**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| UNITED STATES *ex rel.* Albermarle, LLC,<br><br>Plaintiff,<br><br>v.<br><br>CIPLA LIMITED, CIPLA USA INC., and AKORN OPERATING COMPANY LLC,<br><br>Defendants. | ) | Civil Action No.<br><br>FILED UNDER SEAL<br>PURSUANT TO 31 U.S.C. § 3730(b)(2) |

# FALSE CLAIMS ACT COMPLAINT

## Introduction

1. Albermarle, LLC (the "Relator"), brings this action as a *qui tam* relator on behalf of the United States against Cipla Limited, Cipla USA Inc., and Akorn Operating Company LLC (collectively, "Defendants"), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729-33, to recover damages, penalties, attorneys' fees and costs, and other relief.

2. Defendants sell, or cause to be sold, diclofenac sodium topical gel, 1% ("diclofenac gel"), a non-steroidal anti-inflammatory drug, as a prescription drug in the United States, even though the United States Food & Drug Administration ("FDA") approved diclofenac gel as an over-the-counter ("OTC") drug in February 2020.

3. Because drugs that are available OTC are not eligible for Medicare Part D reimbursement, Defendants' continued sale of prescription diclofenac gel causes false claims to be submitted to Medicare, in violation of the False Claims Act, 31 U.S.C. §§ 3729(a)(1)(A) and (B).

4. Prior to the filing of this Complaint, Relator made substantive disclosures to the government of facts and evidence underlying the allegations in this Complaint, in accordance with the requirements of the False Claims Act, 31 U.S.C. § 3730(b)(2).

5. This action is filed *in camera* and under seal pursuant to the requirements of the False Claims Act. 31 U.S.C. § 3730(b)(2).

## Jurisdiction and Venue

6. This action arises under the False Claims Act, as amended, 31 U.S.C. §§ 3729-33. This Court has jurisdiction over this action under 31 U.S.C. § 3732 and 28 U.S.C. §§ 1331 and 1345. This Court may exercise personal jurisdiction over each of the Defendants, and venue is appropriate in this Court, under 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b), because each of the Defendants caused false claims to be submitted in this District.

## The Parties

7. Relator Albermarle, LLC, is a Delaware limited liability company that was formed to serve as the relator in this matter.

8. Defendant Cipla Limited, a generic drug manufacturer, is a corporation registered in India and has a principal place of business in Mumbai, India. Cipla Limited manufactures diclofenac gel with the National Drug Code ("NDC") 69097-0524-44. In the United States, Cipla Limited sells diclofenac gel with NDC 69097-0524-44 through its subsidiary, Cipla USA Inc. Cipla Limited also sells diclofenac gel through at least three other entities: Exelan Pharmaceuticals, Inc., another Cipla Limited subsidiary, with NDC 76282-663-39; Northstar Rx, LLC, a McKesson subsidiary, with NDC 16714-976-01; and A-S Medication Solutions, LLC, with NDCs 50090-4020-0, 50090-4021-0, and 50090-4030-0.

9. Defendant Cipla USA Inc. is a Delaware corporation with a principal place of business in Warren, New Jersey. Cipla USA Inc. markets and sells Cipla Limited products in the United States. Among those products is diclofenac gel with the NDC 69097-0524-44. (Cipla Limited and Cipla USA Inc. are hereafter referred to as "Cipla.")

10. Defendant Akorn Operating Company LLC is a Delaware limited liability company with a principal place of business in Lake Forest, Illinois. Akorn emerged from bankruptcy on October 1, 2020. Akorn markets and sells diclofenac gel with NDC 50383-0272-01. Akorn also sells diclofenac gel through at least one other entity, RemedyRepack, Inc. ("RemedyRepack"), with NDC 70518-2673-00.

## Legal Background

### A. FDA Approval of Drugs

11. Before a pharmaceutical company may introduce or deliver for introduction into interstate commerce any new drug, the company first must submit to FDA, and gain FDA's approval of, a New Drug Application ("NDA") containing, among other things, evidence that the drug is safe and effective for its intended uses, as well as proposed labeling for the drug. *See* 21 U.S.C. § 355(a), (b). Such an approved drug is known as a "reference listed drug."

12. Thereafter, any manufacturer seeking to introduce or deliver for introduction into interstate commerce a generic version of a reference listed drug must file, and gain FDA's approval of, an Abbreviated New Drug Application ("ANDA") showing that, among other things, the generic version's active ingredient, route of administration, dosage form, strength, and labeling are the same as those of the reference listed drug. *See* 21 U.S.C. § 355(a); 21 U.S.C. § 355(j)(2)(A).

**B. FDA Requirements for Prescription and OTC Drugs**

13. Drugs approved pursuant to an NDA or ANDA may be dispensed only with a prescription from a licensed practitioner, unless and until FDA determines otherwise. *See* 21 U.S.C. § 353(b)(1). The label of such a prescription drug must bear the symbol "Rx only." 31 U.S.C. § 353(b)(4)(A). If, however, FDA determines that a prescription requirement is no longer "necessary for the protection of the public health," the agency may remove that requirement, and the drug becomes OTC. *See* 21 U.S.C. § 353(b)(3); *see also* 21 C.F.R. 310.200 (describing procedure for prescription to OTC switch); FDA, *Drug Approvals: Circumstances Under Which an Active Ingredient May Be Simultaneously Marketed in Both a Prescription Drug Product and an Over-the-Counter Drug Product*, 70 Fed. Reg. 52050, 52051 (Sept. 1, 2005) ("[T]he term [OTC] has been adopted to refer to any drug that does not meet the definition of prescription drug in [21 U.S.C. § 353(b)(1)]."). A manufacturer can begin the process of a prescription to OTC switch by filing a petition or a supplement to an approved NDA. *See* 21 C.F.R. § 310.200(b).

**C. Medicare Part D**

14. Congress established Medicare in 1965 to provide health insurance coverage for people aged 65 or older and for people with certain disabilities or afflictions. *See* 42 U.S.C. §§ 1395, *et seq*.

15. Medicare is funded by the federal government and administered by the Centers for Medicare and Medicaid Services ("CMS"), which is part of the United States Department of Health and Human Services.

16. In 2003, Congress passed the Medicare Prescription Drug, Improvement, and Modernization Act, Pub. L. 108-173, 117 Stat. 2066, which established a voluntary prescription

drug benefit program for Medicare enrollees known as Medicare Part D. Under Medicare Part D, Medicare contracts with private entities, known as Part D Plan Sponsors, to administer prescription drug plans. *See* 42 C.F.R. § 423.4.

17. Medicare beneficiaries who wish to receive Part D benefits must enroll in a Part D Plan offered by a Part D Plan Sponsor. CMS regulates and subsidizes the Part D Sponsors pursuant to one-year, annually renewable contracts. Part D Sponsors, in turn, enter into subcontracts with pharmacies, or other "downstream entities," to provide prescription drugs to the Medicare Part D beneficiaries enrolled in their plans.

18. These entities submit claims to Part D plans that pay for the drugs using funds provided by CMS from the Medicare Prescription Drug Account, an account within the Federal Supplementary Medical Insurance Trust Fund. 42 C.F.R. § 423.315(a).

19. Medicare Part D provides coverage for "covered part D drugs." 42 U.S.C. § 1395w-102(a)(1)(B); 42 U.S.C. § 1395w-102(b). A "covered Part D drug" is a "a drug that may be dispensed only upon a prescription" or a biological product of a certain type. 42 U.S.C. § 1395w-102(e)(1); *see also* 42 C.F.R. § 423.100 (defining "Part D drug" to include "[a] drug that may be dispensed only upon a prescription"). With limited exceptions that are not relevant here, Medicare Part D does not cover "[n]onprescription drugs." 42 U.S.C. § 1395w-102(e)(2)(A); 42 U.S.C. § 1396r-8(d)(2)(F).

**D. The False Claims Act**

20. The False Claims Act provides, in pertinent part, that any person who:

> (A) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

> . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

21. For purposes of the False Claims Act, "the terms 'knowing' and 'knowingly' mean that a person, with respect to information[,] (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A). No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1)(B).

22. The False Claims Act defines the term "claim," in pertinent part, as

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

31 U.S.C. § 3729(b)(2).

23. For purposes of the False Claims Act, the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

## Factual Allegations

### A. FDA Approvals of Diclofenac Gel for Prescription

24. On October 17, 2007, FDA approved an NDA for Voltaren Gel®, then the brand name for diclofenac gel, as a prescription drug. The approved label for the drug stated that its

active ingredient was "diclofenac sodium," that it was indicated "for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands," that its dosage form and strength was "1% gel," and that it was to be administered by applying the gel to the affected area four times daily.

25. Between March 2016 and January 2020, FDA approved ANDAs submitted by six different manufacturers for generic versions of diclofenac gel, as follows:

(a) On March 18, 2016, FDA approved an ANDA for diclofenac gel submitted by Amneal Pharmaceuticals LLC ("Amneal").

(b) On August 3, 2018, FDA approved an ANDA for diclofenac gel submitted by Cipla.

(c) On November 21, 2018, FDA approved an ANDA for diclofenac gel submitted by Akorn.

(d) On May 6, 2019, FDA approved an ANDA for diclofenac gel submitted by Aurolife Pharma LLC. This ANDA was subsequently transferred to Mylan Pharmaceuticals, Inc. ("Mylan").

(e) On May 16, 2019, FDA approved an ANDA for diclofenac gel submitted by an affiliate of Perrigo Company, plc ("Perrigo").

(f) On January 27, 2020, FDA approved an ANDA for diclofenac gel submitted by Encube Ethicals Private Limited ("Encube").

27. For each of these generic versions, the label repeated the Voltaren Gel® label and stated that the drug's active ingredient was "diclofenac sodium," that it was indicated "for the relief of the pain of osteoarthritis of joints amenable to topical treatment, such as the knees and those of the hands," that its dosage form and strength was "1% gel," and that it was to be

administered by applying the gel to the affected area four times daily. Further, each of the labels said "Rx only."

**B. FDA Approvals of Prescription to OTC Switches for Diclofenac Gel**

28. In 2020, brand name Voltaren Gel® switched to OTC, and four of the generic versions of diclofenac gel followed, but the generic versions sold by Cipla and Akorn did not.

29. This process began on December 21, 2018, when GlaxoSmithKline Consumer Healthcare Holdings (US) LLC submitted a supplemental NDA to FDA to switch Voltaren Gel® from a prescription drug to an OTC drug. On February 14, 2020, FDA approved this switch, and the name of the drug changed to Voltaren Arthritis Pain®.

30. Shortly thereafter, four of the generic manufacturers of diclofenac gel followed with requests to switch their products to OTC:

(a) On or about February 18, 2020, Perrigo filed a supplemental ANDA to switch its diclofenac gel from prescription to OTC, and FDA approved that application on April 1, 2020.

(b) On or about February 28, 2020, Encube filed a supplemental ANDA to switch its diclofenac gel from prescription to OTC, and FDA approved that application on August 11, 2020.

(c) On or about April 2, 2020, Mylan filed a supplemental ANDA to switch its diclofenac gel from prescription to OTC, and FDA approved that application on August 6, 2020.

(d) On or about April 7, 2020, Amneal filed a supplemental ANDA to switch its diclofenac gel from prescription to OTC, and FDA approved that application on August 13, 2020.

31. On information and belief, neither Cipla nor Akorn has sought to switch its diclofenac gel product to OTC.

32. Meanwhile, Cipla and Akorn have continued to market their prescription-only diclofenac gel products.

33. The Cipla USA Inc. website continues to list diclofenac gel as one of the products that the company sells. The website also has links showing images of the product's carton label and package insert. The carton label, which continues to show that the product is "Rx Only," indicates that it was prepared on October 28, 2020. The package insert, which also shows the product to be a prescription drug, states that it was revised in "10/2020" and was electronically signed by the Manager of the Regulatory Affairs Department of Cipla Limited in Mumbai, India, on February 10, 2021. Further, the labeling for Cipla's diclofenac gel on the FDA website, as submitted by Cipla pursuant to 21 C.F.R. § 207.57(b), shows the product to have a "Marketing Start Date" of August 6, 2018, but no "Marketing End Date."

34. Akorn's website shows that it, too, continues to market diclofenac gel as "Rx Only." The labeling for Akorn's diclofenac gel on the FDA website, as submitted by Akorn, shows it to have a "Marketing Start Date" of November 30, 2018, but no "Marketing End Date." Further, the RemedyRepack labeling for Akorn's diclofenac gel shows a "Marketing Start Date" of April 7, 2020, *i.e.*, after Voltaren switched to OTC, and no "Marketing End Date."

**Count I: False or Fraudulent Claims**
(31 U.S.C. § 3729(a)(1)(A))

35. Relator repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

36. Because FDA approved the switch of diclofenac gel to an OTC drug on February 14, 2020, the diclofenac gel products marketed thereafter by Cipla and Akorn as prescription only are not eligible for Medicare Part D reimbursement.

37. Accordingly, after February 14, 2020, Defendants knowingly caused pharmacies and others to present false or fraudulent claims for payment or approval of Defendants' diclofenac gel products, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A).

38. By virtue of the false or fraudulent claims Defendants caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

**Count II: False Statements**
(31 U.S.C. § 3729(a)(1)(B))

39. Relator repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

40. After February 14, 2020, Defendants knowingly made, used, or caused to be made or used false records or statements, including statements that their diclofenac products were prescription only, that were material to false or fraudulent claims, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

41. By virtue of the false records or statements Defendants made, used, or caused to be made or used, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

**Prayer for Relief**

WHEREFORE, Relator demands and prays for the following relief:

1. On Counts I and II, that judgment be entered in favor of the United States for the amount of the United States' damages, trebled as required by law, and such civil

penalties as are required by law, together with all such further relief as may be just and proper;

2. An award to the Relator of a percentage of the proceeds of the action in accordance with 31 U.S.C. § 3730(d);

3. An award to the Relator of its costs and reasonable attorneys' fees for prosecuting this action; and

4. All other relief as may be required or authorized by law and in the interests of justice.

Dated: June 28, 2021

Respectfully submitted,

ALBERMARLE, LLC

By its attorney

Gregg Shapiro (BBO No. 642069)
Newman and Shapiro
75 State Street, Suite 100
Boston, MA 02109
Tel: 617-582-3875
gshapiro@newmanshapiro.com