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

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| DERMIRA, INC. and ROSE U, LLC,<br><br>Plaintiffs,<br><br>v.<br><br>PERRIGO PHARMA INTERNATIONAL DAC,<br><br>Defendant. | C.A. No. 1:20-cv-01413-CFC |

**ANSWER AND SEPARATE DEFENSES OF DEFENDANT PERRIGO PHARMA INTERNATIONAL DAC TO PLAINTIFFS' COMPLAINT AND COUNTERCLAIMS**

Defendant Perrigo Pharma International DAC ("Perrigo" or "Defendant") by and through the undersigned attorneys, hereby answers the Complaint of Dermira, Inc. ("Dermira") and Rose U, LLC ("Rose") (collectively, "Plaintiffs") as follows:

## NATURE OF THE ACTION

**COMPLAINT:**

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the submission by defendant Perrigo Pharma International DAC ( "Perrigo") of an Abbreviated New Drug Application ("ANDA") No. 214448 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell a Glycopyrronium, Cloth, 2.4% product ("Perrigo's ANDA Product") prior to the expiration of U.S. Patent Nos. 8,618,160 ("the '160 patent"); 9,744,105 ("the '105 patent"); 10,052,267 ("the '267 patent"); 8,859,610 ("the '610 patent"); 9,259,414 ("the '414 patent"); 10,004,717 ("the '717 patent"); 10,543,192 ("the '192 patent"); and 10,548,875 ("the '875 patent") (collectively "the Asserted Patents"). Perrigo notified Plaintiffs that it had submitted this ANDA by letters dated September 8, 2020 and September 23, 2020 (each a "Notice Letter" and collectively the "Notice Letters"). Upon information and belief, Perrigo's ANDA Product will be marketed as a competing product to Qbrexza®, a product developed by Plaintiffs for the treatment of hyperhidrosis.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Plaintiffs' Complaint is for

alleged patent infringement of U.S. Patent Nos. 8,618,160 ("the '160 patent"); 9,744,105 ("the '105 patent"); 10,052,267 ("the '267 patent"); 8,859,610 ("the '610 patent"); 9,259,414 ("the '414 patent"); 10,004,717 ("the '717 patent"); 10,543,192 ("the '192 patent"); and 10,548,875 ("the '875 patent"), but denies that Plaintiffs are entitled to any relief. Answering further, Perrigo admits that Perrigo submitted Abbreviated New Drug Application ("ANDA") No. 214448 to the U.S. Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications") to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo further admits that the reference listed drug ("RLD") identified in Perrigo's ANDA No. 214448 is Qbrexza® (glycopyrronium), Cloth, 2.4%. Perrigo further admits that by letters dated September 8, 2020 and September 23, 2020, Perrigo gave written notification to, *inter alia*, Plaintiffs, pursuant to 21 U.S.C. § 355(j)(2)(B), of the paragraph IV certifications contained in Perrigo's ANDA. Perrigo denies the remaining allegations contained in this paragraph.

## PARTIES

**COMPLAINT:**

2. Dermira, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its corporate offices and place of business at 275 Middlefield Road, Suite 150, Menlo Park, CA 94025. Dermira is a wholly-owned subsidiary of Eli Lilly and Company.

**ANSWER:** On information and belief, admitted.

**COMPLAINT:**

3. Rose U, LLC is a limited liability company organized and existing under the laws of California, having its place of business at 41 Deep Well Lane, Los Altos, CA 94022.

**ANSWER:** On information and belief, admitted.

**COMPLAINT:**

4. Upon information and belief, Perrigo is a corporation organized and existing under the laws of The Republic of Ireland, having a place of business at Treasury Building, Lower Grand Canal Street Dublin, 2 Ireland.

**ANSWER:** Perrigo admits that Perrigo is an Irish corporation with a place of business at The Shar Building, Hogan Place, Dublin, 2 Ireland. Perrigo denies the remaining allegations contained in this paragraph.

## JURISDICTION AND VENUE

**COMPLAINT:**

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

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Plaintiffs' Complaint is for alleged patent infringement and for declaratory judgment of alleged patent infringement, but denies that Plaintiffs are entitled to any relief. Answering further, Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims with respect to the '160, '105, '267, '610, '414, '717, '192, and '875 patents against Perrigo under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only.

**COMPLAINT:**

6. Upon information and belief, Perrigo is engaged in developing, manufacturing, marketing, selling, and distributing a broad range of generic pharmaceutical products globally. Upon information and belief, a substantial number of these products are marketed throughout the United States, including in the State of Delaware. Upon information and belief, Perrigo operates its manufacturing, marketing, sales, and distribution infrastructure in the United States either itself or via corporate parents, subsidiaries, and affiliates as a vertically integrated company.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Perrigo does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only.

**COMPLAINT:**

7. Upon information and belief, Perrigo has availed itself of the legal protections of the State of Delaware by filing claims or counterclaims affirmatively seeking relief in other prior actions in this Court, including *Anacor Pharm., Inc. v. Ascent Pharm., Inc., Perrigo PLC et al*, 18-1673-RGA (D. Del.). In that case, Perrigo affirmatively filed counterclaims, asking this court to adjudicate the infringement issues with respect to certain patents asserted in that litigation. Thus, upon information and belief, Perrigo has in the past consented to the jurisdiction of this Court.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo was a named defendant in the complaint filed in Civil Action No. 18-1673-RGA in this Judicial District; and that Perrigo filed counterclaims in Civil Action No. 18-1673-RGA in this Judicial District. Answering further, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

8. Upon information and belief, Perrigo regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Perrigo does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only.

**COMPLAINT:**

9. Upon information and belief, Perrigo has sought approval in ANDA No. 214448 to distribute Perrigo's ANDA Product in the United States, including in Delaware and will do so upon approval of ANDA No. 214448. The filing of ANDA No. 214448 is therefore tightly tied, in purpose and planned effect, to the deliberate making of sales in Delaware, and reliably indicates that Perrigo plans to engage in the marketing of Perrigo's ANDA Product in this State.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only. Perrigo further states that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

10. Upon information and belief, with knowledge of the processes described in the Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 355(b) and the Drug Price Competition and Patent Term Restoration Act of 1984, 21 U.S.C. § 355(j) (the "Hatch Waxman Act"), Perrigo directed its Notice Letters to Plaintiffs, one of which is an entity incorporated in Delaware, and alleged in the Notice Letters the invalidity, unenforceability, and/or non-infringement of the Asserted Patents. Upon information and belief, Perrigo deliberately challenged Plaintiffs' patent rights, and knew when it did so that it was triggering a forty-five-day period for Plaintiffs to bring an action for patent infringement under the FDCA.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. Perrigo admits that Perrigo's ANDA No. 214448 contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717,

'192, and '875 patents. Perrigo further admits that by letters dated September 8, 2020 and September 23, 2020, Perrigo gave written notification to, *inter alia*, Plaintiffs, pursuant to 21 U.S.C. § 355(j)(2)(B), of the paragraph IV certifications contained in Perrigo's ANDA. Perrigo further admits that Perrigo's September 8, 2020 Notice Letter states, in part: "[T]he '160 patent, the '105 patent, the '267 patent, the '610 patent, the '414 patent, and the '717 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or importation of the drug product described in Perrigo's ANDA." Answering further, Perrigo admits that Perrigo's September 23, 2020 Notice Letter states, in part: "[T]he '192 patent and the '875 patent are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, sale, or importation of the drug product described in Perrigo's ANDA." Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

11. Because one of Plaintiffs is incorporated in Delaware, the injury and consequences of Perrigo's filing of ANDA No. 214448, challenging Plaintiffs' patent rights, are suffered in Delaware. Upon information and belief, Perrigo knew that it was deliberately challenging the patent rights of a Delaware entity and seeking to challenge intellectual property held in Delaware and that the effects of any successful challenge of the Asserted Patents would be felt by Plaintiffs in Delaware.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Perrigo does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only.

**COMPLAINT:**

12. Upon information and belief, if the ANDA No. 214448 is approved, Perrigo will directly or indirectly market and/or sell Perrigo's ANDA Product within the United States, including in Delaware, consistent with Perrigo's practices for the marketing and distribution of other pharmaceutical products on its own or through its affiliates. Upon information and belief, Perrigo and/or its affiliates regularly do business in Delaware, and their practices with other

pharmaceutical products have involved the distribution of Perrigo products, directly or indirectly, throughout the United States, including in Delaware. Upon information and belief, Perrigo's pharmaceutical products are used and/or consumed within and throughout the United States, including Delaware.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Perrigo states that Perrigo does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only. Perrigo further states that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

13. Upon information and belief, Perrigo and its affiliates derive substantial revenue from pharmaceutical products that are used and/or consumed within Delaware, and which are manufactured by Perrigo or its affiliates and/or for which Perrigo is the named applicant on approved ANDAs. Upon information and belief, various products for which Perrigo, or its affiliates, is the named applicant on approved ANDAs are available at pharmacies in Delaware.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Perrigo does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only.

**COMPLAINT:**

14. Upon information and belief, if ANDA No. 214448 is approved, Perrigo's ANDA Product, under the direction and control of physicians practicing in Delaware, will be administered to patients of Delaware. These activities, as well as Perrigo's marketing, selling, and/or distributing of Perrigo's ANDA Product, would have a substantial effect within Delaware and

would constitute infringement of the Asserted Patents in the event that Perrigo's ANDA Product is approved before the Asserted Patents expire.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Perrigo does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only.

**COMPLAINT:**

15. For the reasons described above, among others, the filing of ANDA No. 214448 was suit-related conduct with a substantial connection to Delaware and this District, the exercise of personal jurisdiction over Perrigo does not offend traditional notions of fair play and substantial justice, and this Court may properly exercise personal jurisdiction over Perrigo.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Perrigo does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only.

**COMPLAINT:**

16. Alternatively, if the exercise of personal jurisdiction over Perrigo in this Court is not held to be proper, then, upon information and belief, Perrigo is not subject to jurisdiction in any state's courts of general jurisdiction, and there is therefore personal jurisdiction over Perrigo in this Court pursuant to Fed. R. Civ. P. 4(k)(2).

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Perrigo does not contest personal jurisdiction in the District of Delaware solely for the limited purpose of this action only.

**COMPLAINT:**

17. Upon information and belief and based on the foregoing, Perrigo is a foreign entity subject to this Court's personal jurisdiction and is, therefore, a resident of this District for purposes of venue. As a result, venue is proper in this District.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied. Answering further, Perrigo does not contest venue in the District of Delaware solely for the limited purpose of this action only.

**BACKGROUND**

**COMPLAINT:**

18. Qbrexza® is indicated for the topical treatment of primary axillary hyperhidrosis in certain patient populations.

**ANSWER:** Perrigo admits that, according to the approved label for Qbrexza® (glycopyrronium) Cloth, 2.4%, available from the online records of FDA:

> Qbrexza is an anticholinergic indicated for topical treatment of primary axillary hyperhidrosis in adults and pediatric patients 9 years of age and older (1).

Perrigo denies the remaining allegations of this paragraph.

**COMPLAINT:**

19. Dermira, Inc. sells Qbrexza® in the United States pursuant to NDA No. 210361 that has been approved by the FDA.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to FDA's online records, "DERMIRA INC" is the holder of New Drug Application ("NDA") No. 210361 for Qbrexza® (glycopyrronium tosylate) Topical Cloth, eq. 2.4% base, and "Jun 28, 2018" is identified as the "Approval Date" for NDA No. 210361. Answering further, on information and

belief, Dermira sells a glycopyrronium tosylate product under the trade name Qbrexza® (glycopyrronium) Cloth, 2.4%. Perrigo denies the remaining allegations of this paragraph.

**COMPLAINT:**

20. The ’160 patent, titled “Topical Glycopyrrolate Formulations,” was duly and legally issued on December 31, 2013. A copy of the ’160 patent is attached as Exhibit A,

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the U.S. Patent & Trademark Office (“USPTO”), the ‘160 patent is entitled “TOPICAL GLYCOPYRROLATE FORMULATIONS,” and issued on December 31, 2013. Perrigo denies any suggestion that the ‘160 patent was duly and legally issued, as well as any suggestion or implication that the ‘160 patent is valid or enforceable or that Perrigo infringes any claim of the ‘160 patent. Answering further, what purports to be a copy of the ‘160 patent is attached to Plaintiffs’ Complaint as Exhibit A. Perrigo denies the remaining allegations of this paragraph.

**COMPLAINT:**

21. Rose U, LLC is the assignee of the ’160 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, Rose U is the current assignee of the ‘160 patent. Perrigo denies any suggestion that the ‘160 patent was duly and legally issued, as well as any suggestion or implication that the ‘160 patent is valid or enforceable or that Perrigo infringes any claim of the ‘160 patent. Perrigo denies any remaining allegations of this paragraph.

**COMPLAINT:**

22. Dermira, Inc. is the exclusive licensee of the ’160 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo is without sufficient knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies same.

**COMPLAINT:**

23. An actual case or controversy exists between Plaintiffs and Perrigo with respect to infringement of the ’160 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs’ infringement claims with respect to the ‘160 patent against Perrigo under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only.

**COMPLAINT:**

24. The ’105 patent, titled “Topical Glycopyrrolate Formulations,” was duly and legally issued on August 29, 2017. A copy of the ’105 patent is attached as Exhibit B,

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, the ‘105 patent is entitled “TOPICAL GLYCOPYRROLATE FORMULATIONS,” and issued on August 29, 2017. Perrigo denies any suggestion that the ‘105 patent was duly and legally issued, as well as any suggestion or implication that the ‘105 patent is valid or enforceable or that Perrigo infringes any claim of the ‘105 patent. Answering further, what purports to be a copy of the ‘105 patent is attached to Plaintiffs’ Complaint as Exhibit B. Perrigo denies the remaining allegations of this paragraph.

**COMPLAINT:**

25. Rose U, LLC is the assignee of the '105 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, Rose is the current assignee of the '105 patent. Perrigo denies any suggestion that the '105 patent was duly and legally issued, as well as any suggestion or implication that the '105 patent is valid or enforceable or that Perrigo infringes any claim of the '105 patent. Perrigo denies any remaining allegations of this paragraph.

**COMPLAINT:**

26. Dermira, Inc. is the exclusive licensee of the '105 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo is without sufficient knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies same.

**COMPLAINT:**

27. An actual case or controversy exists between Plaintiffs and Perrigo with respect to infringement of the '105 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims with respect to the '105 patent against Perrigo under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only.

**COMPLAINT:**

28. The ’267 patent, titled “Topical Glycopyrrolate Formulations,” was duly and legally issued on August 21, 2018. A copy of the ’267 patent is attached as Exhibit C,

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, the ‘267 patent is entitled “TOPICAL GLYCOPYRROLATE FORMULATIONS,” and issued on August 21, 2018. Perrigo denies any suggestion that the ‘267 patent was duly and legally issued, as well as any suggestion or implication that the ‘267 patent is valid or enforceable or that Perrigo infringes any claim of the ‘267 patent. Answering further, what purports to be a copy of the ‘267 patent is attached to Plaintiffs’ Complaint as Exhibit C. Perrigo denies the remaining allegations of this paragraph.

**COMPLAINT:**

29. Rose U, LLC is the assignee of the ’267 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, Rose is the current assignee of the ‘267 patent. Perrigo denies any suggestion that the ‘267 patent was duly and legally issued, as well as any suggestion or implication that the ‘267 patent is valid or enforceable or that Perrigo infringes any claim of the ‘267 patent. Perrigo denies any remaining allegations of this paragraph.

**COMPLAINT:**

30. Dermira, Inc. is the exclusive licensee of the ’267 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo is without sufficient knowledge to admit or deny the remaining allegations of this paragraph, and therefore denies same.

**COMPLAINT:**

31. An actual case or controversy exists between Plaintiffs and Perrigo with respect to infringement of the '267 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims with respect to the '267 patent against Perrigo under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only.

**COMPLAINT:**

32. The '610 patent, titled "Crystalline Glycopyrrolate Tosylate," was duly and legally issued on October 14, 2014. A copy of the '610 patent is attached as Exhibit D,

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, the '610 patent is entitled "CRYSTALLINE GLYCOPYRROLATE TOSYLATE," and issued on October 14, 2014. Perrigo denies any suggestion that the '610 patent was duly and legally issued, as well as any suggestion or implication that the '610 patent is valid or enforceable or that Perrigo infringes any claim of the '610 patent. Answering further, Perrigo states that what appears to be an incomplete copy of the '610 patent is attached to Plaintiffs' Complaint as Exhibit D. Perrigo denies the remaining allegations of this paragraph.

**COMPLAINT:**

33. Dermira, Inc. is the assignee of the '610 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, Dermira is the current assignee of the '610 patent. Perrigo denies any suggestion that the '610 patent was duly and legally issued, as well as any suggestion or

implication that the '610 patent is valid or enforceable or that Perrigo infringes any claim of the '610 patent. Perrigo denies any remaining allegations of this paragraph.

**COMPLAINT:**

34. An actual case or controversy exists between Dermira, Inc. and Perrigo with respect to infringement of the '610 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims with respect to the '610 patent against Perrigo under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only.

**COMPLAINT:**

35. The '414 patent, titled "Glycopyrrolate Salts," was duly and legally issued on February 16, 2016. A copy of the '414 patent is attached as Exhibit E,

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, the '414 patent is entitled "GLYCOPYRROLATE SALTS," and issued on February 16, 2016. Perrigo denies any suggestion that the '414 patent was duly and legally issued, as well as any suggestion or implication that the '414 patent is valid or enforceable or that Perrigo infringes any claim of the '414 patent. Answering further, what purports to be a copy of the '414 patent is attached to Plaintiffs' Complaint as Exhibit E. Perrigo denies the remaining allegations of this paragraph.

**COMPLAINT:**

36. Dermira, Inc. is the assignee of the '414 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online

records of the USPTO, Dermira is the current assignee of the '414 patent. Perrigo denies any suggestion that the '414 patent was duly and legally issued, as well as any suggestion or implication that the '414 patent is valid or enforceable or that Perrigo infringes any claim of the '414 patent. Perrigo denies any remaining allegations of this paragraph.

**COMPLAINT:**

37. An actual case or controversy exists between Dermira, Inc. and Perrigo with respect to infringement of the '414 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims with respect to the '414 patent against Perrigo under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only.

**COMPLAINT:**

38. The '717 patent, titled "Glycopyrrolate Salts," was duly and legally issued on June 26, 2018. A copy of the '717 patent is attached as Exhibit F,

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, the '717 patent is entitled "GLYCOPYRROLATE SALTS," and issued on June 26, 2018. Perrigo denies any suggestion that the '717 patent was duly and legally issued, as well as any suggestion or implication that the '717 patent is valid or enforceable or that Perrigo infringes any claim of the '717 patent. Answering further, what purports to be a copy of the '717 patent is attached to Plaintiffs' Complaint as Exhibit F. Perrigo denies the remaining allegations of this paragraph.

**COMPLAINT:**

39. Dermira, Inc. is the assignee of the ’717 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, Dermira is the current assignee of the ‘717 patent. Perrigo denies any suggestion that the ‘717 patent was duly and legally issued, as well as any suggestion or implication that the ‘717 patent is valid or enforceable or that Perrigo infringes any claim of the ‘717 patent. Perrigo denies any remaining allegations of this paragraph.

**COMPLAINT:**

40. An actual case or controversy exists between Dermira, Inc. and Perrigo with respect to infringement of the ’717 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs’ infringement claims with respect to the ‘717 patent against Perrigo under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only.

**COMPLAINT:**

41. The ’192 patent, titled “Glycopyrrolate Salts,” was duly and legally issued on January 28, 2020. A copy of the ’192 patent is attached as Exhibit G,

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, the ‘192 patent is entitled “GLYCOPYRROLATE SALTS,” and issued on January 28, 2020. Perrigo denies any suggestion that the ‘192 patent was duly and legally issued, as well as any suggestion or implication that the ‘192 patent is valid or enforceable or that Perrigo infringes any claim of the ‘192 patent. Answering further, what purports to be a copy of

the '192 patent is attached to Plaintiffs' Complaint as Exhibit G. Perrigo denies the remaining allegations of this paragraph.

**COMPLAINT:**

42. Dermira, Inc. is the assignee of the '192 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, Dermira is the current assignee of the '192 patent. Perrigo denies any suggestion that the '192 patent was duly and legally issued, as well as any suggestion or implication that the '192 patent is valid or enforceable or that Perrigo infringes any claim of the '192 patent. Perrigo denies any remaining allegations of this paragraph.

**COMPLAINT:**

43. An actual case or controversy exists between Dermira, Inc. and Perrigo with respect to infringement of the '192 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims with respect to the '192 patent against Perrigo under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only.

**COMPLAINT:**

44. The '875 patent, titled "Glycopyrrolate Salts," was duly and legally issued on February 4, 2020. A copy of the '875 patent is attached as Exhibit H,

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, the '875 patent is entitled "GLYCOPYRROLATE SALTS," and issued on February 4, 2020. Perrigo denies any suggestion that the '875 patent was duly and legally

issued, as well as any suggestion or implication that the '875 patent is valid or enforceable or that Perrigo infringes any claim of the '875 patent. Answering further, what purports to be a copy of the '875 patent is attached to Plaintiffs' Complaint as Exhibit H. Perrigo denies the remaining allegations of this paragraph.

**COMPLAINT:**

45. Dermira, Inc. is the assignee of the '875 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that, according to the online records of the USPTO, Dermira is the current assignee of the '875 patent. Perrigo denies any suggestion that the '875 patent was duly and legally issued, as well as any suggestion or implication that the '875 patent is valid or enforceable or that Perrigo infringes any claim of the '875 patent. Perrigo denies any remaining allegations of this paragraph.

**COMPLAINT:**

46. An actual case or controversy exists between Dermira, Inc. and Perrigo with respect to infringement of the '875 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that this Court has subject matter jurisdiction over Plaintiffs' infringement claims with respect to the '875 patent against Perrigo under 35 U.S.C. § 271(e)(2)(A) for purposes of this action only.

**COMPLAINT:**

47. Plaintiffs received Perrigo's first Notice Letter on September 9, 2020. This action is being filed within 45 days of Plaintiffs' receipt of Perrigo's first Notice Letter.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. Perrigo admits that Perrigo's ANDA No. 214448 contains paragraph IV certifications

to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo further admits that by letters dated September 8, 2020 and September 23, 2020, Perrigo gave written notification to, *inter alia*, Plaintiffs, pursuant to 21 U.S.C. § 355(j)(2)(B), of the paragraph IV certifications contained in Perrigo's ANDA. Answering further, Perrigo admits that according to the online records of this judicial District, Plaintiffs filed the instant action on October 21, 2020. Perrigo denies the remaining allegations contained in this paragraph.

**COUNT I**
**(Infringement of the '160 Patent)**

**COMPLAINT:**

48. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

**COMPLAINT:**

49. Claim 1 of the '160 patent covers "[a]n individually packaged wipe for the treatment of hyperhidrosis comprising about 0.25 to about 6% w/w of a glycopyrrolate compound, a buffering agent, and an alcohol and water in a weight ratio of about 50:50 to about 70:30, wherein said wipe is individually packaged and contained within a pouch resistant to leakage and the glycopyrrolate compound degrades by less than 0.5% when stored at 40° C. for 3 months, wherein the buffering agent maintains a pH at about 4.5, and wherein the buffering agent is at about 10 mM to about 20 mM."

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '160 patent contains the following claim:

> 1. An individually packaged wipe for the treatment of hyperhidrosis comprising about 0.25 to about 6% w/w of a glycopyrrolate compound, a buffering agent, and an alcohol and water in a weight ratio of about 50:50 to about 70:30, wherein said wipe is individually packaged and contained within a pouch resistant to leakage and the glycopyrrolate compound degrades by less than 0.5% when stored at 40° C. for 3 months, wherein the buffering agent maintains a pH at about 4.5, and wherein the buffering agent is at about 10 mM to about 20 mM.

Perrigo denies the remaining allegations of this paragraph, including that the '160 patent was legally issued, as well as any suggestion or implication that the '160 patent claims are valid or enforceable or that Perrigo infringes one or more claims of the '160 patent.

**COMPLAINT:**

50. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '160 patent, including at least claim 1.

**ANSWER:** Denied.

**COMPLAINT:**

51. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more claims of the '160 patent, including at least claim 1, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

52. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '160 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

**COMPLAINT:**

53. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C.

§ 355(b)(2)(A)(iv), asserting that the claims of the '160 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

**ANSWER:** Denied. Answering further, Perrigo states that Perrigo's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '160, '105, '267, '610, '414, '717, '192, and '875 patents.

**COMPLAINT:**

54. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '160 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

55. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '160 patent is an act of infringement of the '160 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

**COMPLAINT:**

56. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '160 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

57. Upon information and belief, Perrigo has knowledge of the claims of the '160 patent at least because the '160 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza® drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '160, '105, '267, '610, '414, '717, '192, and '875 patents currently are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in conjunction with NDA No. 210361 for Qbrexza®. Answering further, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

58. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '160 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '160 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

**ANSWER:** Denied.

**COMPLAINT:**

59. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '160 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '160 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** Denied.

**COMPLAINT:**

60. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '160 patent, active inducement of infringement of the '160 patent, and contribution to the infringement by others of the '160 patent either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

61. Unless Perrigo is enjoined from infringing the '160 patent, actively inducing infringement of the '160 patent, and contributing to the infringement by others of the '160 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**ANSWER:** Denied.

**COUNT II**
**(Infringement of the '105 Patent)**

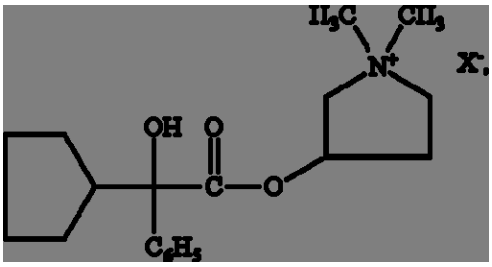
**COMPLAINT:**

62. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

**COMPLAINT:**

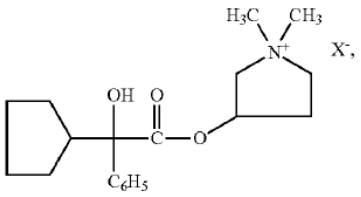
63. Claim 1 of the '105 patent covers "[a] glycopyrrolate base solution comprising: about 0.5 to about 4.0% w/w of a glycopyrrolate compound having the following formula:



wherein X− is a pharmaceutically acceptable counter ion salt; ethanol and water in a weight ratio of about 50:50 to about 60:40; and a buffering agent, comprising citric acid and a base selected from the group consisting of sodium citrate and tromethamine, said acid and base at a total concentration of about 0.2 to about 0.5% w/w and at an acid:base ratio sufficient to maintain a pH of the glycopyrrolate base solution of about 3.5 to about 6 for at least nine months at 25° C.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '105 patent contains the following claim:

1. A glycopyrrolate base solution comprising:
about 0.5 to about 4.0% w/w of a glycopyrrolate compound having the following formula:



wherein $X^-$ is a pharmaceutically acceptable counter ion salt;
ethanol and water in a weight ratio of about 50:50 to about 60:40; and
a buffering agent, comprising citric acid and a base selected from the group consisting of sodium citrate and tromethamine, said acid and base at a total concentration of about 0.2 to about 0.5% w/w and at an acid:base ratio sufficient to maintain a pH of the glycopyrrolate base solution of about 3.5 to about 6 for at least nine months at 25° C.

Perrigo denies the remaining allegations of this paragraph, including that the '105 patent was legally issued, as well as any suggestion or implication that the '105 patent claims are valid or enforceable or that Perrigo infringes one or more claims of the '105 patent.

**COMPLAINT:**

64. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '105 patent, including at least claim 1.

**ANSWER:** Denied.

**COMPLAINT:**

65. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more claims of the '105 patent, including at least claim 1, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

66. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '105 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

**COMPLAINT:**

67. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '105 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

**ANSWER:** Denied. Answering further, Perrigo states that Perrigo's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '160, '105, '267, '610, '414, '717, '192, and '875 patents.

**COMPLAINT:**

68. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '105 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

69. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '105 patent is an act of infringement of the '105 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

**COMPLAINT:**

70. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '105 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of

Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

71. Upon information and belief, Perrigo has knowledge of the claims of the '105 patent at least because the '105 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza® drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '160, '105, '267, '610, '414, '717, '192, and '875 patents currently are listed in the Orange Book in conjunction with NDA No. 210361 for Qbrexza®. Answering further, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

72. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '105 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '105 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

**ANSWER:** Denied.

**COMPLAINT:**

73. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '105 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '105 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** Denied.

**COMPLAINT:**

74. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '105 patent, active inducement of infringement of the '105 patent, and contribution to the infringement by others of the '105 patent either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

75. Unless Perrigo is enjoined from infringing the '105 patent, actively inducing infringement of the '105 patent, and contributing to the infringement by others of the '105 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**ANSWER:** Denied.

**COUNT III**
**(Infringement of the '267 Patent)**

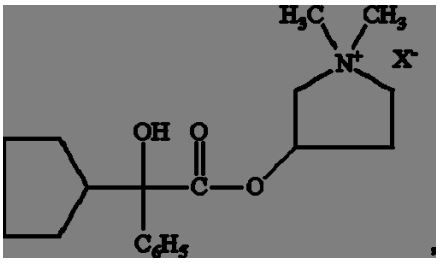
**COMPLAINT:**

76. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

**COMPLAINT:**

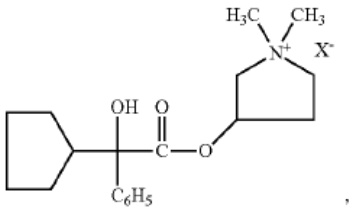
77. Claim 1 of the '267 patent covers "[a] glycopyrrolate solution comprising: about 0.5 to about 4.0% w/w of a glycopyrrolate compound having the following formula:




wherein X− is a pharmaceutically acceptable counter ion salt; ethanol and water in a weight ratio of about 50:50 to about 60:40; a buffering agent, comprising an acid and a base, said acid and base at a total concentration of about 0.2 to about 0.5% w/w and at an acid:base ratio sufficient to maintain a pH of the glycopyrrolate solution of about 3.5 to about 6 at 25° C.; wherein the acid is citric acid and the base is selected from the group consisting of sodium citrate and tromethamine; wherein the pharmaceutically acceptable counter salt is prepared from an inorganic or organic acid selected from hydrochloric acid, hydrobromic acid, hydrogen fluoride, hydrogen iodide, sulfuric acid, nitric acid, phosphoric acid, acetic acid, propionic acid, glycolic acid, pyruvic acid, oxalic acid, malic acid, malonic acid, succinic acid, maleic acid, fumaric acid, tartaric acid, citric acid, benzoic acid, cinnamic acid, mandelic acid, methanesulfonic acid, ethanesulfonic acid, p-toluene-sulfonic acid, and salicylic acid."

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '267 patent contains the following claim:

1. A glycopyrrolate solution comprising:
about 0.5 to about 4.0% w/w of a glycopyrrolate compound having the following formula:




wherein $X^-$ is a pharmaceutically acceptable counter ion salt;
ethanol and water in a weight ratio of about 50:50 to about 60:40;
a buffering agent, comprising an acid and a base, said acid and base at a total concentration of about 0.2 to about 0.5% w/w and at an acid:base ratio sufficient to maintain a pH of the glycopyrrolate solution of about 3.5 to about 6 at 25° C.;
wherein the acid is citric acid and the base is selected from the group consisting of sodium citrate and trometh-amine;
wherein the pharmaceutically acceptable counter salt is prepared from an inorganic or organic acid selected from hydrochloric acid, hydrobromic acid, hydrogen fluoride, hydrogen iodide, sulfuric acid, nitric acid, phosphoric acid, acetic acid, propionic acid, glycolic acid, pyruvic acid, oxalic acid, malic acid, malonic acid, succinic acid, maleic acid, fumaric acid, tartaric acid, citric acid, benzoic acid, cinnamic acid, mandelic acid, methanesulfonic acid, ethanesulfonic acid, p-tolu-ene-sulfonic acid, and salicylic acid.

Perrigo denies the remaining allegations of this paragraph, including that the '267 patent was legally issued, as well as any suggestion or implication that the '267 patent claims are valid or enforceable or that Perrigo infringes one or more claims of the '267 patent.

**COMPLAINT:**

78. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '267 patent, including at least claim 1.

**ANSWER:** Denied.

**COMPLAINT:**

79. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more

claims of the '267 patent, including at least claim 1, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

80. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '267 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

**COMPLAINT:**

81. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '267 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

**ANSWER:** Denied. Answering further, Perrigo states that Perrigo's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '160, '105, '267, '610, '414, '717, '192, and '875 patents.

**COMPLAINT:**

82. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '267 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of

Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

83. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '267 patent is an act of infringement of the '267 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

**COMPLAINT:**

84. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '267 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

85. Upon information and belief, Perrigo has knowledge of the claims of the '267 patent at least because the '267 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza® drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '160, '105, '267, '610, '414, '717, '192, and '875 patents currently are listed in the Orange Book in conjunction with NDA No. 210361 for Qbrexza®. Answering further, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

86. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '267 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '267 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

**ANSWER:** Denied.

**COMPLAINT:**

87. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '267 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '267 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** Denied.

**COMPLAINT:**

88. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '267 patent, active inducement of infringement of the '267 patent, and contribution to the infringement by others of the '267 patent either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

89. Unless Perrigo is enjoined from infringing the '267 patent, actively inducing infringement of the '267 patent, and contributing to the infringement by others of the '267 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

**ANSWER:** Denied.

**COUNT IV**
**(Infringement of the '610 Patent)**

**COMPLAINT:**

90. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

**COMPLAINT:**

91. Claim 1 of the '610 patent covers "An absorbant pad comprising a pharmaceutically acceptable solution comprising a racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate or a solvate thereof and one or more pharmaceutically acceptable additives."

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '610 patent contains the following claim:

> 1. An absorbant pad comprising a pharmaceutically acceptable solution comprising a racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate or a solvate thereof and one or more pharmaceutically acceptable additives.

Perrigo denies the remaining allegations of this paragraph, including that the '610 patent was legally issued, as well as any suggestion or implication that the '610 patent claims are valid or enforceable or that Perrigo infringes one or more claims of the '610 patent.

**COMPLAINT:**

92. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '610 patent, including at least claim 1.

**ANSWER:** Denied.

**COMPLAINT:**

93. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more claims of the '610 patent, including at least claim 1, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

94. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '610 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

**COMPLAINT:**

95. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '610 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

**ANSWER:** Denied. Answering further, Perrigo states that Perrigo's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '160, '105, '267, '610, '414, '717, '192, and '875 patents.

**COMPLAINT:**

96. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '610 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

97. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '610 patent is an act of infringement of the '610 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

**COMPLAINT:**

98. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and

the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '610 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

99. Upon information and belief, Perrigo has knowledge of the claims of the '610 patent at least because the '610 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza® drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '160, '105, '267, '610, '414, '717, '192, and '875 patents currently are listed in the Orange Book in conjunction with NDA No. 210361 for Qbrexza®. Answering further, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

100. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '610 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '610 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

**ANSWER:** Denied.

**COMPLAINT:**

101. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '610 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '610 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** Denied.

**COMPLAINT:**

102. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '610 patent, active inducement of infringement of the '610 patent, and contribution to the infringement by others of the '610 patent either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

103. Unless Perrigo is enjoined from infringing the '610 patent, actively inducing infringement of the '610 patent, and contributing to the infringement by others of the '610 patent, Dermira, Inc. will suffer irreparable injury. Dermira, Inc. has no adequate remedy at law.

**ANSWER:** Denied.

**COUNT V**
**(Infringement of the '414 Patent)**

**COMPLAINT:**

104. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

**COMPLAINT:**

105. Claim 1 of the '414 patent covers "[a] method of treating hyperhidrosis comprising topically administering a therapeutically effective amount of a pharmaceutically acceptable solution of glycopyrrolate tosylate comprising a racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate or solvate thereof to the skin of a mammal, wherein the pH of said pharmaceutically acceptable solution is between 3.5 and 5.5 at 25° C."

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '414 patent contains the following claim:

> **1**. A method of treating hyperhidrosis comprising topically administering a therapeutically effective amount of a pharmaceutically acceptable solution of glycopyrrolate tosylate comprising a racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate or solvate thereof to the skin of a mammal, wherein the pH of said pharmaceutically acceptable solution is between 3.5 and 5.5 at 25° C.

Perrigo denies the remaining allegations of this paragraph, including that the '414 patent was legally issued, as well as any suggestion or implication that the '414 patent claims are valid or enforceable or that Perrigo infringes one or more claims of the '414 patent.

**COMPLAINT:**

106. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '414 patent, including at least claim 1.

**ANSWER:** Denied.

**COMPLAINT:**

107. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more claims of the '414 patent, including at least claim 1, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

108. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '414 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

**COMPLAINT:**

109. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '414 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

**ANSWER:** Denied. Answering further, Perrigo states that Perrigo's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '160, '105, '267, '610, '414, '717, '192, and '875 patents.

**COMPLAINT:**

110. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '414 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

111. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '414 patent is an act of infringement of the '414 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

**COMPLAINT:**

112. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '414 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

113. Upon information and belief, Perrigo has knowledge of the claims of the '414 patent at least because the '414 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza® drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '160, '105, '267, '610, '414, '717, '192, and '875 patents currently are listed in the Orange Book in conjunction with

NDA No. 210361 for Qbrexza®. Answering further, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

114. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '414 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '414 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

**ANSWER:** Denied.

**COMPLAINT:**

115. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '414 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '414 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** Denied.

**COMPLAINT:**

116. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '414 patent, active inducement of infringement of the '414 patent, and contribution to the infringement by others of the '414 patent either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

117. Unless Perrigo is enjoined from actively inducing infringement of the ’414 patent, and contributing to the infringement by others of the ’414 patent, Dermira, Inc. will suffer irreparable injury. Dermira, Inc. has no adequate remedy at law.

**ANSWER:** Denied.

**COUNT VI**
**(Infringement of the ’717 Patent)**

**COMPLAINT:**

118. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

**COMPLAINT:**

119. Claim 1 of the ’717 patent covers “[a]n aqueous glycopyrrolate solution comprising: a racemic mixture of: (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate, and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate, about 0.15% by weight anhydrous citric acid, about 0.06% by weight sodium citrate dihydrate, and between about 57 to about 59.5% by weight of dehydrated ethanol, wherein: the weight percent of said glycopyrrolate tosylate is between about 1% and about 6%; and the pH of said aqueous glycopyrrolate solution is between 3.5 and 5.5.”

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the ‘717 patent contains the following claim:

1. An aqueous glycopyrrolate solution comprising:
a racemic mixture of:
(R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate, and
(S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate,
about 0.15% by weight anhydrous citric acid,
about 0.06% by weight sodium citrate dihydrate, and
between about 57 to about 59.5% by weight of dehydrated ethanol,
wherein:
the weight percent of said glycopyrrolate tosylate is between about 1% and about 6%; and
the pH of said aqueous glycopyrrolate solution is between 3.5 and 5.5.

Perrigo denies the remaining allegations of this paragraph, including that the '717 patent was legally issued, as well as any suggestion or implication that the '717 patent claims are valid or enforceable or that Perrigo infringes one or more claims of the '717 patent.

**COMPLAINT:**

120. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '717 patent, including at least claim 1.

**ANSWER:** Denied.

**COMPLAINT:**

121. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more claims of the '717 patent, including at least claim 1, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

122. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '717 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

**COMPLAINT:**

123. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '717 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

**ANSWER:** Denied. Answering further, Perrigo states that Perrigo's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '160, '105, '267, '610, '414, '717, '192, and '875 patents.

**COMPLAINT:**

124. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '717 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

125. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '717 patent is an act of infringement of the '717 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

**COMPLAINT:**

126. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and

the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '717 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

127. Upon information and belief, Perrigo has knowledge of the claims of the '717 patent at least because the '717 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza® drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '160, '105, '267, '610, '414, '717, '192, and '875 patents currently are listed in the Orange Book in conjunction with NDA No. 210361 for Qbrexza®. Answering further, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

128. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '717 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '717 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

**ANSWER:** Denied.

**COMPLAINT:**

129. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '717 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '717 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** Denied.

**COMPLAINT:**

130. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '717 patent, active inducement of infringement of the '717 patent, and contribution to the infringement by others of the '717 patent either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

131. Unless Perrigo is enjoined from infringing the '717 patent, actively inducing infringement of the '717 patent, and contributing to the infringement by others of the '717 patent, Dermira, Inc. will suffer irreparable injury. Dermira, Inc. has no adequate remedy at law.

**ANSWER:** Denied.

**COUNT VII**
**(Infringement of the '192 Patent)**

**COMPLAINT:**

132. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

**COMPLAINT:**

133. Claim 1 of the '192 patent covers "[a] pharmaceutically acceptable solution comprising: a racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate, and at least one pharmaceutically acceptable additive; between about 57 and about 59.5% by weight dehydrated ethanol, wherein the weight percent of said racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate is between about 1% and about 6%; and the pH of said pharmaceutically acceptable solution is between 3.5 and 5.5."

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '192 patent contains the following claim:

> **1**. A pharmaceutically acceptable solution comprising:
> a racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate, and
> at least one pharmaceutically acceptable additive;
> between about 57 and about 59.5% by weight dehydrated ethanol,
> wherein the weight percent of said racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate is between about 1% and about 6%; and
> the pH of said pharmaceutically acceptable solution is between 3.5 and 5.5.

Perrigo denies the remaining allegations of this paragraph, including that the '192 patent was legally issued, as well as any suggestion or implication that the '192 patent claims are valid or enforceable or that Perrigo infringes one or more claims of the '192 patent.

**COMPLAINT:**

134. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '192 patent, including at least claim 1.

**ANSWER:** Denied.

**COMPLAINT:**

135. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more claims of the '192 patent, including at least claim 1, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

136. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '192 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

**COMPLAINT:**

137. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '192 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

**ANSWER:** Denied. Answering further, Perrigo states that Perrigo's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '160, '105, '267, '610, '414, '717, '192, and '875 patents.

**COMPLAINT:**

138. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '192 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo

seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

139. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '192 patent is an act of infringement of the '192 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

**COMPLAINT:**

140. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '192 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

141. Upon information and belief, Perrigo has knowledge of the claims of the '192 patent at least because the '192 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza® drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '160, '105, '267, '610, '414, '717, '192, and '875 patents currently are listed in the Orange Book in conjunction with NDA No. 210361 for Qbrexza®. Answering further, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

142. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '192 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '192 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

**ANSWER:** Denied.

**COMPLAINT:**

143. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '192 patent, active inducement of infringement of the '192 patent, and contribution to the infringement by others of the '192 patent either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

144. Unless Perrigo is enjoined from infringing the '192 patent, and actively inducing infringement of the '192 patent, Dermira, Inc. will suffer irreparable injury. Dermira, Inc. has no adequate remedy at law.

**ANSWER:** Denied.

## COUNT VIII
**(Infringement of the '875 Patent)**

**COMPLAINT:**

145. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

**ANSWER:** Perrigo restates and incorporates each of its responses to the preceding paragraphs as if fully set forth herein.

**COMPLAINT:**

146. Claim 1 of the '875 patent covers "[a] racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate."

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '875 patent contains the following claim:

> 1. A racemic mixture of (R)-3-((S)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate and (S)-3-((R)-2-cyclopentyl-2-hydroxy-2-phenylacetoxy)-1,1-dimethylpyrrolidinium 4-methylbenzenesulfonate.

Perrigo denies the remaining allegations of this paragraph, including that the '875 patent was legally issued, as well as any suggestion or implication that the '875 patent claims are valid or enforceable or that Perrigo infringes one or more claims of the '875 patent.

**COMPLAINT:**

147. Upon information and belief, Perrigo's ANDA product is covered by one or more claims of the '875 patent, including at least claim 1.

**ANSWER:** Denied.

**COMPLAINT:**

148. Upon information and belief, the use of Perrigo's ANDA Product in accordance with and as directed by Perrigo's proposed labeling for that product will infringe one or more

claims of the '875 patent, including at least claim 1, either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

149. Perrigo did not assert in either of its Notice Letters that the use of Perrigo's ANDA product in accordance with and as directed by Perrigo's proposed labeling for that product would not meet any claim limitation of any claim of the '875 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, denied.

**COMPLAINT:**

150. Upon information and belief, Perrigo filed as part of ANDA No. 214448 a certification of the type described in Section 505(b)(2)(A)(iv) of the FDCA, 21 U.S.C. § 355(b)(2)(A)(iv), asserting that the claims of the '875 patent are invalid, unenforceable, and/or not infringed by the manufacture, use, offer for sale, or sale of Perrigo's ANDA Product.

**ANSWER:** Denied. Answering further, Perrigo states that Perrigo's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the '160, '105, '267, '610, '414, '717, '192, and '875 patents.

**COMPLAINT:**

151. The purpose of filing ANDA No. 214448 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '875 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of

Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

152. Perrigo's submission of ANDA No. 214448 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Perrigo's ANDA Product prior to the expiration of the '875 patent is an act of infringement of the '875 patent under 35 U.S.C. § 271(e)(2)(A).

**ANSWER:** Denied.

**COMPLAINT:**

153. Upon information and belief, Perrigo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto, *i.e.*, prior to the expiration of the '875 patent.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

154. Upon information and belief, Perrigo has knowledge of the claims of the '875 patent at least because the '875 patent is listed in the FDA's *Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations* for Dermira's Qbrexza® drug product. Notwithstanding this knowledge, Perrigo continues to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Perrigo's ANDA Product and the proposed labeling therefor immediately and imminently upon the approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** This paragraph contains legal conclusions to which no answer is required. To the extent an answer is required, Perrigo admits that the '160, '105, '267, '610, '414, '717, '192, and '875 patents currently are listed in the Orange Book in conjunction with NDA No. 210361 for Qbrexza®. Answering further, Perrigo admits that Perrigo submitted ANDA No. 214448 to FDA, pursuant to 21 U.S.C. § 355(j); that Perrigo's ANDA contains paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents; and that Perrigo seeks approval from FDA to engage in the commercial manufacture, use, sale, or importation of Glycopyrronium, Cloth, 2.4%, before the expiration of the '160, '105, '267, '610, '414, '717, '192, and '875 patents. Perrigo denies the remaining allegations contained in this paragraph.

**COMPLAINT:**

155. Upon information and belief, Perrigo plans and intends to, and will, actively induce infringement of the '875 patent when ANDA No. 214448 and any amendments thereto are approved, and will do so with specific intent to induce infringement of the '875 patent. Further upon information and belief, Perrigo plans and intends to, and will, do so immediately and imminently upon approval.

**ANSWER:** Denied.

**COMPLAINT:**

156. Upon information and belief, Perrigo knows that Perrigo's ANDA Product is especially made or adapted for use in infringing the '875 patent, and that Perrigo's ANDA Product is not suitable for substantial noninfringing use. Upon information and belief, Perrigo plans and intends to, and will, contribute to infringement of the '875 patent immediately and imminently upon approval of ANDA No. 214448 and any amendments thereto.

**ANSWER:** Denied.

**COMPLAINT:**

157. The foregoing actions by Perrigo constitute and/or will constitute infringement of the '875 patent, active inducement of infringement of the '875 patent, and contribution to the infringement by others of the '875 patent either literally or under the doctrine of equivalents.

**ANSWER:** Denied.

**COMPLAINT:**

158. Unless Perrigo is enjoined from infringing the '875 patent, actively inducing infringement of the '875 patent, and contributing to the infringement by others of the '875 patent, Dermira, Inc. will suffer irreparable injury. Dermira, Inc. has no adequate remedy at law.

**ANSWER:** Denied.

* * *

**RESPONSE TO REQUESTED RELIEF**

Perrigo denies that Plaintiffs are entitled to any relief as set forth in Paragraphs (a)-(g) of the Complaint, or to any relief whatsoever, and further requests that Plaintiffs' Complaint be dismissed with prejudice and that Perrigo be awarded its attorney fees and costs incurred in defending this suit under 35 U.S.C. § 285.

**SEPARATE DEFENSES**

Without prejudice to the denials set forth in its Answer, without admitting allegations of the Complaint not otherwise admitted (and, for purposes of clarity, those allegations not specifically admitted are denied), and without undertaking any of the burdens imposed by law on Plaintiffs, Perrigo asserts the following defenses to the Complaint:

**First Defense**

The manufacture, use, or sale of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA No. 214448 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '160 patent.

**Second Defense**

The manufacture, use, or sale of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA No. 214448 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '105 patent.

**Third Defense**

The manufacture, use, or sale of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA No. 214448 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '267 patent.

**Fourth Defense**

The manufacture, use, or sale of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA No. 214448 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '610 patent.

**Fifth Defense**

The manufacture, use, or sale of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA No. 214448 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '414 patent.

**Sixth Defense**

The manufacture, use, or sale of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA No. 214448 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '717 patent.

**Seventh Defense**

The manufacture, use, or sale of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA No. 214448 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '192 patent.

**Eighth Defense**

The manufacture, use, or sale of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA No. 214448 has not infringed, does not infringe, and would not, if marketed, sold or used, infringe any valid and enforceable claim of the '875 patent.

**Ninth Defense**

The claims of the '160 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

**Tenth Defense**

The claims of the '105 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

**Eleventh Defense**

The claims of the '267 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

**Twelfth Defense**

The claims of the '610 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

**Thirteenth Defense**

The claims of the '414 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

**Fourteenth Defense**

The claims of the '717 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

**Fifteenth Defense**

The claims of the '192 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

**Sixteenth Defense**

The claims of the '875 patent are invalid for failure to satisfy one or more conditions for patentability set forth in 35 U.S.C. §§ 101 *et seq*.

**Seventeenth Defense**

Plaintiffs fail to state a claim upon which relief can be granted under controlling Federal Circuit case law.

**Eighteenth Defense**

Any additional defenses or counterclaims that discovery may reveal, as Plaintiffs have not begun producing discovery to Perrigo, and Perrigo has not yet had the opportunity to pursue any relevant third-party discovery.

**COUNTERCLAIMS**

Perrigo Pharma International DAC ("Perrigo" or "Defendant"), for its Counterclaims against Dermira, Inc. ("Dermira") and Rose U, LLC ("Rose") (collectively, "Plaintiffs"), alleges as follows:

**The Parties**

1. Perrigo is an Irish entity with a place of business at The Shar Building, Hogan Place, Dublin, 2 Ireland.

2. On information and belief, and according to its Complaint, Dermira is a corporation organized and existing under the laws of the State of Delaware, having its corporate

offices and place of business at 275 Middlefield Road, Suite 150, Menlo Park, CA 94025. (Complaint at ¶ 2).

3. On information and belief, and according to its Complaint, Rose is a limited liability company organized and existing under the laws of California, having its place of business at 41 Deep Well Lane, Los Altos, CA 94022. (Complaint at ¶ 3).

## Jurisdiction and Venue

4. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

5. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 355(j) and 35 U.S.C. § 271(e)(5)).

6. This Court has personal jurisdiction over Plaintiffs because they have purposefully availed themselves of the rights and privileges of this forum by suing Perrigo in this District, and, on information and belief, because Plaintiffs conduct substantial business in, and have regular systematic contact with, this District.

7. Venue is proper under 28 U.S.C. §§ 1391 and 1400.

## Background

### A. FDA Approval of New Brand-Name Drugs.

8. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984) (commonly known as the "Hatch-Waxman Amendments" or

"Hatch-Waxman"), and as further amended by Title XI of the MMA, sets forth a statutory framework that the U.S. Food and Drug Administration ("FDA") follows for the approval of both brand-name and generic drugs.

9. Under the FFDCA, as amended by Hatch-Waxman and the MMA, an applicant seeking to market a new brand-name drug that has not been previously approved must prepare a New Drug Application ("NDA") for consideration by FDA. *See* 21 U.S.C. § 355.

10. An NDA includes, among other things, the number of any patent that the NDA holder asserts claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), (c)(2); 21 C.F.R. § 314.53(b), (c)(2). The decision to submit patent information to FDA rests solely with the NDA holder.

11. Upon approval of the NDA, FDA publishes patent information for the approved drug in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

**B. Generic Competition – Abbreviated New Drug Applications.**

12. In 1984, Congress enacted the Hatch-Waxman Amendments to the FFDCA. Congress passed Hatch-Waxman, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition. Under Hatch-Waxman, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

13. To receive approval of its ANDA, an applicant generally must, *inter alia*, show that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

14. When filing an ANDA seeking approval of a generic version of a drug listed in the Orange Book, the ANDA applicant generally must also "certify" that any patent information listed in the Orange Book does not preclude FDA approval of a generic version of the drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

15. When seeking FDA approval to market prior to patent expiration, an ANDA applicant generally submits a so-called "paragraph IV" certification asserting that the listed patent is invalid, unenforceable, and/or will not be infringed. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

16. An applicant submitting an ANDA containing a paragraph IV certification must notify both the purported patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B).

17. If the patent holder brings suit within 45 days of receiving the notice required by 21 U.S.C. § 355(j)(2)(B), FDA typically cannot approve the ANDA for 30 months, unless the District Court enters an order that shortens that period. *See* 21 U.S.C. § 355(j)(5)(B)(iii). For this reason alone, patentees and NDA holders have a significant financial incentive to bring an infringement suit against an ANDA applicant regardless of the merit – or lack thereof – of that infringement suit.

**C. Qbrexza® (glycopyrronium), Cloth, 2.4%, And The Patents-In-Suit.**

18. On or about December 31, 2013, according to the electronic records of the U.S. Patent and Trademark Office ("USPTO"), U.S. Patent No. 8,618,160 ("the '160 patent"), entitled "Topical Glycopyrrolate Formulations," issued. The '160 patent is assigned on its face to Rose U. The named inventors on the face of the '160 patent are Michael Johnston and Robert James

Houlden. What purports to be a true and correct copy of the '160 patent is attached to Plaintiffs' Complaint as Exhibit A.

19. According to the online records of the USPTO, Rose U is the current assignee of the '160 patent.

20. Plaintiffs assert that "Dermira, Inc. is the exclusive licensee of the '160 patent." (Complaint at ¶ 22).

21. On or about August 29, 2017, according to the electronic records of the USPTO, U.S. Patent No. 9,744,105 ("the '105 patent"), entitled "Topical Glycopyrrolate Formulations," issued. The '105 patent is assigned on its face to Rose. The named inventors on the face of the '105 patent are Michael Johnston and Robert James Houlden. What purports to be a true and correct copy of the '105 patent is attached to Plaintiffs' Complaint as Exhibit B.

22. According to the online records of the USPTO, Rose is the current assignee of the '105 patent.

23. Plaintiffs assert that "Dermira, Inc. is the exclusive licensee of the '105 patent." (Complaint at ¶ 26).

24. On or about August 21, 2018, according to the electronic records of the USPTO, U.S. Patent No. 10,052,267 ("the '267 patent"), entitled "Topical Glycopyrrolate Formulations," issued. The '267 patent is assigned on its face to Rose. The named inventors on the face of the '267 patent are Michael Johnston and Robert James Houlden. What purports to be a true and correct copy of the '267 patent is attached to Plaintiffs' Complaint as Exhibit C.

25. According to the online records of the USPTO, Rose is the current assignee of the '267 patent.

26. Plaintiffs assert that "Dermira, Inc. is the exclusive licensee of the '267 patent." (Complaint at ¶ 30).

27. On or about October 14, 2014, according to the electronic records of the USPTO, U.S. Patent No. 8,859,610 ("the '610 patent"), entitled "Crystalline Glycopyrrolate Tosylate," issued. The '610 patent is assigned on its face to Dermira. The named inventors on the face of the '610 patent are John Allan Statler, Anthony Adrian Shaw, Delphine Caroline Imbert, Jennifer Leigh Nelson, Patricia Andres, Lisa Lynn McQueen, and Stephan Xander Mattheus Boerrigter. On information and belief, a true and correct copy of the '610 patent is attached hereto as Exhibit 1.

28. According to the online records of the USPTO, and according to Plaintiffs, Dermira is the current assignee of the '610 patent. (Complaint at ¶ 33).

29. On or about February 16, 2016, according to the electronic records of the USPTO, U.S. Patent No. 9,259,414 ("the '414 patent"), entitled "Glycopyrrolate Salts," issued. The '414 patent is assigned on its face to Dermira. The named inventors on the face of the '414 patent are John Allan Statler, Anthony Adrian Shaw, Delphine Caroline Imbert, Jennifer Leigh Nelson, Patricia Andres, Lisa Lynn McQueen, Stephan Xander Mattheus Boerrigter, Jon Gordon Selbo, and Mark Christopher Andres. What purports to be a true and correct copy of the '414 patent is attached to Plaintiffs' Complaint as Exhibit E.

30. According to the online records of the USPTO, and according to Plaintiffs, Dermira is the current assignee of the '414 patent. (Complaint at ¶ 36).

31. On or about June 26, 2018, according to the electronic records of the USPTO, U.S. Patent No. 10,004,717 ("the '717 patent"), entitled "Glycopyrrolate Salts," issued. The '717 patent is assigned on its face to Dermira. The named inventors on the face of the '717

patent are John Allan Statler, Anthony Adrian Shaw, Delphine Caroline Imbert, Jennifer Leigh Nelson, Patricia Andres, Lisa Lynn McQueen, Stephan Xander Mattheus Boerrigter, Jon Gordon Selbo, and Mark Christopher Andres. What purports to be a true and correct copy of the '717 patent is attached to Plaintiffs' Complaint as Exhibit F.

32. According to the online records of the USPTO, and according to Plaintiffs, Dermira is the current assignee of the '717 patent. (Complaint at ¶ 39).

33. On or about January 28, 2020, according to the electronic records of the USPTO, U.S. Patent No. 10,543,192 ("the '192 patent"), entitled "Glycopyrrolate Salts," issued. The '192 patent is assigned on its face to Dermira. The named inventors on the face of the '192 patent are John Allan Statler, Anthony Adrian Shaw, Delphine Caroline Imbert, Jennifer Leigh Nelson, Patricia Andres, Lisa Lynn McQueen, Stephan Xander Mattheus Boerrigter, Jon Gordon Selbo, and Mark Christopher Andres. What purports to be a true and correct copy of the '192 patent is attached to Plaintiffs' Complaint as Exhibit G.

34. According to the online records of the USPTO, and according to Plaintiffs, Dermira is the current assignee of the '192 patent. (Complaint at ¶ 42).

35. On or about February 4, 2020, according to the electronic records of the USPTO, U.S. Patent No. 10,548,875 ("the '875 patent"), entitled "Glycopyrrolate Salts," issued. The '875 patent is assigned on its face to Dermira. The named inventors on the face of the '875 patent are John Allan Statler, Anthony Adrian Shaw, Delphine Caroline Imbert, Jennifer Leigh Nelson, Patricia Andres, Lisa Lynn McQueen, Stephan Xander Mattheus Boerrigter, Jon Gordon Selbo, and Mark Christopher Andres. What purports to be a true and correct copy of the '875 patent is attached to Plaintiffs' Complaint as Exhibit H.

36. According to the online records of the USPTO, and according to Plaintiffs, Dermira is the current assignee of the '875 patent. (Complaint at ¶ 45).

37. According to the online records of FDA, "DERMIRA INC" is identified as the holder of NDA No. 210361 for Qbrexza® (glycopyrronium tosylate), Topical Cloth, eq. 2.4% base, and "Jun 28, 2018" is identified as the "Approval Date" for NDA No. 210361.

38. On information and belief, Dermira, or someone on Dermira's behalf, submitted the '160 patent to FDA for listing in the Orange Book in connection with NDA No. 210361.

39. On information and belief, Dermira, or someone on Dermira's behalf, submitted the '105 patent to FDA for listing in the Orange Book in connection with NDA No. 210361.

40. On information and belief, Dermira, or someone on Dermira's behalf, submitted the '267 patent to FDA for listing in the Orange Book in connection with NDA No. 210361.

41. On information and belief, Dermira, or someone on Dermira's behalf, submitted the '610 patent to FDA for listing in the Orange Book in connection with NDA No. 210361.

42. On information and belief, Dermira, or someone on Dermira's behalf, submitted the '414 patent to FDA for listing in the Orange Book in connection with NDA No. 210361.

43. On information and belief, Dermira, or someone on Dermira's behalf, submitted the '717 patent to FDA for listing in the Orange Book in connection with NDA No. 210361.

44. On information and belief, Dermira, or someone on Dermira's behalf, submitted the '192 patent to FDA for listing in the Orange Book in connection with NDA No. 210361.

45. On information and belief, Dermira, or someone on Dermira's behalf, submitted the '875 patent to FDA for listing in the Orange Book in connection with NDA No. 210361.

46. By virtue of the submission of the '160 patent to FDA, FDA listed the '160 patent in the Orange Book in connection with the approved NDA No. 210361.

47. By virtue of the submission of the '105 patent to FDA, FDA listed the '105 patent in the Orange Book in connection with the approved NDA No. 210361.

48. By virtue of the submission of the '267 patent to FDA, FDA listed the '267 patent in the Orange Book in connection with the approved NDA No. 210361.

49. By virtue of the submission of the '610 patent to FDA, FDA listed the '610 patent in the Orange Book in connection with the approved NDA No. 210361.

50. By virtue of the submission of the '414 patent to FDA, FDA listed the '414 patent in the Orange Book in connection with the approved NDA No. 210361.

51. By virtue of the submission of the '717 patent to FDA, FDA listed the '717 patent in the Orange Book in connection with the approved NDA No. 210361.

52. By virtue of the submission of the '192 patent to FDA, FDA listed the '192 patent in the Orange Book in connection with the approved NDA No. 210361.

53. By virtue of the submission of the '875 patent to FDA, FDA listed the '875 patent in the Orange Book in connection with the approved NDA No. 210361.

54. On or about October 21, 2020, Plaintiffs purport to have brought suit against Perrigo, asserting infringement of "at least claim 1" of the '160, '105, '267, '610, '414, '717, '192, and '875 patents, but not otherwise identifying the asserted claims of the '160, '105, '267, '610, '414, '717, '192, and/or '875 patents.

**D. Perrigo's Glycopyrronium, Cloth, 2.4% ANDA.**

55. Perrigo filed an ANDA with FDA seeking approval for Glycopyrronium, Cloth, 2.4% ("Perrigo's ANDA").

56. FDA assigned Perrigo's ANDA No. 214448.

57. Perrigo's ANDA identifies Qbrexza® (glycopyrronium), Cloth, 2.4% (NDA No. 210361) as the reference listed drug ("RLD").

58. Because Perrigo's ANDA seeks FDA approval to market its generic Glycopyrronium, Cloth, 2.4% before expiration of the Orange Book-listed '160, '105, '267, '610, '414, '717, '192, and '875 patents, Perrigo's ANDA includes paragraph IV certifications to the '160, '105, '267, '610, '414, '717, '192, and '875 patents.

59. By letter dated September 8, 2020, in accordance with 21 U.S.C. § 355(j)(2)(B) and applicable regulations, Perrigo provided, *inter alia*, Plaintiffs with notice that Perrigo submitted an ANDA containing a paragraph IV certification to the '160, '610, '414, '105, '717, and '267 patents ("Perrigo's September 8 Notice Letter").

60. Perrigo's September 8 Notice Letter included a detailed statement setting forth factual and legal bases as to why the '160, '610, '414, '105, '717, and '267 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo's ANDA No. 214448, and *inter alia*, expressly reserved the right to raise additional defenses in the event that suit was filed on the '160, '610, '414, '105, '717, and/or '267 patents.

61. Dermira received a copy of Perrigo's September 8 Notice Letter.

62. Rose received a copy of Perrigo's September 8 Notice Letter.

63. By letter dated September 23, 2020, in accordance with 21 U.S.C. § 355(j)(2)(B) and applicable regulations, Perrigo provided, *inter alia*, Plaintiffs with notice that Perrigo's ANDA had been amended to contain a paragraph IV certification to the '192 and '875 patents ("Perrigo's September 23 Notice Letter").

64. Perrigo's September 23 Notice Letter included a detailed statement setting forth factual and legal bases as to why the '192 and '875 patents are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo's ANDA No. 214448, and *inter alia*, expressly reserved the right to raise additional defenses in the event that suit was filed on the '192 and/or '875 patents.

65. Dermira received a copy of Perrigo's September 23 Notice Letter.

66. Rose received a copy of Perrigo's September 23 Notice Letter.

67. The claims of the '160 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo's ANDA No. 214448.

68. The claims of the '610 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo's ANDA No. 214448.

69. The claims of the '414 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo's ANDA No. 214448.

70. The claims of the '105 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo's ANDA No. 214448.

71. The claims of the '717 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo's ANDA No. 214448.

72. The claims of the '267 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo's ANDA No. 214448.

73. The claims of the '192 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo's ANDA No. 214448.

74. The claims of the '875 patent are invalid, unenforceable and/or will not be infringed by the manufacture, use, offer for sale, sale, or importation of the product described in Perrigo's ANDA No. 214448.

75. Prior to bringing suit against Perrigo for alleged infringement of the '160, '105, '267, '610, '414, '717, '192, and '875 patents, neither Plaintiffs, nor anyone on Plaintiffs' behalf, requested confidential access to Perrigo's ANDA.

**COUNT I**
**(Declaration of Non-Infringement of the '160 Patent)**

76. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-75.

77. A present, genuine, and justiciable controversy exists between Plaintiffs and Perrigo regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would infringe any valid or enforceable claim of the '160 patent.

78. The manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '160 patent, either literally or under the doctrine of equivalents, directly or indirectly.

79. Perrigo is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '160 patent.

**COUNT II**
**(Declaration of Invalidity of the '160 Patent)**

80. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-79.

81. A present, genuine, and justiciable controversy exists between Plaintiffs and Perrigo regarding, *inter alia*, the invalidity of the '160 patent.

82. The claims of the '160 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '160 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

b. The alleged invention of the '160 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

c. The alleged invention of the '160 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '160 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to

achieve the alleged invention of the '160 patent and would have had a reasonable expectation of success in doing so.

d. The '160 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention which the claims purport to cover.

e. The claims of the '160 patent are invalid because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

f. The subject matter claimed in the '160 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains. Non-limiting examples of prior art rendering each of the claims of the '160 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Perrigo's September 8 Notice Letter. Such references and products include, but are not limited to: U.S. Patent No. 4,355,020; U.S. Patent No. 5,403,588; U.S. Patent No. 5,648,083; U.S. Patent No. 5,962,505; U.S. Patent No. 6,211,250; U.S. Patent No. 6,433,003; U.S. Patent No. 6,446,795; U.S. Patent No.

7,060,289; U.S. Patent No. 8,252,316; U.S. Patent Appl. Publ. No. 2003/0115837; U.S. Patent Appl. Publ. No. 2006/0165765; U.S. Patent Appl. Publ. No. 2006/0211729; U.S. Patent Appl. Publ. No. 2008/0292562; Spanish Patent Appl. Publ. No. 2 118 053; L.L. Hays, "The Frey Syndrome: A Review And Double Blind Evaluation Of The Topical Use Of A New Anticholinergic Agent," *The Laryngoscope*, vol. 88, pp. 1796-1824 (1978); J.E. Shaw, *et al*., "A randomised controlled trial of topical glycopyrrolate, the first specific treatment for diabetic gustatory sweating," *Diabetologia*, vol. 40, pp. 299-301 (1997); REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY (21st ed., 2006); PHYSICIANS' DESK REFERENCE (54th ed., 2000); Labeling for Robinul Injection (Glycopyrrolate Injection, USP) (NDA 017558); Labeling for Robinul® and Robinul® Forte Tablets (Glycopyrrolate Tablets, USP) (NDA 012827); Robinul® Injection Product (Glycopyrrolate Injection, USP); Robinul® Tablets Product (Glycopyrrolate Tablets, USP); Robinul® Forte Tablets Product (Glycopyrrolate Tablets, USP).

83. Perrigo is entitled to a declaration that the claims of the '160 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

**COUNT III**
**(Declaration of Non-Infringement of the '105 Patent)**

84. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-83.

85. A present, genuine, and justiciable controversy exists between Plaintiffs and Perrigo regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would infringe any valid or enforceable claim of the '105 patent.

86. The manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '105 patent, either literally or under the doctrine of equivalents, directly or indirectly.

87. Perrigo is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '105 patent.

**COUNT IV**
**(Declaration of Invalidity of the '105 Patent)**

88. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-87.

89. A present, genuine, and justiciable controversy exists between Plaintiffs and Perrigo regarding, *inter alia*, the invalidity of the '105 patent.

90. The claims of the '105 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '105 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

b. The alleged invention of the '105 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

c. The alleged invention of the '105 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '105 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '105 patent and would have had a reasonable expectation of success in doing so.

d. The '105 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention which the claims purport to cover.

e. The claims of the '105 patent are invalid because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

f. The subject matter claimed in the '105 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains. Non-limiting examples of prior art rendering each of the claims of the '105 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not*

*limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Perrigo's September 8 Notice Letter. Such references and products include, but are not limited to: U.S. Patent No. 4,355,020; U.S. Patent No. 5,403,588; U.S. Patent No. 5,648,083; U.S. Patent No. 5,962,505; U.S. Patent No. 6,211,250; U.S. Patent No. 6,433,003; U.S. Patent No. 6,446,795; U.S. Patent No. 7,060,289; U.S. Patent No. 8,252,316; U.S. Patent Appl. Publ. No. 2003/0115837; U.S. Patent Appl. Publ. No. 2006/0165765; U.S. Patent Appl. Publ. No. 2006/0211729; U.S. Patent Appl. Publ. No. 2008/0292562; Spanish Patent Appl. Publ. No. 2 118 053; L.L. Hays, "The Frey Syndrome: A Review And Double Blind Evaluation Of The Topical Use Of A New Anticholinergic Agent," *The Laryngoscope*, vol. 88, pp. 1796-1824 (1978); J.E. Shaw, *et al*., "A randomised controlled trial of topical glycopyrrolate, the first specific treatment for diabetic gustatory sweating," *Diabetologia*, vol. 40, pp. 299-301 (1997); REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY (21st ed., 2006); PHYSICIANS' DESK REFERENCE (54th ed., 2000); Labeling for Robinul Injection (Glycopyrrolate Injection, USP) (NDA 017558); Labeling for Robinul® and Robinul® Forte Tablets (Glycopyrrolate Tablets, USP) (NDA 012827); Robinul® Injection Product (Glycopyrrolate Injection, USP); Robinul® Tablets Product (Glycopyrrolate Tablets, USP); Robinul® Forte Tablets Product (Glycopyrrolate Tablets, USP).

91. Perrigo is entitled to a declaration that the claims of the '105 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

**COUNT V**
**(Declaration of Non-Infringement of the '267 Patent)**

92. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-91.

93. A present, genuine, and justiciable controversy exists between Plaintiffs and Perrigo regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would infringe any valid or enforceable claim of the '267 patent.

94. The manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '267 patent, either literally or under the doctrine of equivalents, directly or indirectly.

95. Perrigo is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '267 patent.

**COUNT VI**
**(Declaration of Invalidity of the '267 Patent)**

96. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-95.

97. A present, genuine, and justiciable controversy exists between Plaintiffs and Perrigo regarding, *inter alia*, the invalidity of the '267 patent.

98. The claims of the '267 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35

U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '267 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

b. The alleged invention of the '267 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

c. The alleged invention of the '267 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '267 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '267 patent and would have had a reasonable expectation of success in doing so.

d. The '267 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention which the claims purport to cover.

e. The claims of the '267 patent are invalid because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

f. The subject matter claimed in the '267 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains. Non-limiting examples of prior art rendering each of the claims of the '267 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Perrigo's September 8 Notice Letter. Such references and products include, but are not limited to: U.S. Patent No. 4,355,020; U.S. Patent No. 5,403,588; U.S. Patent No. 5,648,083; U.S. Patent No. 5,962,505; U.S. Patent No. 6,211,250; U.S. Patent No. 6,433,003; U.S. Patent No. 6,446,795; U.S. Patent No. 7,060,289; U.S. Patent No. 8,252,316; U.S. Patent Appl. Publ. No. 2003/0115837; U.S. Patent Appl. Publ. No. 2006/0165765; U.S. Patent Appl. Publ. No. 2006/0211729; U.S. Patent Appl. Publ. No. 2008/0292562; Spanish Patent Appl. Publ. No. 2 118 053; L.L. Hays, "The Frey Syndrome: A Review And Double Blind Evaluation Of The Topical Use Of A New Anticholinergic Agent," *The Laryngoscope*, vol. 88, pp. 1796-1824 (1978); J.E. Shaw, *et al*., "A randomised controlled trial of topical glycopyrrolate, the first specific treatment for diabetic gustatory sweating," *Diabetologia*, vol. 40, pp. 299-301 (1997); REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY (21st ed., 2006); PHYSICIANS' DESK REFERENCE (54th ed., 2000); Labeling for Robinul Injection (Glycopyrrolate Injection, USP) (NDA 017558); Labeling for Robinul® and Robinul®

Forte Tablets (Glycopyrrolate Tablets, USP) (NDA 012827); Robinul® Injection Product (Glycopyrrolate Injection, USP); Robinul® Tablets Product (Glycopyrrolate Tablets, USP); Robinul® Forte Tablets Product (Glycopyrrolate Tablets, USP).

99. Perrigo is entitled to a declaration that the claims of the '267 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

**COUNT VII**
**(Declaration of Non-Infringement of the '610 Patent)**

100. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-99.

101. A present, genuine, and justiciable controversy exists between at least Dermira and Perrigo regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would infringe any valid or enforceable claim of the '610 patent.

102. The manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '610 patent, either literally or under the doctrine of equivalents, directly or indirectly.

103. Perrigo is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '610 patent.

**COUNT VIII**
**(Declaration of Invalidity of the '610 Patent)**

104. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-103.

105. A present, genuine, and justiciable controversy exists between at least Dermira and Perrigo regarding, *inter alia*, the invalidity of the '610 patent.

106. The claims of the '610 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '610 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

b. The alleged invention of the '610 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

c. The alleged invention of the '610 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '610 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '610 patent and would have had a reasonable expectation of success in doing so.

d. The '610 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention which the claims purport to cover.

e. The claims of the '610 patent are invalid because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

f. The subject matter claimed in the '610 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains. Non-limiting examples of prior art rendering each of the claims of the '610 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Perrigo's September 8 Notice Letter. Such references and products include, but are not limited to: U.S. Patent Appl. Publ. No. 2010/0276329; Labeling for Cuvposa (glycopyrrolate) Oral Solution (NDA 022571); Cuvposa (glycopyrrolate) Oral Solution Product; U.S. Patent No. 4,355,020; U.S. Patent No. 5,403,588; U.S. Patent No. 5,648,083; U.S. Patent No. 5,962,505; U.S. Patent No. 6,211,250; U.S. Patent No. 6,433,003; U.S. Patent No. 6,446,795; U.S. Patent No.

7,060,289; U.S. Patent No. 8,252,316; U.S. Patent Appl. Publ. No. 2003/0115837; U.S. Patent Appl. Publ. No. 2006/0165765; U.S. Patent Appl. Publ. No. 2006/0211729; U.S. Patent Appl. Publ. No. 2008/0292562; Spanish Patent Appl. Publ. No. 2 118 053; L.L. Hays, "The Frey Syndrome: A Review And Double Blind Evaluation Of The Topical Use Of A New Anticholinergic Agent," *The Laryngoscope*, vol. 88, pp. 1796-1824 (1978); J.E. Shaw, *et al*., "A randomised controlled trial of topical glycopyrrolate, the first specific treatment for diabetic gustatory sweating," *Diabetologia*, vol. 40, pp. 299-301 (1997); REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY (21st ed., 2006); PHYSICIANS' DESK REFERENCE (54th ed., 2000); Labeling for Robinul Injection (Glycopyrrolate Injection, USP) (NDA 017558); Labeling for Robinul® and Robinul® Forte Tablets (Glycopyrrolate Tablets, USP) (NDA 012827); Robinul® Injection Product (Glycopyrrolate Injection, USP); Robinul® Tablets Product (Glycopyrrolate Tablets, USP); Robinul® Forte Tablets Product (Glycopyrrolate Tablets, USP).

107. Perrigo is entitled to a declaration that the claims of the '610 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

**COUNT IX**
**(Declaration of Non-Infringement of the '414 Patent)**

108. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-107.

109. A present, genuine, and justiciable controversy exists between at least Dermira and Perrigo regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would infringe any valid or enforceable claim of the '414 patent.

110. The manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '414 patent, either literally or under the doctrine of equivalents, directly or indirectly.

111. Perrigo is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '414 patent.

**COUNT X**
**(Declaration of Invalidity of the '414 Patent)**

112. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-111.

113. A present, genuine, and justiciable controversy exists between at least Dermira and Perrigo regarding, *inter alia*, the invalidity of the '414 patent.

114. The claims of the '414 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '414 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

b. The alleged invention of the '414 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

c. The alleged invention of the '414 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '414 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '414 patent and would have had a reasonable expectation of success in doing so.

d. The '414 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention which the claims purport to cover.

e. The claims of the '414 patent are invalid because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

f. The subject matter claimed in the '414 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains. Non-limiting examples of prior art rendering each of the claims of the '414 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not*

*limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Perrigo's September 8 Notice Letter. Such references and products include, but are not limited to: U.S. Patent Appl. Publ. No. 2010/0276329; Labeling for Cuvposa (glycopyrrolate) Oral Solution (NDA 022571); Cuvposa (glycopyrrolate) Oral Solution Product; U.S. Patent No. 4,355,020; U.S. Patent No. 5,403,588; U.S. Patent No. 5,648,083; U.S. Patent No. 5,962,505; U.S. Patent No. 6,211,250; U.S. Patent No. 6,433,003; U.S. Patent No. 6,446,795; U.S. Patent No. 7,060,289; U.S. Patent No. 8,252,316; U.S. Patent Appl. Publ. No. 2003/0115837; U.S. Patent Appl. Publ. No. 2006/0165765; U.S. Patent Appl. Publ. No. 2006/0211729; U.S. Patent Appl. Publ. No. 2008/0292562; Spanish Patent Appl. Publ. No. 2 118 053; L.L. Hays, "The Frey Syndrome: A Review And Double Blind Evaluation Of The Topical Use Of A New Anticholinergic Agent," *The Laryngoscope*, vol. 88, pp. 1796-1824 (1978); J.E. Shaw, *et al*., "A randomised controlled trial of topical glycopyrrolate, the first specific treatment for diabetic gustatory sweating," *Diabetologia*, vol. 40, pp. 299-301 (1997); REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY (21st ed., 2006); PHYSICIANS' DESK REFERENCE (54th ed., 2000); Labeling for Robinul Injection (Glycopyrrolate Injection, USP) (NDA 017558); Labeling for Robinul® and Robinul® Forte Tablets (Glycopyrrolate Tablets, USP) (NDA 012827); Robinul® Injection Product (Glycopyrrolate Injection, USP); Robinul® Tablets Product (Glycopyrrolate Tablets, USP); Robinul® Forte Tablets Product (Glycopyrrolate Tablets, USP).

115. Perrigo is entitled to a declaration that the claims of the '414 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

**COUNT XI**
**(Declaration of Non-Infringement of the '717 Patent)**

116. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-115.

117. A present, genuine, and justiciable controversy exists between at least Dermira and Perrigo regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would infringe any valid or enforceable claim of the '717 patent.

118. The manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '717 patent, either literally or under the doctrine of equivalents, directly or indirectly.

119. Perrigo is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '717 patent.

**COUNT XII**
**(Declaration of Invalidity of the '717 Patent)**

120. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-119.

121. A present, genuine, and justiciable controversy exists between at least Dermira and Perrigo regarding, *inter alia*, the invalidity of the '717 patent.

122. The claims of the '717 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35

U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '717 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

b. The alleged invention of the '717 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

c. The alleged invention of the '717 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '717 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '717 patent and would have had a reasonable expectation of success in doing so.

d. The '717 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention which the claims purport to cover.

e. The claims of the '717 patent are invalid because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

f. The subject matter claimed in the '717 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains. Non-limiting examples of prior art rendering each of the claims of the '717 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Perrigo's September 8 Notice Letter. Such references and products include, but are not limited to: U.S. Patent Appl. Publ. No. 2010/0276329; Labeling for Cuvposa (glycopyrrolate) Oral Solution (NDA 022571); Cuvposa (glycopyrrolate) Oral Solution Product; U.S. Patent No. 4,355,020; U.S. Patent No. 5,403,588; U.S. Patent No. 5,648,083; U.S. Patent No. 5,962,505; U.S. Patent No. 6,211,250; U.S. Patent No. 6,433,003; U.S. Patent No. 6,446,795; U.S. Patent No. 7,060,289; U.S. Patent No. 8,252,316; U.S. Patent Appl. Publ. No. 2003/0115837; U.S. Patent Appl. Publ. No. 2006/0165765; U.S. Patent Appl. Publ. No. 2006/0211729; U.S. Patent Appl. Publ. No. 2008/0292562; Spanish Patent Appl. Publ. No. 2 118 053; L.L. Hays, "The Frey Syndrome: A Review And Double Blind Evaluation Of The Topical Use Of A New Anticholinergic Agent," *The Laryngoscope*, vol. 88, pp. 1796-1824 (1978); J.E. Shaw, *et al*., "A randomised controlled trial of topical glycopyrrolate, the first specific treatment for diabetic gustatory sweating," *Diabetologia*, vol. 40, pp. 299-301 (1997); REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY (21st ed., 2006);

PHYSICIANS' DESK REFERENCE (54th ed., 2000); Labeling for Robinul Injection (Glycopyrrolate Injection, USP) (NDA 017558); Labeling for Robinul® and Robinul® Forte Tablets (Glycopyrrolate Tablets, USP) (NDA 012827); Robinul® Injection Product (Glycopyrrolate Injection, USP); Robinul® Tablets Product (Glycopyrrolate Tablets, USP); Robinul® Forte Tablets Product (Glycopyrrolate Tablets, USP).

123. Perrigo is entitled to a declaration that the claims of the '717 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

**COUNT XIII**
**(Declaration of Non-Infringement of the '192 Patent)**

124. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-123.

125. A present, genuine, and justiciable controversy exists between at Dermira and Perrigo regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would infringe any valid or enforceable claim of the '192 patent.

126. The manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '192 patent, either literally or under the doctrine of equivalents, directly or indirectly.

127. Perrigo is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '192 patent.

**COUNT XIV**
**(Declaration of Invalidity of the '192 Patent)**

128. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-127.

129. A present, genuine, and justiciable controversy exists between at least Dermira and Perrigo regarding, *inter alia*, the invalidity of the '192 patent.

130. The claims of the '192 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '192 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

b. The alleged invention of the '192 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

c. The alleged invention of the '192 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '192 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '192 patent and would have had a reasonable expectation of success in doing so.

d. The '192 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention which the claims purport to cover.

e. The claims of the '192 patent are invalid because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

f. The subject matter claimed in the '192 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains. Non-limiting examples of prior art rendering each of the claims of the '192 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Perrigo's September 23 Notice Letter. Such references and products include, but are not limited to: U.S. Patent Appl. Publ. No. 2010/0276329; Labeling for Cuvposa (glycopyrrolate) Oral Solution (NDA 022571); Cuvposa (glycopyrrolate) Oral Solution Product; U.S. Patent No. 4,355,020; U.S. Patent No. 5,403,588; U.S. Patent No. 5,648,083; U.S. Patent No. 5,962,505; U.S. Patent No. 6,211,250; U.S. Patent No. 6,433,003; U.S. Patent No. 6,446,795; U.S. Patent No.

7,060,289; U.S. Patent No. 8,252,316; U.S. Patent Appl. Publ. No. 2003/0115837; U.S. Patent Appl. Publ. No. 2006/0165765; U.S. Patent Appl. Publ. No. 2006/0211729; U.S. Patent Appl. Publ. No. 2008/0292562; Spanish Patent Appl. Publ. No. 2 118 053; L.L. Hays, "The Frey Syndrome: A Review And Double Blind Evaluation Of The Topical Use Of A New Anticholinergic Agent," *The Laryngoscope*, vol. 88, pp. 1796-1824 (1978); J.E. Shaw, *et al*., "A randomised controlled trial of topical glycopyrrolate, the first specific treatment for diabetic gustatory sweating," *Diabetologia*, vol. 40, pp. 299-301 (1997); REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY (21st ed., 2006); PHYSICIANS' DESK REFERENCE (54th ed., 2000); Labeling for Robinul Injection (Glycopyrrolate Injection, USP) (NDA 017558); Labeling for Robinul® and Robinul® Forte Tablets (Glycopyrrolate Tablets, USP) (NDA 012827); Robinul® Injection Product (Glycopyrrolate Injection, USP); Robinul® Tablets Product (Glycopyrrolate Tablets, USP); Robinul® Forte Tablets Product (Glycopyrrolate Tablets, USP).

131. Perrigo is entitled to a declaration that the claims of the '192 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

**COUNT XV**
**(Declaration of Non-Infringement of the '875 Patent)**

132. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-131.

133. A present, genuine, and justiciable controversy exists between at least Dermira and Perrigo regarding, *inter alia*, the issues of whether the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would infringe any valid or enforceable claim of the '875 patent.

134. The manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '875 patent, either literally or under the doctrine of equivalents, directly or indirectly.

135. Perrigo is entitled to a declaration that the manufacture, use, offer for sale, sale, or importation of the Glycopyrronium, Cloth, 2.4%, product described in Perrigo's ANDA would not infringe any valid or enforceable claim of the '875 patent.

**COUNT XVI**
**(Declaration of Invalidity of the '875 Patent)**

136. Perrigo realleges and incorporates by reference the allegations of Paragraphs 1-135.

137. A present, genuine, and justiciable controversy exists between at least Dermira and Perrigo regarding, *inter alia*, the invalidity of the '875 patent.

138. The claims of the '875 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, including, but not limited to 35 U.S.C. §§ 101, 102, 103 and 112, the bases for which include, at the very least, one or more of the following:

a. The alleged invention of the '875 patent was known or used by others in this country or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent.

b. The alleged invention of the '875 patent was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.

c. The alleged invention of the '875 patent does no more than combine familiar elements according to known methods to yield predictable results. Any alleged improvement set forth in the '875 patent over the prior art is no more than the predictable use of prior art elements according to their established functions. A person of ordinary skill in the art would have been motivated to combine the teachings of the prior art to achieve the alleged invention of the '875 patent and would have had a reasonable expectation of success in doing so.

d. The '875 patent does not contain a written description of the alleged invention, and of the manner and process of making and using it, in such full, clear, concise and exact terms as required by the statutes of the United States to enable any person skilled in the art to practice the invention which the claims purport to cover.

e. The claims of the '875 patent are invalid because they do not inform those skilled in the art about the scope of the invention with reasonable certainty and they do not particularly point out and distinctly claim the subject matter of the alleged invention, as required by 35 U.S.C. § 112.

f. The subject matter claimed in the '875 patent fails to comply with, *inter alia*, 35 U.S.C. §§ 102 and/or 103 at least in that the claimed subject matter as a whole was anticipated by the prior art and/or any differences between the subject matter claimed in the patent and the prior art are such that the subject matter as a whole would have been obvious at the time the alleged invention was made to a person having knowledge of such prior art and having ordinary skill in the art to which the claimed subject matter pertains. Non-limiting examples of prior art rendering each of the claims of the '875 patent invalid under, at the very least, 35 U.S.C. §§ 102 and/or 103, include, *but are expressly not*

*limited to*, one or more (or a combination of one or more) of the references and/or products set forth, and discussed, in Perrigo's September 23 Notice Letter. Such references and products include, but are not limited to: U.S. Patent Appl. Publ. No. 2010/0276329; Labeling for Cuvposa (glycopyrrolate) Oral Solution (NDA 022571); Cuvposa (glycopyrrolate) Oral Solution Product; U.S. Patent No. 4,355,020; U.S. Patent No. 5,403,588; U.S. Patent No. 5,648,083; U.S. Patent No. 5,962,505; U.S. Patent No. 6,211,250; U.S. Patent No. 6,433,003; U.S. Patent No. 6,446,795; U.S. Patent No. 7,060,289; U.S. Patent No. 8,252,316; U.S. Patent Appl. Publ. No. 2003/0115837; U.S. Patent Appl. Publ. No. 2006/0165765; U.S. Patent Appl. Publ. No. 2006/0211729; U.S. Patent Appl. Publ. No. 2008/0292562; Spanish Patent Appl. Publ. No. 2 118 053; L.L. Hays, "The Frey Syndrome: A Review And Double Blind Evaluation Of The Topical Use Of A New Anticholinergic Agent," *The Laryngoscope*, vol. 88, pp. 1796-1824 (1978); J.E. Shaw, *et al*., "A randomised controlled trial of topical glycopyrrolate, the first specific treatment for diabetic gustatory sweating," *Diabetologia*, vol. 40, pp. 299-301 (1997); REMINGTON: THE SCIENCE AND PRACTICE OF PHARMACY (21st ed., 2006); PHYSICIANS' DESK REFERENCE (54th ed., 2000); Labeling for Robinul Injection (Glycopyrrolate Injection, USP) (NDA 017558); Labeling for Robinul® and Robinul® Forte Tablets (Glycopyrrolate Tablets, USP) (NDA 012827); Robinul® Injection Product (Glycopyrrolate Injection, USP); Robinul® Tablets Product (Glycopyrrolate Tablets, USP); Robinul® Forte Tablets Product (Glycopyrrolate Tablets, USP).

139. Perrigo is entitled to a declaration that the claims of the '875 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code.

## REQUEST FOR RELIEF

WHEREFORE, Perrigo respectfully requests that this Court enter a Judgment and Order in its favor and against Plaintiffs/Counterclaim-Defendants Dermira and Rose as follows:

(a) Declaring that the manufacture, sale, offer for sale, use or importation of the Glycopyrronium, Cloth, 2.4% product described in Perrigo's ANDA No. 214448 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '160 patent;

(b) Declaring that the claims of the '160 patent are invalid;

(c) Declaring that the manufacture, sale, offer for sale, use or importation of the Glycopyrronium, Cloth, 2.4% product described in Perrigo's ANDA No. 214448 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '105 patent;

(d) Declaring that the claims of the '105 patent are invalid;

(e) Declaring that the manufacture, sale, offer for sale, use or importation of the Glycopyrronium, Cloth, 2.4% product described in Perrigo's ANDA No. 214448 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '267 patent;

(f) Declaring that the claims of the '267 patent are invalid;

(g) Declaring that the manufacture, sale, offer for sale, use or importation of the Glycopyrronium, Cloth, 2.4% product described in Perrigo's ANDA No. 214448 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '610 patent;

(h) Declaring that the claims of the '610 patent are invalid;

(i) Declaring that the manufacture, sale, offer for sale, use or importation of the Glycopyrronium, Cloth, 2.4% product described in Perrigo's ANDA No. 214448 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '414 patent;

(j) Declaring that the claims of the '414 patent are invalid;

(k) Declaring that the manufacture, sale, offer for sale, use or importation of the Glycopyrronium, Cloth, 2.4% product described in Perrigo's ANDA No. 214448

does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '717 patent;

(l) Declaring that the claims of the '717 patent are invalid;

(m) Declaring that the manufacture, sale, offer for sale, use or importation of the Glycopyrronium, Cloth, 2.4% product described in Perrigo's ANDA No. 214448 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '192 patent;

(n) Declaring that the claims of the '192 patent are invalid;

(o) Declaring that the manufacture, sale, offer for sale, use or importation of the Glycopyrronium, Cloth, 2.4% product described in Perrigo's ANDA No. 214448 does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid and enforceable claim of the '875 patent;

(p) Declaring that the claims of the '875 patent are invalid;

(q) Ordering that Plaintiffs' Complaint be dismissed with prejudice and judgment entered in favor of Perrigo;

(r) Declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Perrigo attorneys' fees, costs, and expenses in this action; and

(s) Awarding Perrigo any further and additional relief as the Court deems just and proper.

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Dated: November 30, 2020