

UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF OHIO  
EASTERN DIVISION

IN RE NATIONAL OPIATE LITIGATION

MDL No. 2804

This document relates to:

Case No. 17-md-2804

*The County of Summit, Ohio, et al. v. Purdue  
Pharma L.P., et al.*

Hon. Dan Aaron Polster

Case No. 18-op-45090

**ANSWER AND AFFIRMATIVE DEFENSES OF WARNER CHILCOTT  
COMPANY, LLC; ACTAVIS SOUTH ATLANTIC LLC; ACTAVIS ELIZABETH LLC;  
ACTAVIS MID ATLANTIC LLC; ACTAVIS TOTOWA LLC; ACTAVIS LLC;  
ACTAVIS KADIAN LLC; ACTAVIS LABORATORIES UT, INC., F/K/A WATSON  
LABORATORIES, INC.-SALT LAKE CITY; ACTAVIS LABORATORIES FL, INC.,  
F/K/A WATSON LABORATORIES, INC.-FLORIDA**

Defendants Warner Chilcott Company, LLC; Actavis South Atlantic LLC; Actavis Elizabeth LLC; Actavis Mid Atlantic LLC; Actavis Totowa LLC; Actavis LLC;<sup>1</sup> Actavis Kadian LLC; Actavis Laboratories UT, Inc. f/k/a Watson Laboratories, Inc.-Salt Lake City; and Actavis Laboratories FL, Inc. f/k/a Watson Laboratories, Inc.-Florida (collectively, the “Newly-Named Actavis Entities”),<sup>2</sup> by and through their undersigned counsel, hereby submit their Answer, Defenses, and Affirmative Defenses responding, by corresponding paragraph numbers, to each of the numbered paragraphs in the Third Amended Complaint (“Complaint”) of Plaintiffs the County

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<sup>1</sup> Actavis LLC was previously named in the Second Amended Complaint. However, it was inadvertently characterized as a newly-named defendant in the Court’s April 25, 2010 Order (Dkt. 1576). Out of an abundance of caution, Actavis LLC will respond to allegations directed to it in the Third Amended Complaint.

<sup>2</sup> The Newly-Named Actavis Entities’ parent corporation, Defendant Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”), is an Israeli corporation that is not subject to personal jurisdiction in the United States. Teva Ltd. only recently waived service pursuant to the Court’s November 9, 2018 Order and has filed a motion to dismiss the (Corrected) Second Amended Complaint. If Teva Ltd. is required to file an answer at a later date, it will do so.

of Summit, Ohio, *et al.*<sup>3</sup> (“Plaintiffs”) that are directed at the Newly-Named Actavis Entities. For convenience only, the Newly-Named Actavis Entities use the same headings and sub-headings used by Plaintiffs in the Complaint.

### **PRELIMINARY STATEMENT**

The following matters are incorporated by reference into the Newly-Named Actavis Entities’ responses to each paragraph of the Complaint.

A. The Newly-Named Actavis Entities submit this Answer and Affirmative Defenses (“Answer”) only on behalf of themselves. Where allegations are made against “Defendants” as a group, however described, the Newly-Named Actavis Entities’ responses only apply to themselves.

B. The Complaint contains purported references to several documents and third-party publications and statements that have often been excerpted, paraphrased, characterized, and otherwise taken out of context. These third-party publications and statements should be considered, if at all, in context and in unmodified form, and the Newly-Named Actavis Entities hereby respectfully refer the Court to the respective third-party publications and statements for their complete contents.

C. Except as otherwise expressly stated herein, the Newly-Named Actavis Entities expressly deny each and every allegation contained in the Complaint, including without limitation any allegations contained in the preamble, unnumbered paragraphs, subparagraphs, headings, subheadings, table of contents, footnotes, and exhibits of the Complaint, and specifically deny any liability to Plaintiffs. To the extent that the titles, headings, subheadings, paragraphs, and

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<sup>3</sup> The Plaintiffs in this action are: the County of Summit, Ohio; Summit County Public Health; and the City of Akron, as well as, for purposes of the statutory public nuisance claim, the State of Ohio by and through the chief legal officers of the foregoing jurisdictions, as set forth more fully in that claim for relief.

footnotes of the Complaint are intended to be allegations directed to the Newly-Named Actavis Entities, they are, unless otherwise admitted, denied.

D. Except as set forth below, and Pursuant to this Court's Order dated April 25, 2019 (Dkt. 1576), the Newly-Named Actavis Entities join in and incorporate by reference the entirety of Answer/Responsive Pleadings already submitted by Defendants Watson Laboratories, Inc., Actavis LLC, and Actavis Pharma, Inc. f/k/a Watson Pharma Inc. (collectively, the "Acquired Generic Actavis Entities") in the Acquired Generic Actavis Entities' Corrected Answer and Affirmative Defenses to the Corrected Second Amended Complaint as filed on February 5, 2019 (Dkt. 1340). Pursuant to the Court's April 25, 2019 Order, the Newly-Named Actavis Entities will respond only to the new allegations that relate to the Newly-Named Actavis Entities.

E. The Newly-Named Actavis Entities reserve the right to seek to amend and supplement their Answer as may be appropriate or necessary.

#### **ADMISSIONS AND DENIALS**

1. The allegations in Paragraph 1, and footnotes 1 and 2, state argument and conclusions of law to which no response is required. To the extent a response is required, the Newly-Named Actavis Entities deny the allegations in Paragraph 1 and footnotes 1 and 2.

51. The Newly-Named Actavis Entities admit that in 2008, Actavis, Inc. (n/k/a Allergan Finance, LLC), acquired the opioid Kadian through its subsidiary, Actavis Elizabeth LLC, which had been the contract manufacturer of Kadian since 2005. The Newly-Named Actavis Entities further answer that to the extent the allegations in Paragraph 51 appear to rely on the FDA-approved labels for Kadian, those documents speak for themselves and all characterizations thereof are denied. To the extent the allegations in Paragraph 51 relate to other Defendants, the Newly-

Named Actavis Entities are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 51 and therefore deny the same.

54. The allegations of Paragraph 54 are directed to parties other than the Newly-Named Actavis Entities and therefore do not require any response from the Newly-Named Actavis Entities. To the extent a response is required, the Newly-Named Actavis Entities admit that Watson Laboratories, Inc. is a Nevada corporation, but deny that its principal place of business is in Corona, California. Watson Laboratories, Inc. has its principal place of business in Parsippany, New Jersey. The Newly-Named Actavis Entities deny as stated that Watson Laboratories, Inc. “was sold to Teva Pharmaceutical Industries Ltd.” By way of clarification, the Newly-Named Actavis Entities admit that Watson Laboratories, Inc. is a subsidiary of Actavis Holdco US, Inc., whose shares were acquired by Teva Pharmaceuticals USA, Inc. (“Teva USA”), an indirect subsidiary of Teva Pharmaceutical Industries Ltd. (“Teva Ltd.”), as part of Allergan plc’s 2016 sale of its generic businesses. The Newly-Named Actavis Entities deny that between 2000 and 2015, Watson Laboratories, Inc. held all of the ANDAs for Norco and was the manufacturer of the drug.

55. The Newly-Named Actavis Entities deny that Warner Chilcott Company, LLC is a limited liability company incorporated in Puerto Rico. Warner Chilcott Company, LLC is now known as Teva Puerto Rico LLC. The Newly-Named Actavis Entities deny that since 2015, Warner Chilcott Company, LLC has been the manufacturer of Norco. The Newly-Named Actavis Entities admit that Warner Chilcott Company, LLC was a subsidiary of Warner Chilcott plc until Warner Chilcott plc became a wholly owned subsidiary of Allergan plc in 2013. The Newly-Named Actavis Entities deny as stated that Warner Chilcott Company, LLC “was sold to Teva

Pharmaceutical Industries Ltd.” By way of clarification, the Newly-Named Actavis Entities admit that Warner Chilcott Company, LLC is an indirect subsidiary of Teva Ltd.

56. The allegations of Paragraph 56 are directed to parties other than the Newly-Named Actavis Entities and therefore do not require any response from the Newly-Named Actavis Entities. To the extent a response is required, the Newly-Named Actavis Entities admit that Actavis Pharma, Inc. (f/k/a Watson Pharma, Inc.) is registered to do business with the Ohio Secretary of State as a Delaware corporation with its principal place of business in New Jersey. The allegation that Actavis Pharma, Inc. was previously responsible for sales of Kadian and Norco is a conclusion of law to which no response is required. The Newly-Named Actavis Entities deny as stated that Actavis Pharma, Inc. “was sold to Teva Pharmaceutical Industries Ltd.” By way of clarification, the Newly-Named Actavis Entities admit that Actavis Pharma, Inc. is a subsidiary of Actavis Holdco US, Inc., whose shares were acquired by Teva USA, an indirect subsidiary of Teva Ltd., as part of Allergan plc’s 2016 sale of its generic businesses.

57. The Newly-Named Actavis Entities admit that Actavis South Atlantic LLC is a Delaware limited liability company, but deny that its principal place of business is Sunrise, Florida. Actavis South Atlantic LLC’s principal place of business is Parsippany, New Jersey. The Newly-Named Actavis Entities further admit that Actavis South Atlantic LLC was, at one time, listed as the ANDA holder for oxymorphone and fentanyl transdermal. The Newly-Named Actavis Entities deny as stated that Actavis South Atlantic LLC “was sold to Teva Pharmaceutical Industries Ltd.” By way of clarification, the Newly-Named Actavis Entities admit that Actavis South Atlantic LLC is a subsidiary of Actavis Holdco US, Inc., whose shares were acquired by Teva USA, an indirect subsidiary of Teva Ltd., as part of Allergan plc’s 2016 sale of its generic businesses.

58. The Newly-Named Actavis Entities deny as stated that Actavis Elizabeth LLC “was sold to Teva Pharmaceutical Industries Ltd.” By way of clarification, the Newly-Named Actavis Entities admit that Actavis Elizabeth LLC is a subsidiary of Actavis Holdco US, Inc., whose shares were acquired by Teva USA, an indirect subsidiary of Teva Ltd., as part of Allergan plc’s 2016 sale of its generic businesses. The Newly-Named Actavis Entities admit the remaining allegations in Paragraph 58 of the Third Amended Complaint.

59. The Newly-Named Actavis Entities deny as stated that Actavis Mid Atlantic LLC “was sold to Teva Pharmaceutical Industries Ltd.” By way of clarification, the Newly-Named Actavis Entities admit that Actavis Mid Atlantic LLC is a subsidiary of Actavis Holdco US, Inc., whose shares were acquired by Teva USA, an indirect subsidiary of Teva Ltd., as part of Allergan plc’s 2016 sale of its generic businesses. The Newly-Named Actavis Entities admit the remaining allegations in Paragraph 59 of the Third Amended Complaint.

60. The Newly-Named Actavis Entities admit the allegations in Paragraph 60 of the Third Amended Complaint.

61. The Newly-Named Actavis Entities deny as stated that Actavis LLC “was sold to Teva Pharmaceutical Industries Ltd.” By way of clarification, the Newly-Named Actavis Entities admit that Actavis LLC is a subsidiary of Actavis Holdco US, Inc., whose shares were acquired by Teva USA, an indirect subsidiary of Teva Ltd., as part of Allergan plc’s 2016 sale of its generic businesses. The Newly-Named Actavis Entities admit the remaining allegations in Paragraph 61 of the Third Amended Complaint.

62. The Newly-Named Actavis Entities admit that Actavis Kadian LLC is a Delaware limited liability company, but deny that its principal place of business in Morristown, New Jersey. Actavis Kadian LLC has its principal place of business in Parsippany, New Jersey. The Newly-

Named Actavis Entities admit that Actavis Kadian LLC has been identified on Kadian's label as a distributor of Kadian, but deny that Actavis Kadian LLC has been identified on Kadian's label as a manufacturer of Kadian. The Newly-Named Actavis Entities deny as stated that Actavis Kadian LLC "was sold to Teva Pharmaceutical Industries Ltd." By way of clarification, the Newly-Named Actavis Entities admit that Actavis Kadian LLC is a subsidiary of Actavis Holdco US, Inc., whose shares were acquired by Teva USA, an indirect subsidiary of Teva Ltd., as part of Allergan plc's 2016 sale of its generic businesses. Further, to the extent Paragraph 62 purports to be based on documents, those documents speak for themselves and all characterizations thereof are denied.

63. The Newly-Named Actavis Entities deny the allegation in Paragraph 63 that Actavis Laboratories UT, Inc. is a limited liability company. Actavis Laboratories UT, Inc. is a Delaware corporation with its principal place of business in Salt Lake City, Utah. The Newly-Named Actavis Entities deny as stated that Actavis Laboratories UT, Inc. "was sold to Teva Pharmaceutical Industries Ltd." By way of clarification, the Newly-Named Actavis Entities admit that Actavis Laboratories UT, Inc. is a subsidiary of Actavis Holdco US, Inc., whose shares were acquired by Teva USA, an indirect subsidiary of Teva Ltd., as part of Allergan plc's 2016 sale of its generic businesses. The Newly-Named Actavis Entities admit the remaining allegations in Paragraph 63 of the Third Amended Complaint.

64. The Newly-Named Actavis Entities deny the allegation in Paragraph 64 that Actavis Laboratories FL, Inc. is a limited liability company. Actavis Laboratories FL, Inc. is a Florida corporation with its principal place of business in Davie, Florida. The Newly-Named Actavis Entities deny as stated that Actavis Laboratories FL, Inc. "was sold to Teva Pharmaceutical Industries Ltd." By way of clarification, the Newly-Named Actavis Entities

admit that Actavis Laboratories FL, Inc. is a subsidiary of Actavis Holdco US, Inc., whose shares were acquired by Teva USA, an indirect subsidiary of Teva Ltd., as part of Allergan plc's 2016 sale of its generic businesses. The Newly-Named Actavis Entities admit the remaining allegations in Paragraph 64 of the Third Amended Complaint.

65. To the extent the allegations in Paragraph 65 relate to other Defendants, the Newly-Named Actavis Entities are without knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 65 and therefore deny the same. Insofar as the remaining allegations in Paragraph 65 are pleaded against the Newly-Named Actavis Entities, the Newly-Named Actavis Entities deny those allegations. The Newly-Named Actavis Entities specifically deny that they ever promoted or marketed the opioids Kadian, Norco, or any other "branded" opioid products.

#### **AFFIRMATIVE AND OTHER DEFENSES**

The Newly-Named Actavis Entities join in and incorporate by reference the affirmative and other defenses to the allegations and claims in Plaintiffs' Complaint already asserted by the Acquired Generic Actavis Entities in the Corrected Second Amended Complaint with the same legal force and effect as if fully set forth herein.

#### **DEFENSES RESERVED**

The Newly-Named Actavis Entities hereby give notice that they intend to rely upon any other defenses that may become available or apparent during the discovery proceedings in this matter, and hereby reserve their right to amend their Answer and to assert any such defenses.

#### **DEMAND FOR JURY TRIAL**

The Newly-Named Actavis Entities hereby demand a trial by jury of all issues so triable. The Newly-Named Actavis Entities also hereby reserve the right to remand each case to its original jurisdiction for trial.



WHEREFORE, The Newly-Named Actavis Entities demand judgment dismissing Plaintiffs' Complaint in its entirety, together with costs and disbursements. The Newly-Named Actavis Entities further demand such other relief, both general and specific, at law or in equity, to which they are justly entitled.

Dated: May 3, 2019

Respectfully submitted,

/s/ Steven A. Reed

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**CERTIFICATE OF SERVICE**

I hereby certify that on this 3rd day of May 2019, the foregoing was electronically filed with the Clerk of the Court by using the CM/ECF system, which will send a notice of electronic filing to all counsel of record. Pursuant to Fed. R. Civ. P. 5, if electronic notice is not indicated through the court's e-filing system, a true and correct copy of the foregoing document will be served via electronic mail or U.S. Mail.

/s/ Steven A. Reed  
Steven A. Reed