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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

GALDERMA LABORATORIES, L.P., GALDERMA S.A., GALDERMA RESEARCH & DEVELOPMENT, S.N.C., and GALDERMA HOLDING, S.A.,

Plaintiffs,

v.

TEVA PHARMACEUTICALS, INC., TEVA PHARMACEUTICALS USA, INC., TEVA PHARMACEUTICALS INTERNATIONAL GMBH, and TEVA PHARMACEUTICAL INDUSTRIES LTD.

Defendants.

Civil Action No. _____

Document Electronically Filed

COMPLAINT

Plaintiffs Galderma Laboratories, L.P., Galderma S.A., Galderma Research & Development, S.N.C., and Galderma Holding, S.A., (collectively, "Galderma" or "Plaintiffs"), by its undersigned attorneys, for its Complaint against defendants Teva Pharmaceuticals, Inc. ("Teva Pharmaceuticals"), Teva Pharmaceuticals USA, Inc. ("Teva USA"), Teva Pharmaceuticals International GmbH ("Teva International") and Teva Pharmaceutical Industries Ltd. ("Teva Industries") (collectively, "Teva" or "Defendants") herein, allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, involving United States Patent No. 9,084,778 ("the '778 patent") (attached as Exhibit A hereto); United States Patent No. 9,498,465 ("the '465 patent") (attached as Exhibit B hereto) (collectively, "the Patents-in-Suit"). This action relates to Teva's recent submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Plaintiff's commercial pharmaceutical product AKLIEF® (trifarotene cream, for topical use), submitted under New Drug Application ("NDA") No. 211527, prior to the expiration of patents listed in the Approved Drug Products with Therapeutic Equivalence Evaluations (an FDA publication commonly known as the "Orange Book") for AKLIEF®, including the Patents-in-Suit. Teva has submitted ANDA No. 218739 ("Teva's ANDA"), which seeks approval to market its generic version of AKLIEF® (trifarotene cream (0.005%), for topical use) ("Teva's ANDA Product"), prior to the expiration of the Patents-in-Suit.

THE PARTIES

2. Plaintiff Galderma Laboratories, L.P. is a Texas limited partnership with its principal place of business at 2001 Ross Avenue, Suite 1600, Dallas, Texas 75201. Galderma Laboratories, L.P. distributes AKLIEF® in the United States and its territories.

3. Plaintiff Galderma S.A. is a Swiss company with its principal place of business at Zählerweg 10, 6300 Zug, Switzerland. Galderma S.A. is an exclusive licensee of the Patents-in-Suit.

4. Galderma Laboratories, L.P. markets AKLIEF® in the United States under FDA approval of NDA No. 211527, approved October 4, 2019. Moreover, Galderma Laboratories, L.P. owns NDA No. 211527.

5. Galderma Research & Development, S.N.C. is a French corporation with its principal place of business at 2400 Route Des Colles, Les Templiers, Biot, France 06410. Galderma Research & Development, S.N.C. is the current owner of the Patents-in-Suit. Galderma Research & Development, S.N.C. granted to Galderma S.A. an exclusive and worldwide license, with the right to grant sublicenses, to use and exploit the Patents-in-Suit.

6. Plaintiff Galderma Holding S.A. is a Swiss company with its principal place of business at Zählerweg 10, 6300 Zug, Switzerland. Galderma Laboratories, L.P. and Galderma S.A. are subsidiaries of Galderma Holding S.A.

7. On information and belief, Defendant Teva Pharmaceuticals is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

8. On information and belief, Defendant Teva USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054.

9. On information and belief, Defendant Teva International is a limited liability company organized and existing under the laws of Switzerland with its principal place of business at Schlüsselstrasse 12, 8645 Jona (SG) 8645, Switzerland.

10. On information and belief, Defendant Teva Industries is a corporation organized and existing under the laws of Israel, with a principal place of business at 124 Dvora HaNevi'a St. Tel Aviv 6944020, Israel.

11. On information and belief, Teva Pharmaceuticals is a wholly-owned subsidiary of Teva Industries.

12. On information and belief, Teva USA is a wholly owned subsidiary of Teva Industries.

13. On information and belief, Teva International is a wholly owned subsidiary of Teva Industries.

14. On information and belief, Teva is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District.

JURISDICTION AND VENUE

15. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

16. This Court has personal jurisdiction over the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Galderma in the State of New Jersey and throughout the United States. For example, on information and belief, by and through Teva Pharmaceuticals, Defendants prepared and submitted Teva's ANDA to FDA in New Jersey. Further, on information and belief, following approval of Teva's ANDA, Defendants will make, use, import, sell, and/or offer for sale Teva's ANDA Product in the United States, including in New Jersey, prior to the expiration of the Patents-in-Suit.

17. This Court also has personal jurisdiction over Teva Pharmaceuticals by virtue of

the fact that Teva Pharmaceuticals is at home in New Jersey as reflected by the fact that it maintains a place of business in New Jersey, regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, including by selling its pharmaceutical products in New Jersey and, therefore, can reasonably expect to be subject to jurisdiction in the New Jersey courts. Among other things, on information and belief, Teva Pharmaceuticals conducts marketing and sales activities in the State of New Jersey, including, but not limited to, distribution, marketing, and/or sales of pharmaceutical products to New Jersey residents that are continuous and systematic. Additionally, on information and belief, Teva Pharmaceuticals intends to market and sell its proposed product in the State of New Jersey.

18. On information and belief, Teva Pharmaceuticals maintains a regular and established, physical place of business in this Judicial District, in at least Parsippany, New Jersey. Teva's website states that its "US Headquarters" is located in Parsippany, New Jersey. *See* https://www.tevausa.com/contact-us/ (last visited January 11, 2024). On information and belief, Teva Pharmaceuticals is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business Id. No. 0450614134. In recent court filings, Teva has admitted that it has a "a principal place of business" in Parsippany, New Jersey. *See, e.g.*, *Neurocrine Bioscis., Inc. v. Teva Pharm., Inc.*, et. al., No. 22-965, ECF No. 14 at ¶ 12 (D. Del. Nov. 1, 2022).

19. This Court has personal jurisdiction over Teva USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of New Jersey. On information and belief, Teva USA's principal place of business is in Parsippany, New Jersey. On information and belief, Teva USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as

a business operating in New Jersey under Business Id. No. 0100250184. On information and belief, Teva USA is registered with the State of New Jersey's Department of Health as a drug manufacturer under Registration Nos. 5000583 and 5003436. On information and belief, Teva USA purposefully has conducted and continues to conduct business in this Judicial District. By virtue of its physical presence in New Jersey, this Court has personal jurisdiction over Teva USA.

20. On information and belief, Teva USA is in the business of, among other things, manufacturing, marketing, importing, offering for sale, and selling pharmaceutical products, including generic drug products, throughout the United States, including in this Judicial District. On information and belief, this Judicial District will be a destination for the generic drug products described in Teva's ANDA. On information and belief, Teva USA also prepares and/or aids in the preparation and submission of ANDAs to FDA.

21. On information and belief, Teva USA is involved in the preparation and development of the Teva ANDA Product. Teva USA is listed as an applicant for International Application Number PCT/US2021/028279, filed April 21, 2021, titled "Solid State Forms of Trifarotene and Process for Preparation Thereof." Teva USA is also listed as the Sponsor and Responsible Party for Clinical Trial ID No. NCT05550337 titled "Study Comparing Trifarotene Cream, 0.005% To AKLIEF® (Trifarotene 0.005% Cream) In The Treatment of Acne Vulgaris."

22. This Court has personal jurisdiction over Teva USA because Teva USA has purposefully availed itself of the rights and benefits of New Jersey law by engaging in systematic and continuous contact with the State of New Jersey. On information and belief, Teva USA regularly and continuously transacts business within New Jersey, including by making pharmaceutical products for sale in New Jersey and selling pharmaceutical products in New Jersey. On information and belief, Teva USA derives substantial revenue from the sale of those products

in New Jersey and has availed itself of the privilege of conducting business within New Jersey. On information and belief, Teva USA derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

23. This Court has personal jurisdiction over Teva International because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, Teva USA, a company registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler and a company registered with the State of New Jersey as a business operating in New Jersey, and Teva Pharmaceuticals, a company registered with the State of New Jersey as a business operating in New Jersey; and (2) maintained extensive and systematic contacts with the State of New Jersey, including preparation and submission of Teva's ANDA to FDA in New Jersey including through, directly or indirectly, Teva Pharmaceuticals, and/or the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Teva USA.

24. This Court has personal jurisdiction over Teva International because Teva International derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District.

25. On information and belief, Teva International is involved in the preparation and development of the Teva ANDA Product. Teva International is the listed as an applicant for International Application Number PCT/US2021/028279, filed April 21, 2021, titled "Solid State Forms of Trifarotene and Process for Preparation Thereof."

26. This Court has personal jurisdiction over Teva Industries because, *inter alia*, it: (1) has purposefully availed itself of the privilege of doing business in New Jersey, including directly or indirectly through its subsidiaries, agents, and/or alter egos, Teva USA, a company registered with the State of New Jersey's Department of Health as a drug manufacturer and wholesaler, and Teva Pharmaceuticals, a company registered with the State of New Jersey as a business operating in New Jersey; and (2) maintained extensive and systematic contacts with the State of New Jersey, including preparation and submission of Teva's ANDA to FDA in New Jersey including through, directly or indirectly, Teva Pharmaceuticals, and/or the marketing, distribution, and/or sale of generic pharmaceutical drugs in New Jersey including through, directly or indirectly, Teva USA.

27. This Court has personal jurisdiction over Teva Industries because Teva Industries derives substantial revenue from selling generic pharmaceutical products and/or active pharmaceutical ingredient(s) used in generic pharmaceutical products sold throughout the United States, including in this Judicial District. Teva Industries's Securities and Exchange Commission Form 10-K filing for the fiscal year ended December 31, 2022 ("Teva Industries Form 10-K") states that it is "one of the leading generic pharmaceutical companies in the United States" and that it markets "approximately 500 generic prescription products in more than 1,400 dosage strengths, packaging sizes and forms, including oral solid dosage forms, injectable products, inhaled products, transdermal patches, liquids, ointments and creams." Teva Industries Form 10-K at 3. The Teva Industries Form 10-K further states that its revenue for the year ending December 31, 2022 of generic products in the North America segment was $3.549 billion. *Id*. at 58. It further states that, "[i]n 2022, [Teva's] total prescriptions were approximately 306 million (based on trailing twelve months), representing 8.2% of total U.S. generic prescriptions according IQVIA

data." *Id.*

28. On information and belief, Teva Pharmaceuticals, Teva USA, Teva International, and Teva Industries work in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in this Judicial District.

29. On information and belief, Teva Pharmaceuticals and Teva USA are United States agents acting at the direction of, and for the benefit of, Teva Industries regarding Teva's ANDA.

30. On information and belief, Teva Pharmaceuticals and Teva USA are generic pharmaceutical companies that, in coordination with each other and Teva Industries and at the direction of Teva Industries, are in the business of making and selling generic pharmaceutical products, which they distribute throughout the United States including in this Judicial District.

31. On information and belief, Teva Pharmaceuticals, Teva USA, Teva International, and Teva Industries operate as a single integrated business.

32. On information and belief, Teva Pharmaceuticals intends to benefit directly if Teva's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Teva's ANDA Product.

33. On information and belief, Teva USA intends to benefit directly if Teva's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Teva's ANDA Product.

34. On information and belief, Teva International intends to benefit directly if Teva's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Teva's ANDA Product.

35. On information and belief, Teva Industries intends to benefit directly if Teva's ANDA is approved by participating in the manufacture, importation, distribution, and/or sale of Teva's ANDA Product.

36. On information and belief, Teva Pharmaceuticals, Teva USA, Teva International, and Teva Industries actively participated in the submission of Teva's ANDA. On information and belief, Teva Pharmaceuticals, Teva USA, Teva International, and Teva Industries work in privity and in concert with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products, including Teva's ANDA Product, throughout the United States, including in this Judicial District, prior to the expiration of the Patents-in-Suit.

37. On information and belief, Teva Pharmaceuticals, Teva USA, Teva International, and Teva Industries has previously invoked, stipulated, and/or consented to personal jurisdiction in this Judicial District in numerous patent infringement actions.

38. In the alternative, this Court has personal jurisdiction over Teva International because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Teva International is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Teva Industries has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva International satisfies due process.

39. In the alternative, this Court has personal jurisdiction over Teva Industries because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met as (a) Plaintiffs' claims arise under federal law; (b) Teva Industries is a foreign defendant not subject to general

personal jurisdiction in the courts of any state; and (c) Teva Industries has sufficient contacts with the United States as a whole, including, but not limited to, preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Teva Industries satisfies due process.

40. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c), and § 1400(b).

FACTS AS TO ALL COUNTS

41. Galderma Laboratories LP is the owner of NDA No. 211527, which was approved by the FDA for the manufacture and sale of AKLIEF®. AKLIEF® is the trade name for trifarotene cream (0.005%), for topical use and is approved for the for the topical treatment of acne vulgaris in patients 9 years of age and older.

42. Pursuant to 21 U.S.C. § 355(b)(1), the Patents-in-Suit are listed in the Orange Book as covering the AKLIEF® product.

43. Galderma Research & Development S.N.C owns the Patents-in-Suit.

44. Galderma Laboratories, L.P. markets Galderma's patented products in the United States, including AKLIEF®.

45. The '778 patent, titled "Topical Compositions Containing a Retinoid of the Oil-In-Water Emulsion Type" was duly and legally issued on July 21, 2015. The '778 patent is generally directed to pharmaceutical formulations comprising trifarotene.

46. The '465 patent, titled "Topical Compositions In the Form of a Gel Containing a Particular Solubilized Retinoid" was duly and legally issued on November 22, 2016. The '465 patent is generally directed to pharmaceutical formulations comprising trifarotene.

47. Teva prepared, submitted, and filed Teva's ANDA to the FDA under § 505(j) of

the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)) seeking approval to engage in the commercial manufacture, use, sale, offer for sale and/or importation of generic trifarotene cream (0.005%), for topical use before the expiration of the Patents-in-Suit.

48. On information and belief, Teva will market and distribute Teva's ANDA Product throughout the United States, if approved.

49. Teva Pharmaceuticals sent a letter to Galderma Laboratories LP and Galderma Research & Development purporting to provide notification that Teva's ANDA contains certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "paragraph IV certification") with regard to the Patents-In-Suit ("the Teva Notice Letter").

50. 21 U.S.C. § 355(j)(2)(B)(iv)(II) requires that a letter notifying a patent holder of the filing of an ANDA containing a paragraph IV certification "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires a paragraph IV notification to include "[a] detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement is to include "(i) [f]or each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "(ii) [f]or each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the grounds supporting the allegation." 21 C.F.R. §§ 314.95(c)(7)(i)–(ii).

51. The Teva Notice Letter does not assert non-infringement for every claim of every patent for which Teva has made a paragraph IV certification.

52. The Teva Notice Letter does not assert invalidity for every claim of every patent for which Teva has made a paragraph IV certification.

53. The Teva Notice Letter does not provide a full and detailed explanation of Teva's factual and legal basis of noninfringement, invalidity and/or unenforceability for any claim of any patent for which Teva has made a paragraph IV certification.

FIRST COUNT
(Infringement of the '778 Patent by Defendants)

54. Galderma repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

55. On information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of Teva's ANDA Product.

56. On information and belief, in connection with Teva's ANDA, Defendants submitted a paragraph IV certification to the '778 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Teva's ANDA Product before the expiration of the '778 patent.

57. On information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import Teva's ANDA Product upon FDA approval of Teva's ANDA.

58. On information and belief, as of the date of the Teva Notice Letter, Teva was aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

59. The inclusion of a paragraph IV certification to the '778 patent in Teva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Teva's ANDA Product before the expiration of the '778 patent is an act of infringement by Defendants of one or more claims of the '778 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

60. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Teva's ANDA Product that is the subject of Teva's ANDA will infringe one or more claims of the '778 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

61. On information and belief, Defendants are aware of the existence of the '778 patent. On information and belief, Defendants acted without a reasonable basis for believing that it would not be liable for infringement of the '778 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

62. The acts of infringement set forth above will cause Galderma irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

SECOND COUNT
(Infringement of the '465 Patent by Defendants)

63. Galderma repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

64. On information and belief, Defendants seek FDA approval for the manufacture, marketing, sale, and/or distribution of Teva's ANDA Product.

65. On information and belief, in connection with Teva's ANDA, Defendants submitted a paragraph IV certification to the '465 patent to obtain approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Teva's ANDA Product before the expiration of the '465 patent.

66. On information and belief, Defendants will commercially manufacture, sell, offer for sale, and/or import Teva's ANDA Product upon FDA approval of Teva's ANDA.

67. On information and belief, as of the date of the Teva Notice Letter, Teva was

aware of the statutory provisions and regulations set forth in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

68. The inclusion of a paragraph IV certification to the '465 patent in Teva's ANDA for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of Teva's ANDA Product before the expiration of the '465 patent is an act of infringement by Teva of one or more claims of the '465 patent under 35 U.S.C. § 271(e)(2)(A) directly and/or indirectly, including by inducement and/or contributory infringement.

69. On information and belief, Defendants' commercial manufacture, use, sale, offer for sale, and/or importation into the United States of Teva's ANDA Product that is the subject of Teva's ANDA will infringe one or more claims of the '465 patent under 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c).

70. On information and belief, Defendants are aware of the existence of the '465 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '465 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

71. The acts of infringement set forth above will cause Galderma irreparable harm for which it has no adequate remedy at law, unless Defendants are preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Galderma respectfully requests the following relief:

i. A judgment declaring that the '778 patent is valid and enforceable;

ii. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of Teva's ANDA with a paragraph IV certification to obtain

approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of Teva's ANDA was an act of infringement of the '778 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iii. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of Teva's ANDA prior to the expiration of the '778 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

iv. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of Teva's ANDA shall be no earlier than the date on which the '778 patent expires including any regulatory extensions;

v. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of Teva's ANDA until the expiration of the '778 patent including any regulatory extensions;

vi. A judgment awarding Galderma damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of Teva's ANDA that infringes the '778 patent;

vii. A judgment declaring that infringement of the '778 patent is willful if

Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of Teva's ANDA that infringes the '778 patent;

viii. A judgment declaring that the '465 patent is valid and enforceable;

ix. A judgment declaring that, pursuant to 35 U.S.C. § 271(e)(2)(A), the submission to the FDA and filing of Teva's ANDA with a paragraph IV certification to obtain approval for the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of Teva's ANDA was an act of infringement of the '465 patent by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

x. A judgment declaring that, pursuant to 35 U.S.C. § 271(a), 35 U.S.C. § 271(b), and/or 35 U.S.C. § 271(c), the commercial manufacture, use, sale, offer for sale, and/or importation in the United States of the product that is the subject of Teva's ANDA prior to the expiration of the '465 patent, including any regulatory extensions, will constitute an act of infringement by Defendants directly and/or indirectly, including by inducement and/or contributory infringement;

xi. An order that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the product that is the subject of Teva's ANDA shall be no earlier than the date on which the '465 patent expires including any regulatory extensions;

xii. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) preliminarily and permanently enjoining Defendants and their officers, agents, servants, employees and attorneys, and those persons in active concert or participation or privity with them or any of them, from engaging in the commercial manufacture, use, sale, offer to sale, and/or importation in the United States of the product that is the subject of Teva's ANDA until the expiration of the '465 patent

including any regulatory extensions;

xiii. A judgment awarding Galderma damages or other monetary relief, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of Teva's ANDA that infringes the '465 patent;

xiv. A judgment declaring that infringement of the '465 patent is willful if Defendants commercially manufacture, use, sell, offer to sell, and/or import any product that is the subject of Teva's ANDA that infringes the '465 patent;

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

xvi. Such other and further relief as this Court may deem just and proper.

Respectfully submitted,

Dated: January 11, 2024
Newark, New Jersey

s/ Charles H. Chevalier
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