IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ENDOCYTE, INC., NOVARTIS PHARMACEUTICALS CORPORATION, and PURDUE RESEARCH FOUNDATION Plaintiffs, v. POINT BIOPHARMA GLOBAL INC., POINT BIOPHARMA INC., AND ELI LILLY AND CO., Defendants.	Case No. 1:24-cv-1011

COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL

Plaintiffs Endocyte, Inc. ("Endocyte"), Novartis Pharmaceuticals Corporation ("NPC"), and Purdue Research Foundation ("Purdue"), by their attorneys, bring this Complaint against Defendants POINT Biopharma Global Inc. and POINT Biopharma Inc. (together, "POINT") and Eli Lilly and Co. ("Eli Lilly"), and allege the following:

NATURE OF THE CASE

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of POINT's manufacture, use, offers to sell, sale, and/or importation of POINT's prostate-cancer-targeting radiotherapeutic drug "PNT2002." Plaintiffs own, exclusively license, and/or practice patents relating to radiotherapeutic drugs for prostate cancer, including U.S. Patent No. 10,624,970 ("the '970 patent"). PNT2002 falls within the scope of at least claims 1, 2, and 6 of the '970 patent, and POINT thus infringes the '970 patent by manufacturing, using, offering to sell, selling, and/or importing PNT2002 and its components and precursors.

BACKGROUND

2. Endocyte is a pioneer in the field of small molecule drug conjugates, with decades of experience in the research and development of innovative and lifesaving therapies for devastating diseases, such as cancer. Since its founding in 1996, Endocyte has dedicated substantial resources and countless hours to research, develop, and bring to patients new cancer therapies.

3. Endocyte was co-founded by one of the inventors of the patent at issue, Dr. Philip Low. Endocyte built on research conducted at Purdue University by Dr. Low and his co-inventor Dr. Sumith Kularatne. Through years of innovation, the inventors and Endocyte have revolutionized the treatment of prostate cancer.

4. With funding and laboratory resources from Endocyte, the inventors discovered and developed a new class of prostate cancer drugs that target a particular protein, known as prostate specific membrane antigen ("PSMA"), that is selectively overexpressed on certain prostate cancer cells. The U.S. Patent and Trademark Office granted Purdue a set of patents covering this work, including the '970 patent. Ex. A (the '970 patent). Purdue exclusively licensed this family of patents to Endocyte.

5. As the exclusive licensee, Endocyte invested enormous time and resources into building on the inventors' pioneering research and Purdue's intellectual property to develop a safe and effective treatment for prostate cancer.

6. In 2018, Endocyte was acquired by Novartis, which continued Endocyte's work in developing Purdue's intellectual property. Novartis built on Endocyte's and the inventors' discoveries and development by further developing and obtaining FDA approval for a revolutionary new therapy to treat certain types of prostate cancer characterized by cancer cells that overexpress PSMA. Novartis manufactures and sells this treatment under the name

PLUVICTO®. PLUVICTO® is protected by another patent in the same family as the ’970 patent that likewise arises from the same work at Purdue. Development of PLUVICTO® for new indications continues, so that more prostate cancer patients can benefit from PLUVICTO® in the future.

7. Endocyte has exclusively sublicensed rights in the ’970 patent to another Novartis company, NPC.

8. Using intellectual property licensed to Endocyte and now NPC, and protected by at least claims 1, 2, and 6 of the ’970 patent, POINT is also developing a radiopharmaceutical to treat PSMA-positive prostate cancer, PNT2002.

9. POINT has entered into an agreement with Lantheus Two, LLC, a wholly owned subsidiary of Lantheus Holdings, Inc. (together with all subsidiaries, “Lantheus”), which includes provisions regarding commercialization of PNT2002 (the “Commercialization Agreement”).

10. On information and belief, via the Commercialization Agreement, POINT has offered to sell a specific minimum quantity of PNT2002 for commercial purposes at a set price.

11. Further, on information and belief, since at least September 2023, POINT has been collaborating with Lantheus to provide PNT2002 to certain patients through an expanded access program. On information and belief, POINT has manufactured and supplied PNT2002 for use in the expanded access program. Based upon Lantheus’s publicly available guidance regarding its expanded access program, the patients being treated with PNT2002 in this context are not eligible for clinical trials and, accordingly, the patients being treated are not being treated for purposes related to the development and submission of information to FDA in connection with PNT2002.

12. Additionally, on information and belief, pursuant to the Commercialization Agreement, Lantheus will seek FDA approval for PNT2002 in the coming months.

13. In December 2023, Eli Lilly acquired POINT. On information and belief, under Eli Lilly's ownership, POINT will continue its efforts to commercialize PNT2002, will continue performing its obligations under the Commercialization Agreement with Lantheus, and will continue manufacturing and supplying PNT2002 for use by patients in the Lantheus expanded access program.

PARTIES, JURISDICTION, AND VENUE

14. Plaintiff Endocyte is a corporation organized under the laws of Delaware, with a principal place of business in East Hanover, New Jersey.

15. Plaintiff NPC is a corporation organized under the laws of Delaware, with a principal place of business in East Hanover, New Jersey.

16. Plaintiff Purdue is a corporation organized under the laws of Indiana, with a principal place of business in West Lafayette, Indiana.

17. On information and belief, Defendant POINT Biopharma Global Inc. is a corporation organized under the laws of Delaware, with a principal place of business in Indianapolis, Indiana.

18. On information and belief, Defendant POINT Biopharma Inc. is a corporation organized under the laws of Delaware, with a principal place of business in Indianapolis, Indiana.

19. On information and belief, Defendant Eli Lilly is a corporation organized under the laws of Indiana, with a principal place of business in Indianapolis, Indiana.

20. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

21. This Court has personal jurisdiction over POINT Biopharma Global Inc. and POINT Biopharma Inc. because each has its principal place of business in this District and because

each regularly transacts and/or solicits business in Indiana and has purposefully availed itself of this forum such that it should reasonably anticipate being haled into court in this District.

22. This Court has personal jurisdiction over Eli Lilly because Eli Lilly is incorporated in Indiana and has its principal place of business in this District, and because Eli Lilly regularly transacts and/or solicits business in Indiana and has purposefully availed itself of this forum such that it should reasonably anticipate being haled into court in this District.

23. Venue is proper under 28 U.S.C. § 1400(b) as to POINT Biopharma Global Inc. and POINT Biopharma Inc. in the Southern District of Indiana, Indianapolis Division, because each has its principal place of business in this District and has committed acts of infringement in this District.

24. On information and belief, each of POINT Biopharma Global Inc. and POINT Biopharma Inc. has at all relevant points in time maintained a physical place in this District that serves as a regular and established physical place of business, including but not limited to headquarters and manufacturing facilities in Indianapolis.

25. Further, on information and belief, employees or agents of POINT Biopharma Global Inc. and POINT Biopharma Inc. have negotiated, made offers related to, and/or executed the Commercialization Agreement with Lantheus in this District, thus making an offer to sell PNT2002 in this District.

26. In the alternative, on information and belief, the activities of POINT Biopharma Global Inc. and POINT Biopharma Inc. in negotiating, making offers related to, and/or executing the Commercialization Agreement with Lantheus were directed from this District. These activities thus constituted an offer to sell PNT2002 in this District.

27. POINT's Commercialization Agreement with Lantheus provides that POINT manufacture infringing PNT2002. On information and belief, POINT owns and operates a radioligand manufacturing facility in Indianapolis, Indiana, within this District. Accordingly, on information and belief, to perform its obligations under the Commercialization Agreement, POINT will manufacture PNT2002 for commercial purposes in this District.

28. On information and belief, POINT has manufactured and presently manufactures PNT2002 in this District for use in the expanded access program.

29. Venue is proper under 28 U.S.C. § 1400(b) as to Eli Lilly in the Southern District of Indiana, Indianapolis Division, because Eli Lilly is incorporated in Indiana.

THE '970 PATENT

30. On April 21, 2020, the United States Patent and Trademark Office issued the '970 patent, entitled "PSMA Binding Ligand-Linker Conjugates and Methods for Using." Ex. A. The '970 patent discloses PSMA-binding conjugates that are useful for delivering targeted therapeutic, diagnostic, and imaging agents, including radiopharmaceuticals. The '970 patent also describes pharmaceutical formulations containing those radiopharmaceuticals and methods of using them to treat prostate cancer.

31. The '970 patent is assigned to Purdue.

32. Purdue exclusively licensed the '970 patent to Endocyte. Endocyte, in turn, exclusively licensed rights in the '970 patent to NPC, but Endocyte retained the right to sue for infringement of the patent if NPC elects not to.

33. Plaintiffs together own all substantial rights in the '970 patent.

POINT'S DEVELOPMENT OF PNT2002

34. On information and belief, POINT is developing PNT2002 for commercial sales to patients for the treatment of PSMA-positive metastatic castration-resistant prostate cancer.

35. In November 2022, POINT entered into an agreement with Lantheus to commercialize PNT2002. A public version of the agreement is available on the SEC's website. Ex. B (Commercialization Agreement).

36. Via the Commercialization Agreement, POINT has offered to supply Lantheus with doses of PNT2002, including doses for commercial use.

37. The Commercialization Agreement provides that "LANTHEUS shall purchase from POINT, and POINT shall supply, under the Manufacture and Supply Agreement at least [REDACTED] patient doses of the Licensed Products in the first full Calendar Year after the First Commercial Sale." Ex. B § 5.4.4; *see also id.* § 1.1.56 (defining "Licensed Product" as "product containing PNT-2002"); *id.* § 1.1.36 (defining "First Commercial Sale" as, "with respect to a country in the Territory, the first sale for use or consumption by the general public of [PNT2002] by LANTHEUS . . . after [PNT2002] has been granted Regulatory Approval by the appropriate Regulatory Authority(ies) in such country"); *id.* § 5.4.1 (describing the Manufacture and Supply Agreement). The Commercialization Agreement also sets an initial purchase price and method of payment terms for commercial sales of PNT2002. *Id.* at Ex. C.

38. In addition, the Commercialization Agreement grants Lantheus "the unilateral right . . . to Commercialize [PNT2002]," *id.* § 4.2, with "Commercialization" defined as "promoting, marketing, importing, exporting, distributing, selling or offering to sell [PNT2002] following or in expectation of receipt of Regulatory Approval," *id.* § 1.1.19. Lantheus further commits to "use Commercially Reasonable Efforts to Commercialize [PNT2002] in the Initial Indication in the U.S." *Id.* § 4.3.

39. The Commercialization Agreement provides for ongoing performance, including, for example, ongoing meetings, *see, e.g.*, *id.* §§ 2.2.3, 3.1.3, 4.1.3, 5.1.3, completion of POINT's

clinical trial, *see, e.g.*, *id.* § 3.2.1(i), ongoing cooperation in development, *see, e.g.*, *id.* § 3.2.2(i), and ongoing knowledge transfers, *see, e.g.*, *id.* § 3.3.2. On information and belief, POINT continues to perform under that agreement, including continuing to prepare for the commercialization of PNT2002.

40. The Commercialization Agreement further provides that Lantheus is responsible for submitting a New Drug Application ("NDA") to the U.S. Food and Drug Administration for approval of PNT2002. *Id.* § 3.4.1. The parties recite that they intend for "LANTHEUS, with POINT's cooperation and assistance, to prepare and submit the [PNT2002] NDA in a timely manner after POINT's completion of all necessary Clinical Trials and related data collection and analysis." *Id.* at 3 (recitals).

41. According to POINT's 2022 10-K, POINT has already received $250,000,000 pursuant to the Commercialization Agreement with Lantheus.

42. POINT has announced that it has entered into a long-term commercial agreement with ITM Isotope Technologies for the supply of ^{177}Lu, the radioactive isotope used in PNT2002, following the regulatory approval of PNT2002. POINT has also announced agreements with other entities for the supply of ^{177}Lu, including Isotopia and Eckert & Ziegler. On information and belief, POINT will use the supply of ^{177}Lu it obtains from ITM and other entities to manufacture PNT2002 for commercial purposes.

43. The provisions and actions outlined above, and others, are related to future commercial sales and are not limited to POINT's ongoing clinical trials.

44. Additionally, on information and belief, in September 2023, Lantheus initiated an expanded access program for PNT2002, with POINT as a collaborator. According to Lantheus's public SEC filings, the initial patients in the PNT2002 expanded access program began treatment

in the first quarter of 2024. On information and belief, the expanded access program is still ongoing.

45. On information and belief, the purpose of the program is to provide PNT2002 to patients who have been diagnosed with PMSA-positive metastatic castration-resistant prostate cancer. On information and belief, the program is available only to patients in the United States who cannot be treated by currently available drugs or clinical trials.

46. On information and belief, POINT has manufactured and supplied PNT2002 for use in the expanded access program. On information and belief, Lantheus has provided PNT2002 to patients and/or healthcare providers as part of the expanded access program.

47. On information and belief, POINT continues to manufacture and supply PNT2002 for use in the expanded access program. On information and belief, Lantheus continues to provide PNT2002 to patients and/or healthcare providers as part of the expanded access program.

COUNT I
(Infringement of U.S. Patent No. 10,624,970)

48. Plaintiffs incorporate by reference and re-allege each of the foregoing paragraphs of this Complaint as if recited herein.

49. On information and belief, during the term of the ’970 patent, POINT has made, used, offered to sell, sold, and/or imported PNT2002, and will continue to make, use, offer to sell, sell, and/or import PNT2002.

A. PNT2002 Meets the Limitations of Claims 1, 2, and 6 of the ’970 Patent

50. PNT2002 meets the limitations of at least claims 1, 2, and 6 of the ’970 patent.

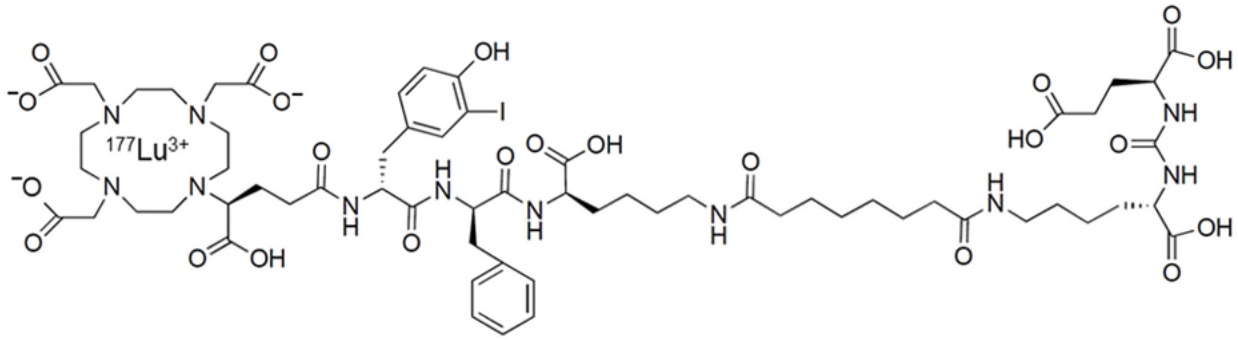
51. Specifically, claim 1 recites:

> A conjugate comprising a ligand of PSMA (B), a linker (L), and a drug (D) wherein the linker is covalently bound to the drug and the linker is covalently bound to the ligand, wherein B is a ligand of prostate specific membrane antigen (PSMA) that is a urea of two

> amino acids, wherein the two amino acids are independently selected from asparagine, aspartic acid, cysteine, glutamic acid, lysine, glutamine, arginine, serine, ornithine, threonine and combinations thereof; L is a divalent linker of 14 to 24 atoms in length, the divalent linker comprising a divalent tripeptide comprising one or more optionally substituted Phe and one or more optionally substituted Tyr; and D is a radioactive isotope of a metal coordinated to a chelating group.

Ex. A.

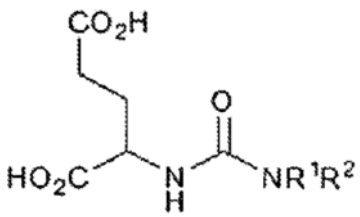
52. The chemical structure of PNT2002 is shown below.



53. PNT2002 is a conjugate comprising a ligand of PSMA, a linker, and a drug, wherein the linker is covalently bound to the drug and the linker is covalently bound to the ligand. The ligand in PNT2002 is a urea of two amino acids, glutamic acid and lysine. The drug in PNT2002 is a radioactive isotope of the metal lutetium coordinated to a chelating group. The linker in PNT2002 is a divalent linker of 14 to 24 atoms in length and comprises a tripeptide comprising a Phe residue and a substituted Tyr residue.

54. Accordingly, PNT2002 meets the limitations of claim 1 of the ’970 patent.

55. Claim 2 of the ’970 patent recites “The conjugate of claim 1, wherein B [the ligand of PSMA] is of the formula:



wherein R^1 is hydrogen and R^2 is a substituted carboxylic acid, wherein the substituted carboxylic acid is covalently bound to the linker." Ex. A (including Oct. 18, 2022 Certificate of Correction).

56. PNT2002 meets the limitations of claim 1, and its ligand of PSMA has the same chemical structure depicted in claim 2, wherein R^1 is hydrogen and R^2 is a substituted carboxylic acid, covalently bound to the linker.

57. Accordingly, PNT2002 meets the limitations of claim 2 of the '970 patent.

58. Claim 6 of the '970 patent recites "A pharmaceutical composition comprising a conjugate of claim 1 and at least one pharmaceutically acceptable carrier, excipient, or a combination thereof." Ex. A.

59. On information and belief, PNT2002 is a pharmaceutical composition comprising a conjugate of claim 1 and at least one carrier or excipient.

60. Accordingly, PNT2002 meets the limitations of claim 6 of the '970 patent.

61. To the extent that any limitations of Claims 1, 2, and 6 are not literally found in PNT2002, PNT2002 infringes those limitations under the doctrine of equivalents.

B. POINT Has Infringed Claims 1, 2, and 6 of the '970 Patent Through Its Actions with Respect to PNT2002

62. POINT has directly infringed the claims of the '970 patent under 35 U.S.C. § 271(a) by, at minimum, offering to sell PNT2002 for commercial use and manufacturing and supplying PNT2002 for an expanded access program sponsored by Lantheus.

63. As described above, by offering to supply a specific quantity of PNT2002 at a specific price for commercial purposes in the Commercialization Agreement, POINT has offered to sell PNT2002 within the United States. This offer to engage in commercial sales bears no reasonable relation to development and submission of information under any federal law which regulates the manufacture, use, or sale of drugs.

64. Accordingly, POINT has directly infringed the ’970 patent under 35 U.S.C. § 271(a) because the Commercialization Agreement’s provisions regarding the supply of PNT2002 for commercial purposes constitutes an offer to sell PNT2002 under the statute.

65. POINT has also directly infringed the ’970 patent under 35 U.S.C. § 271(a) by making and/or selling PNT2002 for use in Lantheus’s expanded access program.

66. As described above, POINT manufactures and supplies PNT2002 for an expanded access program sponsored by Lantheus. The expanded access program bears no reasonable relation to the development and submission of information under any federal law which regulates the manufacture, use, or sale of drugs.

67. Further, on information and belief, POINT’s commercialization partner, Lantheus, will seek FDA approval of PNT2002 in the coming months pursuant to the terms of the Commercialization Agreement.

68. On information and belief, POINT has stockpiled, or will in the coming months stockpile, PNT2002, and/or its components or precursors, in the United States for commercial purposes.

69. On information and belief, POINT will make PNT2002 and sell it to Lantheus following receipt of FDA approval, directly infringing the patent under 35 U.S.C. § 271(a). On information and belief, Lantheus will then sell PNT2002 to patients and/or healthcare providers.

70. POINT has been aware that PNT2002 infringes claims 1, 2, and 6 of the ’970 patent since at least February 26, 2024, when Endocyte sent a letter to POINT offering POINT a license to the ’970 patent. POINT’s parent company, Eli Lilly, confirmed receipt of that letter on March 21, 2024.

71. POINT’s commercialization partner, Lantheus, has been aware that PNT2002 infringes claims 1, 2, and 6 of the ’970 patent since at least February 26, 2024, when Endocyte sent a letter to Lantheus offering Lantheus a license to the ’970 patent. Lantheus confirmed receipt of that letter on March 22, 2024.

72. On information and belief, POINT’s agreement to supply PNT2002 to Lantheus has been maintained with knowledge of the ’970 patent and that Lantheus will sell or offer to sell PNT2002 to patients and/or healthcare providers, infringing the claims of the ’970 patent.

73. Further, on information and belief, POINT knew and/or was willfully blind to the fact that the Commercialization Agreement would infringe the ’970 patent prior to entering into that agreement.

74. On information and belief, POINT’s manufacture and supply of PNT2002 to Lantheus for the expanded access program has been maintained with knowledge of the ’970 patent and that Lantheus’s provision of PNT2002 to healthcare providers and/or patients infringes the claims of the ’970 patent.

75. POINT has committed these infringing acts without Plaintiffs’ permission, consent, authorization, or license.

76. POINT’s actions and contractual commitments, including but not limited to its agreement with Lantheus for the development and commercial supply of PNT2002 and its

manufacture and supply of PNT2002 for the expanded access program, have encouraged and continue to actively encourage Lantheus to infringe the ’970 patent.

77. By entering into the Commercialization Agreement with Lantheus and continuing performance under that Agreement, and by manufacturing and supplying PNT2002 for the expanded access program, with knowledge that PNT2002 infringes the claims of the ’970 patent, POINT has actively induced and will actively induce Lantheus to infringe the ’970 patent under 35 U.S.C. § 271(b).

78. PNT2002 and its components and/or precursors, including the molecule known as zadavotide guraxetan or “PSMA I&T,” are especially made or adapted for use in infringement of the ’970 patent, are not staple articles of commerce, and have no substantial noninfringing uses.

79. By supplying PNT2002 and/or its components and precursors to Lantheus, including in connection with the expanded access program, with knowledge that PNT2002 infringes the ’970 patent, POINT has contributed and will contribute to Lantheus’s infringement under 35 U.S.C. § 271(c).

80. Defendants have undertaken their actions despite knowing that such actions infringed the ’970 patent. As such, Defendants have willfully infringed and continue to willfully infringe the ’970 patent.

81. Defendants’ infringement has damaged and continues to damage Plaintiffs.

82. Plaintiffs will be substantially and irreparably damaged by infringement of the ’970 patent. Unless POINT is enjoined from infringing the ’970 patent, actively inducing infringement of the ’970 patent, and contributing to the infringement by others of the ’970 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

83. In the alternative, Plaintiffs have been and will continue to be damaged in an amount yet to be determined in the form of lost profits or of at least a reasonable royalty.

JURY DEMAND

84. Plaintiffs request a trial by jury on all claims and issues so triable.

* * *

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

1. A judgment that POINT has infringed the ’970 patent by importing, making, using, offering to sell, and/or selling PNT2002 in the United States;

2. A judgment that POINT has induced and/or contributed to the infringement of the ’970 patent by importing, making, using, offering to sell, and/or selling PNT2002 in the United States;

3. A declaratory judgment that POINT will infringe and/or induce and/or contribute to the infringement of the ’970 patent by manufacturing, using, offering to sell, and/or selling PNT2002 in the United States;

4. An order permanently enjoining (and/or, to the extent necessary, preliminarily enjoining) POINT and its affiliates, subsidiaries, and parent companies, and each of their officers, agents, servants, and employees and those acting in privity or in concert with POINT, from importing, making, using, offering to sell, or selling PNT2002 in the United States for commercial purposes (*i.e.*, for purposes other than clinical trials and/or the Lantheus expanded access program), including by enjoining the performance of its commercially-related obligations under POINT’s Commercialization Agreement with Lantheus, until after the expiration date of the ’970 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

5. Actual damages, including a reasonable royalty and lost profits, together with interest;

6. That Defendants' infringement be deemed willful, and that Plaintiffs be awarded enhanced damages under 35 U.S.C. § 284;

7. A declaration that this is an exceptional case and an award of Plaintiffs' attorneys' fees pursuant to 35 U.S.C. § 285;

8. An award to Plaintiffs of their costs and expenses in this action; and

9. Such further and additional relief as this Court deems just and proper.

By: */s/ Kandi Kilkelly Hidde*

Kandi Kilkelly Hidde, #18033-49
Patricia Román Hass, #29461-45
FROST BROWN TODD LLP
111 Monument Circle, Suite 4500
P.O. Box 44961
Indianapolis, IN 46244-0961
Telephone: (317) 237-3800
Facsimile: (317) 237-3900
Email: khidde@fbtlaw.com
promanhass@fbtlaw.com

Jessamyn Berniker (admission pending)
Thomas S. Fletcher (admission pending)
M. Elaine Horn (admission pending)
Stephen J. Fuzesi (admission pending)
Melissa B. Collins (admission pending)
WILLIAMS & CONNOLLY, LLP
680 Maine Ave SW
Washington, DC 20024
Telephone: (202) 434-5000
Fax: (202) 434-5029
Email: JBerniker@wc.com
TFletcher@wc.com
ehorn@wc.com
sfuzesi@wc.com
MCollins@wc.com

Counsel for Plaintiffs