Stephanie L. Jonaitis, Esq.
PEPPER HAMILTON LLP
(A Pennsylvania Limited Liability Partnership)
301 Carnegie Center, Suite 400
Princeton, New Jersey 08543-5276
Tel.: 609.452.0808
Fax: 609.452.1147
E-mail: jonaitis@pepperlaw.com

Andrew P. Zappia, Esq. (*pro hac vice* to be filed)
PEPPER HAMILTON LLP
(A Pennsylvania Limited Liability Partnership)
70 Linden Oaks, Suite 210
Rochester, New York 14625
Tel.: 585.270.2100
Fax: 585.270.2179
E-mail: zappiaa@pepperlaw.com

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ENCORE DERMATOLOGY INC., Plaintiff, v. GLENMARK PHARMACEUTICALS LIMITED, Defendant.	CIVIL ACTION NO. **COMPLAINT**

Plaintiff Encore Dermatology Inc. ("Encore" or "Plaintiff"), as and for its Complaint against Glenmark Pharmaceuticals Limited ("Glenmark Ltd." or "Glenmark"), hereby alleges as follows:

THE PARTIES

1. Plaintiff Encore is a corporation organized and existing under the laws of the state of Delaware with a principal place of business at 5 Great Valley Pkwy, Suite 200, Malvern, Pennsylvania 19355.

2. Upon information and belief, Defendant Glenmark Ltd. is an Indian corporation with a principal place of business at Glenmark Pharmaceuticals Limited, B/2, Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai, India – 400 026. Upon information and belief, Defendant Glenmark Ltd., itself or through its wholly-owned subsidiaries and agents, develops, manufactures, markets, sells, and/or imports generic pharmaceutical versions of branded products throughout the United States, including in this judicial district. In that regard, Glenmark Pharmaceuticals Inc., USA ("Glenmark USA"), is a Delaware corporation having a place of business at 750 Corporate Drive, Mahwah, New Jersey 07430. Upon information and belief, Glenmark USA is a wholly-owned direct or indirect subsidiary of Glenmark Ltd. Upon information and belief, Glenmark USA develops, markets, and/or sells various drug products in the United States, including in this judicial district, in coordination with Glenmark Ltd. Upon information and belief, as a wholly-owned direct or indirect subsidiary of Glenmark Ltd., and as what appears to be a United States business operating entity of Glenmark Ltd., Glenmark USA, and/or its officers, director, or employees, are believed to have worked directly with, and/or contributed to, Glenmark Ltd.'s preparation and submission of Abbreviated New Drug Applications ("ANDAs"), including without limitation, Glenmark's ANDA (defined below). Further, upon information and belief, if Glenmark's ANDA is approved and its proposed Generic Product (defined below), is launched in the United States, Glenmark USA, and/or its officers,

director, or employees, are believed to likely participate and assist in commercial activities relating to the proposed Generic Product.

NATURE OF THE ACTION

3. This is a civil action for patent infringement arising under the Patent Laws of the United States and the Food and Drug Laws of the United States pursuant to Titles 35 and 21 of the United States Code.

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

JURISDICTION AND VENUE

5. Upon information and belief, this Court has personal jurisdiction over Glenmark Ltd.

6. In its 2017-2018 Annual Report, Glenmark Ltd. states that its Global Clinical Development Centre was located at 461 From Road, Paramus, NJ 07652. *See* **Exhibit A** hereto.

7. Upon information and belief, Glenmark Ltd. regularly does and/or solicits business in New Jersey, through among other things, that listed United States business address in New Jersey and directly or through one or more wholly-owned subsidiaries, agents, and/or alter egos, including without limitation, Glenmark USA. Upon information and belief, Glenmark Ltd. has purposefully availed itself of the privilege of conducting business activities in New Jersey such that it should reasonably anticipate being subject to jurisdiction in this Court and in New Jersey.

8. Glenmark Ltd. is also subject to jurisdiction in New Jersey based on its relationship with Glenmark USA. Upon information and belief, Glenmark USA is resident in New Jersey and regularly does and/or solicits business in New Jersey, through among other

things, its listed United States business address in New Jersey, and has purposefully availed itself of the privilege of conducting business activities in New Jersey. For example, Glenmark USA is registered to do business in the State of New Jersey under Business ID Number 0400025135, and Glenmark USA is registered with the State of New Jersey as a manufacturer and wholesale distributor of drugs under Registration Number 5003119.

9. Among other things, Glenmark Ltd., either directly or through its affiliated entities, including without limitation Glenmark USA, regularly develops, manufactures, obtains regulatory approval for, markets, sells, and/or distributes drug products in New Jersey and throughout the United States, from which Glenmark Ltd. derives revenues.

10. Upon information and belief, Glenmark Ltd. is in the business of manufacturing and/or selling pharmaceutical products that are distributed throughout the United States, including in New Jersey. Glenmark Ltd. directly or through its affiliates and agents, develops, formulates, manufactures, markets, sells, and/or distributes pharmaceutical products, including drug products, throughout the United States and in this judicial district.

11. Upon information and belief, Glenmark Ltd., through its own actions and/or through the actions of its agents and subsidiaries, including, without limitation, Glenmark USA, has engaged in the research and development, and the preparation and filing of, ANDA No. 214191, continues to engage in seeking Food and Drug Administration ("FDA") approval of ANDA No. 214191, intends to engage in the commercial manufacture, marketing, offer for sale, sale, or importation of Glenmark Ltd.'s proposed Generic Product throughout the United States, including in New Jersey, and stands to benefit from the approval of ANDA No. 214191.

12. This Court also has personal jurisdiction over Glenmark Ltd. at least because: (a) Glenmark Ltd. has filed ANDA No. 214191 seeking approval to engage in the commercial

manufacture, use, offer for sale, sale, or importation of the proposed Generic Product in the United States, including in the State of New Jersey; (b) Glenmark Ltd., through its own actions and through the actions of its agents and subsidiaries, will market, distribute, offer to sell, or sell the proposed Generic Product in the United States, including in New Jersey and to residents of this judicial district, upon approval of ANDA No. 214191, and will derive substantial revenue from the use and consumption of the proposed Generic Product in New Jersey; and (c) Glenmark Ltd. has purposefully availed itself of the privilege of doing business in New Jersey by placing goods into the stream of commerce for distribution throughout the United States and within New Jersey, and/or by selling, directly or through its agents, pharmaceutical products in New Jersey. Upon information and belief, if ANDA No. 214191 is approved, the proposed Generic Product would be marketed, distributed, offered for sale, sold, prescribed by physicians, dispensed by pharmacies, and used by patients in New Jersey, all of which would have a substantial effect on New Jersey.

13. Upon information and belief, Glenmark Ltd.'s actions will injure Encore by displacing a significant portion of Encore's sales of the Impoyz® drug product in this judicial district, as well as resulting in price erosion and loss of goodwill with the purchasers and distributors of the Impoyz® drug product in this judicial district.

14. Glenmark Ltd. knows it will be subject to, and has not contested being subject to, jurisdiction in the State of New Jersey. Public information available on Pacer shows that Glenmark Ltd., Glenmark USA, and other Glenmark entities have been sued in this judicial district for patent infringement not less than 20 times since 2010 and in those suits (*see* **Exhibit B** hereto), the Glenmark entities have not challenged personal jurisdiction.

15. As a pleading in the alternative, this Court also has personal jurisdiction over Glenmark Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Encore's claims arise under federal law; (b) Glenmark Ltd. is a foreign defendant who could try to claim it is not subject to jurisdiction in the courts of any state; and (c) Glenmark Ltd. has sufficient contacts with the United States as a whole (and New Jersey in particular), including, but not limited to, preparing and submitting ANDAs to the FDA and/or marketing, manufacturing, importing, offering to sell, or selling pharmaceutical products that are distributed throughout the United States (and New Jersey in particular), such that this Court's exercise of jurisdiction over Glenmark Ltd. comports with due process.

16. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391 and 1400(b) because Glenmark Ltd. has or had an office for business operations located in this judicial district, and its affiliate Glenmark USA is located in this judicial district. For example, venue is proper in this district under 28 U.S.C. § 1400(b) because Glenmark Ltd. "committed an act of infringement" in this judicial district and has a "regular place and established place of business" in this district. Glenmark Ltd. submitted ANDA No. 214191, and, upon receiving approval of the ANDA, will manufacture, sell, offer to sell, and/or import its proposed Generic Product throughout the United States, including in this judicial district. Thus, Glenmark Ltd. has committed an act of infringement in this judicial district. Glenmark Ltd. and/or Glenmark USA also have a "regular and established place of business in this judicial district.

FACTUAL BACKGROUND

The Patent-in-Suit and Encore's Branded Product

17. Encore owns by assignment U.S. Patent No. 9,956,231 (the "'231 Patent"). The '231 Patent was issued on May 1, 2018. The '231 Patent is valid and legally enforceable. A true

and correct copy of the '231 Patent is attached hereto as **Exhibit C**. The '231 Patent expires on August 31, 2030.

18. Claim 1 of the '231 Patent claims:

> 1. A topical pharmaceutical composition comprising: clobetasol;
>
> an emulsifying agent from about 0.25% w/w to about 45% w/w of the composition;
>
> a skin penetration enhancer from about 0.001% w/w to about 15% w/w of the composition;
>
> a water-immiscible substance; and
> water;
>
> wherein the composition is non-foaming, propylene glycol-free, and propellant free.

Exhibit C, 27:11-20.

19. Claim 9 of the '231 Patent claims:

> 9. A method of treating a skin condition in a subject comprising
>
> topically administering an effective amount of a composition according to claim 1 to the subject;
>
> wherein the skin condition is one or more of atopic dermatitis, seborrheic dermatitis, eczema, plaque psoriasis, erythroderma psoriasis, and psoriasis of the scalp, steroid responsive dermatoses, erythema, or contact sensitivity reaction.

Exhibit C, 28:23-31.

20. The specification of the '231 Patent states that "many formulations contain propylene glycol, which is an excellent vehicle and solvent for preparation of dermatologic dosage forms; however, since propylene glycol has a tendency to induce irritant or allergic skin reactions, such formulations do not promote patient compliance." **Exhibit C**, 3:54-59.

21. The specification of the '231 Patent provides that "compositions of the present application are substantially alcohol-free and/or propylene glycol-free, such that any amounts present do not cause significant skin irritation or impart any undesired attributes to the composition." **Exhibit C**, 7:13-17. Thus, the specification of the '231 Patent teaches that the patentee intended those terms to be understood in the context of amounts that "do not cause significant skin irritation or impart any undesired attributes to the composition." *Id.*

22. Encore holds New Drug Application No. 209483 (the "NDA") for Impoyz® (clobetasol propionate) Cream, 0.025%, which is prescribed and sold in the United States under the name Impoyz®. The NDA was approved on November 28, 2017.

23. Impoyz® is indicated for the treatment of moderate to severe plaque psoriasis in patients 18 years of age or older.

24. The '231 Patent, among other patents, is listed in the FDA's *Approved Drug Products with Therapeutic Equivalents Evaluations*, more commonly known as the "Orange Book," for Impoyz®.

Glenmark Ltd.'s ANDA

25. Upon information and belief, Glenmark Ltd. submitted to the FDA ANDA No. 214191 ("Glenmark's ANDA"), to seek approval to engage in the commercial manufacture, use, or sale of a clobetasol propionate cream USP, 0.025% (the proposed "Generic Product").

26. Pursuant to 35 U.S.C. § 271(e)(2)(A), Glenmark Ltd.'s submission of Glenmark's ANDA with a Paragraph IV Certification (defined below) is an act of infringement.

27. By letter dated January 24, 2020 (received by Encore on January 27, 2020), and pursuant to 21 U.S.C. §§ 355(j)(2)(B) and 21 C.F.R. § 314.95, Glenmark Ltd. notified Encore that Glenmark Ltd. had submitted Glenmark's ANDA and any required bioavailability and/or

bioequivalence data to the FDA, seeking approval to engage in the commercial manufacture, use, or sale of the proposed Generic Product prior to the expiration of the '231 Patent and other Encore patents listed in the Orange Book (the "Notice Letter").

28. In the Notice Letter, Glenmark Ltd. notified Encore that, as part of Glenmark's ANDA, Glenmark Ltd. had included a certification of the type described in 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") with respect to, *inter alia*, the '231 Patent.

29. With the Notice Letter, Encore also received a Factual and Legal Basis for Glenmark's Certification that the Claims of U.S. Patent Nos. 9,855,334, 9,956,231, and 10,064,875 are Invalid, Unenforceable, and/or Will Not Be Infringed (the "Detailed Statement"), setting forth the basis for Glenmark Ltd.'s Paragraph IV Certification. In that Detailed Statement, Glenmark Ltd. sets forth no specific grounds for invalidity or unenforceability of any patent listed in the Orange Book for Impoyz®.

30. In the Detailed Statement, regarding the '231 Patent, the only basis asserted by Glenmark Ltd. for non-infringement is the assertion that its proposed Generic Product contains more than 10% propylene glycol.

31. On or about January 27, 2020, Encore also received from Glenmark Ltd. an Offer of Confidential Access (the "OCA") to Glenmark's ANDA.

32. In view of the Notice Letter and Detailed Statement, Glenmark Ltd. had knowledge of the '231 Patent at least since the date on which Glenmark's ANDA was submitted to the FDA.

33. In order to trigger the thirty-month stay provided for in the statute, 21 U.S.C. § 355(c)(3)(C) affords Encore only forty-five (45) days from receipt of the Notice Letter to determine whether to file an infringement lawsuit under 21 U.S.C. § 355(j)(5)(B)(iii).

34. Pursuant to the Notice Letter, Glenmark Ltd. offered confidential access to Glenmark's ANDA "for the sole and exclusive purpose of determining whether an infringement action referred to in § 355(j)(5)(B)(iii) can be brought."

35. The OCA permitted attorneys from one outside law firm access to certain information from Glenmark's ANDA, which information was selected by Glenmark Ltd. for disclosure to Encore.

36. In the OCA, Glenmark Ltd. offered no input to Encore on the ANDA information provided by Glenmark Ltd.

37. Pursuant to the OCA, Encore's outside counsel were prohibited from sharing the selected portions of Glenmark's ANDA with any other person or entity, including without limitation, any expert or other scientific consultant, without prior written approval from Glenmark Ltd.

38. Given the short time-frame provided for in 21 U.S.C. § 355(c)(3)(C), although Encore was given access to the selected portions of Glenmark's ANDA, Encore did not have sufficient time to seek Glenmark Ltd.'s approval of an expert, and have such an expert perform any analysis of any selected portions of Glenmark's ANDA disclosed to Encore's outside counsel.

39. Encore further has not been provided with any samples of the proposed Generic Product.

40. The OCA further required Encore's outside counsel to return the provided excerpts of Glenmark's ANDA to Glenmark Ltd.'s outside litigation counsel within thirty-five (35) days of receipt. Encore's outside counsel was also prohibited from having a copy of the selected disclosed portions of Glenmark's ANDA when this Complaint was filed.

41. Pursuant to the terms of the OCA, Encore was also prohibited from publicly disclosing the contents of Glenmark's ANDA in any manner. This prohibition therefore prohibited Encore from including or referencing any aspect of the selected disclosed portions of Glenmark's ANDA in this Complaint.

42. This action is being commenced before the expiration of forty-five (45) days from the date Encore received the Notice Letter under 21 U.S.C. § 355(j)(5)(B)(iii).

The Proposed Generic Product

43. Pursuant to the Detailed Statement, Glenmark Ltd. alleges that it does not infringe, *inter alia*, the '231 Patent, because its proposed Generic Product contains greater than 10% propylene glycol. No other basis for non-infringement of the '231 Patent is provided in the Detailed Statement and the Detailed Statement sets forth no specific grounds for any asserted invalidity of the '231 Patent.

44. A showing of bioequivalence is necessary to obtain approval from the FDA for a proposed Generic Product pursuant to 21 U.S.C. § 355(j).

45. As a result, Glenmark Ltd. must be asserting that its proposed Generic Product is bioequivalent to Impoyz®.

46. Upon information and belief, the proposed Generic Product will have instructions for use that substantially copy the instructions accompanying Impoyz®, including instructions for administering the proposed Generic Product to patients for treatment of plaque psoriasis, and those instructions will therefore induce healthcare providers and patients to use that product in a manner set forth in those instructions.

47. Upon information and belief, upon FDA approval of Glenmark's ANDA, Glenmark Ltd. intends to have healthcare providers and patients use the proposed Generic

Product in the manner set forth in the proposed label for that product, which label will instruct healthcare providers to administer the proposed Generic Product to patients for treatment of plaque psoriasis, and Glenmark Ltd. knowingly intends to encourage healthcare providers and patients to administer said product to treat plaque psoriasis in the manner set forth in the proposed label.

48. Upon information and belief, upon FDA approval of Glenmark's ANDA, Glenmark Ltd. intends to market the proposed Generic Product throughout the United States, including in New Jersey.

The Adverse Characteristics of Propylene Glycol

49. Encore's Impoyz® does not contain propylene glycol.

50. Topical corticosteroids are categorized by their ability to penetrate into the dermis of the skin and cause localized vasoconstriction. The more vasoconstriction observed, the more potent the topical corticosteroid. *See* **Exhibit D** – Goa, K. et al., Clinical Pharmacology and Pharmacokinetic Properties of Topically Applied Corticosteroids - A review, *Drugs* 36(5):51-61 (1988).

51. Impoyz® contains the high potency corticosteroid clobetasol propionate.

52. Prior to the approval of Impoyz®, clobetasol propionate (0.05%) was considered a class 1 corticosteroid, indicating that it is a "Super High Potency" corticosteroid, which is the strongest category of corticosteroid available. *See* **Exhibit E** – Topical Steroid Potencies, *Monthly Prescribing Reference* (2017). Impoyz®, which contains 0.025% clobetasol propionate, is considered a class 2 corticosteroid due to its optimized formulation characteristics and notably the absence of propylene glycol.

53. Localized cutaneous effects resulting from topical administration of clobetasol propionate that penetrates can result in permanent damage including epidermal thinning, melanocyte inhibition, atrophy, striae, easy rupture on trauma, blot hemorrhage, stellate scars, prematurely aged skin appearance, telangiectasia, stellate pseudoscars, ulceration, easy bruising, rosacea, perioral dermatitis, acne and purpura. Hypertrichosis, pigment alteration, delayed wound healing and exacerbation of skin infections are less frequent. *See* **Exhibit F** – Coondoo, A. et al., Side effects of topical steroids: A long overdue revisit, *Indian Dermatology Online Journal* 5(4):416–425 (2014).

54. Systemic exposure resulting from topical administration and absorption of clobetasol propionate can cause reversible hypothalamic-pituitary-adrenal ("HPA") axis suppression with the potential for glucocorticosteroid insufficiency. *See* **Exhibit G** hereto – *Impoyz® Package Insert*.

55. The HPA axis plays a major role in the stress response and HPA axis suppression can result in adrenal insufficiency and glucocorticosteroid insufficiency, which in turn results in an impaired stress response, including an inadequate host defense against infections, which can result in death.

56. In rare cases, systemic exposure to high levels of topical corticosteroids may also manifest as Cushing's syndrome, hyperglycemia, and glucosuria. *See* **Exhibit G**.

57. The unwanted risks from both localized and systemic exposure to topical corticosteroids can be minimized by reducing systemic exposure of corticosteroids such as clobetasol propionate. *See* **Exhibit G**.

58. Propylene glycol is a highly effective skin penetration agent, with the amount of propylene glycol present in a topical formulation being correlated to the amount of active

ingredient in topical formulations making it into the human blood stream (*e.g.*, increased systemic exposure and absorption), which in turn can augment the potency of a topical corticosteroid.

59. For example, the corticosteroid betamethasone dipropionate is available in two different formulations: betamethasone dipropionate and augmented betamethasone dipropionate. The only difference between these formulations is an increased percentage of propylene glycol in augmented betamethasone dipropionate. The additional epidermal penetration of the augmented betamethasone dipropionate due to the higher concentration of propylene glycol increased the potency of the augmented betamethasone dipropionate from a class 2 to a class 1 corticosteroid due to its increased ability to cause vasoconstriction. This evidences how the presence of propylene glycol increases potency and thereby risk factors, such as increased systemic absorption of the topical corticosteroid.

60. Propylene glycol is also a strong skin irritation agent.

61. Propylene glycol is a known cause of irritant and allergic contact dermatitis. *See* **Exhibit H** – Coloe, J. et al., Allergens in Corticosteroid Vehicles, *Dermatitis* 19(1):38-42 (2008).

62. Studies have shown that propylene glycol is the most common allergen in topical corticosteroids. *See* **Exhibit H.**

63. Factors that predispose a patient to HPA axis suppression include an altered skin barrier. *See* **Exhibit G**.

64. Skin irritation agents result in an altered skin barrier, which increases the risk of localized cutaneous effects and HPA axis suppression in a patient taking clobetasol propionate formulated with propylene glycol. *See* **Exhibit I** – Del Rosso, J. et al., Understanding the

Epidermal Barrier in Healthy and Compromised Skin: Clinically Relevant Information for the Dermatology Practitioner, *J Clin Aesthet Dermatol.* 9(4 Suppl 1):S2-S8 (Apr. 2016).

65. Encore has internal confidential studies that likewise show the skin penetration characteristics of propylene glycol when present in formulations like that for Impoyz®.

66. The combination of propylene glycol with clobetasol for a topical drug product intended to perform like Impoyz® is therefore problematic.

67. The formulation for Impoyz® is designed to allow clobetasol propionate to act topically and to minimize its systemic exposure and absorption.

68. This is critical because Impoyz® is designed for the management of chronic inflammatory diseases of the skin such as plaque psoriasis. However, even with Impoyz®'s formulation being designed to minimize absorption, Impoyz®'s package insert instructs that Impoyz® should not be used for more than 2 consecutive weeks (with repeat dosage permissible after a rest period) and the total dosage should not exceed 50g per week. *See* **Exhibit G**. Significant amounts of a potent steroid like clobetasol propionate applied topically may result in significant absorption into the human blood stream, which can cause numerous undesirable localized and systemic side effects and potential health effects, as discussed above. Although Impoyz® is indicated for two weeks of use for each course of treatment, the chronic nature of the diseases for which Impoyz® and other high potency corticosteroids are prescribed demands long term use by patients. It is, therefore, critical that Impoyz® minimizes systematic absorption of the steroid in order to reduce the risk of adverse events and serious long term health effects and issues discussed above.

69. Since Impoyz® is a topical cream for the treatment of a local condition (plaque psoriasis), it is formulated to react well with human skin with maximal local delivery of clobetasol propionate and with, among other things, minimal systemic absorption.

70. The presence of a skin irritation agent like propylene glycol in such a topical formulation is undesirable because the repeated exposure of such a formulation to human skin is likely to cause significant irritation, which in turn may result in an altered skin barrier and greater local and systematic exposure and absorption, which can lead to other adverse effects.

71. For these reasons, Encore has a reasonable and good faith basis to question Glenmark Ltd.'s assertions regarding its proposed Generic Product.

Need for Complete Data and Testing Regarding the Proposed Generic Product

72. Based on the foregoing known issues relating to propylene glycol, Encore doubts that the proposed Generic Product can contain the Detailed Statement's asserted amount of propylene glycol or any propylene glycol, while asserting that the proposed Generic Product is safe and is bioequivalent to Impoyz®.

73. In view of this, Encore needs to see the complete regulatory submissions by Glenmark Ltd. to the FDA and all information and data relating to the proposed Generic Product. That information and data will be critical to understanding and assessing the true composition and formulation of the proposed Generic Product.

74. The OCA by its terms prevented any such analysis before this Complaint was filed. It banned any reference to the contents of the selected disclosed portions of Glenmark's ANDA in any public Complaint, banned analysis by any expert or consultant without the permission of Glenmark Ltd., only allowed Encore outside counsel to keep the selected disclosed

portions of Glenmark's ANDA for 35 days, and required that the selected disclosed portions of the ANDA not be in the possession of Encore's outside counsel when this Complaint was filed.

75. Under statute, Glenmark Ltd. has committed an act of infringement by filing Glenmark's ANDA.

76. Encore needs discovery to understand the composition of the proposed Generic Product. Encore also needs the ability to test samples of the proposed Generic Product.

77. However, based on the very limited information available to Encore, and the extensive information Encore has in its possession relating to the problematic nature of the presence of propylene glycol in a formulation for a product like Impoyz®, Encore has a current good faith basis to question Glenmark Ltd.'s assertions regarding its proposed Generic Product and therefore to assert that the proposed Generic Product infringes the '231 Patent. Encore will likely have further evidentiary support for its infringement allegations after a reasonable opportunity for discovery. In its Detailed Statement, Glenmark Ltd. does not contest that the proposed Generic Product (or a treatment so using) meets all the limitations of claims 1 and 9 of the '231 Patent other than the propylene glycol-free limitation. As to propylene glycol, Encore has a good faith basis grounded in scientific literature, including without limitation that cited herein, to question Glenmark Ltd.'s assertions regarding the proposed Generic Product. Thus, Encore has a current good faith basis to believe that there is, and after discovery believes it will have further additional evidentiary support for, infringement of claims 1 and 9 either literally or under the doctrine of equivalents, based on a proper construction of the propylene glycol-free limitation.

78. Encore reserves the right to assert infringement claims regarding other patents listed in the Orange Book for Impoyz® after Glenmark Ltd. has provided required disclosures and discovery.

COUNT I – Patent Infringement

79. Encore repeats and realleges the foregoing paragraphs as if fully set forth herein.

80. Glenmark Ltd. prepared and submitted Glenmark's ANDA seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States of the proposed Generic Product.

81. Glenmark Ltd.'s submission of Glenmark's ANDA with the Paragraph IV Certification is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

82. Encore has a current good faith belief that the proposed Generic Product is covered by one or more properly construed claims of the '231 Patent, either literally or under the doctrine of equivalents.

83. Upon information and belief, Glenmark Ltd. has made and will continue to make substantial preparation to commercially manufacture, use, sell, offer for sale, and distribute throughout the United States and import into the United States the proposed Generic Product before the expiration of the '231 Patent.

84. Unless enjoined by this Court, Glenmark Ltd. intends to, and will, engage in the commercial manufacture, use, sale, offer for sale, and distribution throughout the United States and importation into the United States of the proposed Generic Product that is the subject of ANDA No. 214191 immediately and imminently upon FDA approval, and will instruct healthcare providers and patients to use said product in accordance with the proposed labeling for said product.

85. Upon information and belief and based on the above allegations, when the proposed Generic Product is manufactured, used, sold, offered for sale, and distributed in the United States and imported into the United States, Encore has a current good faith belief that it will directly infringe at least claims 1 and 9 of the '231 Patent under 35 U.S.C. § 271 either literally or under the doctrine of equivalents.

86. Upon information and belief, Glenmark Ltd. will infringe at least claim 1 of the '231 Patent either literally or under the doctrine of equivalents under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and distributing in the United States and importing into the United States the proposed Generic Product, and will infringe at least claim 9 of the '231 Patent under 35 U.S.C. §§ 271(b) and/or (c) by actively inducing and/or contributing to infringement of claim 9 by others either literally or under the doctrine of equivalents.

87. Unless enjoined by this Court, upon FDA approval, Glenmark Ltd. intends to, and will, actively induce infringement of at least claim 9 of the '231 Patent at least by physicians treating plaque psoriasis and patients using the proposed Generic Product, and intends to, and will do so, immediately and imminently upon FDA approval.

88. Upon information and belief, Glenmark Ltd. knows that the proposed Generic Product and its proposed labeling are especially made and adapted for use in infringing the '231 Patent, and that said product and proposed labeling are not suitable for substantial non-infringing use, and unless enjoined by this Court, immediately and imminently upon FDA approval, Glenmark Ltd. intends to, and will, contribute to the infringement of at least claim 9 of the '231 Patent either literally or under the doctrine of equivalents, at least by patients and physicians treating patients with plaque psoriasis using said product in accordance with said label.

89. The foregoing actions by Glenmark Ltd. prior to the expiration of the '231 Patent constitute and/or will constitute infringement of at least claim 1 of the '231 Patent under 35 U.S.C. § 271(a), and constitute and/or will constitute infringement of at least claim 9 of the '231 Patent under 35 U.S.C. § 271(b) and/or (c), either literally or under the doctrine of equivalents.

90. Encore is entitled to a declaratory judgment that the future commercial manufacture, use, offer for sale, sale, and distribution in the United States, and importation into the United States of the proposed Generic Product will directly infringe the '231 Patent and will induce and/or contribute to infringement of the '231 Patent at least by patients and by prescribing physicians treating patients with plaque psoriasis, either literally or under the doctrine of equivalents.

91. Glenmark Ltd. has knowledge of the '231 Patent.

92. The factual and legal bases contained in the Notice Letter and the Detailed Statement supporting the allegations regarding the invalidity, and unenforceability of the '231 Patent are devoid of substantiation or any stated objective good-faith basis.

93. The commercial manufacture, use, sale, offer for sale, and distribution in the United States and importation into the United States of the proposed Generic Product in violation of Encore's rights in the '231 Patent will cause harm to Encore for which damages are inadequate.

94. Unless Glenmark Ltd. is enjoined from infringing the '231 Patent, actively inducing infringement of the '231 Patent, and/or contributing to the infringement of the '231 Patent, Encore will suffer irreparable injury for which there is no adequate remedy at law, and pursuant to 35 U.S.C. § 271(e)(4) and Fed. R. Civ. P. 65, a preliminary and permanent injunction should be entered preventing further infringement.

95. Encore is entitled to relief provided by 35 U.S.C. § 271(e)(4), including an Order of this Court that the effective date of the approval of Glenmark's ANDA be a date that is not earlier than the expiration date of the '231 Patent, or any later expiration of exclusivity for the '231 Patent to which Encore may become entitled.

COUNT II – Declaratory Judgment of Patent Infringement

96. Encore repeats and realleges the foregoing paragraphs as if fully set forth herein.

97. Encore's infringement claims herein also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

98. Glenmark Ltd.'s submission of Glenmark's ANDA with the Paragraph IV Certification is an act of infringement under 35 U.S.C. § 271(e)(2)(A).

99. Upon information and belief and based on the above allegations, Encore has a current good faith belief that the proposed Generic Product is covered by one or more properly construed claims of the '231 Patent, either literally or under the doctrine of equivalents.

100. Upon information and belief and based on the above allegations, if Glenmark's ANDA is approved, Glenmark Ltd.'s proposed Generic Products will be made, offered for sale, sold, or otherwise distributed in the United States, including in New Jersey, or will be imported into the United States, including New Jersey, by Glenmark Ltd. and/or its affiliates. Encore has a current good faith belief that Glenmark Ltd. will directly infringe one or more claims of the '231 Patent, including without limitation claim 1, either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a).

101. Upon information and belief and based on the above allegations, Glenmark Ltd. knows that healthcare professionals or patients will use Glenmark Ltd.'s proposed Generic Product in accordance with the labeling sought by Glenmark's ANDA. Upon information and

belief, the product label and product insert accompanying Glenmark Ltd.'s proposed Generic Product will include instructions that are substantially similar to the instructions found in the prescribing information for Impoyz®, and which, if followed, will infringe the '231 Patent, including without limitation claim 9, either literally or under the doctrine of equivalents. Encore has a current good faith belief that Glenmark Ltd. will contribute to, or induce, the infringement of one or more claims of the '231 Patent either literally or under the doctrine of equivalents. *See* 35 U.S.C. § 271(a), (b), and (c).

102. Upon information and belief, Glenmark Ltd.'s infringing activities, including the commercial manufacture, use, offer for sale, sale, or importation of Glenmark Ltd.'s proposed Generic Product, will begin immediately after the FDA approves Glenmark's ANDA. Any such conduct before the expiration of the '231 Patent will directly infringe, contribute to the infringement of, or induce the infringement of one or more claims of the '231 Patent under one or more of 35 U.S.C. § 271(a), (b), or (c) either literally or under the doctrine of equivalents.

103. As a result of the foregoing, there is a real, substantial, and continuing justiciable controversy between Encore and Glenmark Ltd. concerning liability for the infringement of the '231 Patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

104. Encore will be substantially and irreparably harmed by Glenmark Ltd.'s infringing activities unless those activities are enjoined by this Court. Encore has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment as follows:

A. Glenmark Ltd. has directly or indirectly infringed one or more claims of the '231 Patent, either literally or under the doctrine of equivalents;

B. A declaration under 28 U.S.C. § 2201 that, if Glenmark Ltd., its officers, directors, agents, servants, employees, representatives, attorneys, parents, subsidiaries, affiliates, other related business entities, or other persons acting or attempting to act in concert, participation, or in privity with Glenmark Ltd., or acting on Glenmark Ltd.'s behalf, engage in the commercial manufacture, use, offer for sale, or sale in the United States, or importation into the United States, of Glenmark Ltd.'s proposed Generic Product, then it will constitute an act of direct or indirect infringement of the '231 Patent, either literally or under the doctrine of equivalents;

C. That, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Glenmark's ANDA No. 214191 shall not be a date that is earlier than the latest expiration date of the '231 Patent, including any applicable exclusivities or extensions;

D. That Glenmark Ltd.'s officers, agents, servants, and employees, and those persons acting in concert, participation, or in privity with any of them, and their successors or assigns, be preliminary and permanently enjoined from commercially manufacturing, using, offering for sale, selling, or importing into the United States the proposed Generic Product and any other product that infringes or induces or contributes to the infringement of one or more claims of the '231 Patent prior to their expiration, including any exclusivities or extensions to which Plaintiff is or becomes entitled; and

E. That Plaintiff be awarded such other and further relief as this Court deems just and proper, including exceptional case remedies under 35 U.S.C. § 285 if deemed applicable.

Dated: March 6, 2020

PEPPER HAMILTON LLP
(A Pennsylvania Limited Liability Partnership)

By: */s/ Stephanie L. Jonaitis*
Stephanie L. Jonaitis, Esq.
Suite 400
301 Carnegie Center
Princeton, NJ 08543-5276
Tel.: 609.452.0808
Email: jonaitis@pepperlaw.com

OF COUNSEL

PEPPER HAMILTON LLP
(A Pennsylvania Limited Liability Partnership)
Andrew P. Zappia, Esq.
(*pro hac vice to be filed*)
70 Linden Oaks, Suite 210
Rochester, New York 14625
Tel.: 585.270.2100
E-mail: zappiaa@pepperlaw.com

Attorneys for Plaintiff