IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT MASSACHUSETTS

RADIUS HEALTH, INC. Plaintiff, v. ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED, CIPLA LIMITED, and CIPLA USA, INC. Defendant.	Civil Action No. 1:24-CV-11770-RGS

DEFENDANTS' ANSWER TO PLAINTIFF'S COMPLAINT

Orbicular Pharmaceutical Technologies Private Limited ("Orbicular"), Cipla Limited, and Cipla USA, Inc. (together "Cipla") (collectively "Defendants") answer and respond to the Complaint of Plaintiff Radius Health, Inc. ("Radius" or "Plaintiff") 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").

ANSWER:

Defendants admit the Complaint alleges this is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(A). Defendants admit this action relates to Abbreviated New Drug Application ("ANDA") No. 217245, filed by Orbicular with the United States Food and Drug Administration ("FDA") ("ANDA No. 217245" or "Orbicular's ANDA"). Defendants admit Orbicular filed its ANDA with the FDA seeking approval, for the matters described therein, prior to the expiration

of U.S. Patent No. 11,977,067 (the "'067 patent"). Defendants deny the remaining allegations in Paragraph 1 of the Complaint.

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.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 2 of the Complaint and, on that basis, deny them.

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.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 3 of the Complaint and, on that basis, deny them.

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.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 4 of the Complaint and, on that basis, deny them.

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.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 5 of the Complaint and, on that basis, deny them.

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.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to whether Radius is an owner and assignee of the '067 patent and deny this allegation on this basis. Defendants admit the FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") speaks for itself. Defendants deny infringement of the '067 patent and deny Radius is entitled to obtain any relief or alleged damages for alleged infringement of the Patent-in-Suit. Defendants deny the remaining allegations in Paragraph 6 of the Complaint.

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.

ANSWER:

Orbicular admits it is an India business entity with a place of business at P. No. 53, ALEAP Industrial Estate, Behind Pragati Nagar Kukatpally, Hyderabad, 500 090 Telangana, India. Whether Orbicular does or does not have a place of business in the United States is a conclusion

of law to which no response is required. To the extent a further response is required, Defendants deny the remaining allegations contained in Paragraph 7 of the Complaint.

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.

ANSWER:

Orbicular admits that, with respect to Orbicular's ANDA, pursuant to 21 C.F.R. § 314.95(c)(9) Orbicular designated Andrew J. Miller, Esq., Windels Marx Lane & Mittendorf, LLP, 1 Giralda Farms, Suite 100, Madison, New Jersey, 07940 (e-mail: amiller@windelsmarx.com) as an agent in the United States, authorized to accept service of process. Defendants deny the remaining allegations contained in Paragraph 8 of the Complaint.

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.

ANSWER:

Orbicular admits it manufactures and/or markets pharmaceutical products. Defendants deny the remaining allegations in Paragraph 9 of the Complaint.

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.

ANSWER:

Cipla Limited admits it is an Indian business entity with a place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013, Maharashtra,

India. To the extent a further response is required, Defendants deny the remaining allegations contained in Paragraph 10 of the Complaint.

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.

ANSWER:

Cipla USA Inc. admits that it is a Delaware corporation with a principal place of business at 10 Independence Boulevard, Suite 300, Warren, New Jersey 07059. To the extent a further response is required, Defendants deny the remaining allegations contained in Paragraph 11 of the Complaint.

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.

ANSWER:

Cipla admits it manufactures and/or markets pharmaceutical products. Defendants deny the remaining allegations in Paragraph 12 of the Complaint.

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]

ANSWER:

Orbicular admits it filed Orbicular's ANDA with the FDA seeking approval for the matters described therein and that Orbicular's ANDA is a document that speaks for itself. Orbicular admits

[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").

Orbicular's 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 U.S. Patent 7,803,770 ("the '770 patent"), and the '333, '382 and '208 patents. Orbicular admits that Plaintiff asserted infringement of these patents in the Related Litigation (Case No. 22-cv-11546-RGS, D. Mass.). Defendants deny the remaining allegations in Paragraph 13 of the Complaint.

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.

ANSWER:

Orbicular admits on April 12, 2024, in support of Orbicular's ANDA No. 217245, Orbicular submitted a Paragraph IV Certification to each of U.S. Patent Nos. 11,680,942 (the "'942 patent"), 11,782,041 (the "'041 patent"), and RE49,444 (the "'444 patent"). Defendants admit that the Paragraph IV Certification and the '444 patent are documents that speak for themselves. Defendants deny the remaining allegations in Paragraph 14 of the Complaint.

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

ANSWER:

Admitted.

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

ANSWER:

Orbicular admits its Paragraph IV Certification Notice Letter dated August 8, 2022 is a document that speaks for itself, that its Notice Letter was sent to Radius at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210 and to Ipsen, among others, and that its Notice Letter was received by Radius and Ipsen on August 9, 2022 and that the Complaint in the Related Litigation (Case No. 22-cv-11546-RGS, D. Mass.) was filed within 45 days of August 9, 2022. Defendants deny the remaining allegations in Paragraph 16 of the Complaint.

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.

ANSWER:

Orbicular admits its Paragraph IV Certification Notice Letter dated April 12, 2024 is a document that speaks for itself, that its Notice Letter was sent to Radius at 22 Boston Wharf Road, 7th Floor, Boston, Massachusetts 02210, and to Ipsen, among others. Defendants deny the remaining allegations in Paragraph 17 of the Complaint.

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.

ANSWER:

Orbicular admits it filed Orbicular's ANDA with the FDA seeking approval for the matters described therein and that Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 18 of the Complaint.

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.

ANSWER:

Defendants admit that Orbicular filed Orbicular's ANDA with the FDA seeking approval for the matters described therein, prior to the expiration of the '067 patent. Defendants deny the remaining allegations in Paragraph 19 of the Complaint.

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.

ANSWER:

Defendants admit that Orbicular filed Orbicular's ANDA with the FDA seeking approval of a generic version of Radius's Tymlos® (abaloparatide) in the United States. Defendants deny the remaining allegations in Paragraph 20 of the Complaint.

ALLEGATIONS OF 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.

ANSWER:

Defendants admit the Complaint alleges this is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, including 35 U.S.C. § 271(e)(2)(A), allegedly arising out of the submission of Orbicular's ANDA to the FDA. To the extent a further response is required, Defendants deny the remaining allegations in Paragraph 21 of the Complaint.

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

ANSWER:

Paragraph 22 of the Complaint contains legal conclusions to which no response is required. To the extent an answer is required, for purposes of this action only, Defendants do not contest subject matter jurisdiction in this Court. Defendants deny the remaining allegations of Paragraph 22 of the Complaint.

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.

ANSWER:

Paragraph 23 of the Complaint contains legal conclusions to which no response is required. Orbicular denies it has committed, induced, or contributed to acts of patent infringement with respect to the '067 patent. Orbicular admits it filed Orbicular's ANDA, a document that speaks for itself, with the FDA seeking approval, for the matters described therein, prior to the expiration of the '067 patent. To the extent any further response is required, for purposes of this action only, Orbicular does not contest personal jurisdiction in this Court. Defendants deny the remaining allegations of Paragraph 23 of the Complaint.

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.

ANSWER:

Paragraph 24 of the Complaint contains legal conclusions to which no response is required. Cipla denies it has committed, induced, or contributed to acts of patent infringement with respect to the '067 patent. Cipla admits that Orbicular filed Orbicular's ANDA, a document that speaks for itself, with the FDA seeking approval, for the matters described therein, prior to the expiration of the '067 patent. Cipla admits that it has an agreement with Orbicular with respect to ANDA No. 217245. To the extent any further response is required, for purposes of this action only, Cipla does not contest personal jurisdiction in this Court. Defendants deny the remaining allegations of Paragraph 24 of the Complaint.

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.

ANSWER:

Paragraph 25 of the Complaint contains legal conclusions to which no response is required. Defendants admit that Orbicular filed Orbicular's ANDA, a document that speaks for itself. To the extent any further response is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Defendants deny the remaining allegations of Paragraph 25 of the Complaint.

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.

ANSWER:

Paragraph 26 of the Complaint contains legal conclusions to which no response is required. Defendants admit that Orbicular filed Orbicular's ANDA, a document that speaks for itself. To the extent any further response is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Defendants deny the remaining allegations of Paragraph 26 of the Complaint.

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.

ANSWER:

Paragraph 27 of the Complaint contains legal conclusions to which no response is required. Defendants admit that Orbicular filed Orbicular's ANDA, a document that speaks for itself. To the extent any further response is required, for purposes of this action only, Defendants do not contest personal jurisdiction in this Court. Defendants deny the remaining allegations of Paragraph 27 of the Complaint.

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.

ANSWER:

Paragraph 28 of the Complaint contains legal conclusions to which no response is required. To the extent any further response is required, for purposes of this action only, Defendants do not

contest venue in this Court. Defendants deny the remaining allegations of Paragraph 28 of the Complaint.

ALLEGED FACTS AS TO ALL COUNTS

Allegations Regarding 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.

ANSWER:

Defendants deny Radius is entitled to obtain any relief or alleged damages for alleged infringement of the ’067 patent and deny Defendants are potential infringers of the ’067 patent. Defendants lack knowledge or information sufficient to form a belief as to the remaining allegations in Paragraph 29 and deny on this basis.

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

ANSWER:

Defendants deny the ’067 patent is valid or enforceable. Defendants lack knowledge or information sufficient to form a belief as to whether the ’067 patent has expired and deny on this basis. Defendants deny the remaining allegations in Paragraph 30 of the Complaint.

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

ANSWER:

Defendants admit the '067 patent is document that speaks for itself. Defendants deny the '067 patent was duly and legally issued. To the extent a further response is required, Defendants deny the remaining allegations in Paragraph 31 of the Complaint.

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

ANSWER:

Defendants admit that the Complaint purports to attach a copy of the '067 patent as Exhibit A.

Allegations Regarding 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.

ANSWER:

Defendants admit the FDA-approved Label for Tymlos® is a document that speaks for itself. To the extent a further response is required, Defendants deny the remaining allegations in Paragraph 33 of the Complaint.

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.

ANSWER:

Defendants admit the FDA-approved Label for Tymlos® is a document that speaks for itself. To the extent a further response is required, Defendants deny the remaining allegations in Paragraph 34 of the Complaint.

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

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 35 of the Complaint and, on that basis, deny them.

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

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 36 of the Complaint and, on that basis, deny them.

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

ANSWER:

Defendants admit that the '067 patent is a document that speaks for itself. To the extent a further response is required, Defendants deny the remaining allegations in Paragraph 37 of the Complaint.

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

ANSWER:

Defendants admit on information and belief as of the date the Complaint was filed that the '067 patent was listed in the FDA's Orange Book in conjunction with NDA No. 208743. Defendants deny the remaining allegations in Paragraph 38 of the Complaint.

Allegations Regarding 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.

ANSWER:

Orbicular admits its First Notice Letter regarding Orbicular's ANDA, dated August 8, 2022 and signed by Louis H. Weinstein of the law firm Windels Marx Lane & Mittendorf, LLP as outside counsel for Defendant, is a document that speaks for itself, that it was sent pursuant to at least § 505(j)(2)(B)(ii) and § 505(j)(2)(B)(iv) of the FD&C Act and 21 C.F.R. § 314.95, that its Notice Letter was sent to Defendants and that its Notice Letter was received by Defendants on August 9, 2022. Defendants deny the remaining allegations in Paragraph 39 of the Complaint.

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.

ANSWER:

Paragraph 40 of the Complaint contains legal conclusions to which no response is required. Defendants admit that Radius and Ipsen filed the initial Complaint in the Related Litigation on September 20, 2022. To the extent a further response is required, Defendants deny the remaining allegations in Paragraph 40 of the Complaint.

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.

ANSWER:

Paragraph 41 of the Complaint contains legal conclusions to which no response is required. Defendants admit that Radius and Ipsen filed a First Amended Complaint in the Related Litigation on April 17, 2023. To the extent a further response is required, Defendants deny the remaining allegations in Paragraph 41 of the Complaint.

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").

ANSWER:

Paragraph 42 of the Complaint contains legal conclusions to which no response is required. Defendants admit that Radius and Ipsen filed a Second Amended Complaint in the Related Litigation on November 2, 2023. Defendants admit that the '041 patent is a document that speaks for itself. To the extent a further response is required, Defendants deny the remaining allegations in Paragraph 42 of the Complaint.

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.

ANSWER:

Orbicular admits its Notice Letter dated April 12, 2024 is a document that speaks for itself, that its Notice Letter was sent in accordance with § 505(j)(2)(B)(ii) and § 505(j)(2)(B)(iv) of the FD&C Act and 21 C.F.R. § 314.95, and that Ajay Kayal of the law firm Windels Marx Lane & Mittendorf, LLP on behalf of Orbicular. Defendants deny the remaining allegations in Paragraph 43 of the Complaint.

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.

ANSWER:

Orbicular admits its Paragraph IV Certification Notice Letters dated August 8, 2022 and April 12, 2024 are documents that speak for themselves. Defendants deny the remaining allegations in Paragraph 44 of the Complaint.

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.

ANSWER:

Orbicular admits its Paragraph IV Certification Notice Letters dated August 8, 2022 and April 12, 2024 are documents that speak for themselves. Defendants deny the remaining allegations in Paragraph 45 of the Complaint.

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®.

ANSWER:

Defendants admit that counsel for Radius informed counsel for Defendants of the application that led to the '067 patent prior to its issuance. Defendants deny they are infringing the '067 patent, knowingly or otherwise. Defendants deny the remaining allegations of Paragraph 46 of the Complaint.

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).

ANSWER:

Defendants admit Orbicular filed Orbicular's ANDA with the FDA seeking approval for the matters described therein and that Orbicular's ANDA is a document that speaks for itself. To the extent the allegations of Paragraph 47 of the Complaint are consistent with Orbicular's ANDA

Defendants admit those allegations. Defendants deny the remaining allegations in Paragraph 47 of the Complaint.

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

ANSWER:

Defendants admit that Orbicular's First and Second Notice Letters are documents that speak for themselves, and that among other statements they state: "The active ingredient present in Orbicular's proposed product is 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-NH2, commonly known as abaloparatide and the dosage form is an injection solution for subcutaneous use." Defendants deny the remaining allegations in Paragraph 48 of the Complaint.

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

ANSWER:

Defendants admit that the proposed Label in Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 49 of the Complaint.

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

ANSWER:

Defendants admit that the proposed Label in Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 50 of the Complaint.

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

ANSWER:

Defendants admit that the proposed Label in Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 51of the Complaint.

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.

ANSWER:

Defendants admit that the proposed Label in Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 52 of the Complaint.

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.

ANSWER:

Defendants lack knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 53 of the Complaint and, on that basis, deny them.

Allegations Regarding 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.

ANSWER:

Defendants admit that the License & Supply Agreement between Orbicular and Cipla USA, Inc. pertaining to the ANDA No. 217245 is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 54 of the Complaint.

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

ANSWER:

Defendants admit that the License & Supply Agreement between Orbicular and Cipla USA, Inc. pertaining to the ANDA No. 217245 is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 55 of the Complaint.

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.

ANSWER:

Defendants admit that the License & Supply Agreement between Orbicular and Cipla USA, Inc. pertaining to the ANDA No. 217245 is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 56 of the Complaint.

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).

ANSWER:

Denied.

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.

ANSWER:

Defendants repeats and re-alleges their Answers to each of the foregoing Paragraphs as if fully set forth herein.

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

ANSWER:

Defendants admit Orbicular filed Orbicular's ANDA with the FDA seeking approval for the matters described therein and that Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 59 of the Complaint.

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.

ANSWER:

Defendants admit Orbicular filed Orbicular's ANDA with the FDA seeking approval for the matters described therein and that Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 60 of the Complaint.

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

ANSWER:

Defendants admit Orbicular filed Orbicular's ANDA with the FDA seeking approval for the matters described therein and that Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 61 of the Complaint.

62. The ANDA Product is an abaloparatide product.

ANSWER:

Defendants admit Orbicular filed Orbicular's ANDA with the FDA seeking approval for the matters described therein and that Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 62 of the Complaint.

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.

ANSWER:

Defendants admit Orbicular filed Orbicular's ANDA with the FDA seeking approval for the matters described therein before the expiration of the '067 patent and that Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 63 of the Complaint.

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.

ANSWER:

Paragraph 64 of the Complaint contains legal conclusions to which no response is required. To the extent an answer is required, Defendants deny infringement of any valid claim of the '067 patent. Defendants deny the remaining allegations of Paragraph 64 of the Complaint.

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."

ANSWER:

Defendants admit that the '067 patent is a document that speaks for itself. Defendants deny the remaining allegations of Paragraph 65 of the Complaint.

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.

ANSWER:

Defendants admit that the '067 patent and Orbicular's ANDA are documents that speak for themselves. Defendants deny infringement of any valid claim of the '067 patent. Defendants deny the remaining allegations of Paragraph 66 of the Complaint.

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.

ANSWER:

Defendants admit Orbicular filed Orbicular's ANDA with the FDA seeking approval for the matters described therein and that Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 67 of the Complaint.

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.

ANSWER:

Defendants admit Orbicular filed Orbicular's ANDA with the FDA seeking approval for the matters described therein and that Orbicular's ANDA is a document that speaks for itself. Defendants deny the remaining allegations in Paragraph 68 of the Complaint.

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.

ANSWER:

Denied.

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.

ANSWER:

Denied.

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.

ANSWER:

Defendants admit that counsel for Radius informed counsel for Defendants of the application that led to the '067 patent prior to its issuance. Defendants deny they are infringing the '067 patent, knowingly or otherwise. Defendants deny the remaining allegations of Paragraph 71 of the Complaint.

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.

ANSWER:

Denied.

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

ANSWER:

Denied.

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.

ANSWER:

Denied.

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.

ANSWER:

Denied.

GENERAL DENIAL

Defendants deny each allegation of the Complaint not expressly admitted.

DEFENDANTS' RESPONSE TO PLAINTIFF'S PRAYER FOR RELIEF

Defendants deny that Plaintiff is entitled to any relief sought in Plaintiff's Prayer for Relief.

DEFENDANTS' SEPARATE DEFENSES

Without prejudice to the admissions and denials set forth in its Answer, and without admitting any allegations of the Complaint not expressly admitted, Defendants assert the following separate defenses to the Complaint without assuming the burden of proof on any such defense that would otherwise rest with Plaintiff.

FIRST SEPARATE DEFENSE
(Non-infringement of the '067 Patent)

Defendants have not infringed, are not infringing and will not infringe any valid claim of the '067 patent.

SECOND SEPARATE DEFENSE
(Invalidity of the '067 Patent)

Each and every claim of the '067 patent is invalid for failure to comply with at least 35 U.S.C. §§ 101, 102, 103 and/or 112.

THIRD SEPARATE DEFENSE
(Failure to State a Claim)

The Complaint, in whole or in part, fails to state a claim upon which relief can be granted.

FOURTH SEPARATE DEFENSE
(Additional Defenses)

Defendants reserve the right to present any additional defenses or counterclaims that discovery may reveal.

DEFENDANTS' PRAYER FOR RELIEF

Defendants respectfully request that this Court enter judgment in its favor and against Plaintiff as follows:

A. Dismissing the Complaint with prejudice, denying each and every request for relief in Items (A) to (H) of Plaintiff's Prayer for Relief, and that Plaintiff takes nothing thereby;

B. Finding that each and every claim of the '067 patent is invalid;

C. Finding that each and every claim of the '067 patent was not, is not and will not be infringed by Defendants;

D. Declaring that Plaintiff is not entitled to any injunctive remedy for any of the '067 patent;

E. Awarding Defendants their costs and expenses in this action;

F. Declaring that this case is exceptional under 35 U.S.C. § 285, and awarding to Defendants their reasonable attorneys' fees; and

G. Awarding to Defendants such further relief this Court may deem just, proper, or equitable.

Dated: September 6, 2024

Respectfully submitted,

ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED,
By and through its attorneys,

/s/ Catherine Rajwani
Catherine Rajwani, Esq. (BBO# 674443)

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Application for Admission Pro Hac Vice to be filed
Attorneys for Defendants Orbicular Pharmaceutical Technologies Private Limited

CERTIFICATE OF SERVICE

I hereby certify that the foregoing document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing.

/s/ Catherine Rajwani
Catherine Rajwani