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*Attorneys for Defendant
Arena Pharmaceuticals, Inc.*

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

JULIE ROSE,

Plaintiff,

v.

EISAI, INC and ARENA
PHARMACEUTICALS, INC.,

Defendants.

Civil Action No.

**DEFENDANT ARENA
PHARMACEUTICALS, INC.'S
NOTICE OF REMOVAL**

State Action Filed: February 22, 2021

State Action Served: Not Served

THE CLERK OF THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF NEW JERSEY:

PLEASE TAKE NOTICE that, pursuant to 28 U.S.C. §§ 1332, 1441 and 1446, Defendant Arena Pharmaceuticals, Inc. (“Arena”) hereby removes to this Court the above-styled action, pending as Case No. BER-L-001208-21 in the Superior Court of New Jersey, Law Division, Bergen County (the “State Court Action”), to the United States District Court for the District of New Jersey.

INTRODUCTION

1. On or about February 22, 2021, Plaintiff Julie Rose filed the State Court Action against Arena and Eisai, Inc. (“Eisai”) in the Bergen County Superior Court. Plaintiff’s Complaint is attached hereto.

2. The Complaint alleges that Plaintiff Julie Rose suffered breast cancer as a result of using Belviq (Compl. at ¶ 52).

3. Based on these allegations, Plaintiff asserts claims under New Jersey law for: (1) strict products liability (design defect and failure to warn); (2) breach of express warranty; and (3) punitive damages. *Id.* at ¶¶ 54-112.

4. Plaintiff seeks, among other relief, compensatory damages, punitive damages, attorney’s fees and costs, and pre-judgment interest. *Id.* at 22-24.

5. The United States District Court for the District of New Jersey has subject matter jurisdiction over this action under 28 U.S.C. § 1332(d)(11), and removal is proper under 28 U.S.C. §§ 1441 and 1446.

I. REMOVAL IS PROPER UNDER 28 U.S.C. § 1332(a).

A. The Parties are Diverse.

6. To be removed under 28 U.S.C. § 1332(a), an action must be between “citizens of different States.” This requirement is satisfied here because Plaintiff alleges that she is (and at the time of the filing of the action was) a citizen of Virginia (*see* Compl. at ¶ 1), while Arena is (and at the time of the filing of the action was) a citizen of Delaware and Utah and Defendant Eisai is

(at the time of the filing of the action was) a citizen of Delaware and New Jersey. 28 U.S.C. § 1332(c)(1) (“[A] corporation shall be deemed to be a citizen of every State and foreign state by which it has been incorporated and of the State or foreign state where it has its principal place of business.”).

B. The Alleged Amount in Controversy Exceeds \$75,000.

7. To be removed under 28 U.S.C. § 1332(a), the amount in controversy must “exceed[] the sum or value of \$75,000.” Arena denies that Plaintiff is entitled to any relief sought in the Complaint and does not waive any defenses with respect to any of Plaintiff’s claims. However, the amount in controversy is guided by accepting Plaintiff’s allegations as true. *See Dart Cherokee Basin Operating Co., LLC v. Owens*, 574 U.S. 81, 87-88 (2014). Moreover, a “defendant’s notice of removal need include only a plausible allegation that the amount in controversy exceeds the jurisdictional threshold[;]” only when the defendant’s “assertion of the amount in controversy is challenged” do the parties need to submit proof. *Dart Cherokee Basin Operating Co., LLC*, 574 U.S. at 88.

8. Here, Plaintiff’s allegations and the relief sought conclusively demonstrate that the amount in controversy exceeds \$75,000. *See* Compl. at 22-24.

9. Plaintiff alleges that she was prescribed Belviq and that she was diagnosed with breast cancer. *See id.* at ¶ 52.

10. Based on those allegations, Plaintiff seeks compensatory damages for alleged injuries, including pain and suffering, health care costs, and lost earnings. *See id.* at ¶ 81.

11. In addition to these substantial purported compensatory damages, Plaintiff seeks an unspecified amount of punitive damages, plus attorney’s fees and costs, all of which a court must also consider in determining the amount in controversy. *See* Compl. at 22-24; *see also Gonzales v. CarMax Auto Superstores, LLC*, 840 F.3d 644, 648–49 (9th Cir. 2016) (recognizing that the amount in controversy “includes, *inter alia*, damages (compensatory, punitive, or otherwise) and the cost of complying with an injunction, as well as attorneys’ fees awarded under fee shifting statutes”); *see also Ross v. First Family Fin. Servs., Inc.*, No. 2:01CV218-P-B, 2002

WL 31059582, at *8 (N.D. Miss. Aug. 29, 2002) (“[U]nspecified claims for punitive damage sufficiently serve to bring the amount in controversy over the requisite jurisdictional threshold set out in 28 U.S.C. § 1332.”).

12. Given the nature of Plaintiff’s allegations, the nature of the relief sought, and the lack of any express limitation on the amount of damages sought, the \$75,000 amount in controversy requirement is clearly satisfied here.

II. ARENA HAS SATISFIED THE PROCEDURAL REQUIREMENTS FOR REMOVAL.

13. Under 28 U.S.C. § 1441(a) and (b), any civil action over which this Court would have original jurisdiction may be removed to this Court by any defendant.

14. Under section 1441(b)(2): “A civil action otherwise removable solely on the basis of the jurisdiction under section 1332(a) of this title may not be removed if any of the parties in interest *properly joined and served* as defendants is a citizen of the State in which such action is brought.” 28 U.S.C. § 1441(b)(2) (emphasis added). However, as the Third Circuit has made clear, section 1441(b)(2) does not apply here because, upon information and belief, neither Arena nor Eisai has been served with the Complaint in this action. *Encompass Insurance Co. v. Stone Mansion Restaurant, Inc.*, 902 F. 3d 147, 154 (3d Cir. 2018) (denying motion to remand where case removed prior to service on in-state defendant based on diversity of citizenship).

15. This Court is the proper venue for this action under 28 U.S.C. § 1441(a), as the State Court Action is pending in the County of Bergen, and the United States District Court for the District of New Jersey is the United States District Court embracing the place where the State Court Action is pending.

16. Pursuant to 28 U.S.C. § 1446(a), a copy of Plaintiff’s Complaint is attached hereto. Upon information and belief, neither Arena nor Eisai has been served with the Complaint or any other process, pleadings, or orders in this case.

17. Because, upon information and belief, neither Arena nor Eisai has been served with a copy of the Complaint in this case, this Notice of Removal is timely filed under 28 U.S.C. § 1446(b).

18. Pursuant to 28 U.S.C. § 1446(d), Arena will promptly file a removal notice with the Clerk of the Superior Court of the State of New Jersey for the County of Bergen and will serve written notice of the same upon counsel of record for Plaintiff.

19. No other defendants have been properly joined and served in this action, and so the consent of other defendants is not required. 28 U.S.C. § 1446(b)(2)(A); *see also United Steel v. Shell Oil Co.*, 549 F.3d 1204, 1208 (9th Cir. 2008).

20. By filing this Notice of Removal, Arena does not waive, either expressly or implicitly, its rights to assert any defense that it could have asserted in the Superior Court of the State of New Jersey for the County of Bergen.

WHEREFORE, Arena respectfully requests that the Court assume jurisdiction over this action.

Dated: February 22, 2021

SIDLEY AUSTIN LLP

By: /s/ Beth S. Rose

Beth S. Rose

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*Attorneys for Defendant
Arena Pharmaceuticals, Inc.*

CERTIFICATE OF SERVICE

I hereby certify that on February 22, 2021, I caused a copy of this Notice of Removal to be served via e-mail on the following counsel for Plaintiff:

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I certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are willfully false I am subject to punishment.


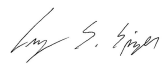
s/ Beth S. Rose
BETH S. ROSE

Dated: February 22, 2021

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	<h2 style="margin: 0;">Civil Case Information Statement</h2> <h3 style="margin: 0;">(CIS)</h3> <p style="margin: 5px 0;">Use for initial Law Division Civil Part pleadings (not motions) under <i>Rule</i> 4:5-1 Pleading will be rejected for filing, under <i>Rule</i> 1:5-6(c), if information above the black bar is not completed or attorney's signature is not affixed</p>		For Use by Clerk's Office Only	
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			Chg/Ck Number:	
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		Batch Number:		
Attorney/Pro Se Name Gregory Spizer		Telephone Number (215) 960-0402		County of Venue Bergen
Firm Name (if applicable) VSCP Law			Docket Number (when available)	
Office Address 1500 Market Street, 12th Floor, East Tower Philadelphia, PA 19102			Document Type Complaint	
			Jury Demand <input checked="" type="checkbox"/> Yes <input type="checkbox"/> No	
Name of Party (e.g., John Doe, Plaintiff) Julie Rose		Caption JULIE ROSE v. EISAI, INC. and ARENA PHARMACEUTICALS, INC.		
Case Type Number (See reverse side for listing) 606	Are sexual abuse claims alleged? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No	Is this a professional malpractice case? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If you have checked "Yes," see N.J.S.A. 2A:53A-27 and applicable case law regarding your obligation to file an affidavit of merit.		
Related Cases Pending? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		If "Yes," list docket numbers		
Do you anticipate adding any parties (arising out of same transaction or occurrence)? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		Name of defendant's primary insurance company (if known) <input type="checkbox"/> None <input checked="" type="checkbox"/> Unknown		
The Information Provided on This Form Cannot be Introduced into Evidence.				
Case Characteristics for Purposes of Determining if Case is Appropriate for Mediation				
Do parties have a current, past or recurrent relationship? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		If "Yes," is that relationship: <input type="checkbox"/> Employer/Employee <input type="checkbox"/> Friend/Neighbor <input type="checkbox"/> Other (explain) <input type="checkbox"/> Familial <input type="checkbox"/> Business		
Does the statute governing this case provide for payment of fees by the losing party? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No				
Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition				
Do you or your client need any disability accommodations? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		If yes, please identify the requested accommodation:		
Will an interpreter be needed? <input type="checkbox"/> Yes <input checked="" type="checkbox"/> No		If yes, for what language?		
I certify that confidential personal identifiers have been redacted from documents now submitted to the court and will be redacted from all documents submitted in the future in accordance with <i>Rule</i> 1:38-7(b).				
Attorney Signature: 				

VSCP LAW

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Attorney for Plaintiff

_____	:	SUPERIOR COURT OF NEW JERSEY
		BERGEN COUNTY: LAW DIVISION
JULIE ROSE,	:	
	:	
Plaintiff,	:	
	:	Docket No.: BER- L-
v.	:	
	:	
EISAI, INC., and ARENA PHARMACEUTICALS, INC.,	:	COMPLAINT AND JURY DEMAND
	:	
	:	
Defendants.	:	
_____	:	

COMPLAINT

Plaintiff Julie Rose, by and through her undersigned counsel, hereby files this Complaint and alleges against Defendants Eisai, Inc., (“Eisai”) and Arena Pharmaceuticals, Inc., (“Arena”) as follows:

PARTIES, JURISDICTION, AND VENUE

1. Julie Rose is an adult resident and citizen of Midlothian, Virginia.
2. Upon information and belief, Defendant Eisai, Inc., is a Delaware corporation, having a principal place of business at 100 Tice Boulevard, Woodcliff Lake, New Jersey 07677. As part of its business, Eisai, Inc., is involved in the research, development, sales, and marketing of pharmaceutical products, including Belviq and lorcaserin hydrochloride.

3. Upon information and belief, Defendant Eisai is a subsidiary of Eisai Co., Ltd., which is a Japanese pharmaceutical company headquartered in Tokyo, Japan.

4. Defendant Eisai is subject to general jurisdiction in the State of New Jersey because it has continuous and systematic contacts that render it essentially at home in New Jersey. Defendant Eisai is also subject to specific jurisdiction in New Jersey because it transacted substantial Belviq-related business in New Jersey.

5. Defendant Arena Pharmaceuticals, Inc., is a Delaware corporation with its principal place of business located at 6154 Nancy Ridge Drive, San Diego, California 92121.

6. Defendant Arena is subject to personal jurisdiction in the State of New Jersey under New Jersey's Long-Arm Statute because:

- (a) Arena regularly transacts, solicits, and conducts business in New Jersey, including manufacturing, testing, advertising, promoting, marketing, selling, and distributing Belviq for use in which its primary purpose is chronic weight management; and
- (b) Arena engages in substantial and not isolated activity with New Jersey directly and through agents, subsidiaries, or business affiliates.

7. Arena is subject to specific jurisdiction in the State of New Jersey because it has sufficient minimum contacts that arise out of or relate to Plaintiff's claims so that it could reasonably anticipate being subject to suit in the State of New Jersey:

- (a) Arena has derived substantial revenue from Belviq-related activities and business with Eisai within the State of New Jersey.
- (b) Arena and Eisai collectively launched Belviq in the United States in 2012 and named Defendant Eisai in New Jersey as the exclusive distributor.
- (c) Arena collaborated with Eisai in New Jersey to communicate with the United States Food & Drug Administration regarding Belviq.
- (d) Arena worked closely and collaborated with Eisai in New Jersey regarding marketing of Belviq.

- (e) Arena worked closely and collaborated with Eisai in New Jersey regarding the instructions and labeling for Belviq.
- (f) Arena worked closely and collaborated with Eisai in New Jersey to provide guidance and instructions for packaging the final product for Belviq in New Jersey.
- (g) Arena worked closely and collaborated with Eisai in New Jersey in planning and conducting the CAMELLIA-TIMI 61 trial involving Belviq.
- (h) Arena worked closely and collaborated with Eisai in New Jersey to review the data from the CAMELLIA-TIMI 61 trial.
- (i) Arena worked closely and collaborated with Eisai in New Jersey to publish the findings of the CAMELLIA-TIMI 61 trial.
- (j) Arena worked closely and in collaboration with Eisai in New Jersey on research for Belviq and Belviq XR.
- (k) Arena worked closely and in collaboration with Eisai in New Jersey on the development of Belviq and Belviq XR.
- (l) Arena worked closely and in collaboration with Eisai in New Jersey on the research, development, sales, and marketing of Belviq XR and lorcaserin hydrochloride in New Jersey.
- (m) These contacts arise out of or relate to the Plaintiff's products liability claims for Belviq causing Plaintiff's cancer.
- (n) New Jersey has an interest in adjudicating this dispute since Belviq was distributed and sold from New Jersey.

8. At all relevant times, Defendants Eisai and Arena were the representatives, agents, employees, co-conspirators, servants, employees, partners, joint-venturers, franchisees, or alter egos of the other Defendants Eisai and Arena and were acting within the scope of such authority in such conspiracy, service, agency, employment, partnership, joint venture and/or franchise.

9. Defendants Eisai and Arena were involved, either directly or as described in the paragraph above, in the business of designing, licensing, manufacturing, distributing, selling, marketing, and introducing into interstate commerce, either directly or indirectly through third

parties or related entities, numerous products, including Belviq or lorcaserin hydrochloride, as well as monitoring and reporting adverse events.

10. Venue is in this action properly lies in the Superior Court of New Jersey, Bergen County, in that the Defendant Eisai, Inc., maintains its principal place of business in Bergen County. In addition, Defendant Arena did regular business with Defendant Eisai in Bergen County arising out of the product at issue, Belviq and/or lorcaserin hydrochloride.

11. This suit is brought under the New Jersey Products Liability Act, N.J.S.A. 2A:58C-1 *et seq.* (“Products Liability Act”), the New Jersey Punitive Damages Act, N.J.S.A. 2A:15-5.9, *et seq.* (“Punitive Damages Act”), and the common law of the State of New Jersey to recover damages and other relief, including the costs of suit and reasonable attorneys’ and expert fees, for the injuries the Plaintiff has sustained as a result of the Defendants Eisai’s and Arena’s negligent and wrongful conduct in connection with the design, development, manufacturer, testing, packing, promoting, marketing, distributing, labeling and/or sale of the product at issue, Belviq.

BACKGROUND

12. At all relevant times, Defendants Eisai and Arena were in the business of and did design, research, manufacture, test, advertise, promote, market, sell, and distribute Belviq and lorcaserin hydrochloride for chronic weight management.

13. Arena received FDA approval for Belviq, also known as lorcaserin hydrochloride, on June 27, 2012 as an adjunct to reduced-calorie diet and increased physical activity for chronic weight management in adult patients with a body mass index (hereinafter referred to as “BMI”) greater than or equal to 30 kg/m² or adult patients with a BMI greater than or equal to 27 kg/m² and at least one weight- related comorbid condition.

14. Arena received additional FDA approval for Belviq XR, an extended release tablet of lorcaserin hydrochloride, on July 15, 2016 for the same indication as Belviq (hereinafter Belviq and Belviq XR will be collectively referred to as “Belviq”).

15. Upon information and belief, Arena continued to maintain control over manufacturing responsibilities for a period of time before transitioning those responsibilities to Eisai, Inc.

16. Arena and Eisai jointly launched Belviq in the United States in 2012, with Arena manufacturing Belviq and Eisai as the exclusive distributor.

17. In 2017, Eisai purchased the global rights to develop and market Belviq from Arena.

18. Belviq is a first-in-class oral selective serotonin 5HT_{2c} receptor agonist and is available by prescription in oral tablets at doses of 10mg taken twice daily or 20mg extended release taken once daily.

19. During the preclinical trial program, Defendants Eisai and Arena conducted a two-year carcinogenicity study in rats in which lorcaserin was identified as a non-genotoxic carcinogen inducing multiple tumor types, primarily due to an increase in mammary tumors in both sexes near clinical exposure and at all doses in female rats. There was also an increase in astrocytomas, malignant schwannomas, hepatocellular adenoma and carcinoma, skin subcutis fibroma, skin squamous carcinoma, and thyroid follicular cell adenoma in male rats. Adenocarcinoma in the lorcaserin groups demonstrated increased tumor onset, multiplicity, and lung metastases. Fibroadenoma in the lorcaserin groups also demonstrated greater incidence and multiplicity. While the study was ongoing, the FDA required bi-monthly updates due to the consistently increased incidence of tumors and mortality in the lorcaserin groups. However, in the final report the incidence of adenocarcinoma was lower in the mid- and high-dose groups than that reported at week 96 and had increased in the control group, while the incidence of fibroadenoma increased across all doses from week 96, with notable variations in the mid- and high-dose groups. Due to the apparent increase in fibroadenoma accompanying the decrease in adenocarcinoma after week 96, the FDA suspected reclassification of tumor types.

20. Arena attributed the increased incidence of tumors seen in the two-year rat study to elevated prolactin levels induced by lorcaserin in rats, which they claim was a rodent-specific phenomenon.

21. During the preclinical trial program, Arena also conducted a two-year carcinogenicity study in mice, which demonstrated an increase in malignant hepatocellular carcinoma in males and schwannoma in females. Although the dosing levels were below the clinical dose and therefore likely inadequate, these findings provide further context for potential carcinogenicity in combination with the two-year rat study results.

22. From September 2006 through February 2009, Arena conducted the Behavioral modification and Lorcaserin for Overweight and Obesity Management (BLOOM) trial, a two-year, randomized, placebo-controlled, double-blind, multicenter clinical trial involving 3,182 patients to examine the efficacy of lorcaserin in reducing body weight in the U.S. While weight reduction was seen in the first year, all treatment groups experienced weight regains during the second year. In July 2010, the results of the BLOOM trial were published in the New England Journal of Medicine (hereinafter referred to as “NEJM”). Smith S.R., et al. Multicenter, Placebo-Controlled Trial of Lorcaserin for Weight Management. N. Engl. J. Med 2010;363:245-56.

23. From December 2007 to July 2009, Arena conducted the Behavioral modification and Lorcaserin Second Study for Obesity Management (BLOSSOM) trial, a one-year randomized, placebo-controlled, double-blind, parallel arm trial involving 4,008 patients to examine the effects of lorcaserin on body weight, cardiovascular risk, and safety in the U.S. In July 2011, the results of the BLOSSOM trial were published in the Journal of Clinical Endocrinology and Metabolism. Fidler, M.C., et al. A One-Year Randomized Trial of Lorcaserin for Weight Loss in Obese and Overweight Adults: the BLOSSOM trial. J Clin Endocrinol Metab 2011;96:3067-3077.

24. Combined data from the BLOOM and BLOSSOM trials demonstrated only a 3.3% mean weight loss after one year with lorcaserin over that of the placebo group, which failed to meet the mean efficacy criterion of FDA’s obesity draft guidance.

25. On December 18, 2009, Arena and Eisai submitted its first New Drug Application for Belviq.

26. On September 16, 2010, the Endocrinologic and Metabolic Drugs Advisory Committee (hereinafter referred to as “EMDAC”) met to discuss approval of Belviq based on the results of preclinical trials and the BLOOM and BLOSSOM Phase 3 clinical trials. The EMDAC

panel voted nine (9) to five (5) against approval of Belviq as the potential benefits did not outweigh the potential risks based on concerns about the preclinical carcinogenicity findings (i.e., increased mammary adenocarcinoma/fibroadenoma and brain astrocytomas in rats) and marginal weight loss demonstrated by the clinical trials.

27. On October 28, 2010, the FDA issued a Complete Response Letter (CRL) rejecting approval of Belviq. The bases for the CRL included uncertainty in diagnosis of mammary masses in rats, unresolved issues with the exposure-response relationship between lorcaserin and mammary adenocarcinoma, failure to identify a mode of action and a clear safety margin for brain astrocytoma, and marginal weight loss results.

28. In response to the CRL, Arena convened a pathology working group (hereinafter referred to as “PWG”) to blindly readjudicate the preclinical mammary tumor data in rats.

29. The CRL also requested that Arena submit the final report from the third Phase 3 trial in overweight and obese patients with Type 2 Diabetes Mellitus.

30. From December 2007 to August 2010, Arena conducted the Behavioral modification and Lorcaserin for Obesity and Overweight Management in Diabetes Mellitus (BLOOM-DM) trial, a one- year, randomized, placebo-controlled trial involving 604 patients to examine the efficacy and safety of lorcaserin for weight loss in patients with Type 2 Diabetes Mellitus in the U.S. After one year, there was only a 3.1% mean weight loss with lorcaserin over that of the placebo group. In April 2012, the results of the BLOOM-DM trial were published in the journal of The Obesity Society. O’Neil, P.M., et al. Randomized Placebo-Controlled Clinical Trial of Lorcaserin for Weight Loss in Type 2 Diabetes Mellitus: The BLOOM-DM Study. Obesity 2012;20:1426-1436.

31. On December 27, 2011, in response to the CRL, Arena submitted to the FDA the final report of the BLOOM-DM study and data from the PWG readjudication, as well as new studies to support their continued assertion that the increase in tumors seen in the two-year rat study was due to elevated prolactin levels induced by lorcaserin.

32. The PWG found a decreased number of adenocarcinoma and an increased number of fibroadenoma in both the control and the lorcaserin groups of the two-year rat study. For adenocarcinoma, the number decreased to a larger extent in the lorcaserin group compared to the control group, but lorcaserin still increased the incidence, tumor onset and multiplicity, and lethality of mammary adenocarcinoma, and the high-dose lorcaserin group maintained a statistically significant increase in adenocarcinomas compared to the control group. Regarding fibroadenoma, there was an increase in the incidence, tumor onset and multiplicity, and lethality across all lorcaserin dose groups compared to the control group, however these results were disregarded as irrelevant to risk of carcinoma in FDA's review of the readjudication data.

33. On May 10, 2012, a second EMDAC panel met to discuss approval of Belviq with a focus on the PWG readjudication of preclinical data to determine the potential carcinogenicity risk, lorcaserin levels in human cerebrospinal fluid to determine a safety margin for astrocytoma, and the results of the BLOOM-DM Phase 3 clinical trial to further determine efficacy. The panel voted 18 to four (4) (with one abstention) that the benefits of Belviq outweighed the risks for an overweight and obese population. The panel also recommended a post-approval assessment of risk for Belviq, with a focus on cardiovascular risk. Ultimately, the FDA required that Defendants Eisai and Arena conduct six (6) post-marketing studies, including a cardiovascular outcomes trial.

34. On June 26, 2012, in her Summary Review of Eisai's and Arena's application for approval following submission of data in response to the CRL, the FDA Deputy Division Director,

Dr. Eric Colman, indicated that the PWG's analysis addressed the concerns raised by the data in the original application, and that he did not believe Belviq posed a risk for mammary adenocarcinoma in humans. He also stated that the cerebrospinal fluid data provided an adequate safety margin for brain astrocytoma. However, regarding tumorigenic mechanism of action, Dr. Colman noted that the FDA Pharmacology/Toxicology reviewer, Dr. Fred Alavi, concluded that the prolactin studies, while supportive of a plausible role of prolactin in tumor formation, fell short of definitive proof.

35. In contrast, on May 3, 2013, Arena withdrew the application for marketing authorization for Belviq with the European Medicines Agency (hereinafter referred to as "EMA"). The EMA Committee for Medicinal Products for Human Use (hereinafter referred to as "CHMP") determined that Belviq was not approvable due to major objections regarding carcinogenicity and efficacy. Specifically, the CHMP found that, even with the PWG readjudication, the risk of carcinogenicity in humans needed further consideration and the overall clinical risk/benefit balance was negative in that the modest efficacy results did not outweigh safety concerns. The CHMP further stated that the increased occurrence of several tumor types in male rats was particularly concerning due to the lack of any persuasive mechanism of action that would provide assurance of safety in human use, which also undermined any discussion on exposure margins. Thus, the CHMP concluded that the clinical relevance of the tumors found in the rat study must be evaluated as part of the risk-benefit assessment.

36. From January 2014 to June 2018, Arena conducted a post-marketing trial, the Cardiovascular and Metabolic Effects of Lorcaserin in Overweight and Obese Patients – Thrombolysis in Myocardial Infarction 61 (CAMELLIA-TIMI 61). CAMELLIA-TIMI 61 was a randomized, double-blind, placebo-controlled, multicenter, parallel group clinical trial involving

12,000 patients conducted in the U.S., Canada, Mexico, the Bahamas, Europe, South America, Australia, and New Zealand to evaluate the risk of heart-related issues with Belviq. CAMELLIA-TIMI 61 began in 2014 and concluded in 2018.

37. The primary safety outcome of major adverse cardiovascular events showed noninferiority. The results of CAMELLIA-TIMI 61 were published in September 2018 in NEJM. Bohula, E.A., et al. Cardiovascular Safety of Lorcaserin in Overweight or Obese Patients. N. Engl. J. Med. 2018;379:1107-17.

38. In January of 2017, Eisai announced that it acquired all global development and marketing rights to Belviq from Arena.

39. Under the 2017 agreement between Eisai and Arena, Eisai became “solely responsible for all decision-making and implementation related to global development and submissions for regulatory approvals,” as well as global marketing rights.

40. Pursuant to the agreement between Eisai and Arena, all post-2017 regulatory approvals sought from the FDA were submitted by Eisai.

41. On January 14, 2020, the FDA issued a safety communication regarding clinical trial results showing a possible increased risk of cancer with Belviq. The FDA stated that its evaluation of the potential signal was ongoing, and a causal association was at that time uncertain.

42. On February 13, 2020, the FDA announced that Eisai had submitted a request to voluntarily withdraw Belviq from the market.

43. The FDA reported that analysis of the CAMELLIA-TIMI 61 data indicated an imbalance of cancer in patients taking Belviq that increased with treatment duration, including pancreatic, colorectal, and lung cancer. Specifically, one additional cancer was observed per 470 patients treated for one year, with 462 (7.7%) Belviq patients diagnosed with 520 primary cancers

compared to 423 (7.1%) with 470 cancers in the placebo group. The FDA further stated that the risks of Belviq outweigh its benefits and recommended that patients stop taking Belviq and dispose of any unused pills. The FDA also instructed all health care professionals to stop prescribing Belviq and to contact their patients taking Belviq to inform them of the increased risk of cancer and ask that they stop taking Belviq.

44. Prior to applying for and obtaining approval of Belviq in 2012, Eisai and Arena knew or should have known that human consumption of Belviq was associated with significant risks of cancer.

45. Defendant possessed pre-clinical scientific studies, which evidence Eisai and Arena knew or should have known was the signal that the cancer risk needed further testing and studies prior to its introduction to the market.

46. Upon information and belief, despite cancer findings in animal carcinogenicity studies, Eisai and Arena failed to adequately conduct complete and proper testing of Belviq prior to filing their New Drug Application for Belviq.

47. Upon information and belief, from the date Defendants Eisai and Arena received FDA approval to market Belviq, Eisai and Arena devised a plan to manufacture, distribute market, and sell Belviq without adequate warnings to prescribing physicians or Plaintiff that Belviq was associated with and/or could cause cancer, presented a risk of cancer in patients who used it, and that Eisai and Arena had not adequately conducted complete and proper testing and studies of Belviq with regard to carcinogenicity.

48. Eisai and Arena's failure to disclose information that they possessed regarding failure to adequately test and study Belviq for cancer risk further rendered warnings for this medication inadequate.

CASE SPECIFIC FACTUAL ALLEGATIONS

49. In 2013, Plaintiff Julie Rose learned about Belviq by reading a magazine advertisement.

50. A few months later in December 2013, Plaintiff Julie Rose was prescribed Belviq for weight loss and diet control by Dr. Sigmund Seiler in Midlothian, Virginia.

51. From December 2013 to June of 2014, Plaintiff continued to take Belviq for her weight loss without knowing of the significant increased risk that Belviq could cause her to develop cancer.

52. In September 2019, Plaintiff was diagnosed with invasive breast cancer.

53. Plaintiff's use of Belviq caused or significantly contributed to her development of breast cancer, which has permanently changed her life.

COUNT I
STRICT PRODUCTS LIABILITY – DESIGN DEFECT (N.J.S.A. 2A:58C-1 *et seq.*)
(Defendants Eisai and Arena)

54. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

55. At all times herein mentioned, Defendants Eisai and Arena were/are the researchers, designers, manufacturers, testers, advertisers, promoters, marketers, packagers, labelers, sellers and/or distributors of Belviq, which is defective and unreasonably dangerous.

56. Belviq is defective in its design or formulation in that it is not reasonably fit, suitable, or safe for its intended purpose and/or its foreseeable risks exceed the benefits associated with its design. Belviq is defective in design because it poses an increased risk of cancers, is more dangerous than other available drugs indicated for similar conditions and uses, and the utility of the Belviq drug does not outweigh its risks.

57. The defective condition of Belviq rendered it unreasonably dangerous and/or not reasonably safe, and Belviq was in this defective condition at the time it left the hands of Defendants Eisai and Arena. Belviq was expected to and did reach Plaintiff and her physician without substantial change in the condition in which it was designed, manufactured, labeled, sold, distributed, marketed, promoted, supplied, and otherwise released into the stream of commerce.

58. Belviq was used for its intended purposes and the product was not materially altered or modified prior to its use.

59. Belviq is defective in design because of its likelihood for, among other things, the increase of cancers in its consumers at an unreasonable rate.

60. At or before the time Belviq was released on the market and/or sold to Plaintiff, Defendants Eisai and Arena could have designed the Belviq to make it less prone to causing cancers, a technically feasible safer alternative design that would have prevented the harm Plaintiff suffered without substantially impairing the function of the drug.

61. Plaintiff was not able to discover, nor could she have discovered through the exercise of reasonable diligence, the defective nature of Belviq. Further, in no way could Plaintiff have known that Defendants Eisai and Arena had designed, developed, and manufactured Belviq in a way as to make the risk of harm or injury outweigh any benefits.

62. Belviq is and was being used in the Defendants Eisai's and Arena's intended manner at the time it was prescribed to Plaintiff.

63. Defendants Eisai and Arena had a duty to create a product that was not unreasonably dangerous for its normal, intended use and breached this duty.

64. Defendant Eisai and Arena knew or should have known that Belviq would be prescribed to patients and that physicians and patients were relying on them to furnish a suitable

product. Further, Defendants Eisai and Arena knew or should have known that patients in whom Belviq would be used, such as Plaintiff, could be and would be affected by the defective design and composition of Belviq.

65. Defendants Eisai and Arena researched, designed, manufactured, tested, advertised, promoted, marketed, sold and distributed a defective product which, when used in its intended or reasonably foreseeable manner, created an unreasonable risk to the health of consumers, such as Plaintiff, and Defendants Eisai and Arena are therefore strictly liable for the injuries sustained by Plaintiff.

66. As a direct and proximate result of Defendants Eisai's and Arena's placement of Belviq into the stream of commerce and Plaintiff's use of Belviq as designed, manufactured, sold, supplied, and introduced into the stream of commerce by Defendants Eisai and Arena, Plaintiff suffered serious physical and mental injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiff demands judgment against Defendants Eisai and Arena, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT II
STRICT PRODUCTS LIABILITY- FAILURE TO WARN (N.J.S.A. 2A:58C-1 et seq.)
(Defendants Eisai and Arena)

67. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

68. At all times herein mentioned, Defendants Eisai and Arena designed, researched, manufactured, tested, advertised, promoted, marketed, sold, distributed, and/or have recently

acquired the Defendants Eisai and Arena who have designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed Belviq as hereinabove described that was used by the Plaintiff.

69. Belviq was expected to and did reach the usual consumers, handlers, and persons coming into contact with said product without substantial change in the condition in which it was produced, manufactured, sold, distributed, and marketed by the Defendants Eisai and Arena.

70. Defendants Eisai's and Arena's duty to provide adequate warnings extends not only to consumers of its own product, but also to those persons whose doctors foreseeably rely on Defendant Eisai's and Arena's product information when prescribing a medication, even if the prescription is filled with a generic version of that prescribed drug. Defendant Eisai and Arena also had a continuing duty to warn Plaintiff and her physicians of the dangers associated with the subject product.

71. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants Eisai and Arena was defective due to inadequate warnings or instructions and/or inadequate testing as the Defendants Eisai and Arena knew or should have known that the product created a risk of serious and dangerous side effects including cancer, as well as other severe and personal injuries which are permanent and lasting in nature and the Defendant Eisai and Arena failed to adequately warn of said risk.

72. The Belviq designed, researched, manufactured, tested, advertised, promoted, marketed, sold, and distributed by Defendants Eisai and Arena was defective due to inadequate post-marketing surveillance and/or warnings because, after Defendants Eisai and Arena knew or should have known of the risks of serious side effects including cancer, as well as other severe and permanent health consequences from Belviq, they failed to provide adequate warnings to users or

consumers of the product, and continued to improperly advertise, market and/or promote their product, Belviq.

73. Information provided by Defendants Eisai and Arena to the medical community, consumers, and ultimately Plaintiff concerning the safety and efficacy of Belviq did not accurately reflect the serious and potentially fatal adverse events Plaintiff could suffer.

74. At all times relevant hereto, Belviq was dangerous and presented a substantial danger to consumers like Plaintiff who were prescribed with Belviq, and these risks and dangers were known or knowable at the times of distribution and/or prescription to Plaintiff. Ordinary consumers like Plaintiff would not have recognized the potential risks and dangers that Belviq posed to patients, because its use was specifically promoted to improve the health of such patients, including Plaintiff.

75. Had adequate warnings and instructions been provided, Plaintiff would not have been prescribed Belviq, and would not have been at risk of the harmful injuries, including but not limited to breast cancer described herein. Defendants Eisai and Arena failed to provide warnings of such risks and dangers to the Plaintiff and her medical providers as described herein.

76. Neither Plaintiff nor Plaintiff's physicians knew, nor could they have learned through the exercise of reasonable care, the risks of serious injury and/or death associated with and/or caused by Belviq.

77. Defendants Eisai and Arena knew or should have known that the warnings given failed to properly warn both medical professionals and consumers of the increased risks of serious injury and/or death associated with and/or caused by Belviq.

78. Defendants Eisai and Arena deliberately concealed and did not disclose knowledge acquired after Belviq's 510(k) clearance that Belviq caused serious health issues and side effects, including cancers.

79. Defendants Eisai and Arena also engaged in an economically driven manipulation of the post-market regulatory process involving Belviq.

80. Plaintiff, individually and through her treating physicians, reasonably relied upon the skill, superior knowledge and judgment of Defendants Eisai and Arena.

81. As a direct and proximate result of Belviq's defects as described herein, Plaintiff suffered permanent and continuous injuries, pain and suffering, disability, and impairment. Plaintiff has further suffered emotional trauma, harm and injuries that will continue into the future. Plaintiff has lost her ability to live a normal life and will continue to be so diminished in the future. Furthermore, Plaintiff has lost earnings and will continue to lose earnings into the future and have medical bills, both past and future, related to care because of Belviq's defects.

82. Based on the foregoing, Defendants Eisai and Arena are liable to the Plaintiff for damages as a result of its failure to warn and/or adequately warn or instruct the Plaintiff and her healthcare professionals about the increased risk of serious injury and death caused by Belviq.

WHEREFORE, Plaintiff demands judgment against Defendants Eisai and Arena, and each of them, individually, jointly and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

COUNT III
BREACH OF EXPRESS WARRANTY (N.J.S.A. 12A:2-313 *et seq.*)
(Defendants Eisai and Arena)

83. Plaintiffs repeat, reiterate and reallege each and every allegation of this Complaint contained in each of the foregoing paragraphs inclusive, with the same force and effect as if more fully set forth herein.

84. Defendants Eisai and Arena expressly warranted that Belviq was safe and well accepted by users.

85. Belviq does not conform to these express representations because Belviq is not safe and has numerous serious side effects, many of which were not accurately warned about by Defendants Eisai and Arena. As a direct and proximate result of the breach of said warranties, Plaintiff suffered and/or will continue to suffer severe and permanent personal injuries, harm, and economic loss.

86. Plaintiff did rely on the express warranties of the Defendants Eisai and Arena herein.

87. The Defendants Eisai and Arena herein breached the aforesaid express warranties, as their drug Belviq was defective.

88. Defendants Eisai and Arena expressly represented to Plaintiff, her physicians, healthcare providers, and/or the FDA that Belviq was safe and fit for use for the purposes intended, that it was of merchantable quality, that it did not produce any dangerous side effects in excess of those risks associated with other forms of treatment for chronic weight management, that the side effects it did produce were accurately reflected in the warnings and that it was adequately tested and fit for its intended use.

89. Defendants Eisai and Arena falsely and fraudulently represented to the medical and healthcare community, and to the Plaintiff, and/or the FDA, and the public in general, that said product, Belviq, had been tested and was found to be safe and/or effective for chronic weight management.

90. Eisai also aired television commercials about “willpower” for eating habits, which stated numerous potential side effects, including heart-related issues, depression, suicidal thoughts, low blood sugar, decreased blood cell count, headache, dizziness, fatigue, nausea, dry mouth, constipation, back pain, and coughing. But Eisai’s “willpower” commercial failed to warn or even mention a potential cancer link.

91. Eisai’s “willpower” commercial even warned users to contact their doctors if their breasts begin to make milk or decrease in size. However, Eisai’s commercial never warned about the potential risk of breast cancer.

92. Eisai’s Vice President of Specialty Marketing, Michael O’Brien, said in 2014 that: “For many Americans trying to lose weight, diet and exercise alone are not enough. Further, O’Brien added that Eisai’s “goal with this new ad is to turn up the volume on the conversation using realistic situations and questions that real people encounter to raise awareness and encourage those who continue to struggle with their weight to speak to their doctor about BELVIQ as part of a weight loss regimen.”

93. In addition, Plaintiff first learned of Belviq through Arena’s consumer magazine advertisement in 2013 a few months before being prescribed Belviq. Arena’s advertisement stated that “You could be carrying more than just extra weight” and states in large, bold print that Belviq was “FDA approved for weight loss.”

94. Further, Arena's magazine advertisement detailed warnings indicating a possible increase in prolactin and that women should not take Belviq while breastfeeding. However, the advertisement made no mention of a potential risk for any type of cancer, including breast cancer.

95. Plaintiff was ultimately unaware and did not know that Belviq was unsafe for the purpose of weight loss because it caused a significant increased risk of cancer until after she was diagnosed with cancer.

96. The representations and/or omissions made by Defendants Eisai and Arena were false and substantially misleading.

97. Defendants Eisai and Arena knew or should have known that, in fact, said representations and warranties were false, misleading and untrue in that Belviq was not safe and fit for the use intended, and, in fact, produced serious injuries to the users that were not accurately identified and represented by Defendants Eisai and Arena, including Plaintiff.

98. As a result of the foregoing acts and omissions, the Plaintiff was caused to suffer serious and dangerous side effects including breast cancer, as well as other severe and personal injuries which are permanent and lasting in nature, physical pain and mental anguish, including diminished enjoyment of life, as well as the need for lifelong medical treatment, monitoring and/or medications, and fear of redeveloping cancer.

99. By reason of the foregoing, Plaintiff has been severely and permanently injured, and will require more constant and continuous medical monitoring and treatment than prior to Plaintiff's use of Defendant Eisai's and Arena's Belviq drug.

100. As a result of the foregoing acts and omissions the Plaintiff requires and/or will require more health care and services and did incur medical, health, incidental, and related

expenses. Plaintiff is informed and believes and further alleges that Plaintiff will in the future be required to obtain further medical and/or hospital care, attention, and services.

WHEREFORE, Plaintiff demands judgment against Defendants Eisai and Arena, and each of them, individually, jointly, and severally, and requests compensatory damages, together with costs and interest, and any further relief as the Court deems proper.

PUNITIVE DAMAGES UNDER COMMON LAW, NEW JERSEY PUNITIVE DAMAGES ACT (N.J.S.A. 2A:15-15-5.9 *et seq.*), and PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-1 *et seq.*)

101. Plaintiff adopts and incorporates by reference all of the foregoing language of this Complaint as if fully set forth herein and further states as follows.

102. The acts and omissions of Defendants Eisai and Arena described herein consisted of oppression, fraud, and/or malice, and were done with advance knowledge, conscious disregard of the safety of others, and/or ratification by Defendants Eisai's and Arena's officers, directors, and/or managing agents.

103. Despite this knowledge, Defendants Eisai and Arena, for financial reasons, sought to create and market a weight loss and diet control drug, and Defendants did in fact create such drug, Belviq, that had substantial and unreasonable risks and side effects of Belviq, including breast cancer.

104. Yet, despite having substantial information about the serious and unreasonable side effects of Belviq, Defendants Eisai and Arena intentionally and recklessly failed to adequately instruct physicians, including Plaintiff's physicians, of the serious and unreasonable side effects of Belviq, and failed to warn physicians, including Plaintiff's physician, and consumers, including Plaintiff, of the significant risks of cancers from Belviq. Further, Defendants Eisai and Arena failed to pull Belviq from the market after indications of serious, unreasonable side effects such as

cancers were prevalent among Belviq consumers, and instead unjustifiably delayed its inevitable removal until the FDA forced such in February of 2020.

105. Specifically, Defendants Eisai and Arena downplayed and recklessly disregarded their knowledge of the defective nature of Belviq's clear and unequivocal indications of cancers.

106. Defendants Eisai and Arena undertook a marketing campaign to globally market Belviq despite conducting proper testing.

107. Additionally, Defendants Eisai and Arena undertook this marketing campaign despite its own preclinical trial results showing an increased risk of tumors and cancers in rats.

108. Defendants Eisai and Arena intentionally and recklessly omitted information in the Instructions for Use to warn and instruct physicians on Belviq's increased risks for cancers.

109. Defendants Eisai and Arena downplayed, understated, and disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Belviq.

110. Finally, Defendants Eisai and Arena were aware prior to marketing Belviq that there was a potential increase and/or risk of cancers.

111. Defendants Eisai and Arena recklessly failed to warn and adequately instruct physicians, including Plaintiff's physician, regarding this significant increase in cancers among Belviq users.

112. Consequently, Defendants Eisai and Arena are liable for punitive damages in an amount to be determined by the jury.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff Julie Rose prays for judgment against Defendants Eisai and Arena, individually and collectively, jointly and severally, as follows:

- (a) Trial by jury;

- (b) Judgment against all Defendants for all compensatory allowable to Plaintiff;
- (c) Judgment against all Defendants for all other relief sought by Plaintiff under this Complaint;
- (d) For reasonable attorneys' fees and costs;
- (e) For pre-judgment interest; and
- (f) For such further and other relief the Court deems just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff demands a trial by jury on all counts and as to all issues.

Dated: February 22, 2021

Respectfully Submitted,

VSCP LAW

/s/ Gregory S. Spizer

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**Pro Hac Vice* Admission to be Sought

Counsel for Plaintiff Julie Rose

Civil Case Information Statement

Case Details: BERGEN | Civil Part Docket# L-001208-21

Case Caption: ROSE JULIE VS EISAI, INC

Case Initiation Date: 02/22/2021

Attorney Name: GREGORY STEVEN SPIZER

Firm Name: VSCP LAW

Address: 1500 MARKET ST 12TH FL, EAST TOWER
PHILADELPHIA PA 19102

Phone: 2159600399

Name of Party: PLAINTIFF : Rose, Julie

Name of Defendant's Primary Insurance Company
(if known): None

Case Type: PRODUCT LIABILITY

Document Type: Complaint with Jury Demand

Jury Demand: YES - 12 JURORS

Is this a professional malpractice case? NO

Related cases pending: NO

If yes, list docket numbers:

Do you anticipate adding any parties (arising out of same transaction or occurrence)? NO

Are sexual abuse claims alleged by: Julie Rose? NO

THE INFORMATION PROVIDED ON THIS FORM CANNOT BE INTRODUCED INTO EVIDENCE

CASE CHARACTERISTICS FOR PURPOSES OF DETERMINING IF CASE IS APPROPRIATE FOR MEDIATION

Do parties have a current, past, or recurrent relationship? NO

If yes, is that relationship:

Does the statute governing this case provide for payment of fees by the losing party? NO

Use this space to alert the court to any special case characteristics that may warrant individual management or accelerated disposition:

Do you or your client need any disability accommodations? NO

If yes, please identify the requested accommodation:

Will an interpreter be needed? NO

If yes, for what language:

Please check off each applicable category: Putative Class Action? NO Title 59? NO Consumer Fraud? NO

I certify that confidential personal identifiers have been redacted from documents now submitted to the court, and will be redacted from all documents submitted in the future in accordance with *Rule 1:38-7(b)*

02/22/2021
Dated

/s/ GREGORY STEVEN SPIZER
Signed