IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

RADIUS HEALTH, INC. Plaintiff, v. ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED, CIPLA LIMITED, and CIPLA USA, INC. Defendants.	)	C.A. No. _____

COMPLAINT

Plaintiff Radius Health, Inc. f/k/a Nuvios, Inc. ("Radius"), by and through its undersigned attorneys, for its Complaint against defendants Orbicular Pharmaceutical Technologies Private Limited ("Orbicular") and Cipla Limited and Cipla USA, Inc. (together, "Cipla") (collectively, "Defendants"), hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, including 35 U.S.C. § 271(e)(2)(A). This action relates to Abbreviated New Drug Application ("ANDA") No. 217245, filed by and for the benefit of Defendants with the United States Food and Drug Administration ("FDA") ("ANDA No. 217245"). Through ANDA No. 217245, Defendants seek to market generic versions of Tymlos® (abaloparatide) (the "ANDA Product"), prior to the expiration of U.S. Patent No. 11,977,067 (the "'067 patent").

THE PARTIES

2. Plaintiff Radius is a Massachusetts-based corporation, having its principal place of business at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210. Radius is organized and existing under the laws of the State of Delaware. Radius is a science-driven, fully-integrated biopharmaceutical company that is committed to developing and commercializing innovative endocrine and other therapeutics.

3. Radius is the holder of New Drug Application ("NDA") No. 208743, which was first approved by the FDA for the manufacture and sale of Tymlos® (abaloparatide) on April 28, 2017.

4. Tymlos® (abaloparatide) is approved for the treatment of postmenopausal women and men with osteoporosis at high risk for fracture defined as history of osteoporotic fracture, multiple risk factors for fracture, or patients who have failed or are intolerant to other available osteoporosis therapy. In postmenopausal women with osteoporosis, Tymlos® (abaloparatide) reduces the risk of vertebral and nonvertebral fractures.

5. The FDA granted approval of Tymlos® based on positive results from two landmark clinical trials in osteoporosis patients that were sponsored by Radius. Specifically, results reported at 18 months from the human clinical trial known as the ACTIVE Trial and from the first six months of the ACTIVExtend Trial demonstrated consistent significant and rapid reductions in the risk of vertebral and nonvertebral fractures in participating osteoporosis patients regardless of age, years since menopause, presence or absence of prior fracture (vertebral or nonvertebral) and bone mineral density (BMD) at baseline. At approval, Tymlos® (abaloparatide) was the first new anabolic (bone building) agent for postmenopausal women with osteoporosis in the United States in nearly fifteen years.

6. Radius is an owner and assignee of the '067 patent, which issued on May 7, 2024 and shortly thereafter, on May 16, 2024, was listed in the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering the Tymlos® (abaloparatide) product. Radius possesses the right to sue for and obtain equitable relief and damages for infringement of the '067 patent.

7. Upon information and belief, Defendant Orbicular is incorporated in India with its principal place of business at P. No. 53, ALEAP Industrial Estate, Behind Pragati Nagar Kukatpally, Hyderabad, 500 090 Telangana, India. On information and belief, Orbicular has no place of business in the United States.

8. Orbicular has designated the following agent in the United States as authorized to accept service of process: Andrew J. Miller, Esq., Windels Marx Lane & Mittendorf, LLP, 1 Giralda Farms, Suite 100, Madison, New Jersey 07940.

9. Upon information and belief, Orbicular is in the business of, among other things, the development and manufacture of generic and specialty pharmaceutical products for sale throughout the United States, including in Massachusetts.

10. Upon information and belief, Defendant Cipla Limited is a corporation in India with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013, Maharashtra, India.

11. Upon information and belief, Defendant Cipla USA Inc. is incorporated in Delaware with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. Upon information and belief, Defendant Cipla USA, Inc. is a subsidiary of Cipla Limited.

12. Upon information and belief, Cipla is in the business of, among other things, the development and manufacture of generic and specialty pharmaceutical products for sale throughout the United States, including in Massachusetts.

13. Orbicular submitted ANDA No. 217245 to the FDA pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") (codified at 21 U.S.C. § 355(j)). ANDA No. 217245 included a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") to, *inter alia*, U.S. Patent Nos. 7,803,770 (the "'770 patent"), 8,148,333 (the "'333 patent"), 8,748,382 (the "'382 patent"), 11,255,842 (the "'842 patent") and 10,996,208 (the "'208 patent").[1]

14. On April 12, 2024, Orbicular submitted a second Paragraph IV Certification encompassing three new patents: U.S. Patent Nos. 11,680,942 (the "'942 patent"), 11,782,041 (the "'041 patent"), and RE49,444 (the "'444 patent"), which is a reissue of the '770 patent.

15. Upon information and belief, Orbicular will further amend ANDA No. 217245 to contain a Paragraph IV Certification that includes the '067 patent.

16. Orbicular initially mailed a Notice of Paragraph IV Certification Re: Orbicular Pharmaceutical Technologies Private Limited's Abaloparatide Injection, 3120 MCG / 1.56 ML (2000 MCG/ML); U.S. Patent Nos. 7,803,770; 8,148,333; 8,748,382; 10,996,208; and 11,255,842 ("First Notice Letter") to Radius and Ipsen Pharma S.A.S. ("Ipsen"). The First Notice Letter is dated August 8, 2022 and was mailed to Radius at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210, among others. Radius and Ipsen received the First Notice Letter on August 9, 2022 and commenced the Related Litigation (Case No. 22-cv-11546-RGS, D. Mass.) alleging

[1] Plaintiff (along with Ipsen Pharma S.A.S.) has alleged infringement of these patents by Orbicular in a separately pending litigation: *Radius Health Inc. and Ipsen Pharma S.A.S. v. Orbicular Pharmaceutical Technologies Private Limited*, No. 22-cv-11546 (D. Mass.) (the "Related Litigation").

infringement of the '770, '333, '382, and '208 patents within 45 days of receiving the First Notice Letter.

17. Orbicular subsequently mailed a second Notice of Paragraph IV Certification Re: Orbicular Pharmaceutical Technologies Private Limited's Abaloparatide Injection, 3120 MCG / 1.56 ML (2000 MCG/ML); U.S. Patent Nos. RE49,444, 11,680,942, and 11,782,041 ("Second Notice Letter") to Radius. The Second Notice Letter is dated April 12, 2024 and was mailed to Radius at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210, among others. Upon information and belief, Orbicular will send another Notice of Paragraph IV Certification notifying Radius that it has amended ANDA No. 217245 to contain a Paragraph IV Certification that includes the '067 patent.

18. Upon information and belief, Orbicular developed the ANDA Product that is the subject of ANDA No. 217245. Orbicular submitted ANDA No. 217245 to the FDA, seeking approval for Cipla to market and sell the ANDA Product throughout the United States, including in Massachusetts.

19. ANDA No. 217245 seeks approval to commercially manufacture, use, offer for sale, sell, and/or import a generic version of Radius's Tymlos® (abaloparatide) prior to the expiration of the Patents-in-Suit.

20. Upon information and belief, Defendants and/or their agents will manufacture, use, market, offer for sale, sell, and/or import a generic version of Radius's Tymlos® (abaloparatide) throughout the United States, including in Massachusetts, upon FDA approval of the ANDA Product.

JURISDICTION AND VENUE

21. This is a complaint for patent infringement under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. §§ 271(e)(2)(A) and 271(b), arising out of the submission of ANDA No. 217245 to the FDA.

22. This Court has subject matter jurisdiction of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

23. This Court has personal jurisdiction over Orbicular at least because, upon information and belief: (i) Orbicular, directly or through its affiliates, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes generic pharmaceutical products throughout the United States, including in Massachusetts, and therefore does business in Massachusetts, derives revenue from conducting business in Massachusetts, and maintains continuous and systematic contacts with Massachusetts; and (ii) Orbicular has committed, induced, or contributed to acts of patent infringement in Massachusetts by submitting ANDA No. 217245 that includes a Paragraph IV Certification (a technical act of infringement under 35 U.S.C. § 271(e)(2)(A)) that Orbicular seeks to import, offer for sale, and sell its ANDA Product throughout the United States, including in this judicial district, before the expiration of the '067 patent.

24. This Court has personal jurisdiction over Cipla at least because, upon information and belief: (i) Cipla, directly or through its affiliates, develops, manufactures, imports, markets, offers to sell, sells, and/or distributes generic pharmaceutical products throughout the United States, including in Massachusetts, and therefore does business in Massachusetts, derives revenue from conducting business in Massachusetts, and maintains continuous and systematic contacts with Massachusetts; (ii) Cipla through an agreement with Orbicular, has certain rights and responsibilities regarding ANDA No. 217245; and (iii) Cipla will actively induce acts of patent infringement in Massachusetts by manufacturing, using, marketing, offering for sale, selling,

and/or importing the ANDA Product throughout the United States, including Massachusetts, upon FDA approval of the ANDA Product.

25. This Court has personal jurisdiction over Defendants at least because, upon information and belief, if ANDA No. 217245 is approved, the ANDA Product will be manufactured, marketed, sold, distributed, imported, and/or used by Defendants throughout the United States, including in Massachusetts; prescribed by physicians practicing in Massachusetts; and/or administered to patients in Massachusetts, all of which would have a substantial effect on Massachusetts. For example, upon information and belief, Defendants know that Tymlos® (abaloparatide) has been and will be distributed and used in Massachusetts. Upon information and belief, and because of, among other things, the Commonwealth's generic substitution laws, upon approval of its ANDA, Defendants intend to replace Tymlos® (abaloparatide) sales with its generic drug as set forth in their ANDA.

26. In the alternative, Orbicular and Cipla Limited are subject to jurisdiction throughout the United States, and specifically in the Commonwealth of Massachusetts pursuant to Fed. R. Civ. P. 4(k)(2) because (a) these claims arise under federal law; (b) Orbicular and Cipla Limited would be foreign defendants not subject to personal jurisdiction in the courts of any state; and (c) Orbicular and Cipla Limited have sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and/or, upon information and belief, manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Orbicular and Cipla Limited satisfies due process and is otherwise consistent with the United States Constitution and laws.

27. For the reasons set forth above, Defendants are subject to personal jurisdiction in this District. In addition, Defendants have stated that they do not contest that they are subject to personal jurisdiction in this District for purposes of this action.

28. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b) at least because Orbicular and Cipla Limited are foreign corporations that do not have a state of residence in the United States and Cipla USA, Inc. is subject to personal jurisdiction in this District. In addition, Defendants do not contest that venue is proper in this District.

FACTS AS TO ALL COUNTS

The Patent-in-Suit

29. The '067 patent is assigned to Radius and, as of the date of this Complaint, Radius holds the rights to enforce the '067 patent against potential infringers in the United States and to seek damages.

30. The '067 patent is valid, enforceable, and has not expired.

31. The '067 patent, entitled "Abaloparatide Formulations and Methods of Testing, Storing, Modifying, and Using Same," was duly and legally issued on May 7, 2024. The '067 patent is a continuation of the '208 and '041 patents and claims, *inter alia*, an isomer of abaloparatide comprising beta-Asp10 abaloparatide as set forth in the below sequence, and certain pharmaceutical compositions and/or formulated drug products comprising said abaloparatide isomer:

Ala-Val-Ser-Glu-His-Gln-Leu-Leu-His-b-Asp-Lys-Gly-Lys-Ser-Ile-Gln-Asp-Leu-Arg-Arg-Arg-Glu-Leu-Leu-Glu-Lys-Leu-Leu-Aib-Lys-Leu-His-Thr-Ala-NH_2

32. A copy of the '067 patent is attached as Exhibit A.

Tymlos® (abaloparatide)

33. Tymlos® (abaloparatide) is a human parathyroid hormone related peptide [PTHrP (1-34)] analog indicated for the treatment of postmenopausal women and men with osteoporosis at high risk for fracture. The recommended dose of Tymlos® (abaloparatide) is 80 mcg subcutaneously once daily.

34. According to the Tymlos® (abaloparatide) label, "Dosage Forms and Strengths," 3120 mcg/1.56 mL (2000 mcg/mL) is provided in a single-patient-use prefilled pen. The prefilled pen delivers 30 daily doses of 80 mcg abaloparatide in 40 mcL of sterile, clear, colorless solution.

35. Tymlos® (abaloparatide) is sold and marketed in the United States under NDA No. 208743.

36. Radius is the holder of NDA No. 208743.

37. Tymlos® (abaloparatide) is covered by at least one claim of the '067 patent.

38. The '067 patent is listed in the FDA's Orange Book in conjunction with NDA No. 208743.

ANDA No. 217245

39. Orbicular sent the First Notice Letter to Radius and Ipsen, dated August 8, 2022 and received by Radius on August 9, 2022, purportedly pursuant to § 505(j)(2)(B)(ii) and § 505(j)(2)(B)(iv) of the FD&C Act and 21 C.F.R. § 314.95, regarding ANDA No. 217245. The First Notice Letter was signed by Louis H. Weinstein of the law firm Windels Marx Lane & Mittendorf, LLP on behalf of Orbicular.

40. Within 45 days of receiving the First Notice Letter, on September 20, 2022, Radius and Ipsen initiated the Related Litigation alleging infringement of the '770, '333, '382, '842, and '208 patents, thereby triggering a 30-month stay of regulatory approval of the ANDA Product.

41. On April 17, 2023, with leave of this Court, Radius and Ipsen filed a First Amended Complaint in the Related Litigation, substituting the '770 patent with its reissue, the '444 patent, and removing the '842 patent.

42. On November 2, 2023, with leave of this Court, Radius and Ipsen filed a Second Amended Complaint in the Related Litigation, adding a newly issued and Orange Book-listed patent, U.S. Patent No. 11,782,041 (the "'041 patent").

43. Orbicular sent the Second Notice Letter to Radius and Ipsen, dated April 12, 2024, and received by Radius on April 16, 2024, purportedly pursuant to § 505(j)(2)(B)(ii) and § 505(j)(2)(B)(iv) of the FD&C Act and 21 C.F.R. § 314.95, regarding ANDA No. 217245. The Second Notice Letter was signed by Ajay Kayal of the law firm Windels Marx Lane & Mittendorf, LLP on behalf of Orbicular.

44. Orbicular's First Notice Letter states that ANDA No. 217245 was submitted with a Paragraph IV Certification to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '770 patent, '333 patent, '382 patent, '842 patent, and '208 patent. Orbicular's Second Notice Letter states that Orbicular filed a further Paragraph IV Certification regarding ANDA No. 217245 to obtain approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '444 patent, '942 patent, and '041 patent. Upon information and belief, Orbicular will further amend ANDA No. 217245 to contain a Paragraph IV Certification that includes the '067 patent.

45. The First Notice Letter also states that ANDA No. 217245 was submitted with a Paragraph IV Certification pursuant to § 505(j)(2)(A)(vii)(IV) of the FD&C Act and 21 C.F.R. § 314.94(a)(12)(i)(A)(4) alleging that the '770 patent, '333 patent, '382 patent, '842 patent, and '208 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of

the ANDA Product. The Second Notice Letter similarly states that a recently submitted Paragraph IV Certification alleges that the '444 patent, '942 patent, and '041 patent are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the ANDA Product. Upon information and belief, Orbicular will further amend ANDA No. 217245 to contain a Paragraph IV Certification that includes the '067 patent.

46. Upon information and belief, Defendants had knowledge of the '067 patent, which is a continuation of the '208 and '041 patents, prior to its issuance and at least since May 16, 2024, the date on which it was listed in the Orange Book as covering Tymlos®.

47. ANDA No. 217245 refers to and relies upon the NDA for Tymlos® (abaloparatide), NDA No. 208743, and contains data that, according to Orbicular, demonstrate the bioequivalence of the ANDA Product and Tymlos® (abaloparatide). *See* 21 U.S.C. § 355(j)(2); 21 C.F.R. § 314.94(a)(7).

48. Both the First and Second Notice Letters state that the active ingredient in the ANDA Product is abaloparatide.

49. Upon information and belief, the label for the ANDA Product will recommend the same Indication and Usage as Tymlos® (abaloparatide).

50. Upon information and belief, the label for the ANDA Product will reference the same Clinical Studies as Tymlos® (abaloparatide).

51. Upon information and belief, the label for the ANDA Product will recommend the same Dosage and Administration as Tymlos® (abaloparatide).

52. Upon information and belief, administration of the ANDA Product, like Tymlos® (abaloparatide), will be used for the treatment of postmenopausal women with osteoporosis at high risk for fracture.

53. Pursuant to 21 C.F.R. § 314.53(c)(2), on May 16, 2024, Radius submitted Form FDA 3542 for the '067 patent to the FDA in connection with NDA No. 208743.

Cipla's Rights and Responsibilities

54. Prior to the date of this Complaint, Orbicular and Cipla USA, Inc. entered into a License & Supply Agreement (the "License Agreement") for, among other things, the commercialization of the ANDA Product.

55. Upon information and belief, Cipla stands to benefit substantially from the approval of Orbicular's ANDA.

56. Pursuant to the License Agreement, Cipla presently has access to ANDA No. 217245, including the Paragraph IV Certifications disclosed in the First and Second Notice Letters.

57. Plaintiffs are entitled to full relief from Defendants' acts of infringement, including entry of judgment that any final approval of ANDA No. 217245 shall be effective no earlier than the expiration date of the '067 patent, or any later expiration of exclusivity for the '067 patent to which Plaintiff is or may become entitled. *See* 35 U.S.C. § 271(e)(4).

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,977,067

58. Plaintiffs repeat and re-allege each of the foregoing paragraphs as if fully set forth herein.

59. Upon information and belief, Orbicular prepared ANDA No. 217245.

60. Orbicular submitted ANDA No. 217245 to the FDA pursuant to § 505(j) of the FD&C Act (codified at 21 U.S.C. § 355(j)) for the purpose of seeking FDA approval to market the ANDA Product prior to the expiration of the '067 patent.

61. ANDA No. 217245 is based upon Tymlos® (abaloparatide), as its reference-listed drug.

62. The ANDA Product is an abaloparatide product.

63. Upon information and belief, Orbicular and Cipla seek FDA approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of the ANDA Product throughout the United States before the expiration of the '067 patent.

64. Under 35 U.S.C. § 271(e)(2)(A), Orbicular's submission of ANDA No. 217245 for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '067 patent constitutes infringement of one or more claims of the '067 patent, including at least claim 8.

65. For example, Claim 1 of the '067 patent claims "[a]n isomer of abaloparatide comprising beta-Asp10 abaloparatide as set forth in the sequence: Ala-Val-Ser-Glu-His-Gln-Leu-Leu-His-b-Asp-Lys-Gly-Lys-Ser-Ile-Gln-Asp-Leu-Arg-Arg-Arg-Glu-Leu-Leu-Glu-Lys-Leu-Leu-Aib-Lys-Leu-His-Thr-Ala-NH_2." Claim 2, in turn, claims "[t]he isomer of abaloparatide of claim 1, consisting of beta-Asp10 abaloparatide," and Claim 3 claims "[a] pharmaceutical composition comprising the abaloparatide isomer of claim 2." Claim 4 of the '067 patent further claims "[t]he pharmaceutical composition of claim 3, further comprising abaloparatide," and Claim 8 claims "[t]he pharmaceutical composition of claim 4, wherein the pharmaceutical composition is a formulated drug product."

66. Tymlos® (abaloparatide) embodies the formulated drug product claimed in at least claim 8 of the '067 patent. Specifically, the specification for Tymlos® states that Tymlos® contains <5% beta-Asp10 abaloparatide. By its ANDA submission, Orbicular has necessarily represented to the FDA that the ANDA Product will be the same as Tymlos® (abaloparatide), including, on information and belief, that the ANDA Product is "a formulated abaloparatide drug product" comprising "a pharmaceutical composition" comprising "the beta-Asp10 abaloparatide [isomer]." By filing its ANDA which, upon information and belief, will be amended to include a

Paragraph IV Certification with respect to the '067 patent, Orbicular has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Therefore, upon information and belief, Orbicular knowingly infringes at least claim 8 of the '067 patent.

67. Upon information and belief, Defendants and/or their agents will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States the ANDA Product if ANDA No. 217245 ever receives final FDA approval.

68. Upon information and belief, in particular, Defendants will instruct, e.g., patients, prescribers, and healthcare providers to use the ANDA Product in accordance with the proposed product labeling if ANDA No. 217245 ever receives final FDA approval.

69. Upon information and belief, Defendants' commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of the ANDA Product would infringe, directly and/or indirectly, one or more of the '067 patent claims under 35 U.S.C. § 271.

70. Upon information and belief, by commercially offering for sale and/or selling the ANDA Product in accordance with its label, Defendants would knowingly induce and/or contribute to third-party infringement of one or more claims of the '067 patent under 35 U.S.C. § 271.

71. Upon information and belief, Defendants had knowledge of the '067 patent, which is a continuation of the '208 and '041 patents, prior to its issuance and are knowingly infringing the claims in the '067 patent.

72. Upon information and belief, Defendants will act without a reasonable basis for believing that they would not be liable for infringing, actively inducing infringement of, and/or contributing to infringement by others of the '067 patent.

73. This case therefore is "exceptional," and Plaintiff is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

74. The acts of infringement of the '067 patent set forth above will cause Plaintiff to suffer irreparable harm for which there is no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

75. Plaintiff is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an Order of this Court that the effective date of the FDA's final approval of ANDA No. 217245 be a date that is not earlier than the expiration date of the '067 patent, or any later expiration of exclusivity for the '067 patent to which Plaintiff is or may become entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(A) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Orbicular has infringed one or more claims of the '067 patent by submitting to the FDA ANDA No. 217245 with the Paragraph IV Certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '067 patent;

(B) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product by Defendants before the expiration of the '067 patent (including any regulatory extension), would directly and/or indirectly infringe the '067 patent;

(C) An order, pursuant to 35 U.S.C. §§ 271(e)(4)(A), 281, and 283, that the effective date of any final approval of ANDA No. 217245 shall be no earlier than the expiration date of the '067 patent (including any regulatory extension);

(D) An order, pursuant to 35 U.S.C. §§ 271(e)(4)(B), 281, and 283, preliminarily and permanently enjoining Defendants, their officers, agents, servants, employees, attorneys, and any

person in active concert or participation or privy with Defendants, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of the ANDA Product until the expiration of the '067 patent (including any regulatory extension);

(E) A judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, awarding Plaintiff damages or other monetary relief if Defendants commercially manufacture, use, offer to sell, or sell within the United States, and/or import into the United States any product that is the subject of ANDA No. 217245, prior to the expiration of the '067 patent (including any regulatory extension);

(F) A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Plaintiff its attorneys' fees and costs;

(G) A judgment declaring that the '067 patent is valid; and

(H) Such other and further relief as this Court may deem just and proper.

PLAINTIFF RADIUS HEALTH, INC.

By its Counsel,

Dated: July 10, 2024

/s/ Eric J. Marandett

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CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants on the Notice of Electronic Filing (NEF) and that paper copies will be sent to those non-registered participants (if any) on July 10, 2024.

/s/ Eric J. Marandett
Eric J. Marandett (BBO# 561730)