BURSOR & FISHER, P.A.
L. Timothy Fisher (State Bar No. 191626)
1990 North California Blvd., Suite 940
Walnut Creek, CA 94596
Telephone: (925) 300-4455
Facsimile: (925) 407-2700
E-Mail: ltfisher@bursor.com

BURSOR & FISHER, P.A.
Joshua D. Arisohn (*pro hac vice* forthcoming)
Andrew J. Obergfell (*pro hac vice* forthcoming)
888 Seventh Avenue
New York, NY 10019
Telephone: (646) 837-7150
Facsimile: (212) 989-9163
E-Mail: jarisohn@bursor.com
aobergfell@bursor.com

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT

EASTERN DISTRICT OF CALIFORNIA

BRIAN KAMLADE, on behalf of himself and all others similarly situated,

Plaintiff,

v.

LEO PHARMA INC. and LEO PHARMA A/S,

Defendants.

Case No.

CLASS ACTION COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Brian Kamlade ("Plaintiff") brings this action on behalf of himself and all others similarly situated against Defendants LEO Pharma Inc. and LEO Pharma A/S (collectively "LEO Pharma" or "Defendants"). Plaintiff makes the following allegations pursuant to the investigation of his counsel and based upon information and belief, except as to the allegations specifically pertaining to himself, which are based on personal knowledge.

NATURE OF THE ACTION AND FACTS COMMON TO ALL CLAIMS

1. This is a class action lawsuit about LEO Pharma's manufacturing and distribution of prescription Picato gel (ingenol mebutate) ("Picato"). Picato was indicated to treat precancerous actinic keratosis, but it instead increased the risk of squamous cell skin cancer. Accordingly, Picato is worthless and Defendants should be required to fully refund consumers like Plaintiff.

2. LEO Pharma has sold Picato in the United States since 2012.

3. Picato is used to treat actinic keratosis, a scaly, crusty lesion on the skin, caused by too much sunlight exposure.

4. For the treatment of actinic keratosis on the face or scalp, LEO Pharma recommended applying a 0.015% formulation of Picato gel to the affected area once daily for three consecutive days. For the treatment of actinic keratosis on the trunk or extremities, LEO Pharma recommended applying a 0.05% formulation of Picato gel to the affected area once daily for two consecutive days.

5. In September 2019, following reports of Picato-related skin cancer incidents, the European Commission requested a safety review of the drug.

6. In January 2020, the European Medicines Agency ("EMA") suspended sale of Picato while its Pharmacovigilance Risk Assessment Committee ("PRAC") conducted the review.

7. The January 2020 EMA suspension announcement cited troubling results from several studies and clinical trials:

- The final results of a three-year study in 484 patients showed a higher incidence of skin malignancy with ingenol mebutate than with the comparator imiquimod (3.3% of patients developed cancer in the Picato group versus 0.4% in the comparator group).

- A higher incidence of skin tumours occurred in the ingenol mebutate arm of an 8-week vehicle-controlled trial in 1,262 patients (1% of patients in the ingenol mebutate arm versus 0.1% in the vehicle arm).

- In addition, in four clinical trials involving 1,234 patients with a related ester, ingenol disoxate, a higher incidence of skin tumours occurred with ingenol disoxate than with a vehicle control (7.7% versus 2.9% of patients, respectively). As ingenol disoxate is closely related to Picato, the results were considered relevant in the ongoing review of Picato.

8. In February 2020, LEO Pharma requested that its marketing authorization in the EU be withdrawn.

9. In April 2020, PRAC issued a report confirming that Picato "may increase the risk of skin cancer" and concluded "that the risks of the medicine outweigh its benefits." PRAC added that "Picato's effectiveness is not maintained over time and noted that other treatment options are available for actinic keratosis."

10. The PRAC report included the following information for healthcare professionals:

- Studies have found a higher incidence of skin tumours, especially squamous cell carcinoma, in the treatment area in patients treated with Picato (ingenol mebutate) or ingenol disoxate (a related ester not currently authorised and no longer in development) than with a comparator or vehicle (gel not containing any active substance).

- In the final results of a 3-year safety study in 484 patients, skin tumours were observed inside the treatment area in 6.3% of patients treated with ingenol mebutate compared with 2% of those treated with imiquimod. The difference was driven by squamous cell carcinoma (3.3% versus 0.4% of patients) and Bowen's disease (2.5% versus 1.2%).

- In a pooled analysis of four 14-month trials involving 1234 patients, higher incidence of tumours, including basal cell carcinoma, Bowen's disease and squamous cell carcinoma, was seen with the related ester ingenol disoxate than with vehicle (7.7% versus 2.9% of patients).

- Picato has already been taken off the market and is therefore no longer a treatment option for actinic keratosis.

- Other treatment options for actinic keratosis include topical diclofenac, fluorouracil and imiquimod, as well as photodynamic therapy, cryotherapy, curettage or excisional surgery.

- Healthcare professionals should advise patients who have been treated with Picato to be vigilant for any skin lesions developing and to seek medical advice promptly should any occur. Time to onset can range from weeks to months following treatment.

11. The EMA warned patients treated with Picato that they "should look out for unusual skin changes or growths, which could occur from weeks to months after use, and seek medical advice if any occur."

12. In July 2020, Health Canada, the department of the Government of Canada responsible for national health policy, issued a report stating that it had reviewed 29 case reports of skin cancer in patients treated with Picato, and that "26 cases were found to be possibly linked."

13. In addition, Health Canada "assessed 12 studies published in scientific and medical literature in order to determine the link between the use of Picato and skin cancer" and "found that 6 of the 12 studies had evidence of skin cancer with the use of Picato."

14. Based on this evidence, Health Canada concluded "that there may be a link between Picato and the risk of skin cancer."

15. In October 2020, at Health Canada's request, LEO Pharma Inc. initiated a recall of Picato from the Canadian market.

16. Health Canada advised patients being treated with Picato to "stop their treatment" and to "contact their healthcare professional to discuss other treatment options."

17. Health Canada also advised patients to "monitor and immediately report to their healthcare professional any signs or symptoms of skin cancer, such as new scaly red patches on their skin, open sores, or elevated or warty growths within the treatment area, which could occur after stopping treatment."

18. In October 2020, LEO Pharma announced that it would permanently discontinue the manufacture of Picato.

PARTIES

19. Plaintiff Brian Kamlade is a citizen of California who resides in Sanger, California. In or about July 2018, Mr. Kamlade's doctor diagnosed him with actinic keratosis and prescribed Picato. Thereafter, Mr. Kamlade filled his prescription for Picato at the Cedar Pharmacy & Medical Supplies ("CPMC") located in Fresno, California and used the Picato as directed by his doctor. Mr. Kamlade paid a total of approximately $20.00 out of pocket in copayment for Picato.

The Picato that Mr. Kamlade purchased was manufactured by LEO Pharma A/S, distributed by LEO Pharma Inc. and sold by CPMC. After using the Picato gel as directed, he developed cancer in the area where the Picato was applied. When purchasing the Picato, Mr. Kamlade reviewed the accompanying labels and disclosures, and understood them as representations and warranties by the manufacturer, distributor, and pharmacy that the medications were properly designed, effective, free from defects and safe. Mr. Kamlade relied on these representations and warranties in deciding to purchase Picato from Defendants, and these representations and warranties were part of the basis of the bargain, in that he would not have purchased Picato if he had known that it was not, in fact, properly designed, effective, free from defects and safe.

20. Defendant LEO Pharma Inc. is a corporation incorporated under the laws of Delaware with a principal place of business at 7 Giralda Farms, 2nd Floor, Madison, New Jersey 08807. LEO Pharma Inc. is a wholly owned subsidiary of Defendant LEO Pharma A/S. LEO Pharma Inc. conducts substantial business in the United States, and specifically in the State of California. LEO Pharma Inc. distributes and sells Picato in the United States, including in the State of California.

21. Defendant LEO Pharma A/S is a corporation incorporated under the laws of Denmark with a principal place of business at Industriparken 55, DK-2750, Ballerup, Denmark. LEO Pharma A/S conducts substantial business in the United States, and specifically in the State of California. LEO Pharma A/S manufactures Picato, which it sells in the United States, including in the State of California, through its agent and wholly-owned subsidiary LEO Pharma Inc.

JURISDICTION AND VENUE

22. The Court has jurisdiction over this action pursuant to 28 U.S.C. § 1332(d)(2)(A), as modified by the Class Action Fairness Act of 2005, because at least one member of the Class, as defined below, is a citizen of a different state than Defendants, there are more than 100 members of the Class, and the aggregate amount in controversy exceeds $5,000,000 exclusive of interest and costs.

23. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because many of the acts and transactions giving rise to this action occurred in this District, and because Defendants (a) are authorized to conduct business in this District and have intentionally availed themselves of the laws and markets within this District through the promotion, marketing, distribution, and sale of Picato in this District; (b) conduct substantial business in this District; and (c) are subject to personal jurisdiction in this District.

CLASS ALLEGATIONS

24. Plaintiff seeks to represent a class defined as all persons in the United States who purchased Picato (the "Class"). Specifically excluded from the Class are persons who made such purchase for the purpose of resale, Defendants, Defendants' officers, directors, agents, trustees, parents, children, corporations, trusts, representatives, employees, principals, servants, partners, joint ventures, or entities controlled by Defendants, and their heirs, successors, assigns, or other persons or entities related to or affiliated with Defendants and/or Defendants' officers and/or directors, the judge assigned to this action, and any member of the judge's immediate family.

25. Plaintiff also seeks to represent a subclass of all Class members who purchased Picato in California (the "California Subclass").

26. Subject to additional information obtained through further investigation and discovery, the foregoing definition of the Class and California Subclass may be expanded or narrowed by amendment or amended complaint.

27. **Numerosity.** The members of the Class are geographically dispersed throughout the United States and are so numerous that individual joinder is impracticable. Upon information and belief, Plaintiff reasonably estimates that there are hundreds of thousands of members in the Class. Although the precise number of Class members is unknown to Plaintiff, the true number of Class members is known by Defendants and may be determined through discovery. Class members may be notified of the pendency of this action by mail and/or publication through the distribution records of Defendants and third-party retailers and vendors.

28. **Existence and predominance of common questions of law and fact.** Common

questions of law and fact exist as to all members of the Class and predominate over any questions affecting only individual Class members. These common legal and factual questions include, but are not limited to, the following:

(a) whether the Picato manufactured, distributed, and sold by Defendants poses an unreasonably high risk of causing cancer in users;

(b) whether Defendants breached implied warranties to Plaintiff and the Class and California Subclass; and

(c) whether Plaintiff and the Class and California Subclass have sustained monetary loss and the proper measure of damages.

29. **Typicality.** Plaintiff's claims are typical of the claims of the other members of the Class and New York Subclass in that Defendants mass marketed and sold defective Picato to consumers throughout the United States. This defect was present in all of the Picato manufactured, distributed, and sold by Defendants. Therefore, Plaintiff's claims are typical in that Plaintiff and Class members were uniformly harmed in purchasing and using the defective Picato. Plaintiff's claims are further typical in that Defendants deceived Plaintiff in the very same manner as they deceived each member of the Class and California Subclass. Further, there are no defenses available to Defendants that are unique to Plaintiff.

30. **Adequacy of Representation.** Plaintiff will fairly and adequately protect the interests of the Class and California Subclass. Plaintiff has retained counsel that is highly experienced in complex consumer class action litigation, and Plaintiff intends to vigorously prosecute this action on behalf of the Class and California Subclass. Furthermore, Plaintiff has no interests that are antagonistic to those of the Class and California Subclass.

31. **Superiority.** A class action is superior to all other available means for the fair and efficient adjudication of this controversy. The damages or other financial detriment suffered by individual Class and California Subclass members are relatively small compared to the burden and expense of individual litigation of their claims against Defendants. It would thus be virtually impossible for the Class and California Subclass, on an individual basis, to obtain effective redress

for the wrongs committed against them. Furthermore, even if Class and California Subclass members could afford such individualized litigation, the court system could not. Individualized litigation would create the danger of inconsistent or contradictory judgments arising from the same set of facts. Individualized litigation would also increase the delay and expense to all parties and the court system from the issues raised by this action. By contrast, the class action device provides the benefits of adjudication of these issues in a single proceeding, economies of scale, and comprehensive supervision by a single court, and presents no unusual management difficulties under the circumstances.

32. In the alternative, the Class and California Subclass may also be certified because:

(a) the prosecution of separate actions by individual Class and California Subclass members would create a risk of inconsistent or varying adjudications with respect to individual Class and California Subclass members that would establish incompatible standards of conduct for the Defendants;

(b) the prosecution of separate actions by individual Class and California Subclass members would create a risk of adjudications with respect to them that would, as a practical matter, be dispositive of the interests of other Class and California Subclass members not parties to the adjudications, or substantially impair or impede their ability to protect their interests; and/or

(c) Defendants have acted or refused to act on grounds generally applicable to the Class and California Subclass as a whole, thereby making appropriate final declaratory and/or injunctive relief with respect to the members of the Class and California Subclass as a whole.

COUNT I
Breach Of The Implied Warranty Of Merchantability
(On Behalf Of Plaintiff And The Class And California Subclass)

33. Plaintiff hereby incorporates by reference the allegations contained in all preceding paragraphs of this Complaint

34. Plaintiff brings this claim individually and on behalf of the members of the proposed Class and California Subclass against Defendants.

35. Defendants, as the designers, manufacturers, and marketers of Picato, impliedly warranted that Picato was (i) fit for use as a medication to treat precancerous actinic keratosis, and (ii) generally recognized as safe for human consumption.

36. Defendants breached the warranty implied in the contract for the sale of the defective Picato medications because they could not pass without objection in the trade under the contract description, the Picato medications were not of fair or average quality within the description, and the Picato medications were unfit for their intended and ordinary purpose because the Picato medications manufactured, distributed, and sold by Defendants were defective in that they are carcinogenic and not fit for use, and as such are not generally recognized as safe for human consumption. The fact that Defendants voluntarily ceased manufacturing and distributing the medications after recalls in other countries shows that they are unmerchantable and unfit for human use. As a result, Plaintiff and Class and California Subclass members did not receive the goods as impliedly warranted by Defendants to be merchantable.

37. Plaintiff and Class and California Subclass members purchased Picato medications in reliance upon Defendants' skill and judgment and the implied warranties of merchantability and fitness for the purpose.

38. The Picato medications were not altered by Plaintiff or Class and California Subclass members.

39. The Picato medications were defective when they left the exclusive control of Defendants.

40. Defendants knew that the Picato medications would be purchased and used without additional testing by Plaintiff and Class and California Subclass members.

41. The defective Picato medications were defectively manufactured and unfit for their intended purpose, and Plaintiff and Class and California Subclass members did not receive the goods as warranted.

42. As a direct and proximate cause of Defendants' breach of the implied warranty, Plaintiff and Class and California Subclass members have been injured and harmed because: (a)

they would not have purchased Picato if they knew the medications caused a significantly elevated risk of cancer and that the medications are not generally recognized as safe for human consumption; and (b) the Picato medications do not have the characteristics, ingredients, uses, or benefits as promised by Defendants. Plaintiff and members of the Class and California Subclass would have used a different medication had they known the truth about Picato.

43. On March 23, 2021, Plaintiff provided Defendants with timely notice of this claim by letter that complied in all respects with U.C.C. § 2-607(3)(a). The March 23, 2021 letter is attached hereto as **Exhibit A**.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff, individually and on behalf of all others similarly situated, seeks judgment against Defendants, as follows:

A. For an order certifying the nationwide Class and the California Subclass under Rule 23 of the Federal Rules of Civil Procedure and naming Plaintiff as representative of the Class and California Subclass and Plaintiff's attorneys as Class Counsel to represent the Class and members of the California Subclass;

B. For an order declaring the Defendants' conduct constitutes a breach of its implied warranty of merchantability;

C. For an order finding in favor of Plaintiff, the nationwide Class, and the California Subclass on all counts asserted herein;

D. For compensatory damages in amounts to be determined by the Court and/or jury; and

E. For prejudgment interest on all amounts awarded.

DEMAND FOR TRIAL BY JURY

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiff demands a trial by jury of any and all issues in this action so triable of right.

Dated: March 29, 2021

Respectfully submitted,

BURSOR & FISHER, P.A.

By: */s/ L. Timothy Fisher*
L. Timothy Fisher

L. Timothy Fisher (State Bar No. 191626)
1990 North California Blvd., Suite 940
Walnut Creek, CA 94596
Telephone: (925) 300-4455
Facsimile: (925) 407-2700
E-Mail: ltfisher@bursor.com

BURSOR & FISHER, P.A.
Joshua D. Arisohn
Andrew J. Obergfell
888 Seventh Avenue
New York, NY 10019
Telephone: (212) 837-7150
Facsimile: (212) 989-9163
Email: jarisohn@bursor.com
aobergfell@bursor.com

Attorneys for Plaintiff

EXHIBIT A

BURSOR & FISHER
P.A.

1990 NORTH CALIFORNIA BLVD.
SUITE 940
WALNUT CREEK, CA 94596-7351
www.bursor.com

L. TIMOTHY FISHER
Tel: 925.300-4455
Fax: 925.407.2700
ltfisher@bursor.com

March 23, 2021

Via Certified Mail – Return Receipt Requested

LEO Pharma Inc.
7 Giralda Farms, 2nd Floor
Madison, New Jersey 08807

LEO Pharma A/S
Industriparken 55, DK-2750, Ballerup, Denmark

Re: *Notice and Demand Letter Pursuant to U.C.C. § 2-607*; *California Civil Code § 1782; and all other relevant state and local laws*

To Whom It May Concern:

This letter serves as a preliminary notice and demand for corrective action by LEO Pharma, Inc. and LEO Pharma A/S pursuant to U.C.C. § 2-607(3)(a) concerning breaches of express and implied warranties – and violations of state consumer protection laws – related to our client, Brian Kamlade, and a class of all similarly situated purchasers (the "Class") of defective Picato gel (ingenol mebutate) ("Picato") manufactured and distributed by LEO Pharma Inc. and LEO Pharma A/S. This letter also serves as a preliminary notice and demand for corrective action pursuant to numerous provisions of California law, including but not limited to subsections (a)(5), (7), and (9) of the Consumers Legal Remedies Act, California Civil Code § 1782; § 1770.

Mr. Kamlade was prescribed, purchased and used Picato. However, Mr. Kamlade's Picato medication was defective because use of Picato exposed him to an elevated risk of skin cancer, as noted by the European Medicines Agency ("EMA") following several studies and clinical trials of the product. Indeed, the Pharmacovigilance Risk Assessment Committee ("PRAC") conducted a review and determined that Picato "may increase the risk of skin cancer" and "that the risks of the medicine outweigh its benefits." In October 2020, LEO discontinued manufacture of Picato. This defect rendered the products unusable and unfit for use. In short, the Picato medications that Mr. Kamlade and the Class were purchasing are worthless, as the risk of using the product outweighed any benefit of the same. LEO Pharma Inc. and LEO Pharma A/S each violated express and implied warranties made to our clients and the Class regarding the quality and safety of the Picato medications they purchased. *See* U.C.C. *§§* 2-313, 2-314.

Additionally, this letter also serves as notice of violation of California's Consumer Legal Remedies Act, and all other relevant state and local laws. Had LEO Pharma Inc. and LEO Pharma A/S disclosed on the label that Picato exposed him to an elevated risk of skin cancer, Mr.

Kamlade would have been aware of that fact and would not have purchased Picato. Mr. Kamlade intends to bring an action on behalf of a class defined as all persons in the United States who purchased Picato. Ms. Baker also intends to bring an action on behalf of a subclass of persons who purchased Picato in the state of California. Mr. Kamlade sustained injury as a result of LEO Pharma Inc. and LEO Pharma A/S's actions.

On behalf of Mr. Kamlade and the Class, we hereby demand that LEO Pharma Inc. and LEO Pharma A/S immediately make full restitution to all purchasers of Picato of all purchase money obtained from sales thereof.

We also demand that LEO Pharma Inc. and LEO Pharma A/S preserve all documents and other evidence which refer or relate to any of the above-described practices including, but not limited to, the following:

1. All documents concerning the packaging, labeling, and manufacturing process for Picato;

2. All documents concerning the design, development, supply, production, extraction, and/or testing of Picato;

3. All testing of Picato, including all clinical trials and the findings thereof;

4. All documents concerning the pricing, advertising, marketing, and/or sale of Picato;

5. All communications with customers involving complaints or comments concerning Picato;

6. All documents concerning communications with any retailer involved in the marketing or sale of Picato;

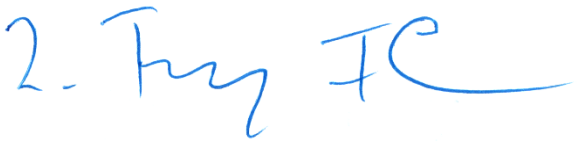
7. All documents concerning communications with federal or state regulators and foreign regulators concerning Picato; and

8. All documents concerning the total revenue derived from sales of Picato.

If you contend that any statement in this letter is inaccurate in any respect, please provide us with your contentions and supporting documents immediately upon receipt of this letter.

Please contact me right away if you wish to discuss an appropriate way to remedy this matter. If I do not hear from you promptly, I will take that as an indication that you are not interested in doing so.

Very truly yours,



L. Timothy Fisher

ClassAction.org