

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

QUEST DIAGNOSTICS INVESTMENTS LLC,

Plaintiff,

v.

LABORATORY CORPORATION OF AMERICA
HOLDINGS, ESOTERIX, INC., and ENDOCRINE
SCIENCES, INC.,

Defendants.

C.A. No. _____

DEMAND FOR JURY TRIAL

COMPLAINT FOR PATENT INFRINGEMENT

Quest Diagnostics Investments LLC (“Plaintiff” or “Quest”) hereby alleges as follows for its complaint against Laboratory Corporation of America Holdings (“LabCorp Holdings”), Esoterix, Inc. (“Esoterix”), and Endocrine Sciences, Inc. (“Endocrine Sciences”) (collectively, “Defendants” or “LabCorp”):

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, and is brought by Quest against LabCorp Holdings, Esoterix, and Endocrine Sciences for each parties’ infringement of U.S. Patent Nos. 8,409,862 (the “’862 patent”); 8,101,427 (the “’427 patent”); 7,972,867 (the “’867 patent”); and 7,972,868 (the “’868 patent”) (collectively, “Patents-in-Suit”).

PARTIES

2. Plaintiff Quest is a limited liability company organized under the laws of Delaware, having a principal place of business at 500 Plaza Drive, Secaucus, New Jersey 07094.

3. Defendant LabCorp Holdings is a corporation organized under the laws of Delaware, having a principal place of business at 358 South Main Street, Burlington, North Carolina 27215.

4. Defendant Esoterix is a corporation organized under the laws of Delaware, having a principal place of business at 358 South Main Street, Burlington, North Carolina 27215. Esoterix is a subsidiary of LabCorp Holdings.

5. Defendant Endocrine Sciences is a corporation organized under the laws of Delaware, having a principal place of business at 531 South Spring Street, Burlington, North Carolina 27215. Endocrine Sciences is held out to be a division of Esoterix and a subsidiary of LabCorp Holdings.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over the claims set forth pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action arises under the patent laws of the United States.

7. This Court has general personal jurisdiction over each of the defendants because each is incorporated in Delaware. This Court also has personal jurisdiction over each defendant because the Defendants have conducted and are conducting business in Delaware, have derived and are deriving revenue from conducting business in Delaware, and have engaged in systematic and continuous contacts with the State of Delaware.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b) because each of the defendants is incorporated in, and therefore resides in, Delaware.

BACKGROUND

9. Mass spectrometry is a method of “filtering, detecting, and measuring ions based on their mass-to-charge ratio.” ’862 patent at 6:29-30.¹ During the mass spectrometry analysis, “one or more molecules of interest are ionized, and the ions are subsequently introduced into a mass spectrographic instrument where, due to a combination of magnetic and electric fields, the ions follow a path in space that is dependent upon mass (‘m’) and charge (‘z’).” *Id.* at 6:30-35. The resolution of mass spectrometry may be enhanced by employing a “tandem mass spectrometry” or “MS/MS” technique. “In this technique, a precursor ion or group of ions generated from a molecule (or molecules) of interest may be filtered in an MS instrument, and these precursor ions subsequently fragmented to yield one or more fragment ions that are then analyzed in a second MS procedure.” *Id.* at 6:63-67.

10. The output received from an MS procedure is typically an “ion scan,” *i.e.*, the relative abundance of each m/z data point over a given range. ’862 patent at 4:19-21. The results of the ion scan are “related to the amount of the analyte in the original sample.” *Id.* at 4:21-23.

PATENTS-IN-SUIT

U.S. PATENT NO. 8,409,862

11. On April 2, 2013, the United States Patent and Trademark Office issued U.S. Patent No. 8,409,862, entitled “Determination of Testosterone by Mass Spectrometry.” Quest is the owner by assignment of all rights, title, and interest in the ’862 patent, including the right to

¹ Each patent reference includes a pin-cite in a x:xx format, indicating the column (number to the left of the colon) and line number (numbers to the right of the colon). Patents are cited herein by referencing the last three numbers of the patent. For example, U.S. Patent No. 8,409,862 is cited as the ’862 patent.

recover damages for past, present, and future infringement of the patent and the right to seek injunctive relief against infringement of the patent. A true and correct copy of the '862 patent is attached hereto as **Exhibit A**.

12. The '862 patent describes and claims an innovative method, superior to the methods described in the prior art, for determining the presence or amount of testosterone using mass spectrometry, and specifically, for detecting low amounts of testosterone present in samples from human females.

13. Testosterone is generally present at much lower levels in females than males. See *e.g.*, '862 patent at 1:49-50. The method described and claimed in the '862 patent relates to “unambiguously detecting testosterone in a test sample,” including those that contain low-levels of testosterone, such as samples from a female. '862 patent at 5:50-51. In particular, the invention includes extraction of testosterone from a sample – via, for example, chromatography or other known extraction methods – prior to mass spectrometry. *Id.* at 3:7-15. Following extraction, the invention describes “methods for determining the presence or amount of testosterone in a test sample, comprising ionizing all or a portion of the testosterone present in the sample to produce one or more testosterone ions that are detectable in a mass spectrometer.” *Id.* at 2:8-12. The presence or amount of one or more testosterone ions relates “to the presence or amount of testosterone in the original test sample.” *Id.* at 2:13-16.

14. The '862 patent invention provides a high-throughput assay system for detecting and quantifying testosterone in a liquid sample. The preferred embodiments of the invention are particularly well suited for application in large clinical laboratories, as they have enhanced specificity and are more efficient to run as compared to earlier assays. See *e.g.*, '862 patent at 5:50-62.

15. Exemplary claim 1 of the '862 patent recites as follows:

A method for determining the amount of testosterone in a sample when taken from a female human, comprising:

- (a) purifying testosterone from a sample from a female human, wherein said purifying comprises extracting testosterone from said sample;
- (b) ionizing said purified testosterone to produce one or more testosterone ions detectable by a mass spectrometer; and
- (c) detecting the amount of one or more of the testosterone ion(s) by a mass spectrometer, wherein the amount of one or more of the testosterone ion(s) is related to the amount of testosterone in the sample;

wherein said testosterone is not derivatized prior to mass spectrometry; and

wherein the method is capable of detecting testosterone at concentrations of less than 10 ng/dL in the sample.

U.S. PATENT NO. 8,101,427

16. On January 24, 2012, the United States Patent and Trademark Office issued U.S. Patent No. 8,101,427, entitled "Methods for Detecting Vitamin D Metabolites by Mass Spectrometry." Quest is the owner by assignment of all rights, title, and interest in the '427 patent, including the right to recover damages for past, present, and future infringement of the patent and the right to seek injunctive relief against infringement of the patent. A true and correct copy of the '427 patent is attached hereto as **Exhibit B**.

17. The '427 patent relates to methods for determining the amount of a vitamin D metabolite in a sample using mass spectrometry, including tandem mass spectrometry. Vitamin D metabolites that can be assessed using these methods include, for example, 25-hydroxyvitamin D₂ (25OHD₂), 1 α ,25-dihydroxyvitamin D₂ (1 α ,25(OH)₂D₂), 25-hydroxyvitamin D₃ (25OHD₃), and 1 α ,25-dihydroxyvitamin D₃ (1 α ,25(OH)₂D₃). '427 patent at 3:16-20.

18. The methods disclosed and claimed in the '427 patent can include generating a protonated and dehydrated precursor ion of the vitamin D metabolite. '427 patent at 2:63-65, 3:5-9. The methods can also include generating one or more fragment ions from a precursor ion.

Id. at 3:5-9. The amount of the precursor ion and/or the fragment ions can be detected and related to the amount of the vitamin D metabolite in the sample. *Id.* at 3:5-12.

19. Exemplary claim 1 of the '427 patent recites as follows:

A method for determining the amount of a vitamin D metabolite in a sample by tandem mass spectrometry, comprising:

- (a) generating a protonated and dehydrated precursor ion of said vitamin D metabolite;
- (b) generating one or more fragment ions of said precursor ion; and
- (c) detecting the amount of one or more of said ions generated in step (a) or (b) or both and relating the detected ions to the amount of said vitamin D metabolite in said sample.

U.S. PATENT NO. 7,972,867

20. On July 5, 2011, the United States Patent and Trademark Office issued U.S. Patent No. 7,972,867, entitled "Methods for Detecting Vitamin D Metabolites by Mass Spectrometry." Quest is the owner by assignment of all rights, title, and interest in the '867 patent, including the right to recover damages for past, present, and future infringement of the patent and the right to seek injunctive relief against infringement of the patent. A true and correct copy of the '867 patent is attached hereto as **Exhibit C**.

21. The '867 patent relates to methods for determining the amount of a vitamin D metabolite in a sample using mass spectrometry, including tandem mass spectrometry. Vitamin D metabolites that can be assessed using these methods include, for example, 25-hydroxyvitamin D₂ (25OHD₂), 1 α ,25-dihydroxyvitamin D₂ (1 α ,25(OH)₂D₂), 25-hydroxyvitamin D₃ (25OHD₃), and 1 α ,25-dihydroxyvitamin D₃ (1 α ,25(OH)₂D₃). '867 patent at 3:14-18.

22. The methods disclosed and claimed in the '867 patent can include generating a protonated and dehydrated precursor ion of the vitamin D metabolite. '867 patent at 2:61-63. The methods can also include generating one or more fragment ions from a precursor ion. *Id.* at

2:49-56, 5:42-48. The amount of the precursor ion and/or the fragment ions can be detected and related to the amount of the vitamin D metabolite in the sample. *See, e.g., id.* at 5:36-50.

23. Exemplary claim 21 of the '867 patent recites as follows:

A method for determining the presence or amount of 25-hydroxyvitamin D₂ in a sample by tandem mass spectrometry, comprising:

- (a) generating a protonated and dehydrated precursor ion of said 25-hydroxyvitamin D₂ with a mass to charge ratio (m/z) of 395.30 ± 0.5 ;
- (b) generating one or more fragment ions of said precursor ion; and
- (c) detecting the presence or amount of one or more of said ions generated in step (a) or (b) or both and relating the detected ions to the presence or amount of said 25-hydroxyvitamin D₂ in said sample.

U.S. PATENT NO. 7,972,868

24. On July 5, 2011, the United States Patent and Trademark Office issued U.S. Patent No. 7,972,868, entitled "Methods for Detecting Dihydroxyvitamin D Metabolites by Mass Spectrometry." Quest is the owner by assignment of all rights, title, and interest in the '868 patent, including the right to recover damages for past, present, and future infringement of the patent and the right to seek injunctive relief against infringement of the patent. A true and correct copy of the '868 patent is attached hereto as **Exhibit D**.

25. The '868 patent relates to and claims methods for determining the amount of a dihydroxyvitamin D metabolite in a sample using mass spectrometry, including tandem mass spectrometry. Dihydroxyvitamin D metabolites that can be assessed using these methods include, for example, 1 α ,25-dihydroxyvitamin D₂ (1 α ,25(OH)₂D₂) and 1 α ,25-dihydroxyvitamin D₃ (1 α ,25(OH)₂D₃). '868 patent at 2:47-53, 3:50-67.

26. The '868 patent teaches that the method can include ionizing the dihydroxyvitamin D metabolite to generate a precursor ion. '868 patent at 2:35-36. The method

can also include generating one or more fragment ions from the precursor ion. *Id.* at 2:36-38, 14:15-32.

27. Exemplary claim 1 of the '868 patent recites as follows:

A method for determining the amount of one or more dihydroxyvitamin D metabolites in a biological sample, when taken from a human, by tandem mass spectrometry, comprising:

- (i) generating a precursor ion of said one or more dihydroxyvitamin D metabolites by ionizing said one or more dihydroxyvitamin D metabolites with atmospheric pressure chemical ionization (APCI);
 - (ii) generating one or more fragment ions of said precursor ion; and
 - (iii) detecting the amount of one or more of said ions generated in step (i) or (ii) or both and relating the amount of detected ions to the amount of said one or more dihydroxyvitamin D metabolites in said sample;
- wherein said one or more dihydroxyvitamin D metabolites are not subject to derivatization.

28. Exemplary claim 9 of the '868 patent recites as follows:

A method for determining the amount of one or more dihydroxyvitamin D metabolites in a sample by tandem mass spectrometry, comprising:

- (a) derivatizing the dihydroxyvitamin D metabolites from said sample with 4'-carboxyphenyl-TAD; and
- (b) determining the amount of the derivatized vitamin D metabolites obtained from step (a) by tandem mass spectrometry comprising:
 - (i) generating a precursor ion of said one or more dihydroxyvitamin D metabolites;
 - (ii) generating one or more fragment ions of said precursor ion; and
 - (iii) detecting the amount of one or more of said ions generated in step (i) or (ii) or both and relating the amount of detected ions to the amount of said one or more dihydroxyvitamin D metabolites in said sample.

THE ACCUSED TESTOSTERONE TESTS

29. LabCorp Holdings, Esoterix, and Endocrine Sciences offer testosterone testing designated with Esoterix Test Nos. 501475 and 500286 and LabCorp Test Nos. 070001, 500726, and 500159 (collectively, the "Accused Testosterone Tests").

30. LabCorp Holdings offers LabCorp Test No. 070001, titled "Testosterone, Total, Women, Children, and Hypogonadal Males, LC/MS-MS." Upon information and belief, LabCorp Holdings performs this test at least at a facility in Burlington, North Carolina. A page

on LabCorp's website, <https://www.labcorp.com/test-menu/35531/testosterone-total-women-children-and-hypogonadal-males-lc-ms-ms>, last visited September 5, 2018, states that this test is performed via "Liquid chromatography/tandem mass spectrometry (LC/MS-MS)." The same page states that "[t]his assay provides the sensitivity and specificity required for the assessment of the low testosterone levels found in women, children, and hypogonadal males." It also provides reference ranges for expected testosterone concentrations in various female populations that are entirely or partially below 10 ng/dL: premature female infants from 26 weeks to 28 weeks, day 4 = 5–16 ng/dL; premature female infants from 31 weeks to 35 weeks, day 4 = 5–22 ng/dL; prepubertal female children = <2.5–10 ng/dL; pubertal females in Tanner Stage I = <2.5–10 ng/dL; pubertal females in Tanner Stage II = 7–28 ng/dL; and postmenopausal female adults = 7–40 ng/dL. This test uses serum samples.

31. LabCorp Holdings offers LabCorp Test No. 500726, titled "Testosterone, Free, Mass Spectrometry/Equilibrium Dialysis (Endocrine Sciences)." Upon information and belief, Endocrine Sciences performs this test at its facility in Calabasas Hills, California. A page on LabCorp's website, <https://www.labcorp.com/test-menu/35521/testosterone-free-mass-spectrometry-equilibrium-dialysis-endocrine-sciences>, last visited September 5, 2018, states "[t]his method is recommended for testing women, children, and hypogonadal men." The same page states that total testosterone is measured in this test by high-pressure liquid chromatography (HPLC) with tandem mass spectrometry. It also provides reference ranges for expected testosterone concentrations in various female populations that are entirely or partially below 10 ng/dL: premature female infants from 26 weeks to 28 weeks, day 4 = 5–16 ng/dL; premature female infants from 31 weeks to 35 weeks, day 4 = 5–22 ng/dL; pubertal females in Tanner

Stage I = <2.5–10 ng/dL; pubertal females in Tanner Stage II = 7–28 ng/dL; and postmenopausal female adults = 7–40 ng/dL. This test uses serum samples.

32. Esoterix offers Esoterix Test No. 501475, titled “Testosterone, Total and Free.” A page on Esoterix’s website, <https://www.esoterix.com/test-menu/testosterone-total-and-free/95a492a8-9ea4-4a8d-b50e-61b500ce11e2>, last visited September 5, 2018, states that this test is also LabCorp Test No. 500726, which is described in paragraph 31. It further states that the test uses “High-pressure liquid chromatography/tandem mass spectrometry (HPLC/MS-MS),” and is performed at Endocrine Sciences. This test uses serum samples.

33. Esoterix offers Esoterix Test No. 500286, titled “Testosterone, Total, Serum, Mass Spectrometry.” A page on Esoterix’s website, <https://www.esoterix.com/test-menu/testosterone-total-serum-mass-spectrometry/7b04771e-8ce9-4d38-a2f7-f89fa4d80735>, last visited September 5, 2018, states that this is also LabCorp Test No. 500159, that it uses “High-pressure liquid chromatography/tandem mass spectrometry (HPLC/MS-MS),” and is performed at Endocrine Sciences. It also provides reference ranges for expected testosterone concentrations in various female populations that are entirely or partially below 10 ng/dL: premature female infants from 26 weeks to 28 weeks, day 4 = 5–16 ng/dL; premature female infants from 31 weeks to 35 weeks, day 4 = 5–22 ng/dL; prepubertal female children = <2.5–10 ng/dL; pubertal females in Tanner Stage I = <2.5–10 ng/dL; pubertal females in Tanner Stage II = 7–28 ng/dL; and postmenopausal female adults = 7–40 ng/dL. This test uses serum samples.

34. The Accused Testosterone Tests determine the amount of testosterone in a sample taken from a human female.

35. The Accused Testosterone Tests include the step of purifying testosterone from a sample from a female human, which comprises extracting testosterone from the sample by, for

example, the use of one or more extraction techniques, such as high turbulence liquid chromatography, liquid-liquid extraction, solid phase extraction or some other extraction method.

36. The Accused Testosterone Tests include the step of ionizing the purified testosterone to produce one or more testosterone ions detectable by a mass spectrometer.

37. The Accused Testosterone tests, as described in Defendants' web sites, use tandem mass spectrometry, which detects the amount of one or more of the testosterone ions, which amount is related to the amount of testosterone in the sample.

38. On information and belief, the Accused Testosterone Tests use testosterone that is not derivatized prior to mass spectrometry.

39. The Accused Testosterone Test are capable of detecting testosterone at concentrations of less than 10 ng/dL in the sample, at least because as noted above in paragraphs 30-33, the Accused Testosterone Tests report expected testosterone concentration in ranges below 10 ng/dL, including as low as 2.5 ng/dL.

THE ACCUSED VITAMIN D TESTS

40. LabCorp Holdings, Esoterix, and Endocrine Sciences offer vitamin D testing designated with LabCorp Test No. 504115 and Esoterix Test Nos. 500337, 500338, 500342, and 803580 (collectively, the "Accused Vitamin D Tests").

41. LabCorp Holdings offers LabCorp Test No. 504115, titled "25-Hydroxy Vitamin D (D₂+D₃ Fractionated), LC/MS-MS." Upon information and belief, LabCorp performs this test through its subsidiaries, Esoterix and Endocrine Sciences, in Calabasa Hills, California. A page on LabCorp's website, <https://www.labcorp.com/test-menu/29021/25-hydroxy-vitamin-d-dsub2-subsub3-sub-fractionated-lc-ms-ms>, last visited September 5, 2018, states that this test is

performed via “Liquid chromatography/tandem mass spectrometry (LC/MS-MS).” The same page states that the test “includes results for total 25-hydroxy vitamin D₂ and 25-hydroxy vitamin D₃.”

42. Esoterix offers Esoterix Test No. 500337, titled “Vitamin D, 25-Hydroxy, Fractionated, Mass Spectrometry.” A page on Esoterix’s website, <https://www.esoterix.com/test-menu/strongvitamin-strong-d-25-hydroxy-fractionated-mass-spectrometry/3f3592fb-c6e7-4dc0-96a6-ae8e62e6148e>, last visited September 5, 2018, states that this test is also LabCorp Test No. 504115, which is described in paragraph 41. It further states that the test uses “High-pressure liquid chromatography/tandem mass spectrometry (HPLC/MS-MS),” and is performed at Endocrine Sciences.

43. Esoterix offers Esoterix Test No. 500338, titled “Vitamin D, 25-Hydroxy, Total, Mass Spectrometry.” A page on Esoterix’s website, <https://www.esoterix.com/test-menu/strongvitamin-strong-d-25-hydroxy-total-mass-spectrometry/3757c053-3415-44eb-a027-579c89a4daa5>, last visited September 5, 2018, identifies this test as also being LabCorp Test No. 500510. It further states that the test uses “High-pressure liquid chromatography/tandem mass spectrometry (HPLC/MS-MS),” and is performed at Endocrine Sciences.

44. Esoterix offers Esoterix Test No. 500342, titled “Vitamin D, 1, 25-Dihydroxy.” A page on Esoterix’s website, <https://www.esoterix.com/test-menu/strongvitamin-strong-d-1-25-dihydroxy/b2737daa-240e-4104-977e-5e258edf1f1a>, last visited September 5, 2018, identifies this test as also being LabCorp Test No. 500600. It further states that the test uses “High-pressure liquid chromatography/tandem mass spectrometry (HPLC/MS-MS),” and is performed at Endocrine Sciences.

45. Esoterix offers Esoterix Test No. 803580, titled “3-Epi-Vitamin D, 25-Hydroxy.” A page on Esoterix’s website, <https://www.esoterix.com/test-menu/3-epi-strongvitamin-strong-d-25-hydroxy/b737db0a-54af-4cd5-8546-e42e34e88a95>, last visited September 5, 2018, identifies this test as also being LabCorp Test No. 503580. It further states that the test uses “High-pressure liquid chromatography/tandem mass spectrometry (HPLC/MS-MS),” and is performed at Endocrine Sciences.

**QUEST’S ATTEMPT TO LEARN THE METHODS
UNDERLYING THE ACCUSED VITAMIN D TESTS**

46. Quest has reviewed publicly available information about LabCorp’s Accused Vitamin D Tests, including the websites described above. That information makes clear that LabCorp is performing, and has performed, methods for determining the amount of one or more vitamin D metabolites in a sample by mass spectrometry, including tandem mass spectrometry. This information also makes clear that LabCorp is using purification steps in the Accused Vitamin D Tests, including liquid chromatography and/or high performance liquid chromatography. Despite ample investigation, Quest is unaware of any publicly-available information describing certain aspects of LabCorp’s Accused Vitamin D Tests, such as the specific details of LabCorp’s mass spectrometry analysis. Quest is unable to learn these details by purchasing the Accused Vitamin D Tests or otherwise analyzing reports for the Accused Vitamin D Tests. Quest is therefore unable to determine the precise steps that LabCorp follows when performing the Accused Vitamin D Tests.

47. For at least several months, Quest attempted to learn from LabCorp the methodologies of the Accused Vitamin D Tests. In particular, Quest conducted multiple telephone calls, exchanged emails, and held an in-person meeting with LabCorp, at which Quest raised, *inter alia*, claims of the ’427 patent, claims of the ’868 patent, and claims of U.S. Patent

No. 8,852,951 (the “’951 patent”). Certain claims of the ’951 patent are similar to those of the ’868 patent, which Quest asserts here.²

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 8,409,862

48. Quest hereby restates and realleges the allegations set forth in paragraphs 1-15 and 29-39.

49. LabCorp Holdings, Esoterix, and Endocrine Sciences infringe and/or have infringed the ’862 patent, including for example at least claim 1, either literally or under the doctrine of equivalents, by offering, selling, and performing the Accused Testosterone Tests among others.

50. Upon information and belief, LabCorp has had constructive notice of the ’862 patent since at least April 2, 2013, and actual notice as of June 15, 2017.

51. Upon information and belief, LabCorp has had constructive and actual notice of the ’862 patent in light of its own active involvement in seeking patent protection for its methods of detecting and measuring testosterone in a sample by liquid chromatography-mass spectrometry.

52. Despite LabCorp’s knowledge and notice of the ’862 patent, LabCorp continues to offer and perform the Accused Testosterone Tests in a manner that willfully infringes the ’862 patent.

53. LabCorp’s continuing infringement of the ’862 patent has damaged and will continue to damage Quest, causing irreparable harm for which there is no remedy at law, unless LabCorp is enjoined by this Court from further acts of infringement.

² The ’868 patent is related to and contains the same written description as the ’951 patent.

54. LabCorp's past and future acts of infringement of the '862 patent have caused and will cause damages to Quest, entitling Quest to recover damages from LabCorp in an amount subject to proof at trial, but in no event less than a reasonable royalty extending through the life of the '862 patent.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 8,101,427

55. Quest hereby restates and realleges the allegations set forth in paragraphs 1-10, 16-19, and 40-47.

56. LabCorp Holdings, Esoterix, and Endocrine Sciences infringe and/or have infringed at least claim 1 of the '427 patent, either literally or under the doctrine of equivalents, by offering, selling, and performing the Accused Vitamin D Tests.

57. Each of the Accused Vitamin D Tests is a method for determining the amount of a vitamin D metabolite in a sample by tandem mass spectrometry (MS/MS). For example, 25-hydroxyvitamin D₂ and 25-hydroxyvitamin D₃ are vitamin D metabolites; 1,25-dihydroxyvitamin D₂, 1 α ,25-dihydroxyvitamin D₂, 1,25-dihydroxyvitamin D₃, and 1 α ,25-dihydroxyvitamin D₃ are further vitamin D metabolites; and 3-*epi*-25-hydroxyvitamin D₂ and 3-*epi*-25-hydroxyvitamin D₃ are vitamin D metabolites possessing a particular chirality. LabCorp Test No. 504115 and Esoterix Test No. 500337 measure both 25-hydroxyvitamin D₂ and 25-hydroxyvitamin D₃. On information and belief, Esoterix Test No. 500338 also measures both 25-hydroxyvitamin D₂ and 25-hydroxyvitamin D₃; Esoterix Test No. 500342 measures 1,25-dihydroxyvitamin D₂, 1 α ,25-dihydroxyvitamin D₂, 1,25-dihydroxyvitamin D₃, and/or 1 α ,25-dihydroxyvitamin D₃; and Esoterix Test No. 803580 measures 3-*epi*-25-hydroxyvitamin D₂ and/or 3-*epi*-25-hydroxyvitamin D₃. LabCorp's websites for each of the Accused Vitamin D

Tests states that LabCorp uses tandem mass spectrometry (MS-MS) to determine the amount of one or more vitamin D metabolites in the sample.

58. On information and belief, as part of each of the Accused Vitamin D Tests for at least some tests performed in the last six years, Defendants generate or generated a protonated and dehydrated precursor ion of the vitamin D metabolite.

59. On information and belief, as part of each of the Accused Vitamin D Tests for at least some tests performed in the last six years, Defendants generate or generated one or more fragment ions of the precursor ion by, for example effecting a collision or collisions with the precursor ion(s), which results in one or more fragments of the precursor ion(s).

60. On information and belief, as part of each of the Accused Vitamin D Tests for at least some tests performed in the last six years, Defendants detect or detected the amount of one or more of the precursor ions or the fragment ions of the precursor ions or both.

61. On information and belief, as part of each of the Accused Vitamin D Tests for at least some tests performed in the last six years, Defendants relate or related the amount of the detected ions to the amount of the vitamin D metabolite in the sample.

62. Upon information and belief, LabCorp has had constructive notice of the '427 patent since at least January 24, 2012, and actual notice as of at least June 15, 2017.

63. Upon information and belief, LabCorp has had constructive and actual notice of the '427 patent as a result of seeking patent protection for methods of detecting and measuring vitamin D metabolites in a sample by liquid chromatography-mass spectrometry.

64. Despite LabCorp's knowledge and notice of the '427 patent, LabCorp continues to offer and perform the Accused Vitamin D Tests in a manner that willfully infringes the '427 patent.

65. LabCorp's continuing infringement of the '427 patent has damaged and will continue to damage Quest, causing irreparable harm for which there is no remedy at law, unless LabCorp is enjoined by this Court from further acts of infringement.

66. LabCorp's past and future acts of infringement of the '427 patent have caused and will cause damages to Quest, entitling Quest to recover damages from LabCorp in an amount subject to proof at trial, but in no event less than a reasonable royalty extending through the life of the '427 patent.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 7,972,867

67. Quest hereby restates and realleges the allegations set forth in paragraphs 1-10, 20-23, and 40-47.

68. LabCorp Holdings, Esoterix, and Endocrine Sciences infringe and/or have infringed at least claim 21 of the '867 patent, either literally or under the doctrine of equivalents, by offering, selling, and performing the Accused Vitamin D Tests.

69. Each of the Accused Vitamin D Tests is a method for determining the amount of a vitamin D metabolite in a sample by tandem mass spectrometry (MS/MS). For example, 25-hydroxyvitamin D₂ is a vitamin D metabolite and 3-*epi*-25-hydroxyvitamin D₂ is a vitamin D metabolite possessing a particular chirality. LabCorp Test No. 504115 and Esoterix Test No. 500337 measure 25-hydroxyvitamin D₂. On information and belief, Esoterix Test No. 500338 also measures 25-hydroxyvitamin D₂; and Esoterix Test No. 803580 measures 3-*epi*-25-hydroxyvitamin D₂. LabCorp's websites for each of the Accused Vitamin D Tests states that LabCorp uses tandem mass spectrometry (MS-MS) to determine the amount of one or more vitamin D metabolites in the sample.

70. On information and belief, as part of at least some of the LabCorp Test No. 504115, Esoterix Test No. 500337, Esoterix Test No. 500338, and/or Esoterix Test No. 803580 tests performed in the last six years, Defendants generate or generated a protonated and dehydrated precursor ion of the vitamin D metabolite.

71. On information and belief, as part of at least some of the LabCorp Test No. 504115, Esoterix Test No. 500337, Esoterix Test No. 500338, and/or Esoterix Test No. 803580 tests performed in the last six years, Defendants generate or generated a precursor ion with a mass to charge ratio (m/z) of 395.30 ± 0.5 .

72. On information and belief, as part of at least some of the LabCorp Test No. 504115, Esoterix Test No. 500337, Esoterix Test No. 500338, and/or Esoterix Test No. 803580 tests performed in the last six years, Defendants generate or generated one or more fragment ions of the 395.30 ± 0.5 precursor ion by, for example effecting a collision or collisions with the precursor ion(s), which results in one or more fragments of the precursor ion(s).

73. On information and belief, as part of at least some of the LabCorp Test No. 504115, Esoterix Test No. 500337, Esoterix Test No. 500338, and/or Esoterix Test No. 803580 tests performed in the last six years, Defendants detect or detected the amount of one or more of the precursor ions or the fragment ions of the precursor ions or both.

74. On information and belief, as part of at least some of the LabCorp Test No. 504115, Esoterix Test No. 500337, Esoterix Test No. 500338, and/or Esoterix Test No. 803580 tests performed in the last six years, Defendants relate or related the amount of the detected ions to the amount of the vitamin D metabolite in the sample.

75. Upon information and belief, LabCorp has had constructive notice of the '867 patent since at least July 5, 2011, and actual notice as of at least June 15, 2017.

76. Upon information and belief, LabCorp has had constructive and actual notice of the '867 patent as a result of seeking patent protection for methods of detecting and measuring vitamin D metabolites in a sample by liquid chromatography-mass spectrometry.

77. Despite LabCorp's knowledge and notice of the '867 patent, LabCorp continues to offer and perform LabCorp Test No. 504115, Esoterix Test No. 500337, Esoterix Test No. 500338, and/or Esoterix Test No. 803580 in a manner that willfully infringes the '867 patent.

78. LabCorp's continuing infringement of the '867 patent has damaged and will continue to damage Quest, causing irreparable harm for which there is no remedy at law, unless LabCorp is enjoined by this Court from further acts of infringement.

79. LabCorp's past and future acts of infringement of the '867 patent have caused and will cause damages to Quest, entitling Quest to recover damages from LabCorp in an amount subject to proof at trial, but in no event less than a reasonable royalty extending through the life of the '867 patent.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 7,972,868

80. Quest hereby restates and realleges the allegations set forth in paragraphs 1-10, 24-28, and 40-47.

81. LabCorp Holdings, Esoterix, and Endocrine Sciences infringe and/or have infringed at least claims 1 and/or 9 of the '868 patent, either literally or under the doctrine of equivalents, by offering, selling, and performing the Accused Vitamin D Tests, including Esoterix Test 500342.

82. Esoterix Test No. 500342 is a method for determining the amount of a dihydroxyvitamin D metabolite in a sample by tandem mass spectrometry (MS/MS). This test

measures 1,25-dihydroxyvitamin D₂, 1 α ,25-dihydroxyvitamin D₂, 1,25-dihydroxyvitamin D₃, and/or 1 α ,25-dihydroxyvitamin D₃.

83. On information and belief, as part of each of the Accused Vitamin D Tests for at least some tests performed in the last six years, including Esoterix Test 500342, Defendants derivatize or derivatized a vitamin D metabolite prior to ionization with 4'-carboxypehnyl-TAD or an equivalent derivatizing agent.

84. On information and belief, as part of each of the Accused Vitamin D Tests for at least some tests performed in the last six years, including Esoterix Test 500342, Defendants ionize or ionized the vitamin D metabolite to generate a precursor ion.

85. On information and belief, as part of each of the Accused Vitamin D Tests for at least some tests performed in the last six years, including Esoterix Test 500342, Defendants generate or generated one or more fragment ions from the precursor ion.

86. On information and belief, as part of each of the Accused Vitamin D Tests for at least some tests performed in the last six years, including Esoterix Test 500342, Defendants detect or detected the amount of one or more of the fragment ions.

87. On information and belief, as part of each of the Accused Vitamin D Tests for at least some tests performed in the last six years, including Esoterix Test 500342, Defendants relate or related the detected ions to the amount of the dihydroxyvitamin D metabolite in the sample.

88. Upon information and belief, LabCorp has had constructive notice of the '868 patent since at least July 5, 2011.

89. Upon information and belief, LabCorp has had constructive notice of the '868 patent as a result of seeking patent protection for methods of detecting and measuring vitamin D metabolites in a sample by mass spectrometry.

90. Despite LabCorp's knowledge of the '868 patent, LabCorp continues to offer and perform the Accused Vitamin D Tests, including Esoterix Test 500342, in a manner that willfully infringes the '868 patent.

91. LabCorp's continuing infringement of the '868 patent has damaged and will continue to damage Quest, causing irreparable harm for which there is no remedy at law, unless LabCorp is enjoined by this Court from further acts of infringement.

92. LabCorp's past and future acts of infringement of the '868 patent have caused and will cause damages to Quest, entitling Quest to recover damages from LabCorp in an amount subject to proof at trial, but in no event less than a reasonable royalty extending through the life of the '868 patent.

DEMAND FOR JURY TRIAL

93. Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Quest hereby demands trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Quest respectfully requests that this Court enter judgment in its favor and against LabCorp as follows:

- A. For a declaration that Defendants have infringed and continue to infringe one or more claims of the Patents-in-Suit under 35 U.S.C. § 271, and a final judgment incorporating the same;

- B. For an order enjoining Defendants and their officers, employees, agents, attorneys, affiliates, successors, assigns, and others acting in privity or in concert with Defendants from offering, selling, or performing any methods that infringe the Patents-in-Suit, including the Accused Testosterone Tests and the Accused Vitamin D Tests;
- C. For an award of damages adequate to compensate Quest for Defendants' infringement of the Patents-in-Suit in an amount no less than a reasonable royalty, together with prejudgment and post-judgment interest and costs pursuant to 35 U.S.C. § 284;
- D. For an order finding that Defendants have willfully infringed one or more of the Patents-in-Suit and trebling damages pursuant to 35 U.S.C. § 284;
- E. For an order finding that this is an exceptional case and awarding Quest its attorneys' fees in this matter pursuant to 35 U.S.C. § 285; and
- F. For such other relief as this Court may deem just and proper.

Dated: September 17, 2018

Respectfully submitted,

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*Applications for admission *pro hac vice* to be submitted