IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

RADIUS HEALTH, INC. and IPSEN PHARMA S.A.S.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Radius Health, Inc. f/k/a Nuvios, Inc. ("Radius") and Ipsen Pharma S.A.S. ("Ipsen") by and through their undersigned attorneys, for their Complaint against defendant Orbicular Pharmaceutical Technologies Private Limited ("Orbicular" or "Defendant") 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 Defendant with the United States Food and Drug Administration ("FDA") ("ANDA No. 217245"). Through ANDA No. 217245, Defendant seeks to market generic versions of Tymlos® (abaloparatide) (the "ANDA Product"), prior to the expiration of U.S. Patent Nos. 7,803,770 (the "'770 patent"), 8,148,333 (the "'333 patent"), 8,748,382 (the "'382 patent"), 10,996,208 (the "'208 patent"), and 11,255,842 (the "'842 patent") (collectively, the "Patents-in-Suit").

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 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 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 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 each of the Patents-in-Suit, which are 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 Patents-in-Suit.

7. Plaintiff Ipsen is a limited company incorporated under French law, having its principal place of business at 65 Quai George Gorse, 92100 Boulogne-Billancourt, France. Ipsen is a specialty-driven biopharmaceutical company that develops and markets new medicines, including biological drugs, for the treatment of debilitating diseases in various therapeutic areas.

8. Ipsen is a co-owner of the '770 patent, '333 patent, and '382 patent. Beginning in 2005, Radius and Ipsen collaborated on the development of the abaloparatide formulations and methods of treatment that are the subject of the '770 patent, '333 patent, and '382 patent. Radius retained the rights to develop, manufacture, and distribute the abaloparatide formulations.

9. 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.

10. 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.

11. 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.

12. Upon information and belief, Defendant 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)). Upon information and belief, ANDA No. 217245 included a paragraph IV certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") to each of the Patents-in-Suit.

13. Defendant 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 ("Notice Letter") to Radius and Ipsen. The 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 Notice Letter on August 9, 2022 and commenced this action within 45 days of receiving the Notice Letter.

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

15. 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.

JURISDICTION AND VENUE

16. 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), arising out of the submission of ANDA No. 217245 to the FDA.

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

18. This Court has personal jurisdiction over Defendant at least because, upon information and belief: (i) Defendant, 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) Defendant 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 Defendant 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 Patents-in-Suit.

19. This Court has personal jurisdiction over Defendant 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 Defendant 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, Defendant knows 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, Defendant intends to replace Tymlos® (abaloparatide) sales with its generic drug as set forth in its ANDA.

20. This Court has personal jurisdiction over Defendant at least because, upon information and belief, Defendant has used the statutory process for challenging infringement

and/or validity of the Patents-in-Suit by filing a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) and sending notice of such certification to the NDA holder, which triggers patent litigation. Upon information and belief, with knowledge of this statutory process, Defendant sent the Notice Letter to Radius at its principal place of business in Massachusetts, knowing that such certification could trigger a patent infringement suit to protect Radius's patent rights in this judicial district.

21. In the alternative, Defendant is 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) Defendant would be a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Defendant has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and, 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 Defendant satisfies due process and is otherwise consistent with the United States Constitution and laws.

22. For the reasons set forth above, and for additional reasons which will be supplied if Defendant challenges personal jurisdiction in this action, Defendant is subject to personal jurisdiction in this District.

23. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b) because Defendant is a foreign corporation that does not have a state of residence in the United States.

FACTS AS TO ALL COUNTS

The Patents-in-Suit

24. The '770 patent, the '333 patent, and the '382 patent are assigned to Radius and Ipsen. The '208 patent and the '842 patent are assigned to Radius. As of the date of this Complaint,

Radius holds the rights to enforce the Patents-in-Suit against potential infringers in the United States and to seek damages.

25. The Patents-in-Suit are valid, enforceable, and have not expired.

26. The '770 patent, entitled "Method of Treating Osteoporosis Comprising Administration of PTHRP Analog," was duly and legally issued on September 28, 2010. The '770 patent claims, *inter alia*, methods of treating osteoporosis comprising daily subcutaneous administration of compositions comprising 80 µg of abaloparatide to a human in need thereof. A copy of the '770 patent is attached as Exhibit A.

27. The '333 patent, entitled "Stable Composition Comprising a PTHRP Analogue," was duly and legally issued on April 3, 2012. The '333 patent claims, *inter alia*, storage-stable compositions suitable for administration to a subject comprising abaloparatide and an effective amount of a pH buffer to maintain the pH in a range of about 4.5 to about 5.6, or wherein said pH is about 5.1. A copy of the '333 patent is attached as Exhibit B.

28. The '382 patent, entitled "Method of Drug Delivery for Bone Anabolic Protein," was duly and legally issued on June 10, 2014. The '382 patent claims, *inter alia*, methods of stimulating bone growth in a subject in need thereof comprising administering to said subject storage-stable compositions comprising abaloparatide and an effective amount of buffer to maintain the pH in a range of about 4.5 to about 5.6. A copy of the '382 patent is attached as Exhibit C.

29. The '208 patent, entitled "Abaloparatide Formulations and Methods of Testing, Storing, Modifying, and Using Same," was duly and legally issued on May 4, 2021. The '208 patent claims, *inter alia*, formulated abaloparatide drug products comprising ≤5% or ≤1.0% w/w beta-Asp10 of the total peptide content, methods of analyzing abaloparatide comprising detecting

and quantifying the presence of ≤5% or ≤1.0% w/w beta-Asp10 of the total peptide content, and methods of establishing the suitability of a formulated abaloparatide drug product for administration to a subject comprising detecting and quantifying the presence of ≤5% w/w beta-Asp10 of the total peptide content. A copy of the '208 patent is attached as Exhibit D.

30. The '842 patent, entitled "Methods for Detecting Neutralizing Antibodies to Parathyroid Hormone (PTH) and Parathyroid Hormone-Related Peptide (PTHrP) Analog," was duly and legally issued on February 22, 2022. The '842 patent claims, *inter alia*, methods for detecting the presence of neutralizing antibodies to abaloparatide in a sample from a subject treated with abaloparatide, as well as a kit for carrying out those methods. A copy of the '842 patent is attached as Exhibit E.

Tymlos® (abaloparatide)

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

32. 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.

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

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

35. Tymlos® (abaloparatide), its method of manufacture, and its FDA-approved use are each covered by at least one claim of the Patents-in-Suit.

36. The Patents-in-Suit are listed in the FDA's Orange Book in conjunction with NDA No. 208743.

ANDA No. 217245

37. Defendant sent the Notice Letter to Radius and Ipsen, dated August 8, 2022 and received by Radius and Ipsen 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 Notice Letter was signed by Louis H. Weinstein of the law firm Windels Marx Lane & Mittendorf, LLP on behalf of Defendant.

38. Defendant's Notice Letter states that ANDA No. 217245 has been 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 Patents-in-Suit.

39. The Notice Letter 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 Patents-in-Suit are invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the ANDA Product.

40. In view of Defendant's Notice Letter and Paragraph IV Certification regarding the Patents-in-Suit contained in ANDA No. 217245, Defendant had knowledge of the Patents-in-Suit at least since the date on which Defendant filed ANDA No. 217245 with the FDA.

41. Upon information and belief, ANDA No. 217245 refers to and relies upon the NDA for Tymlos® (abaloparatide), NDA No. 208743, and contains data that, according to Defendant, 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).

42. The Notice Letter states that the active ingredient in the ANDA Product is abaloparatide.

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

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

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

46. 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.

47. Pursuant to 21 U.S.C. § 355(b)(1), the '770 patent, '382 patent, and '333 patent were submitted to the FDA with NDA No. 208743.

48. Pursuant to 21 C.F.R. § 314.53(c)(2), Form FDA 3542 for the '208 and '842 patents were submitted to the FDA in connection with NDA No. 208743.

49. This action is being commenced within 45 days from the date Radius and Ipsen received Defendant's Notice Letter, which was August 9, 2022.

50. Initiating this action within 45 days of receipt of the Notice Letter triggers a 30-month stay of regulatory approval of Defendant's ANDA. *See* 21 U.S.C. § 355 (j)(5)(B)(iii).

51. Plaintiffs are entitled to full relief from Defendant's 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 last to expire of the Patents-in-Suit, or any later expiration of exclusivity for the Patents-in-Suit to which Plaintiffs are or may become entitled. *See* 35 U.S.C. § 271(e)(4).

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 7,803,770

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

53. Upon information and belief, Defendant prepared ANDA No. 217245.

54. Defendant 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 '770 patent.

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

56. The ANDA Product is an abaloparatide product.

57. Defendant submitted ANDA No. 217245 with a Paragraph IV Certification to the '770 patent for the purpose of obtaining 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 '770 patent.

58. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

59. As of the date of the Notice Letter, Defendant was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

60. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Defendant sent a copy of the Notice Letter to Radius at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210, which was received on August 9, 2022. Defendant also sent a copy to Ipsen at 65 Quai Georges Corse, Boulogne-Billancourt 92100, France, which was received on August 9, 2022.

61. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission of ANDA No. 217245 with a Paragraph IV Certification to the '770 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '770 patent constitutes infringement of one or more claims of the '770 patent, including at least claim 1.

62. For example, claim 1 of the '770 patent claims "[a] method of treating osteoporosis comprising daily subcutaneous administration of a composition comprising 80 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(l-34)NH_2 to a human in need thereof." As set forth in Defendant's Notice Letter, the active ingredient in the ANDA Product is abaloparatide, i.e., "a synthetic 34 amino acid peptide with the amino acid sequence: Ala-Val-Ser-Glu-His-Gln-Leu-Leu-His-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[.]" The Notice Letter also provides that the ANDA Product is "an injection solution for subcutaneous use." The Notice Letter further provides that "the indicated dosage of Orbicular's proposed product [the ANDA Product] will be 80 μg per day and Orbicular's proposed product will deliver 80 μg." The Notice Letter does not assert that use of the ANDA Product does not infringe any of the claims of the '770 patent, including, for example, claim 1.

63. Treatment with Tymlos® (abaloparatide) results in practicing at least the method of claim 1 of the '770 patent. By its ANDA submission, Defendant has necessarily represented to the FDA that the ANDA Product will be the same as Tymlos® (abaloparatide). Accordingly, on information and belief, the ANDA Product label will instruct, e.g., patients, prescribers, and physicians to follow the claimed "method of treating osteoporosis comprising daily subcutaneous administration of a composition comprising 80 μg of [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(l-34)NH_2 to a human in need thereof." On information and belief, patients, prescribers, and physicians will follow instructions in the ANDA Product label and will infringe at least claim 1 of the '770 patent. By submitting an ANDA with a label that, on information and belief, is the same as the Tymlos® (abaloparatide) label, Defendant is knowingly inducing third parties to infringe at least claim 1 of the '770 patent. By filing an ANDA with a Paragraph IV Certification with respect to the '770 patent, Defendant has also committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Therefore, on information and belief, Defendant knowingly infringes, induces others to infringe, and/or contributes to third-party infringement of at least claim 1 of the '770 patent.

64. Upon information and belief, Defendant 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.

65. Upon information and belief, Defendant 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.

66. Upon information and belief, Defendant's 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 '770 patent claims under 35 U.S.C. § 271.

67. Upon information and belief, by commercially offering for sale and/or selling the ANDA Product in accordance with its label, Defendant would knowingly induce and/or contribute to third-party infringement of one or more claims of the '770 patent under 35 U.S.C. § 271.

68. Defendant had knowledge of the '770 patent since at least the time it filed ANDA No. 217245 with a Paragraph IV Certification and is knowingly infringing the '770 patent.

69. Defendant's statements of the factual and legal bases for its opinion regarding the non-infringement of the '770 patent contained in Defendant's Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

70. Defendant acted without a reasonable basis for believing that it would not be liable for infringing the '770 patent, actively inducing infringement of the '770 patent, and/or contributing to infringement by others of the '770 patent.

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

72. The acts of infringement of the '770 patent set forth above will cause Plaintiffs to suffer irreparable harm for which there is no adequate remedy at law, unless Defendant is preliminarily and permanently enjoined by this Court.

73. Plaintiffs are 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 '770 patent, or any later expiration of exclusivity for the '770 patent to which Plaintiffs are or may become entitled.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 8,148,333

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

75. Upon information and belief, Defendant prepared ANDA No. 217245.

76. Defendant 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 '333 patent.

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

78. The ANDA Product is an abaloparatide product.

79. Defendant submitted ANDA No. 217245 with a Paragraph IV Certification to the '333 patent for the purpose of obtaining 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 '333 patent.

80. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

81. As of the date of the Notice Letter, Defendant was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

82. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Defendant sent a copy of the Notice Letter to Radius at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210 which was received on August 9, 2022. Defendant also sent a copy to Ipsen at 65 Quai Georges Corse, Boulogne-Billancourt 92100, France, which was received on August 9, 2022.

83. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission of ANDA No. 217245 with a Paragraph IV Certification to the '333 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '333 patent constitutes infringement of one or more claims of the '333 patent, including at least claim 1.

84. For example, claim 1 of the '333 patent claims "[a] storage-stable composition suitable for administration to a subject comprising: a) a PTHrP analogue having the sequence [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$] hPTHrP(l-34)NH_2 (SEQ ID NO.2); and b) an effective amount of a pH buffer to maintain the pH in a range of about 4.5 to about 5.6." As set forth in Defendant's Notice Letter, the active ingredient in the ANDA Product is abaloparatide, i.e., "a synthetic 34 amino acid peptide with the amino acid sequence: Ala-Val-Ser-Glu-His-Gln-Leu-Leu-His-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[.]" The Notice Letter does not assert that the ANDA Product does not infringe any of the claims of the '333 patent, including, for example, claim 1.

85. Tymlos® (abaloparatide) embodies the storage-stable composition claimed in at least claim 1 of the '333 patent. By its ANDA submission, Defendant 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] storage-stable composition suitable for administration to a subject comprising: a) a PTHrP analogue having the sequence [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$] hPTHrP(l-34)NH_2 (SEQ ID NO.2); and b) an effective amount of a pH buffer to maintain the pH in a range of about 4.5 to about 5.6." By filing an ANDA with a Paragraph IV Certification with respect to the '333 patent, Defendant has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Therefore, on information and belief, Defendant infringes at least claim 1 of the '333 patent.

86. Upon information and belief, Defendant 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.

87. Upon information and belief, Defendant 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.

88. Upon information and belief, Defendant's 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 '333 patent claims under 35 U.S.C. § 271.

89. Defendant had knowledge of the '333 patent since at least the time it filed ANDA No. 217245 with a Paragraph IV Certificate and is knowingly infringing the '333 patent.

90. Defendant's statements of the factual and legal bases for its opinion regarding the non-infringement of the '333 patent contained in Defendant's Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

91. Defendant acted without a reasonable basis for believing that it would not be liable for infringing the '333 patent, actively inducing infringement of the '333 patent, and/or contributing to infringement by others of the '333 patent.

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

93. The acts of infringement of the '333 patent set forth above will cause Plaintiffs to suffer irreparable harm for which there is no adequate remedy at law, unless Defendant is preliminarily and permanently enjoined by this Court.

94. Plaintiffs are 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 '333 patent, or any later expiration of exclusivity for the '333 patent to which Plaintiffs are or may become entitled.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 8,748,382

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

96. Upon information and belief, Defendant prepared ANDA No. 217245.

97. Defendant 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 '382 patent.

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

99. The ANDA Product is an abaloparatide product.

100. Defendant submitted ANDA No. 217245 with a Paragraph IV Certification to the '382 patent for the purpose of obtaining 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 '382 patent.

101. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

102. As of the date of the Notice Letter, Defendant was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

103. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Defendant sent a copy of the Notice Letter to Radius at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210, which was received on August 9, 2022. Defendant also sent a copy to Ipsen at 65 Quai Georges Corse, Boulogne-Billancourt 92100, France, which was received on August 9, 2022.

104. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission of ANDA No. 217245 with a Paragraph IV Certification to the '382 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '382

patent constitutes infringement of one or more claims of the '382 patent, including at least claim 1.

105. For example, claim 1 of the '382 patent claims "[a] method of stimulating bone growth in a subject in need thereof comprising administering to said subject a storage stable composition comprising: a) a PTHrP having the sequence [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(l-34)NH_2 (SEQ ID NO.: 2); and b) an effective amount of buffer to maintain the pH in a range of about 4.5 to about 5.6." As set forth in Defendant's Notice Letter, the active ingredient in the ANDA Product is abaloparatide, i.e., "a synthetic 34 amino acid peptide with the amino acid sequence: Ala-Val-Ser-Glu-His-Gln-Leu-Leu-His-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[.]" The Notice Letter does not assert that use of the ANDA Product does not infringe many claims in the '382 patent, including, for example, claim 1.

106. Treatment with Tymlos® (abaloparatide) results in practicing at least the method of claim 1 of the '382 patent. By its ANDA submission, Defendant has necessarily represented to the FDA that the ANDA Product will be the same as Tymlos® (abaloparatide). Accordingly, on information and belief, the ANDA Product label will instruct, e.g., patients, prescribers, and physicians to follow the claimed "method of stimulating bone growth in a subject in need thereof comprising administering to said subject a storage stable composition comprising: a) a PTHrP having the sequence [$Glu^{22,25}$, $Leu^{23,28,31}$, Aib^{29}, $Lys^{26,30}$]hPTHrP(l-34)NH_2 (SEQ ID NO.: 2); and b) an effective amount of buffer to maintain the pH in a range of about 4.5 to about 5.6." On information and belief, patients, prescribers, and physicians will follow instructions in the ANDA Product label and will infringe at least claim 1 of the '382 patent. By submitting an ANDA with a label that, on information and belief, is the same as the Tymlos® (abaloparatide) label, Defendant

is knowingly inducing third parties to infringe at least claim 1 of the '382 patent. By filing an ANDA with a Paragraph IV Certification with respect to the '382 patent, Defendant has also committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Therefore, on information and belief, Defendant knowingly infringes, induces others to infringe, and/or contributes to third-party infringement of at least claim 1 of the '382 patent.

107. Upon information and belief, Defendant 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.

108. Upon information and belief, Defendant 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.

109. Upon information and belief, Defendant's 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 '382 patent claims under 35 U.S.C. § 271.

110. Upon information and belief, by commercially offering for sale and/or selling the ANDA Product in accordance with its label, Defendant would knowingly induce and/or contribute to third-party infringement of one or more claims of the '382 patent under 35 U.S.C. § 271.

111. Defendant had knowledge of the '382 patent since at least the time it filed ANDA No. 217245 with a Paragraph IV Certification and is knowingly infringing the '382 patent.

112. Defendant's statements of the factual and legal bases for its opinion regarding the non-infringement of the '382 patent contained in Defendant's Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

113. Defendant acted without a reasonable basis for believing that it would not be liable for infringing the '382 patent, actively inducing infringement of the '382 patent, and/or contributing to infringement by others of the '382 patent.

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

115. The acts of infringement of the '382 patent set forth above will cause Plaintiffs to suffer irreparable harm for which there is no adequate remedy at law, unless Defendant is preliminarily and permanently enjoined by this Court.

116. Plaintiffs are 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 '382 patent, or any later expiration of exclusivity for the '382 patent to which Plaintiffs are or may become entitled.

COUNT IV: INFRINGEMENT OF U.S. PATENT NO. 10,996,208

117. Plaintiff Radius repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

118. Upon information and belief, Defendant prepared ANDA No. 217245.

119. Defendant 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 '208 patent.

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

121. The ANDA Product is an abaloparatide product.

122. Defendant submitted ANDA No. 217245 with a Paragraph IV Certification to the '208 patent for the purpose of obtaining 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 '208 patent.

123. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

124. As of the date of the Notice Letter, Defendant was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

125. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Defendant sent a copy of the Notice Letter to Radius at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210, which was received on August 9, 2022. Defendant also sent a copy to Ipsen at 65 Quai Georges Corse, Boulogne-Billancourt 92100, France, which was received on August 9, 2022.

126. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission of ANDA No. 217245 with a Paragraph IV Certification to the '208 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '208

patent constitutes infringement of one or more claims of the '208 patent, including at least claim 14.

127. For example, claim 14 of the '208 patent claims "[a] formulated abaloparatide drug product comprising ≤5% w/w beta-Asp10 of the total peptide content, and an aqueous buffer having a pH from 4.5-5.5, wherein said formulated abaloparatide drug product has an abaloparatide concentration of between 1.8 mg/mL and 2.2 mg/mL, wherein the suitability of the formulated abaloparatide drug product for administration to a subject has been established by a method comprising: detecting and quantifying the presence of ≤5% w/w beta-Asp10 of the total peptide content in the formulated abaloparatide drug product." As set forth in Defendant's Notice Letter, the active ingredient in the ANDA Product is abaloparatide, i.e., "a synthetic 34 amino acid peptide with the amino acid sequence: Ala-Val-Ser-Glu-His-Gln-Leu-Leu-His-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[.]" The Notice Letter does not assert that the ANDA Product does not infringe multiple claims of the '208 patent, including, for example, claim 14.

128. Tymlos® (abaloparatide) embodies the formulated abaloparatide drug product claimed in at least claim 14 of the '208 patent. By its ANDA submission, Defendant 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 ≤5% w/w beta-Asp10 of the total peptide content, and an aqueous buffer having a pH from 4.5-5.5, wherein said formulated abaloparatide drug product has an abaloparatide concentration of between 1.8 mg/mL and 2.2 mg/mL, wherein the suitability of the formulated abaloparatide drug product for administration to a subject has been established by a method comprising: detecting and quantifying the presence of ≤5% w/w beta-Asp10 of the total

peptide content in the formulated abaloparatide drug product." By filing an ANDA with a Paragraph IV Certification with respect to the '208 patent, Defendant has committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Therefore, on information and belief, Defendant knowingly infringes at least claim 14 of the '208 patent.

129. Upon information and belief, Defendant 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.

130. Upon information and belief, Defendant 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.

131. Upon information and belief, Defendant's 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 '208 patent claims under 35 U.S.C. § 271.

132. Upon information and belief, by commercially offering for sale and/or selling the ANDA Product in accordance with its label, Defendant would knowingly induce and/or contribute to third-party infringement of one or more claims of the '208 patent under 35 U.S.C. § 271.

133. Defendant had knowledge of the '208 patent since at least the time it filed ANDA No. 217245 with a Paragraph IV Certification and is knowingly infringing the '208 patent.

134. Defendant's statements of the factual and legal bases for its opinion regarding the non-infringement of the '208 patent contained in Defendant's Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

135. Defendant acted without a reasonable basis for believing that it would not be liable for infringing the '208 patent, actively inducing infringement of the '208 patent, and/or contributing to infringement by others of the '208 patent.

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

137. The acts of infringement of the '208 patent set forth above will cause Radius to suffer irreparable harm for which there is no adequate remedy at law, unless Defendant is preliminarily and permanently enjoined by this Court.

138. Radius 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 '208 patent, or any later expiration of exclusivity for the '208 patent to which Radius is or may become entitled.

COUNT V: INFRINGEMENT OF U.S. PATENT NO. 11,255,842

139. Plaintiff Radius repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

140. Upon information and belief, Defendant prepared ANDA No. 217245.

141. Defendant 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 '842 patent.

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

143. The ANDA Product is an abaloparatide product.

144. Defendant submitted ANDA No. 217245 with a Paragraph IV Certification to the '842 patent for the purpose of obtaining 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 '842 patent.

145. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "[f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

146. As of the date of the Notice Letter, Defendant was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

147. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Defendant sent a copy of the Notice Letter to Radius at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210, which was received on August 9, 2022. Defendant also sent a copy to Ipsen at 65 Quai Georges Corse, Boulogne-Billancourt 92100, France, which was received on August 9, 2022.

148. Under 35 U.S.C. § 271(e)(2)(A), Defendant's submission of ANDA No. 217245 with a Paragraph IV Certification to the '842 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of the ANDA Product before the expiration of the '842

patent constitutes infringement of one or more claims of the '842 patent, including at least claim 1.

149. For example, claim 1 of the '842 patent claims "[a]n in vitro method for detecting the presence of neutralizing antibodies to abaloparatide in a sample from a subject treated with abaloparatide, the method comprising: obtaining the sample from a subject; contacting the sample with a population of cells or a cell, wherein the cell or cells comprise a receptor for abaloparatide; measuring cyclic adenosine monophosphate (cAMP) levels; and detecting the presence of neutralizing antibodies indicated by reduced cAMP levels." The Tymlos® (abaloparatide) label instructs, e.g., patients, prescribers, and physicians that there is potential for immunogenicity and the detection of antibody formation is highly dependent on the sensitivity and specificity of the assay. By its ANDA submission, Defendant has necessarily represented to the FDA that the ANDA Product will be the same as Tymlos® (abaloparatide). On information and belief, the ANDA Product label will instruct, e.g., patients, prescribers, and physicians to perform "[a]n in vitro method for detecting the presence of neutralizing antibodies to abaloparatide in a sample from a subject treated with abaloparatide, the method comprising: obtaining the sample from a subject; contacting the sample with a population of cells or a cell, wherein the cell or cells comprise a receptor for abaloparatide; measuring cyclic adenosine monophosphate (cAMP) levels; and detecting the presence of neutralizing antibodies indicated by reduced cAMP levels." On information and belief, patients, prescribers and physicians will follow instructions in the ANDA Product label and will infringe at least claim 1 of the '842 patent. By submitting an ANDA with a label that, on information and belief, is the same as the Tymlos® (abaloparatide) label, Defendant is knowingly inducing third parties to infringe at least claim 1 of the '842 patent. By filing an ANDA with a Paragraph IV Certification with respect to the '842 patent, Defendant has also

committed an act of infringement pursuant to 35 U.S.C. § 271(e)(2)(A). Therefore, on information and belief, Defendant knowingly infringes, induces others to infringe, and/or contributes to third-party infringement of at least claim 1 of the '842 patent.

150. Upon information and belief, Defendant 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.

151. Upon information and belief, Defendant 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.

152. Upon information and belief, by commercially offering for sale and/or selling the ANDA Product in accordance with its label Defendant would knowingly induce and/or contribute to third-party infringement of one or more claims of the '842 patent under 35 U.S.C. § 271.

153. Defendant had knowledge of the '842 patent since at least the time it filed ANDA No. 217245 with a Paragraph IV Certification and is knowingly infringing the '842 patent.

154. Defendant's statements of the factual and legal bases for its opinion regarding the non-infringement of the '842 patent contained in Defendant's Notice Letter are devoid of any objective good-faith basis in either the facts or the law.

155. Defendant acted without a reasonable basis for believing that it would not be liable for infringing the '842 patent, actively inducing infringement of the '842 patent, and/or contributing to infringement by others of the '842 patent.

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

157. The acts of infringement of the '842 patent set forth above will cause Radius to suffer irreparable harm for which there is no adequate remedy at law, unless Defendant is preliminarily and permanently enjoined by this Court.

158. Radius 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 '842 patent, or any later expiration of exclusivity for the '842 patent to which Radius is or may become entitled.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(A) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Defendant has infringed one or more claims of the '770, '333, '382, '208, and '842 patents 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 '770, '333, '382, '208, and '842 patents;

(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 before the expiration of the '770, '333, '382, '208, and '842 patents (including any regulatory extension), would directly and/or indirectly infringe the '770, '333, '382, '208, and '842 patents;

(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 '770, '333, '382, '208, and '842 patents (including any regulatory extension);

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

person in active concert or participation or privy with Defendant, 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 '770, '333, '382, '208, and '842 patents (including any regulatory extension);

(E) A judgment, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, awarding Plaintiffs damages or other monetary relief if Defendant commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of ANDA No. 217245, prior to the expiration of the '770, '333, '382, '208, and '842 patents (including any regulatory extension);

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

(G) A judgment declaring that the '770 patent is valid;

(H) A judgment declaring that the '333 patent is valid;

(I) A judgment declaring that the '382 patent is valid;

(J) A judgment declaring that the '208 patent is valid;

(K) A judgment declaring that the '842 patent is valid; and

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

PLAINTIFFS RADIUS HEALTH, INC. AND IPSEN PHARMA S.A.S.

By their Counsel,

Dated: September 20, 2022

/s/ Eric. J. Marandett

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