UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

IN RE ALLERGAN PLC SECURITIES LITIGATION

No. 18 Civ. 12089 (CM)(GWG)

DECISION AND ORDER GRANTING DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AND DENYING PLAINTIFF'S MOTION FOR SUMMARY JUDGMENT

McMahon, J.:

Lead Plaintiff DeKalb County Pension Fund (hereinafter referred to as "DeKalb" or "Plaintiff") brings this securities fraud lawsuit on behalf of itself and a class of similarly situated purchasers of shares of Allergan – a global pharmaceutical company. Plaintiff accuses Defendants – Allergan PLC and associated individual defendants (collectively "Allergan") – of failing to disclose information about a potential link between one of the company's products, textured silicone-gel breast implants, and a rare form of cancer.

Presently before the Court are cross motions for summary judgment: one for summary judgment dismissing the complaint, filed by Defendant Allergan (Dkt. No. 347) and one for partial summary judgment on the issue of liability, filed by DeKalb (Dkt. No. 351). Also before the Court are five *Daubert* motions to exclude the opinions and proposed testimony of several experts.

For the reasons set forth below, Defendants' summary judgment motion is granted, Plaintiff's partial summary judgment motion is denied, and the complaint is dismissed. There is

no need to address in detail the parties' *Daubert* motions as the testimony of the parties' experts is not necessary to grant Allergan's motion. Those motions are, therefore, denied as moot.

BACKGROUND

The Court assumes the parties' familiarity with the facts and recounts only the facts relevant to this summary judgment decision.

A more extensive discussion about the background of this case is available in the Court's opinions and orders addressing Allergan's motion to dismiss and the motions for class certification. *See In re Allergan PLC Sec. Litig.* ("*Allergan I*"), No. 18 CIV. 12089 (CM), 2019 WL 4686445 (S.D.N.Y. Sept. 20, 2019) (granting in part and denying in part Defendants' motion to dismiss); *In re Allergan PLC Secs. Litig.* ("*Allergan II*"), No. 18 CIV. 12089 (CM)(GWG), 2020 WL 5796763 (S.D.N.Y. Sept. 29, 2020) (denying motion for class certification filed by the former lead plaintiff, Boston Retirement System); *In re Allergan PLC Sec. Litig. ("Allergan III")*, No. 18 CIV. 12089 (CM)(GWG), 2021 WL 4077942 (S.D.N.Y. Sept. 8, 2021) (granting DeKalb's motion for class certification).

I. Factual Background

A. The Parties

Lead Plaintiff DeKalb is a pension fund that alleges that it purchased shares of Allergan at artificially inflated prices between January 30, 2017 and December 19, 2018, inclusive (the "Class Period"). (Dkt. No. 58 ¶ 19). *See also Allergan III*, 2021 WL 4077942, at *1.

Defendants include Allergan and certain of its senior executives.

Allergan is a global pharmaceutical and medical products company engaged in the development, manufacturing, and distribution of over 100 pharmaceutical and medical-aesthetics

products. (Defs.' 56.1 ¶ 1).[1] The company's stock is publicly traded on the New York Stock Exchange. (Defs.' 56.1 Counter ¶ 3).

The Executive Defendants include Brenton L. Saunders, who was Allergan's President, chief executive officer ("CEO"), and Chairman of the Board during the Class Period (Defs' 56.1 ¶ 286); Maria Teresa Hilado, who served as Allergan's chief financial officer ("CFO") from December 2014 until February 2018 (*id.* ¶ 298); Matthew W. Walsh, Allergan's CFO from February 2018 through the end of the Class Period (*id.* ¶ 299); Frances DeSena, who was vice president of Allergan's U.S. Brand and Research and Development Communication division during the Class Period (*id.* ¶ 300); Mark Marmur, who was global media relations and executive communications director of Allergan from 2015 through 2018, and served as lead for international communications and public relations from 2018 through the end of the Class Period (*id.* ¶ 305); Paul Bisaro, who was a Director on Allergan's Board from December 2016 through August 2018 (*id.* ¶ 309); and William Meury, Allergan's chief commercial officer ("CCO") during the Class Period (*id.* ¶ 315).

B. Allergan's Textured Breast Implants and BIA-ALCL

For over thirty years, Allergan and its corporate predecessors – specifically, McGhan Medical Corporation ("McGhan"), which later changed its name to Inamed Corporation ("Inamed") before Allergan purchased substantially all of the company in March 2006 – have manufactured and sold breast implants for post-mastectomy reconstructive surgery and cosmetic augmentation. (Defs' 56.1 ¶¶ 13, 14).

[1] References to Defendants' Rule 56.1 Statement (Dkt. No. 361) are designated "Defs.' 56.1"; references to Defendants' Counter-Statement of Undisputed Material Facts (Dkt. No. 382) are designated "Defs.' 56.1 Counter"; references to Plaintiff's Rule 56.1 Statement (Dkt. No. 369) are designated "Pl.'s 56.1"; references to Plaintiff's Counter-Statement of Undisputed Material Facts (Dkt. No. 401) are designated "Pl.'s 56.1 Counter".

During the Class Period, Allergan sold breast implants with several different shell textures, including macro-textured breast implants bearing the "BIOCELL" trademark, micro-textured breast implants bearing the "MicroCell" trademark, and smooth breast implants, which were sold under several brand names. (Defs.' 56.1 ¶ 2).

Breast implants with textured shells have been reported to offer several important benefits over breast implants with smooth shells, including: better adherence to tissue; lower rates of movement due to their better adherence; lower rates of capsular contracture, which is a common, disfiguring and painful condition experienced by women with implants. Moreover, because of their lower rates of movement and capsular contracture, women who use textured breast implants need fewer re-operations. (Defs' 56.1 ¶¶ 23-35).

Allergan's textured implants specifically have advantages over other types of implants. As late as the end of September 2018, the chairman of the BIA-ALCL committee of France's National Agency for the Safety of Medicines & Health Products ("ANSM"), Dr. Christian Marinetti, issued a public statement in which she asserted that Allergan's Biocell implants were "essential" and "often irreplaceable" because they are "the only product that can adhere" to certain patients and because they "enable optimal restoration of the body image of patients after amputation," in contrast to "[o]ther implants [that] may prove to be too mobile" and "requir[e] repeat operations that have their own risks." (DSJ Ex. 123; Defs' 56.1 ¶ 200).

Anaplastic large cell lymphoma ("ALCL") is a form of non-Hodgkin lymphoma. (Pl.'s 56.1 ¶ 48). As long ago as 1997, studies suggested that the disease was associated with breast implants. (*Id.* ¶¶ 50-61). In 2016, the World Health Organization designated breast implant-associated anaplastic large-cell lymphoma ("BIA-ALCL") as a distinct subgroup of ALCL. (Pl. Ex. 127; Dkt. No. 424 ¶ 421). BIA-ALCL is rare and generally treatable. (Pl.'s 56.1 Counter ¶ 12).

As of February 6, 2019, the FDA had identified 457 reported cases of BIA-ALCL in the United States, and 9 reported deaths from the disease. (DSJ Ex. 54).

C. Scientific Studies and Regulatory Advisories on BIA-ALCL

Before and during the Class Period, studies analyzed reported cases of BIA-ALCL to understand more about the disease. Due to the rarity of BIA-ALCL and the preliminary nature of the studies, the authors invariably noted that there were many gaps in their data. Specifically researchers said that they lacked access to sales data by manufacturer and that implants were often not labeled by their manufacturer – as well as the fact that there were very few reported cases of the disease. (*See* Defs' 56.1 ¶¶ 49, 77; Dkt. No. 424 ¶ 551).

Plaintiff claims that, by the beginning of the Class Period in January 2017, studies had linked ALCL specifically to breast implants with a textured outer shell. (Dkt. No. 399 at 4). As long ago as 2011, the FDA issued a report detailing the agency's belief that "there is a possible association between breast implants and ALCL," and that "ALCL has been found more frequently in association with breast implants having a textured outer shell rather than a smooth outer shell." (Pl.'s 56.1 ¶ 56). Obviously, this information was in the public domain long before the Class Period.

Plaintiff further alleges that, beginning in 2015, scientists began linking BIA-ALCL specifically to Allergan products, and that substantial evidence showed that Allergan's Biocell textured implants were associated with a higher rate of incidence of the disease than competitors' textured implants were. (Dkt. No. 399 at 4). Plaintiff cites the following studies as evidence:

- *The Gidengil Study*: In March 2015, a study published in the Plastic and Reconstructive Surgery journal reported 54 cases of BIA-ALCL in women with breast implants. 31 of those implants were of unknown manufacture. Of the 23 cases for which manufacturer information was known, 19 of the patients had Allergan implants, 3 had Nagor implants, and 1 had a Silimed implant. (DSJ Ex. 78; Pl.'s 56.1 Counter ¶ 417).

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