12-Person Jury

IN THE CIRCUIT COURT OF COOK COUNTY, ILLINOIS
COUNTY DEPARTMENT, LAW DIVISION

ELLEN BEASLEY,	
Plaintiff,	Cause No. 2022L000833
v.	Hearing Date: 3/29/2022 10:00 AM
ACTAVIS LLC f/k/a ACTAVIS INC., ACTAVIS PHARMA, INC., AND SAGENT PHARMACEUTICALS INC.,	**Plaintiff Demands a Trial by Jury**
Defendants.	

COMPLAINT AT LAW

NOW COMES Plaintiff ELLEN BEASLEY, by and through her attorneys, Kelleher + Holland, LLC, and for her Complaint against defendants Actavis LLC f/k/a Actavis Inc., Actavis Pharma, Inc. and Sagent Pharmaceuticals Inc. (collectively "Defendants"), alleges as follows:

PARTIES

A. Plaintiff

1. Plaintiff is an individual residing in Southside, Alabama who received Docetaxel Injection as part of a weekly chemotherapy regimen after being diagnosed with breast cancer at Hematology & Oncology Associates of Alabama in Gadsden, Alabama.

B. Defendants

2. Defendant Actavis LLC f/k/a Actavis Inc. is a pharmaceutical limited liability

company organized and existing under the laws of the State of Delaware with a principal place of business at 60 Columbia Road, Building B, Morristown, New Jersey 07960 and 400 Interpace Parkway, Parsippany, New Jersey 07054.

3. Defendant Actavis Pharma Inc. is a pharmaceutical company organized and existing under the laws of State of Delaware with a principal place of business at 400 Interpace Parkway, Parsippany, New Jersey 07054. In 2016, Teva Pharmaceuticals, Ltd. Acquired Defendant Actavis Pharma Inc. Prior to 2016, Actavis Pharma Inc. was a wholly owned subsidiary of Defendant Actavis LLC f/k/a Actavis Inc.

4. Defendant Sagent Pharmaceuticals, Inc. ("Sagent") is incorporated under the laws of Delaware and maintains its principal place of business at 1901 N. Roselle Road, Ste. 700, Schaumburg, Illinois 60195.

5. Defendants transacted and conducted business throughout the United States and in the state of Illinois.

6. Defendants derived substantial revenue from goods and products designed, manufactured, marketed, advertised, promoted, sold and distributed throughout the United States.

7. At all relevant times, Defendants were in the business of designing, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing Docetaxel Injection approved by the FDA under NDA #203551.

8. The proprietary name for Defendants' branded drug is Docetaxel Injection

Concentrate.

9. Defendants expected that Docetaxel Injection would be sold, purchased, and used throughout the United States.

10. Defendant Actavis filed NDA #203551 on March 14, 2012 under Section 505(b)(2) of the Federal Food Drug and Cosmetic Act. Its application relied for its approval on FDA's findings of safety and effectiveness for the reference listed drug Taxotere. Sagent also sold this product (NDCs: 25021-222-01, 25021-222-04, and 25021-222-07) manufactured by Actavis under Actavis' NDA

11. Defendants one-vial formulation, however, was different from Taxotere's one-vial formulation because it is offered at an additional 140 mg dosage form, contains excipients citric acid and Kollidor 12 PF (Povidone k12), and uses reduced levels of polysorbate 80. After Actavis' initial Docetaxel Injection approval, a 160 mg dosage form was also introduced.

JURISDICTION AND VENUE

12. As a citizen of Illinois, Defendant Sagent is subject to personal jurisdiction in this Court, and venue is proper here under 735 ILCS 5/2-101. This case is not removable to federal court because Plaintiff sues Sagent in its home state.

13. Defendants Actavis LLC and Actavis Pharma, Inc. regularly conduct business in the state and are subject to its jurisdiction.

14. Because venue is proper as to Sagent, venue is proper for all Defendants under the

rules of permissive joinder.

FACTUAL ALLEGATIONS

I. Development and Approval of Docetaxel Injection

15. Taxotere and Docetaxel Injection are drugs used in the treatment of various forms of cancer, including breast cancer, and are a part of a family of cytoxic drugs referred to as taxanes. Taxanes are derived from yew trees, and unlike other cytoxic drugs, taxanes inhibit the multiplication of cancer cells by over-stabilizing the structure of a cancer cell, which prevents the cell from breaking down and reorganizing for cell reproduction. They are widely used as chemotherapy agents.

16. The FDA first approved Taxotere on May 14, 1996 for limited use—namely, for the treatment of patients with locally advanced or metastatic breast cancer that had either (1) progressed during anthracycline-based therapy or (2) relapsed during anthracycline-based adjuvant therapy.

17. In August, 2004, the manufacturer of Taxotere obtained FDA approval for an expanded use of the drug "in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer." This resulted in a greater number of patients being treated with Taxotere.

18. As the universe of patients taking Taxotere expanded to include patients with a higher survivability rate, more cancer survivors taking Taxotere would now experience a permanent disabling (but preventable) condition—namely, permanent damage to the

lacrimal system.

19. On March 14, 2012, Actavis filed NDA application #203551 to market its Docetaxel Injection under Section 505(b)(2) of the Federal Food, Drug and Cosmetic Act ("FDCA"), codified at §21 U.S.C. 355(b)(2).

20. Actavis received FDA approval for NDA #203551 on April 12, 2013 and began marketing these dosage forms on July 1, 2013.

21. Since approval, Actavis has submitted multiple Changes Being Effected Supplemental New Drug Applications ("CBE sNDA") to update its labeling. It submitted a CBE sNDA (S-001) on May 14, 2013, which was approved on November 4, 2013. It also submitted a "Prior Approval" sNDA (S-002) on March 21, 2014, which was approved on September 17, 2014. Neither submission, however, updated its labeling concerning **permanent** damage to the lacrimal system.

22. Docetaxel Injection is not purchased by patients at a pharmacy; rather, patients' use of this drug occurs via administration through injection and/or intravenously at a physician's office or medical treatment facility.

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