

**UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS**

BIOMODAL LIMITED and CHILDREN'S
MEDICAL CENTER CORPORATION,

Plaintiffs,

v.

NEW ENGLAND BIOLABS, INC.,

Defendant.

[Jury Trial Demanded]

[Preliminary Injunction Requested]

CIVIL ACTION NO. 1:24-cv-11697

COMPLAINT

Plaintiffs biomodal Limited (“biomodal”) and Children’s Medical Center Corporation (“CMCC”) (collectively “Plaintiffs”) by and through counsel, file this Complaint for Patent Infringement and Request for Preliminary Injunction against New England Biolabs, Inc. (“Defendant” or “NEB”) and allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement under the laws of the United States, 35 U.S.C. § 1, et seq.

2. Defendant has infringed and continues to infringe, directly and indirectly, one or more claims of U.S. Patent Nos. 10,337,053 B2 (“the ’053 patent”); 10,443,091 B2 (“the ’091 patent”); 10,533,213 B2 (“the ’213 patent”); 10,731,204 B2 (“the ’204 patent”); 10,774,373 B2 (“the ’373 patent”); 10,767,216 B2 (“the ’216 patent”); 11,072,818 B2 (“the ’818 patent”); and 11,208,683 B2 (“the ’683 patent”) (collectively the “Rao Patents” or the “Asserted Patents”), at least by making or having made, using, offering for sale and selling products that infringe one or more claims of each of the Asserted Patents.

3. Through this case, Plaintiffs seek monetary damages as well as preliminary and permanent injunctive relief to address past and ongoing infringement and to protect their significant investment in this technology and patent portfolio.

PARTIES

4. Plaintiff biomodal is a corporation organized under the laws of the United Kingdom, with a principal place of business at Chesterford Research Park, Cambridge, CB10 1XL, United Kingdom. biomodal is engaged in the business of developing, manufacturing and selling sequencing and computing platforms that provide genetic and epigenetic information. Biomodal is the exclusive licensee of the Asserted Patents.

5. Plaintiff CMCC is a charitable corporation duly organized and existing under the laws of the Commonwealth of Massachusetts and having its principal office at 300 Longwood Avenue, Boston, Massachusetts, 02115, U.S.A. CMCC is the legal co-owner by assignment of the Asserted Patents, which were duly and legally issued by the United States Patent and Trademark Office (“USPTO”).

6. Upon information and belief, Defendant NEB is a company organized and existing under the Commonwealth of Massachusetts with a principal place of business located at 240 County Road, Ipswich, MA 01938-2723, U.S.A. Defendant NEB makes or has made, uses, offers for sale and sells products which, when used as NEB instructs, infringe one or more claims of the Asserted Patents.

JURISDICTION AND VENUE

7. This civil action arises under the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, including, but not limited to, 35 U.S.C. §§ 271 and 281. The Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338.

8. The Court has both general and specific personal jurisdiction over Defendant because Defendant's principal place of business is located in the Commonwealth of Massachusetts and in this judicial district, and Defendant continuously and systematically conducts business in the Commonwealth of Massachusetts and in this judicial district.

9. Exercising personal jurisdiction over Defendant in this lawsuit comports with due process and traditional notions of fair play and substantial justice.

10. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b), in that Defendant resides in this judicial district, is subject to personal jurisdiction in this judicial district, and has committed acts of infringement and has a regular and established place of business in this judicial district.

FACTUAL BACKGROUND

Plaintiff biomodal and the Patented Technology

11. biomodal is a pioneering company developing multiomics technologies to provide both genetic and epigenetic information using sequencing and computing platforms.

12. biomodal creates technologies and products that focus on epigenetics, which is the study of changes in gene expression that are not encoded in the DNA of the genome, including the ability to distinguish between the four canonical bases (i.e., adenosine ("A"), cytosine ("C"), guanine ("G") and thymine ("T")) and two known modifications of cytosine that occur and are

associated with diseases such as cancer, namely, 5-methylcytosine (“5mC”) and 5-hydroxymethylcytosine (“5hmC”).

13. biomodal’s technologies and products are based on the groundbreaking inventions of Anjana Rao and her team, who were the first to discover that 5hmC was present in the human genome, important to epigenetics, and that the “ten eleven translocation” or “TET” enzymes could be exploited to oxidize 5mC to 5hmC. Dr. Rao and her team were also the first to exploit the use of the glucosyltransferase enzymes, which are found in bacteria and viruses, to assist in the detection of 5mC and 5hmC in a human DNA sample.

14. DNA methylation occurs primarily on cytosine (C) in the human genome. These processes are known to become highly aberrant during tumorigenesis and cancer.

15. The Rao Patents are part of a patent family that was first filed on September 28, 2009, claiming priority to provisional applications filed in 2008 and issuing to inventors Anjana Rao, Mamta Tahiliani, Kian Peng Koh, Suneet Agarwal and Aravind Iyer.

16. The Rao Patents are directed to, among other things, novel compositions and methods for detecting the cytosine methylation status of DNA, including to accurately detect the presence of 5mC and 5hmC.

17. biomodal launched its duet multiomics solution +modC in March 2023, which provides the ability to obtain genetic and epigenetic methylation at single base resolution information from a DNA library in a single workflow.

18. In February 2024, biomodal launched its duet multiomics solution evoC which provides the ability to obtain genetic and epigenetic methylation and epigenetic hydroxymethylation information at single base resolution from a DNA library in a single workflow

Plaintiffs' Asserted Patents

19. This Complaint focuses on eight patents in the Rao Family.

20. The '213 patent, entitled "Selective Oxidation of 5-Methylcytosine by TET-Family Proteins," was duly and legally issued on January 14, 2020. The '213 patent is owned by Plaintiff CMCC and The United States of America, as represented by the Secretary, Department of Health & Human Services ("HHS"). A true and correct copy of the '213 patent is attached as Exhibit 1.

21. The '204 patent, entitled "Selective Oxidation of 5-Methylcytosine by TET-Family Proteins," was duly and legally issued on August 4, 2020. The '204 patent is owned by Plaintiff CMCC and HHS. A true and correct copy of the '204 patent is attached as Exhibit 2.

22. The '818 patent, entitled "Selective Oxidation of 5-Methylcytosine by TET-Family Proteins," was duly and legally issued on July 7, 2021. The '818 patent is owned by Plaintiff CMCC and HHS. A true and correct copy of the '818 patent is attached as Exhibit 3.

23. The '683 patent, entitled "Methods of Epigenetic Analysis," was duly and legally issued on December 28, 2021. The '683 patent is owned by Plaintiff CMCC and HHS. A true and correct copy of the '683 patent is attached as Exhibit 4.

24. The '053 patent, entitled "Labeling Hydroxymethylated Residues," was duly and legally issued on July 2, 2019. The '053 patent is owned by Plaintiff CMCC and HHS. A true and correct copy of the '053 patent is attached as Exhibit 5.

25. The '373 patent, entitled "Compositions Comprising Glucosylated Hydroxymethylated Bases," was duly and legally issued on September 15, 2020. The '373 patent is owned by Plaintiff CMCC and HHS. A true and correct copy of the '373 patent is attached as Exhibit 6.

26. The '091 patent, entitled "Selective Oxidation of 5-Methylcytosine by TET-Family Proteins," was duly and legally issued on October 15, 2019. The '091 patent is owned by Plaintiff CMCC and HHS. A true and correct copy of the '091 patent is attached as Exhibit 7.

27. The '216 patent, entitled "Methods for Distinguishing 5-Hydroxymethylcytosine From 5-Methylcytosine," was duly and legally issued on September 8, 2020. The '216 patent is owned by Plaintiff CMCC and HHS. A true and correct copy of the '216 patent is attached as Exhibit 8.

28. biomodal has had an exclusive license to the Rao Patents, which includes the Asserted Patents, since November 28, 2016, by virtue of an exclusive worldwide license agreement for all fields under the Rao Patents. Pursuant to this license, biomodal has the right to bring suit in its own name, at its own expense, and on its own behalf for infringement of the Asserted Patents.

Defendant NEB's Incorporation of Plaintiffs' Patented Technologies

29. The allegations provided below are exemplary and without prejudice to Plaintiffs' infringement contentions. In providing these allegations, Plaintiffs do not convey or imply any particular claim constructions or the precise scope of the claims. Plaintiffs' claim construction contentions regarding the meaning and scope of the claim terms will be provided under the Court's scheduling order and local rules.

30. Defendant NEB sells numerous products to third parties for use in conducting various tests and scientific protocols, including certain products that are used in connection with the study of epigenetics, and more specifically, the study of 5mC and 5hmC.

31. The NEB products that are the subject of this patent infringement action include without limitation: (i) NEBNext[®] Enzymatic Methyl-seq (E7125 S/L) ("EM-seq"); (ii) NEBNext[®] Enzymatic Methyl-Seq Kit (E7120 S/L) ("EM-seq Kit"); (iii) NEBNext[®] Enzymatic 5hmC-seq

Conversion Module (E3365) (“5hmC”); and (iv) NEBNext[®] Enzymatic 5hmC-seq Kit (E3350S/L) (“5hmC Kit”) (collectively the “Accused Products”).

32. Upon information and belief, NEB began offering for sale and selling the 5hmC and 5hmC Kit Products on or about February 12, 2024.

33. Upon information and belief, NEB has not sold or offered to sell the 5hmC and/or 5hmC Kit Products for use in clinical trials or in conjunction with or incorporation into a third party’s product for clinical use.

34. Upon information and belief, while NEB sold and offered for sale the EM-seq and EM-seq Kit Products for use by third parties, NEB has not, as of the filing date of this Complaint, sold or offered for sale the EM-seq and the EM-seq Kit Products for resale by third parties or for the use in clinical trials or in conjunction with or incorporation into a third party’s product for clinical use.

35. The Accused Products are non-limiting examples that were identified based on publicly available information. Plaintiffs reserve the right to identify additional infringing activities, products and services, including, for example, based on information obtained during discovery.

36. As detailed below and in Exhibits 9-16, each limitation of at least one claim of one or more of the Asserted Patents is literally present in the Accused Products, or is literally practiced by Defendant’s personnel, agents, customers or others who use the Accused Products in accordance with Defendant NEB’s explicit instruction. To the extent that any limitation is not literally present or practiced, each such limitation is present or practiced under the doctrine of equivalents.

37. Defendant NEB has made extensive use of Plaintiffs' patented technologies, including the technology described and claimed in the Asserted Patents. Plaintiffs are committed to defending its proprietary and patented technology. Plaintiffs request that this Court (i) award damages sufficient to compensate for Defendant's infringement of the Asserted Patents, (ii) deem this case exceptional and (iii) award Plaintiffs their attorneys' fees and costs, and (iv) grant a preliminary and permanent injunction against Defendant to prevent ongoing infringement of the Asserted Patents.

COUNT I

(Infringement of U.S. Patent No. 10,533,213)

38. Plaintiffs incorporate by reference and reallege all the foregoing paragraphs of the Complaint as though fully set forth herein.

Defendant's Direct Infringement

39. Defendant has directly infringed and will continue to directly infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '213 patent, including at least claim 1, including by making or having made, using, importing, offering for sale or selling the EM-seq and/or the EM-seq Kit.

40. By way of nonlimiting example, NEB's EM-seq and EM-seq Kit, when used in accordance with its instructions, meet each and every limitation of claim 1, either literally or under the doctrine of equivalents, as set forth in Exhibit 9 (Claim Chart of the '213 Patent), which is incorporated herein by reference.

Defendant NEB's Indirect Infringement

41. Upon information and belief, Defendant had actual knowledge of the '213 patent no later than May 21, 2021, when an employee of Plaintiff biomodal spoke with an employee of

Defendant NEB and specifically discussed the Asserted Rao Patent family. NEB further had actual knowledge that NEB's activities constitute direct and indirect infringement of the '213 patent, or has willfully blinded itself to the infringing nature of its activities, and yet continues its infringing activities.

42. Since at least as early as May 2021, and no later than the date of the letter to NEB dated May 8, 2024, ("Notice Letter"), Defendant NEB has known that its EM-seq and EM-seq Kit Products, infringe at least claim 1 of the '213 patent, as evidenced by the Claim Chart attached as Exhibit 9.

43. Since at least as early as May 2021, and no later than the date of the Notice Letter, Defendant NEB has known that use of the EM-seq and EM-seq Kit Products infringes at least one claim of the '213 patent when used by customers or other users, or when sold or offered for sale to third parties, as evidenced by the Claim Chart attached as Exhibit 9.

44. Since at least as early as May 2021, and no later than the date of the Notice Letter, Defendant NEB has knowingly and intentionally induced infringement, and continues to knowingly and intentionally induce infringement, by actively encouraging, instructing and aiding customers and/or other users of the EM-seq and EM-seq Kit Products to directly infringe one or more claims of the '213 Patent. NEB has provided customers or other users of the Accused Products and on NEB's website, access to Manuals and Protocols that induce customers or others to use the EM-seq and EM-seq Kit Products in a manner that infringes at least claim 1 of the '213 patent. For example, NEB's website directs the customer or user to the product manual for the protocol for use of the EM-Seq and EM-seq Kit Products and provides the manual for download: <https://www.neb.com/en-us/products/e7120-nebnext-enzymatic-methyl-seq-kit>; <https://www.neb.com/en-us/products/e7125-nebnext-enzymatic-methyl-seq-conversion-module>.

45. The NEB protocols and manuals for the EM-seq Products, as evidenced by the links recited in Paragraph 44, provide explicit instructions resulting in infringement of at least claim 1 of the '213 patent. *See* Ex. 9 (Claim Chart).

46. Defendant NEB contributes to others' infringement and is liable for contributory infringement of one or more claims of the '213 patent by making, using, selling, offering for sale and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use.

47. The foregoing description of NEB's infringement is based on publicly available information. Plaintiffs reserve the right to modify this description, including for example, on the basis of information about the Accused Products obtained during discovery.

48. Plaintiffs have been, are being and will continue to be irreparably harmed, for which there is no adequate remedy at law, unless NEB is preliminarily and permanently enjoined by this Court.

49. Plaintiffs have incurred and will continue to incur damages as a result of NEB's infringement of the '213 Patent, in an amount to be determined at trial. Additionally, the willful and deliberate nature of NEB's infringing activities entitles Plaintiffs to recover trebled actual damages and to recover their attorneys' fees and costs incurred.

COUNT II

(Infringement of U.S. Patent No. 10,731,204)

50. Plaintiffs incorporate by reference and reallege all the foregoing paragraphs of the Complaint as though fully set forth herein.

Defendant's Direct Infringement

51. Defendant has directly infringed and will continue to directly infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '204 patent, including at least claims 1 and 3, including by making or having made, using, importing, offering for sale or selling the EM-seq and/or the EM-seq Kit.

52. By way of nonlimiting example, use of NEB's EM-seq and EM-seq Kit Products meet each and every limitation of claims 1 and 3, either literally or under the doctrine of equivalents, as set forth in the claim chart attached as Exhibit 10, which is incorporated herein by reference.

Defendant NEB's Indirect Infringement

53. Upon information and belief, Defendant had actual knowledge of the '204 patent no later than May 21, 2021, when an employee of Plaintiff biomodal spoke with an employee of Defendant NEB and specifically discussed the Asserted Patent family. NEB had actual knowledge that NEB's activities constitute direct and indirect infringement of the '204 patent, or has willfully blinded itself to the infringing nature of its activities, and yet continues its infringing activities.

54. Since at least as early as May 2021, and no later than the date of the Notice Letter, Defendant NEB has known that use of the EM-seq and EM-seq Kit Products infringes at least one claim of the '204 patent. *See* Ex. 10 (Claim Chart).

55. Since at least as early as May 2021, and no later than the date of the Notice Letter, Defendant NEB has known that the EM-seq and Em-seq Kit Products infringe at least one claim of the '204 patent when used by customers or other users, or when sold or offered for sale by third parties.

56. Since at least as early as May 2021, and no later than the date of the Notice Letter, Defendant NEB has knowingly and intentionally induced infringement, and continues to knowingly and intentionally induce infringement, by actively encouraging, instructing and aiding customers and/or other users of the EM-Seq and EM-seq Kit Products to directly infringe one or more claims of the '204 Patent. NEB has provided customers or other users of the Accused Products and on NEB's website, access to Manuals and Protocols that induce customers or others to use the EM-seq and EM-seq Kit Products in a manner that infringes at least claim 1 of the '204 patent. For example, NEB's website directs the customer or user to the product's manual for the protocol for use of the EM-Seq and EM-seq Kit Products and provides the manual for download: <https://www.neb.com/en-us/products/e7120-nebnext-enzymatic-methyl-seq-kit>; <https://www.neb.com/en-us/products/e7125-nebnext-enzymatic-methyl-seq-conversion-module>.

57. The NEB protocols and manuals, as evidenced by the links recited in Paragraph 56, provide explicit instructions resulting in infringement of at least claims 1 and 3 of the '204 patent. *See* Ex. 10 (Claim Chart).

58. Defendant NEB contributes to others' infringement and is liable for contributory infringement of one or more claims of the '204 patent by making, using, selling, offering for sale and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use.

59. The foregoing description of NEB's infringement is based on publicly available information. Plaintiffs reserve the right to modify this description, including for example, on the basis of information about the Accused Products obtained during discovery.

60. Plaintiffs have been, are and will continue to be being irreparably harmed, for which there is no adequate remedy at law, unless NEB is preliminarily and permanently enjoined by this Court.

61. Plaintiffs have incurred and will continue to incur damages as a result of NEB's infringement of the '204 Patent, in an amount to be determined at trial. Additionally, the willful and deliberate nature of NEB's infringing activities entitles Plaintiffs to recover trebled actual damages and to recover their attorneys' fees and costs incurred.

COUNT III

(Infringement of U.S. Patent No. 11,072,818)

62. Plaintiffs incorporate by reference and reallege all the foregoing paragraphs of the Complaint as though fully set forth herein.

Defendant's Direct Infringement

63. Defendant has directly infringed and will continue to directly infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '818 patent, including at least claim 1, including by making or having made, using, importing, offering for sale or selling the EM-seq and the EM-seq Kit Products.

64. By way of nonlimiting example, use of NEB's EM-seq and EM-seq Kit Products meet each and every limitation of claim 1, either literally or under the doctrine of equivalents, as set forth in the Claim Chart attached as Exhibit 11, which is incorporated herein by reference.

Defendant NEB's Indirect Infringement

65. Upon information and belief, Defendant had actual knowledge of the '818 patent no later than its July 27, 2021 issue date, given that, in May 2021, an employee of Plaintiff biomodal spoke with an employee of Defendant NEB and specifically discussed the Asserted

Patent family. NEB had actual knowledge that NEB's activities constitute direct and indirect infringement of the '818 patent, or has willfully blinded itself to the infringing nature of its activities, and yet continues its infringing activities.

66. Since at least as early as July 27, 2021, and no later than the date of the Notice Letter, Defendant NEB has known that use of the EM-seq and EM-seq Kit Products infringes at least claim 1 of the '818 patent. *See* Ex. 11 (Claim Chart).

67. Since at least as early as July 27, 2021, and no later than the date of the Notice Letter, Defendant NEB has known that the EM-seq and EM-seq Kit Products infringe at least claim 1 of the '818 patent when used by customers or other users, or when sold or offered for sale by third parties.

68. Since at least as early as July 27, 2021, and no later than the date of the Notice Letter, Defendant NEB has knowingly and intentionally induced infringement, and continues to knowingly and intentionally induce infringement, by actively encouraging, instructing and aiding customers and/or other users of the EM-Seq and EM-seq Kit Products to directly infringe one or more claims of the '818 Patent. NEB has provided customers or other users of the Accused Products and on NEB's website, access to Manuals and Protocols that induce customers or others to use the EM-seq and EM-seq Kit Products in a manner that infringes at least claim 1 of the '818 patent. For example, NEB's website directs the customer or user to the product manual for the protocol for use of the EM-Seq and EM-seq Kit Products and provides the manual for download: <https://www.neb.com/en-us/products/e7120-nebnext-enzymatic-methyl-seq-kit>; <https://www.neb.com/en-us/products/e7125-nebnext-enzymatic-methyl-seq-conversion-module>.

69. The NEB protocols and manuals, as evidenced by the links recited in Paragraph 68, provide explicit instructions resulting in infringement of at least claim 1 of the '818 patent. *See* Ex. 11 (Claim Chart).

70. Defendant NEB contributes to others' infringement and is liable for contributory infringement of one or more claims of the '818 patent by making, using, selling, offering for sale and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use.

71. The foregoing description of NEB's infringement is based on publicly available information. Plaintiffs reserve the right to modify this description, including for example, on the basis of information about the Accused Products obtained during discovery.

72. Plaintiffs have been, are being and will continue to be irreparably harmed, for which there is no adequate remedy at law, unless NEB is preliminarily and permanently enjoined by this Court.

73. Plaintiffs have incurred and will continue to incur damages as a result of NEB's infringement of the '818 Patent, in an amount to be determined at trial. Additionally, the willful and deliberate nature of NEB's infringing activities entitles Plaintiffs to recover trebled actual damages and to recover their attorneys' fees and costs incurred.

COUNT IV

(Infringement of U.S. Patent No. 11,208,683)

74. Plaintiffs incorporate by reference and reallege all the foregoing paragraphs of the Complaint as though fully set forth herein.

Defendant's Direct Infringement

75. Defendant has directly infringed and will continue to directly infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '683 patent, at least claim 1, including by making or having made, using, importing, offering for sale or selling the EM-seq and/or the EM-seq Kit.

76. By way of nonlimiting example, use of NEB's EM-seq and EM-seq Kit Products results in a composition that meets each and every limitation of claim 1, either literally or under the doctrine of equivalents, as set forth in the Claim Chart attached as Exhibit 12, which is incorporated herein by reference.

Defendant NEB's Indirect Infringement

77. Upon information and belief, Defendant had actual knowledge of the '683 patent no later than its December 28, 2021 issue date, given that, in May 2021, an employee of Plaintiff biomodal spoke with an employee of Defendant NEB and specifically discussed the Asserted Patent family. NEB had actual knowledge that NEB's activities constitute direct and indirect infringement of the '683 patent, or has willfully blinded itself to the infringing nature of its activities, and yet continues its infringing activities.

78. Since at least as early as December 28, 2021, and no later than the date of the Notice Letter, Defendant NEB has known that use of the EM-seq and EM-seq Kit Products infringes at least claim 1 of the '683 patent.

79. Since at least as early as December 28, 2021, and no later than the date of the Notice Letter, Defendant NEB has known that use of the EM-seq and EM-seq Kit Products results in the infringement of at least claim 1 of the '683 patent when used by customers or other users, or when sold or offered for sale by third parties.

80. Since at least as early as December 28, 2021, and no later than the date of the Notice Letter, Defendant NEB has knowingly and intentionally induced infringement, and continues to knowingly and intentionally induce infringement, by actively encouraging, instructing and aiding customers and/or other users of the EM-Seq and EM-seq Kit Products to directly infringe one or more claims of the '683 Patent. NEB has provided customers or other users of the Accused Products and on NEB's website, access to Manuals and Protocols that induce customers or others to use the EM-seq and EM-seq Kit Products in a manner that infringes at least claim 1 of the '683 patent. For example, NEB's website directs the customer or user to the product's manual for the protocol for use of the EM-Seq and EM-seq Kit Products and provides the manual for download: <https://www.neb.com/en-us/products/e7120-nebnext-enzymatic-methyl-seq-kit>; <https://www.neb.com/en-us/products/e7125-nebnext-enzymatic-methyl-seq-conversion-module>.

81. The NEB protocols and manuals, as evidenced by the links recited in Paragraph 80, provide explicit instructions resulting in infringement of at least claim 1 of the '683 patent. *See* Ex. 12 (Claim Chart).

82. Defendant NEB contributes to others' infringement and is liable for contributory infringement of one or more claims of the '683 patent by making, using, selling, offering for sale and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use.

83. The foregoing description of NEB's infringement is based on publicly available information. Plaintiffs reserve the right to modify this description, including for example, on the basis of information about the Accused Products obtained during discovery.

84. Plaintiffs have been, are being and will continue to be irreparably harmed, for which there is no adequate remedy at law, unless NEB is preliminarily and permanently enjoined by this Court.

85. Plaintiffs have incurred and will continue to incur damages as a result of NEB's infringement of the '683 Patent, in an amount to be determined at trial. Additionally, the willful and deliberate nature of NEB's infringing activities entitles Plaintiffs to recover trebled actual damages and to recover their attorneys' fees and costs incurred.

COUNT V

(Infringement of U.S. Patent No. 10,337,053)

86. Plaintiffs incorporate by reference and reallege all the foregoing paragraphs of the Complaint as though fully set forth herein.

Defendant's Direct Infringement

87. Defendant has directly infringed and will continue to directly infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '053 patent, including at least claim 1, including by making or having made, using, importing, offering for sale or selling the Accused Products.

88. By way of nonlimiting example, use of each of the Accused Products meets each and every limitation of claim 1, either literally or under the doctrine of equivalents, as set forth in the Claim Chart attached as Exhibit 13, which is incorporated herein by reference.

Defendant NEB's Indirect Infringement

89. Upon information and belief, Defendant had actual knowledge of the '053 patent no later than May 21, 2021 when an employee of Plaintiff biomodal spoke with an employee of Defendant NEB and specifically discussed the Asserted Patent family. NEB had actual knowledge

that NEB's activities constitute direct and indirect infringement of the '053 patent, or has willfully blinded itself to the infringing nature of its activities, and yet continues its infringing activities.

90. Since at least as early as May 2021, and no later than the date of the Notice Letter, Defendant NEB has known that use of the Accused Products infringes at least one claim of the '053 patent.

91. Since at least as early as May 2021, and no later than the date of the Notice Letter, Defendant NEB has known that the Accused Products infringe at least one claim of the '053 patent when used by customers or other users, or when sold or offered for sale by third parties.

92. Since at least as early as May 2021 in the case of the EM-seq Products, and, in the case of the 5hmC and 5hmC Kit Products, at least as early as February 2024 (when NEB introduced them to market), and no later than the date of the Notice Letter for all Accused Products, Defendant NEB has knowingly and intentionally induced infringement, and continues to knowingly and intentionally induce infringement, by actively encouraging, instructing and aiding customers and/or other users of the Accused Products to directly infringe one or more claims of the '053 Patent.

93. NEB has provided customers or other users of the Accused Products and on NEB's website, access to Manuals and Protocols that induce customers or others to use the Accused Products in a manner that infringes at least claim 1 of the '053 patent. For example, NEB's website directs the customer or user to the product manual for the protocol for use of the EM-Seq and EM-seq Kit Products and provides the Manuals for download: <https://www.neb.com/en-us/products/e7120-nebnext-enzymatic-methyl-seq-kit>; <https://www.neb.com/en-us/products/e7125-nebnext-enzymatic-methyl-seq-conversion-module>. NEB's website directs the customer or user to the product's manual for the protocol for use of the 5hmC and 5hmC Kit

Products and provides the Manuals for download: [NEBNext® Enzymatic 5hmC-seq Kit | NEB; https://www.neb.com/en-us/products/e3365nebnext-enzymatic-methyl-seq-5hmc-conversion-module](https://www.neb.com/en-us/products/e3365nebnext-enzymatic-methyl-seq-5hmc-conversion-module). *See* Ex. 13 (Claim Chart).

94. The NEB protocols and manuals for the Accused Products, as evidenced by the links recited in Paragraph 93 provide explicit instructions resulting in infringement of at least claim 1 of the '053 patent. *See* Ex. 13 (Claim Chart).

95. Defendant NEB contributes to others' infringement and is liable for contributory infringement of one or more claims of the '053 patent by making, using, selling, offering for sale and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use.

96. The foregoing description of NEB's infringement is based on publicly available information. Plaintiffs reserve the right to modify this description, including for example, on the basis of information about the Accused Products obtained during discovery.

97. Plaintiffs have been, are being and will continue to be irreparably harmed, for which there is no adequate remedy at law, unless NEB is preliminarily and permanently enjoined by this Court.

98. Plaintiffs have incurred and will continue to incur damages as a result of NEB's infringement of the '053 Patent, in an amount to be determined at trial. Additionally, the willful and deliberate nature of NEB's infringing activities entitles Plaintiffs to recover trebled actual damages and to recover their attorneys' fees and costs incurred.

COUNT VI

(Infringement of U.S. Patent No. 10,774,373)

99. Plaintiffs incorporate by reference and reallege all the foregoing paragraphs of the Complaint as though fully set forth herein.

Defendant's Direct Infringement

100. Defendant has directly infringed and will continue to directly infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '373 patent, including at least claim 1, including by making or having made, using, importing, offering for sale or selling the Accused Products.

101. By way of nonlimiting example, each of the Accused Products, when used, results in a product that meets each and every limitation of claim 1 of the '373 patent, either literally or under the doctrine of equivalents, as set forth in the Claim Chart attached as Exhibit 14, which is incorporated herein by reference.

Defendant NEB's Indirect Infringement

102. Upon information and belief, Defendant had actual knowledge of the '373 patent no later than May 21, 2021 when an employee of Plaintiff biomodal spoke with an employee of Defendant NEB and specifically discussed the Asserted Patent family. NEB had actual knowledge that NEB's activities constitute direct and indirect infringement of the '373 patent, or has willfully blinded itself to the infringing nature of its activities, and yet continues its infringing activities.

103. Since at least as early as May 2021 in the case of the EM-seq Products, and, in the case of the 5hmC and 5hmC Kit Products, at least as early as February 2024 (when NEB introduced them to market), and no later than the date of the Notice Letter for all Accused Products, Defendant

NEB has known that the Accused Products infringe at least one claim of the '373 patent when used by NEB, customers or other users.

104. Since at least as early as May 2021 in the case of the EM-seq Products, and, in the case of the 5hmC and 5hmC Kit Products, at least as early as February 2024 (when NEB introduced them to market), and no later than the date of the Notice Letter for all Accused Products, Defendant NEB has knowingly and intentionally induced infringement, and continues to knowingly and intentionally induce infringement, by actively encouraging, instructing and aiding customers and/or other users of the Accused Products to directly infringe one or more claims of the '373 Patent.

105. NEB has provided customers or other users of the Accused Products and on NEB's website, access to Manuals and Protocols that induce customers or others to use the Accused Products in a manner that infringes at least claim 1 of the '373 patent. For example, NEB's website directs the customer or user to the product's manual for the protocol for use of the EM-Seq and EM-seq Kit Products and provides the manual for download: <https://www.neb.com/en-us/products/e7120-nebnext-enzymatic-methyl-seq-kit>; <https://www.neb.com/en-us/products/e7125-nebnext-enzymatic-methyl-seq-conversion-module>. NEB's website directs the customer or user to the product's manual for the protocol for use of the 5hmC and 5hmC Kit Products and provides the manual for download: [NEBNext® Enzymatic 5hmC-seq Kit | NEB; https://www.neb.com/en-us/products/e3365nebnext-enzymatic-methyl-seq-5hmc-conversion-module](https://www.neb.com/en-us/products/e3365nebnext-enzymatic-methyl-seq-5hmc-conversion-module).

106. The NEB protocols and manuals, as evidenced by the links recited in Paragraph 105 provide explicit instructions resulting in infringement of at least claim 1 of the '373 patent. *See* Ex. 14 (Claim Chart).

107. Defendant NEB contributes to others' infringement and is liable for contributory infringement of one or more claims of the '373 patent by making, using, selling, offering for sale and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use.

108. The foregoing description of NEB's infringement is based on publicly available information. Plaintiffs reserve the right to modify this description, including for example, on the basis of information about the Accused Products obtained during discovery.

109. Plaintiffs have been, are being and will continue to be irreparably harmed, for which there is no adequate remedy at law, unless NEB is preliminarily and permanently enjoined by this Court.

110. Plaintiffs have incurred and will continue to incur damages as a result of NEB's infringement of the '373 Patent, in an amount to be determined at trial. Additionally, the willful and deliberate nature of NEB's infringing activities entitles Plaintiffs to recover trebled actual damages and to recover their attorneys' fees and costs incurred.

COUNT VII

(Infringement of U.S. Patent No. 10,443,091)

111. Plaintiffs incorporate by reference and reallege all the foregoing paragraphs of the Complaint as though fully set forth herein.

Defendant's Direct Infringement

112. Defendant has directly infringed and will continue to directly infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '091 patent, including

at least claim 1, including by making or having made, using, importing, offering for sale or selling the Accused Products.

113. By way of nonlimiting example, each of the Accused Products, when used, meets each and every limitation of claim 1 of the '091 patent, either literally or under the doctrine of equivalents, as set forth in the Claim Chart attached as Exhibit 15, which is incorporated herein by reference.

Defendant NEB's Indirect Infringement

114. Upon information and belief, Defendant had actual knowledge of the '091 patent no later than May 21, 2021, when an employee of Plaintiff biomodal spoke with an employee of Defendant NEB and specifically discussed the Asserted Patent family. NEB had actual knowledge that NEB's activities constitute direct and indirect infringement of the '091 patent, or has willfully blinded itself to the infringing nature of its activities, and yet continues its infringing activities.

115. Since at least as early as May 2021 in the case of the EM-seq Products, and at least as early as February 2024, when NEB introduced the 5hmC and 5hmC Kit Products, and no later than the date of the Notice Letter for all Accused Products, Defendant NEB has known that the Accused Products infringe at least one claim of the '091 patent when used by customers or other users, or when sold or offered for sale by third parties.

116. Since at least as early as May 2021 in the case of the EM-seq Products, and, in the case of the 5hmC and 5hmC Kit Products, at least as early as February 2024 (when NEB introduced them to market), and no later than the date of the Notice Letter for all Accused Products, Defendant NEB has knowingly and intentionally induced infringement, and continues to knowingly and intentionally induce infringement, by actively encouraging, instructing and aiding customers

and/or other users of the Accused Products to directly infringe one or more claims of the '091 patent.

117. NEB has provided customers or other users of the Accused Products and on NEB's website, access to Manuals and Protocols that induce customers or others to use the Accused Products in a manner that infringes at least claim 1 of the '091 patent. For example, NEB's website directs the customer or user to the product's manual for the protocol for use of the EM-Seq and EM-seq Kit Products and provides the manual for download: <https://www.neb.com/en-us/products/e7120-nebnext-enzymatic-methyl-seq-kit>; <https://www.neb.com/en-us/products/e7125-nebnext-enzymatic-methyl-seq-conversion-module>. NEB's website directs the customer or user to the product's manual for the protocol for use of the 5hmC and 5hmC Kit Products and provides the manual for download: [NEBNext® Enzymatic 5hmC-seq Kit | NEB; https://www.neb.com/en-us/products/e3365nebnext-enzymatic-methyl-seq-5hmc-conversion-module](https://www.neb.com/en-us/products/e3365nebnext-enzymatic-methyl-seq-5hmc-conversion-module).

118. The NEB protocols and manuals, as evidenced by the links recited in Paragraph 117 provide explicit instructions resulting in infringement of at least claim 1 of the '091 patent. *See* Ex. 15 (Claim Chart).

119. Defendant NEB contributes to others' infringement and is liable for contributory infringement of one or more claims of the '091 patent by making, using, selling, offering for sale and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use.

120. The foregoing description of NEB's infringement is based on publicly available information. Plaintiffs reserve the right to modify this description, including for example, on the basis of information about the Accused Products obtained during discovery.

121. Plaintiffs have been, are being and will continue to be irreparably harmed, for which there is no adequate remedy at law, unless NEB is preliminarily and permanently enjoined by this Court.

122. Plaintiffs have incurred and will continue to incur damages as a result of NEB's infringement of the '091 Patent, in an amount to be determined at trial. Additionally, the willful and deliberate nature of NEB's infringing activities entitles Plaintiffs to recover trebled actual damages and to recover their attorneys' fees and costs incurred.

COUNT VIII

(Infringement of U.S. Patent No. 10,767,216)

123. Plaintiffs incorporate by reference and reallege all the foregoing paragraphs of the Complaint as though fully set forth herein.

Defendant's Direct Infringement

124. Defendant has directly infringed and will continue to directly infringe, either literally and/or under the doctrine of equivalents, one or more claims of the '216 patent, including at least claim 1, including by making or having made, using, importing, offering for sale or selling the 5hmC and 5hmC Kit Products.

125. By way of nonlimiting example, both the 5hmC and 5hmC Kit Products when used meet each and every limitation of claim 1, either literally or under the doctrine of equivalents, as set forth in the Claim Chart attached as Exhibit 16, which is incorporated herein by reference.

Defendant NEB's Indirect Infringement

126. Upon information and belief, Defendant had actual knowledge of the '216 patent no later than May 21, 2021 when an employee of Plaintiff biomodal spoke with an employee of Defendant NEB and specifically discussed the Asserted Patent family. NEB had actual knowledge that NEB's activities with respect to the 5hmC and 5hmC Kit Products constitute direct and indirect infringement of the '216 patent, or has willfully blinded itself to the infringing nature of its activities, and yet continues its infringing activities.

127. Since at least as early as February 2024 (the introduction of the 5hmC and 5hmC Kit Products), and no later than the date of the Notice Letter, Defendant NEB has known that the 5hmC and 5hmC Kit Products, when used, infringe at least one claim of the '216 patent.

128. Since at least as early as February 2024, and no later than the date of the Notice Letter, Defendant NEB has known that the 5hmC and 5hmC Products infringe at least one claim of the '216 patent when used by customers or other users, or when sold or offered for sale by third parties.

129. Since at least as early as February 2024, and no later than the date of the Notice Letter, Defendant NEB has knowingly and intentionally induced infringement, and continues to knowingly and intentionally induce infringement, by actively encouraging, instructing and aiding customers and/or other users of the 5hmC and 5hmC Products to directly infringe one or more claims of the '216 patent. NEB has provided customers or other users of the Accused Products and on NEB's website, access to Manuals and Protocols that induce customers or others to use the Accused Products in a manner that infringes at least claim 1 of the '216 patent. For example, NEB's website directs the customer or user to the product's manual for the protocol for use of the 5hmC and 5hmC Kit Products and provides the manual for download: [NEBNext® Enzymatic](#)

[5hmc-seq Kit | NEB; https://www.neb.com/en-us/products/e3365nebnext-enzymatic-methyl-seq-5hmc-conversion-module.](https://www.neb.com/en-us/products/e3365nebnext-enzymatic-methyl-seq-5hmc-conversion-module)

130. The protocols and manuals, as evidenced by the links recited in Paragraph 129 provide explicit instructions resulting in infringement of at least claim 1 of the '216 patent. *See* Ex. 16 (Claim Chart).

131. Defendant NEB contributes to others' infringement and is liable for contributory infringement of one or more claims of the '216 patent by making, using, selling, offering for sale and/or importing a patented component or material and/or apparatus used to practice a patented process, constituting a material part of the invention, knowing the same to be especially made or adapted for use in an infringement and not a staple article or commodity of commerce suitable for substantial non-infringing use.

132. The foregoing description of NEB's infringement is based on publicly available information. Plaintiffs reserve the right to modify this description, including for example, on the basis of information about the Accused Products obtained during discovery.

133. Plaintiffs have been, are being and will continue to be irreparably harmed, for which there is no adequate remedy at law, unless NEB is preliminarily and permanently enjoined by this Court.

134. Plaintiffs have incurred and will continue to incur damages as a result of NEB's infringement of the '216 Patent, in an amount to be determined at trial. Additionally, the willful and deliberate nature of NEB's infringing activities entitles Plaintiffs to recover trebled actual damages and to recover their attorneys' fees and costs incurred.

JURY DEMAND

135. Plaintiffs demand a trial by jury on all issues presented in this Complaint so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask this Court to enter judgment against NEB, NEB's subsidiaries, affiliates, agents, servants, employees, and all persons in active concert or participation with NEB, and grant the following relief:

- (A) Enter judgment in favor of Plaintiffs against NEB on all Counts of the Complaint, finding that NEB has directly and indirectly infringed the Asserted Patents;
- (B) Grant Plaintiffs a preliminary and permanent injunction against NEB, enjoining NEB, its owners, affiliates, officers, directors, managers, agents, servants, employees, trainees, customers and all persons in active concert or participation with them, from continuing to infringe the Asserted Patents, including but not limited to under 35 U.S.C. § 283;
- (C) Award Plaintiffs damages adequate to compensate Plaintiffs for NEB's infringement of the Asserted Patents under 35 U.S.C. § 284;
- (D) A determination that NEB's infringement of the Asserted Patents has been willful and deliberate and award Plaintiffs enhanced damages for willful infringement under 35 U.S.C. § 284;
- (E) A determination that this case is "exceptional" under 35 U.S.C. § 285, and award Plaintiffs their attorneys' fees including expenses and interest;
- (F) An award of pre-judgment and post-judgment interest on all damages computed;
- (G) An award of court costs and attorneys' fees as allowed by applicable law; and
- (H) Such other relief as this Court deems fair, just, and appropriate.

Dated: July 1, 2024

Respectfully submitted,

/s/ Sharona H. Sternberg

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