, including the right to exclude others and to sue and recover damages for past and future infringement.

53. The '584 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

54. National Beef is, and has been, on notice of the '584 Patent since at least as early as April 18, 2023. On information and belief, National Beef's knowledge of the '584 Patent occurred earlier than April 18, 2023.

55. On information and belief, under 35 U.S.C. § 271(a), National Beef has directly infringed and continues to directly infringe, literally and/or under the doctrine of equivalents, at least claims 1 and 17 of the '584 Patent by using the National Beef Pooling Methods.

56. National Beef's infringing conduct was and is without authority, consent, or license.

57. On information and belief, National Beef's infringement of the '584 Patent has been willful.

58. IEH has been damaged and continues to be damaged by National Beef's infringement of the '584 Patent.

59. IEH has suffered irreparable harm and will continue to suffer irreparable harm unless National Beef is enjoined from infringing the '584 Patent.

60. National Beef's infringement of the '584 Patent is exceptional and entitles IEH to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

COUNT II: INFRINGEMENT OF THE '143 PATENT

61. IEH repeats and re-alleges the allegations contained in the preceding paragraphs as if fully set forth here.

62. IEH is the assignee of the '143 Patent. IEH has all substantial rights to enforce the '143 Patent, including the right to exclude others and to sue and recover damages for past and future infringement.

63. The '143 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

64. National Beef is, and has been, on notice of the '143 Patent since at least as early as April 18, 2023. On information and belief, National Beef's knowledge of the '143 Patent occurred earlier than April 18, 2023.

65. On information and belief, under 35 U.S.C. § 271(a), National Beef has directly infringed and continues to directly infringe, literally and/or under the doctrine of equivalents, at least one claim of the '143 Patent, including claim 1, by using the National Beef Pooling Methods.

66. National Beef's infringing conduct was and is without authority, consent, or license.

67. On information and belief, National Beef's infringement of the '143 Patent has been willful.

68. IEH has been damaged and continues to be damaged by National Beef's infringement of the '143 Patent.

69. IEH has suffered irreparable harm and will continue to suffer irreparable harm unless National Beef is enjoined from infringing the '143 Patent.

70. National Beef's infringement of the '143 Patent is exceptional and entitles IEH to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

COUNT III: INFRINGEMENT OF THE '771 PATENT

71. IEH repeats and re-alleges the allegations contained in the preceding paragraphs as if fully set forth here.

72. IEH is the assignee of the '771 Patent. IEH has all substantial rights to enforce the '771 Patent, including the right to exclude others and to sue and recover damages for past and future infringement.

73. The '771 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

74. National Beef is, and has been, on notice of the '771 Patent since at least as early as April 18, 2023. On information and belief, National Beef's knowledge of the '771 Patent occurred earlier than April 18, 2023.

75. On information and belief, under 35 U.S.C. § 271(a), National Beef has directly infringed and continues to directly infringe, literally and/or under the doctrine of equivalents, at least one claim of the '771 Patent, including claim 1, by using the National Beef Pooling Methods.

76. National Beef's infringing conduct was and is without authority, consent, or license.

77. On information and belief, National Beef's infringement of the '771 Patent has been willful.

78. IEH has been damaged and continues to be damaged by National Beef's infringement of the '771 Patent.

79. IEH has suffered irreparable harm and will continue to suffer irreparable harm unless National Beef is enjoined from infringing the '771 Patent.

80. National Beef's infringement of the '771 Patent is exceptional and entitles IEH to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

COUNT IV: INFRINGEMENT OF THE '486 PATENT

81. IEH repeats and re-alleges the allegations contained in the preceding paragraphs as if fully set forth here.

82. IEH is the assignee of the '486 Patent. IEH has all substantial rights to enforce the '486 Patent, including the right to exclude others and to sue and recover damages for past and future infringement.

83. The '486 Patent is valid, enforceable, and was duly issued in full compliance with Title 35 of the United States Code.

84. National Beef is, and has been, on notice of the '486 Patent since at least as early as April 18, 2023. On information and belief, National Beef's knowledge of the '486 Patent occurred earlier than April 18, 2023.

85. On information and belief, under 35 U.S.C. § 271(a), National Beef has directly infringed and continues to directly infringe, literally and/or under the doctrine of equivalents, at least claims 1, 9, and 10 of the '486 Patent by using the National Beef Pathogen Testing Methods.

86. National Beef's infringing conduct was and is without authority, consent, or license.

87. On information and belief, National Beef's infringement of the '486 Patent has been willful.

88. IEH has been damaged and continues to be damaged by National Beef's infringement of the '486 Patent.

89. IEH has suffered irreparable harm and will continue to suffer irreparable harm unless National Beef is enjoined from infringing the '486 Patent.

90. National Beef's infringement of the '486 Patent is exceptional and entitles IEH to attorneys' fees and costs incurred in prosecuting this action under 35 U.S.C. § 285.

REQUEST FOR RELIEF

A. Judgment that National Beef has directly and/or indirectly infringed the Asserted Patents;

B. Judgment that National Beef's infringement has been willful;

C. An award of damages adequate to compensate IEH for National Beef's infringing activities, including supplemental damages for any post-verdict infringement up until entry of the final judgment with an accounting as needed, together with prejudgment and post-judgment interest on the damages awarded; all of these damages to be enhanced in an amount up to treble the amount of compensatory damages under 35 U.S.C. § 284;

D. A determination that this case is exceptional under 35 U.S.C. § 285 and awarding IEH its reasonable costs and expenses of litigation, including attorneys' and experts' fees; and

E. A permanent injunction pursuant to 35 U.S.C. § 283 enjoining National Beef, its agents, employees, officers, attorneys, successors, assigns, and all persons in active concert or participation with them, from further infringement of the Asserted Patents and from using methods or making, offering for sale, or selling products that infringe one or more of the independent claims of the patents either literally or under the doctrine of equivalents; and

F. Such other and further relief as the Court may deem just and proper.

JURY DEMAND

IEH demands a trial by jury on all issues so triable.

Respectfully submitted,

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