

**BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION**

IN RE: TAXOTERE (DOCETAXEL) EYE) MDL Docket No.
INJURY CLAIMS)

**MOTION FOR TRANSFER OF RELATED ACTIONS
PURSUANT TO 28 U.S.C. § 1407
FOR COORDINATED PRETRIAL PROCEEDINGS**

Jade Porter, plaintiff in *Porter v. Sanofi US Services, Inc. et al.*, Case No. 3:21-cv-01891 (N.D. Cal.) (the “Porter Action”), moves the Panel under 28 U.S.C. § 1407 to transfer to the Northern District of California, or in the alternative, the District of Arizona, for coordinated pretrial proceedings the related actions (“Related Actions”) listed in the attached Schedule of Actions, and in support thereof, Movant Porter states:

1. The Related Actions allege products liability claims against defendants Sanofi U.S. Services, Inc. (f/k/a Sanofi-Aventis U.S., Inc.) and Sanofi-Aventis U.S., LLC on behalf of cancer patients who received the chemotherapy drug Taxotere (docetaxel) and who know suffer from permanent and irreversible eye damage that could have been prevented with adequate warning.

2. There are currently six pending cases filed against Defendants in four different jurisdictions:

- a. *Porter v. Sanofi U.S. Services, Inc. et al.*, Case. No. 3:21-cv-01891 (N.D. Cal., filed Mar. 17, 2021);

- b. *Estell v. Sanofi U.S. Services, Inc. et al.*, Case No. 3:21-cv-02749 (N.D. Cal., filed Apr. 16, 2021);
- c. *Hamilton-Moews v. Sanofi U.S. Services, Inc. et al.*, Case No. 5:21-cv-00718 (C.D. Cal., filed Apr. 21, 2021);
- d. *Cone v. Sanofi U.S. Services, Inc. et al.*, Case. No. 2:21-cv-00689 (D. Ariz., filed Apr. 21, 2021)
- e. *Vega v. Sanofi U.S. Services, Inc. et al.*, Case No. 2:21-cv-00730 (E.D. Cal., filed Apr. 23, 2021); and
- f. *Burns v. Sanofi U.S. Services, Inc. et al.*, Case No. 2:21-cv-08964 (C.D. Cal., filed Nov. 15, 2021).

3. As required by 28 U.S.C. § 1407(a), the Related Actions “involve[] one or more common questions of fact” arising out of common allegations related to the same product defect causing the same or similar injuries.

4. Transfer and centralization of the Related Actions “will be for the convenience of parties and witnesses and will promote the just and efficient conduct” of the actions, 28 U.S.C. §1407(a), because they allege overlapping causes of action on behalf of a group of cancer patients who took the drug Taxotere (docetaxel).

5. The Northern District of California is the most appropriate venue because it is already presiding over two of the Related Actions, both of which were the first two actions filed for these claims. Alternatively, Movant suggests the District of Arizona.

6. Movant Porter bases this Motion on her Memorandum in Support of this Motion to Transfer and Coordinate, and such other matters as may be presented to the Panel at the time of hearing.

WHEREFORE, Movant respectfully requests that the Panel transfer and consolidate the Related Actions set forth in the Schedule of Actions filed herewith, as well as any tag-along actions that are subsequently filed asserted related or similar claims in the Northern District of California.

Dated: December 1, 2021

Respectfully submitted,

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BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

IN RE: TAXOTERE (DOCETAXEL) EYE) MDL Docket No.
INJURY CLAIMS)

MEMORANDUM IN SUPPORT OF MOTION FOR TRANSFER
OF RELATED ACTIONS PURSUANT TO 28 U.S.C. § 1407
FOR COORDINATED PRETRIAL PROCEEDINGS

Pursuant to Rule 6.2(a) of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, Jade Porter, plaintiff in *Porter v. Sanofi U.S. Services, Inc.*, Case No. 3:21-cv-01891 (N.D. Cal.) (the “Porter Action”), respectfully submits this Memorandum in Support of the Motion for Transfer of Related Actions for coordinated pretrial proceedings under 28 U.S.C. § 1407. Transfer and coordination will promote the just and efficient conduct” of the actions, 28 U.S.C. § 1407, because the Related Actions, of which there are currently six, each allege overlapping causes of action related to the same product defect causing the same or similar injuries. Of the four venues in which the Related Actions are presently filed, transfer and coordination in the Northern District of California is most appropriate because it is currently presiding over two of the Related Actions, both of which were the first two filed cases for these injuries. Further, five of the six Related Actions have been filed in California, and the Northern District Court is an experienced and well-equipped district court to handle this MDL. Further, while busy, it does not have the backlog of cases and unfilled judgeships that other courts suffer with.

INTRODUCTION

Movant Jade Porter filed suit against Sanofi US Services, Inc. (f/k/a Sanofi-Aventis U.S., Inc.) and Sanofi-Aventis US, LLC (collectively “Sanofi”) in the Northern District of California on March 21, 2021. Movant alleges that Sanofi manufactured and sold the chemotherapy drug Taxotere (docetaxel) without adequate warning concerning the risk of permanent eye injuries, specifically punctal and canalicular stenosis. Movant further alleges that had adequate warning been provided, the disabling and irreversible eye damage could have been entirely prevented through appropriate monitoring and intervention during chemotherapy. As a result of this inadequate warning and other misrepresentations, Movant now suffers from permanent and disabling eye damage.

To date, six related actions have been filed in four judicial districts: *Estell v. Sanofi U.S. Services, Inc. et al*, Case No. 3:21-cv-02749 (N.D. Cal., filed Apr. 16, 2021); *Hamilton-Moews v. Sanofi U.S. Services, Inc. et al.*, Case No. 5:21-cv-00718 (C.D. Cal., filed Apr. 21, 2021); *Cone v. Sanofi U.S. Services., Inc. et al.*, Case No. 2:21-cv-00689 (D. Ariz., filed Apr. 21, 2021); *Vega v. Sanofi U.S. Services, Inc. et al.*, Case No. 2:21-cv-00730 (E.D. Calif, filed Apr. 23, 2021); and *Burns v. Sanofi U.S. Services, Inc. et al.*, Case No. 2:21-cv-08964 (C.D. Cal., filed Nov. 15, 2021) (collectively, “Related Actions”).¹

¹ Pursuant to Rule 6.1(b)(ii) of the Rules of Procedure of the United States Judicial Panel on Multidistrict Litigation, attached hereto is a Schedule of Related Actions.

The Related Actions assert similar claims on behalf of cancer patients using the drug Taxotere who suffer from punctal or canalicular stenosis as the result of Sanofi's inadequate warning. Each of these cases involve the same or similar legal issues, claims, and overlapping fact and expert witnesses.

Movant reasonably anticipates that dozens of other actions with similar allegations are likely to follow. The Northern District of California is the most appropriate forum for centralization of pretrial proceedings under 28 U.S.C. § 1407 because it is an experienced jurisdiction that has been involved in the Related Actions for the longest period of time. Alternatively, given the backlog of cases in the Central District of California (venue of the third filed case), Movant suggests the District of Arizona as an appropriate forum given the ease of travel and its relative proximity to the plaintiffs in the other Related Actions.

ARGUMENT

I. Transfer and Coordination of the Related Actions Is Appropriate

Under 28 U.S.C. §1407(a), civil actions pending in different district courts and involving "one or more common questions of fact" may be "transferred to any district for coordinated or consolidated pretrial proceedings." Transfer is appropriate to serve "the convenience of parties and witnesses" and to "promote the just and efficient conduct" of the pending actions. *Id.* Here, these factors support transferring the Related Actions to the Northern District of California, or alternatively, the District of Arizona, for coordinated pretrial proceedings.

A. The Related Actions Involve Common Questions of Fact.

The Related Actions share many common questions of fact that provide a sufficient basis for centralizing the actions in a single forum. Common questions of fact exist where two or more complaints assert similar allegations against similar defendants based on similar transactions and events. *See, e.g., In re UnumProvident Corp. Secs., Derivative & "ERISA" Litig.*, 280 F. Supp. 2d 1377, 1379 (J.P.M.L. 2003) (centralization appropriate where "all actions [could] be expected to focus on a significant number of common events, defendants, and/or witnesses" and "core factual allegations" were consistent among the actions); *see also, e.g., In re Plavix Marketing, Sales Practices and Products Liab. Litig. (No. II)*., 923 F.Supp.2d 1376, 1379 (J.P.M.L. 2013) (centralization appropriate where shared factual issues arise from allegations that drug manufacturer defendants misrepresented and failed to disclose certain risks associated with using a drug).

The individual complaints in the Related Actions involve overlapping causes of action that give rise to questions of fact about the same inadequate warning label and Sanofi's knowledge thereof, that are not merely common, but virtually identical. The Related Actions all allege that Sanofi failed to amend the warning label for Taxotere despite knowing the label being inadequate to alert patients and the medical community of the risk of permanent and irreversible eye damage that may result from its use without diligent ophthalmologic monitoring. *See, e.g., In re Bair Hugger Forced Air Warming Devices Prods. Liab. Litig.*, 148 F. Supp. 3d 1383, 1385 (J.P.M.L. 2015) (transfer under § 1407

appropriate where related actions shared factual issues related to allegations of injuries from defective warning system). Centralizing the Related Actions will thus allow for coordinated discovery efforts aimed at the adequacy of the drug warning label and Sanofi's knowledge thereof, as well as coordinated motion practice related to any defenses Sanofi may raise that will largely be generally applicable to all cases.

Specifically, the Related Actions allege that Sanofi knew that the warning label provided for the drug Taxotere was inadequate to properly warn patients and physicians of the risk of severe and permanent lacrimal duct obstruction resulting in persistent life-long epiphora. *See, e.g., In re Bair Hugger*, 148 F. Supp. 3d at 1385 (common factual issues existed where plaintiffs alleged same defective condition of same product); *In re: Stryker Rejuvenate and ABG II Hip Implant Prods. Liab. Litig.*, 949 F. Supp. 2d 1378, 1379 (transfer to District of Minnesota under § 1407 appropriate due to shared factual questions "concerning design, manufacture, marketing and performance..." of the Stryker product).

Common questions of fact and law at issue in the Related Actions include, *inter alia*:

1. Whether Sanofi's warning label for Taxotere was adequate;
2. Whether Sanofi knew the warning label was inadequate;
3. Whether Sanofi misrepresented the risks associated with Taxotere;
4. Whether Sanofi's misrepresentations about the risks of Taxotere caused Plaintiff and other users to suffer permanent eye damage.

These substantially overlapping factual allegations and legal issues present common issues concerning the marketing and labeling of Taxotere sufficient to merit transfer and coordination. *See In re: Darvocet, Darvon and Propoxyphene Prod. Liab. Litig.*, 780 F. Supp. 2d 1379, 1380 (J.P.M.L. 2011) (transfer appropriate where common factual issues as to whether products “defectively designed and marketed...whether defendants knew or should have known about the increase risk...and failed to provide adequate warnings of them”); *In re: Cook Medical, Inc., IVC Filters Mktg., Sales Pract. and Prod. Liab. Litig.*, 53 F. Supp. 3d 1379, 1380 (J.P.M.L. 2014) (transfer under § 1407 appropriate where related acts “share paramount issues concerning the design, manufacture, testing, and marketing of a single medical device...” (citation omitted).

B. Transfer Will Promote the Just and Efficient Conduct of the Related Actions.

Because the same conduct of Sanofi regarding the same product and the same defect are at issue, and the plaintiffs in the Related Actions pursue the same or similar legal theories regarding the alleged defective product, centralizing these actions will promote the just and efficient conduct of the Related Actions. Transfer and consolidation will eliminate duplication in discovery and discovery rulings, avoid conflicting rulings on the merits, avoid conflicting schedules, reduce litigation costs, and save time and effort of the parties, the attorneys, the witnesses, and the courts. *See Manual for Complex Litigation*, § 20.131 (4th ed. 2016).

Plaintiffs will seek to develop similar evidence of Sanofi's knowledge of the marketing, labeling, science, testing, warnings and representations accompanying Taxotere and ocular risk. Absent centralization, the parties will engage in overlapping and duplicative discovery. Centralizing the Related Actions for pretrial proceedings will eliminate duplicative discovery on these common issues. *See In re: Fluoroquinolone Prod. Liab. Litig.*, 122 F. Supp. 3d 1378, 1380 (J.P.M.L. 2015) (finding where issues of "general causation, the background science, regulatory history, and labeling will be common to all action" centralization will "...facilitate the establishment of a uniform pretrial approach"); *see also In re Darvocet*, 780 F. Supp. 2d at 1380-81 ("Centralization would help limit duplicative discovery, prevent inconsistent pretrial rulings on discovery and other issues, and conserve the resources of the parties, their counsel and particularly the judiciary.").

Centralization will also permit the transferee judge to establish a uniform pretrial approach to conserve judicial and party resources to reduce duplicative fact discovery and reducing "potentially costly expert discovery." *See In re: Fluoroquinolone*, 122 F. Supp. 3d at 1380. Centralization will also avoid the necessity for multiple and potentially inconsistent rulings on *Daubert* motions in this action involving questions of the performance and testing of Taxotere. *See In re Stryker Orthopaedics*, 249 F. Supp. 3d at 1355 (centralization avoids duplicative discovery on "complex issues such as the design, testing, manufacturing, and marketing" in products liability action).

Thus, where, as here, transfer to a single court will avoid duplicative discovery and potentially conflicting pretrial and other rulings, transfer for pretrial purposes is warranted to promote the interest of judicial economy and efficiency.

II. The Northern District of California Is the Most Appropriate Transferee Forum

Under 28 U.S.C. § 1407(a), transfer is needed to serve “the convenience of the parties and witnesses” and to “promote the just and efficient conduct” of the Related Actions. *Id.* The Northern District of California is the most appropriate forum for the Related Actions because (A) it is the forum with the most meaningful nexus to the Related Actions; (B) it has proven itself to have the judicial resources and expertise to efficiently manage an MDL like this one; and (C) the convenience of the parties and witnesses is best served there.

A. This Litigation Has a Strong Nexus to the Northern District of California.

The Panel looks to the “nexus” between the allegations and the proposed forum when determining an appropriate transferee district. *See In re Delphi Corp. Sec., Derivative & “ERISA” Litig.*, 403 F. Supp. 2d 1358, 1360 (J.P.M.L. 2005). Here, the Northern District of California has been presiding over the related issues the longest, with two of the first filed Related Actions pending there. All but one of the Related Actions involve California law, and the majority of the Plaintiffs are California residents. Defendants regularly conduct business in the District, and the District has an interest in the outcome of this litigation.

B. The Northern District of California Has the Judicial Resources and Expertise to Efficiently Manage the Related Actions.

The Panel weighs the experience and ability of the forum in managing complex multidistrict litigation in selecting the appropriate transferee district, and then takes into account the number of pending MDLs in transferring cases for coordinated pretrial proceedings. *See, e.g., In re Baycol*, 180 F. Supp. 2d at 1380 (transferring to the District of Minnesota as “i) centrally located, ii) is not currently overtaxed with other multidistrict dockets, and iii) possesses the necessary resources, facilities, and technology to sure-handedly devote the substantial time and effort to pretrial matters that this complex docket is likely to require”). The Northern District of California has served as a transferee forum for many MDLs over the years. Judges in the Northern District of California possess deep experience in overseeing complex litigation, in particular products liability actions. The only other judicial district in which, at present, multiple Related Actions are pending is the Central District of California, which has an overtaxed docket and far less resources to take on another MDL. Thus, the Northern District of California is the most appropriate venue to transfer this litigation. Further, District Judge Edward M. Chen, of the Northern District of California, is presiding over both the *Porter* action and *Estell* action. He is familiar with the issues at hand.

C. The Northern District of California is the Most Convenient Forum for the Parties and Witnesses.

Convenience of the parties and witnesses is another important factor considered by the Panel in selecting a transferee forum. *See generally* 28 U.S.C. § 1407(a). The majority of Plaintiffs reside in California, and the Northern District is a centrally located venue. The Northern District is also already overseeing more than one Related Action. Finally, Sanofi regularly conducts business in the Northern District and can just as easily litigate this action there as it can in any of the other districts in which these actions are pending.

In the alternative, the District of Arizona is also convenient for the parties and witnesses. Phoenix offers ease of travel with a major airport and many direct flights. The District of Arizona also has few MDLs and has the resources to efficiently preside over another one.

CONCLUSION

For the reasons set forth above, Movant respectfully requests that the Panel transfer the Related Actions, as well as any tag-along actions that are subsequently filed asserting related or similar claims, in the Northern District of California, or in the alternative, to the District of Arizona.

Dated: December 1, 2021

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**BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION**

IN RE: TAXOTERE (DOCETAXEL) EYE) MDL Docket No.
INJURY CLAIMS)

SCHEDULE OF ACTIONS

Case Captions	Court	Civil Action No.	Judge
Plaintiff: Jade Porter Defendants: Sanofi Services, Inc. f/k/a Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S. LLC	N.D. Cal.	3:21-cv-01891	Hon. Edward M. Chen
Plaintiff: Cathy Estell Defendants: Sanofi Services, Inc. f/k/a Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S. LLC	N.D. Cal.	3:21-cv-02749	Hon. Edward M. Chen
Plaintiff: Jeannie Hamilton-Moews Defendants: Sanofi Services, Inc. f/k/a Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S. LLC	C.D. Cal.	5:21-cv-00718	Hon. John W. Holcomb
Plaintiff: Deenen Cone Defendants: Sanofi Services, Inc. f/k/a Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S. LLC	D. Ariz.	2:21-cv-00689	Hon. Diane J. Humetewa
Plaintiff: Teresa Vega Defendants: Sanofi Services, Inc. f/k/a Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S. LLC	E.D. Cal.	2:21-cv-00730	Hon. Troy Nunley
Plaintiff: Jennifer Burns Defendants: Sanofi Services, Inc. f/k/a Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S. LLC	C.D. Cal.	2:21-cv-08964	Hon. John W. Holcomb

**BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION**

IN RE: TAXOTERE (DOCETAXEL) EYE) MDL Docket No.
INJURY CLAIMS)

PROOF OF SERVICE

In compliance with Rule 4.1(a) of the Rules of Procedure for the United States Judicial Panel on Multidistrict Litigation, I hereby certify that copies of the foregoing Motion, Brief, Schedule of Actions and this Proof of Service were filed electronically with the Clerk of the JPML using the CM/ECF system and were served on all counsel or parties in the manner indicated below:

Via US Mail on December 1, 2021:

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Northern District of California
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Porter, N.D. Cal., 3:21-cv-1891
Hamilton-Moews, C.D. Cal, 5:21-cv-718
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Burns, C.D. Cal., 2:21-cv-8964

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U.S. District Court
California Northern District (San Francisco)
CIVIL DOCKET FOR CASE #: 3:21-cv-01891-EMC

Porter v. Sanofi US Services, Inc. et al
Assigned to: Judge Edward M. Chen
Cause: 28:1332 Diversity-Product Liability

Date Filed: 03/17/2021
Jury Demand: Plaintiff
Nature of Suit: 367 Personal Injury: Health Care/Pharmaceutical
Personal Injury Product Liability
Jurisdiction: Diversity

Plaintiff

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V.

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Date Filed	#	Docket Text
03/17/2021	1	COMPLAINT against All Defendants (Filing fee \$ 402, receipt number 0971-15715936.). Filed byJade Porter. (Attachments: # 1 Civil Cover Sheet)(Fitzpatrick, Bernard) (Filed on 3/17/2021) (Entered: 03/17/2021)
03/17/2021	2	Proposed Summons. (Fitzpatrick, Bernard) (Filed on 3/17/2021) (Entered: 03/17/2021)
03/17/2021	3	Proposed Summons. (Fitzpatrick, Bernard) (Filed on 3/17/2021) (Entered: 03/17/2021)
03/18/2021	4	Case assigned to Magistrate Judge Sallie Kim. Counsel for plaintiff or the removing party is responsible for serving the Complaint or Notice of Removal, Summons and the assigned judge's standing orders and all other new case documents upon the opposing parties. For information, visit <i>E-Filing A New Civil Case</i> at http://cand.uscourts.gov/ecf/caseopening . Standing orders can be downloaded from the court's web page at www.cand.uscourts.gov/judges . Upon receipt, the summons will be issued and returned electronically. Counsel is required to send chambers a copy of the initiating documents pursuant to L.R. 5-1(e)(7). A scheduling order will be sent by Notice of Electronic Filing (NEF) within two business days. Consent/Declination due by 4/1/2021. (anjS, COURT STAFF) (Filed on 3/18/2021) (Entered: 03/18/2021)
03/18/2021	5	Initial Case Management Scheduling Order with ADR Deadlines: Case Management Statement due by 6/14/2021. Initial Case Management Conference set for 6/21/2021 01:30 PM. (mclS, COURT STAFF) (Filed on 3/18/2021) (Entered: 03/18/2021)
03/18/2021	6	Summons Issued as to Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Attachments: # 1 Sanofi-Aventis U.S. LLC)(mclS, COURT STAFF) (Filed on 3/18/2021) (Entered: 03/18/2021)
03/30/2021	7	CONSENT/DECLINATION to Proceed Before a US Magistrate Judge by Jade Porter.. (Fitzpatrick, Bernard) (Filed on 3/30/2021) (Entered: 03/30/2021)
03/30/2021	8	CLERK'S NOTICE OF IMPENDING REASSIGNMENT TO A U.S. DISTRICT COURT JUDGE: The Clerk of this Court will now randomly reassign this case to a District Judge because either (1) a party has not consented to the jurisdiction of a Magistrate Judge, or (2) time is of the essence in deciding a pending judicial action for which the necessary consents to Magistrate Judge jurisdiction have not been secured. You will be informed by separate notice of the district judge to whom this case is reassigned. ALL HEARING DATES PRESENTLY SCHEDULED BEFORE THE CURRENT MAGISTRATE JUDGE ARE VACATED AND SHOULD BE RE-NOTICED FOR HEARING BEFORE THE JUDGE TO WHOM THIS CASE IS REASSIGNED. <i>This is a text only docket entry; there is no document associated with this notice.</i> (mklS, COURT STAFF) (Filed on 3/30/2021) (Entered: 03/30/2021)
03/31/2021	9	ORDER REASSIGNING CASE. Case reassigned using a proportionate, random, and blind system pursuant to General Order No. 44 to Judge Edward M. Chen for all further proceedings. Magistrate Judge Sallie Kim no longer assigned to case, Notice: The assigned judge

		participates in the Cameras in the Courtroom Pilot Project. See General Order No. 65 and http://cand.uscourts.gov/cameras.. Signed by Clerk on 03/31/2021. (Attachments: # 1 Notice of Eligibility for Video Recording)(mbs, COURT STAFF) (Filed on 3/31/2021) (Entered: 03/31/2021)
04/12/2021	10	CASE MANAGEMENT CONFERENCE ORDER IN REASSIGNED CASE: Initial Case Management Conference set for 7/22/2021 09:30 AM in San Francisco, - Videoconference Only. Joint Case Management Statement due by 7/15/2021. Signed by Judge Edward M. Chen on 4/12/2021. (afmS, COURT STAFF) (Filed on 4/12/2021) (Entered: 04/12/2021)
04/13/2021	11	WAIVER OF SERVICE Returned Executed filed by Jade Porter. Service waived by All Defendants. (Fitzpatrick, Bernard) (Filed on 4/13/2021) (Entered: 04/13/2021)
04/26/2021	12	MOTION for leave to appear in Pro Hac Vice (Filing fee \$ 317, receipt number 0971-15888066.) filed by Jade Porter. (Hotze, Patrick) (Filed on 4/26/2021) (Entered: 04/26/2021)
04/27/2021	13	ORDER by Judge Edward M. Chen granting 12 Motion for Pro Hac Vice. (afmS, COURT STAFF) (Filed on 4/27/2021) (Entered: 04/27/2021)
05/07/2021	14	MOTION for leave to appear in Pro Hac Vice (Filing fee \$ 317, receipt number 0971-15940546.) filed by Jade Porter. (Attachments: # 1 Exhibit Certificate of Good Standing, # 2 Exhibit Certificate of Good Standing)(Paul, Richard) (Filed on 5/7/2021) (Entered: 05/07/2021)
05/10/2021	15	MOTION for leave to appear in Pro Hac Vice (Filing fee \$ 317, receipt number 0971-15946090.) filed by Jade Porter. (Shanks, Karen) (Filed on 5/10/2021) (Entered: 05/10/2021)
05/13/2021	16	Order by Judge Edward M. Chen granting 14 Motion for Pro Hac Vice for Richard Paul. (tmiS, COURT STAFF) (Filed on 5/13/2021) (Entered: 05/13/2021)
05/13/2021	17	Order by Judge Edward M. Chen granting 15 Motion for Pro Hac Vice for Karen Shanks. (tmiS, COURT STAFF) (Filed on 5/13/2021) (Entered: 05/13/2021)
05/21/2021	18	CERTIFICATE OF SERVICE by Jade Porter of 10 Case Management Conference Order and Standing Orders (Paul, Richard) (Filed on 5/21/2021) Modified on 5/21/2021 (mclS, COURT STAFF). (Entered: 05/21/2021)
05/21/2021	19	NOTICE of Appearance by Amir M. Nassihi (Nassihi, Amir) (Filed on 5/21/2021) (Entered: 05/21/2021)
05/21/2021	20	STIPULATION WITH PROPOSED ORDER re 1 Complaint for Extension of Time to Respond To Complaint filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Nassihi, Amir) (Filed on 5/21/2021) (Entered: 05/21/2021)
05/22/2021	21	ORDER by Judge Edward M. Chen granting 20 Stipulation. Defendants Sanofi US Services, Inc. f/k/a Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S., LLCs response to Plaintiff Jade Porters Complaint is due on 6/23/2021. (afmS, COURT STAFF) (Filed on 5/22/2021) (Entered: 05/22/2021)
06/01/2021	22	Corporate Disclosure Statement by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC identifying Corporate Parent Sanofi for Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Nassihi, Amir) (Filed on 6/1/2021) (Entered: 06/01/2021)
06/17/2021	23	Minute Entry for proceedings held before Magistrate Judge Virginia K. DeMarchi: Settlement Conference held by Zoom on 6/17/2021. Settlement conference held; case did not settle. Plaintiff Attorney: Stephen Ferguson, Joseph Boyle; plaintiff representative: Alex Fonoroff. Defendant Attorney: Mark Punzalan, Shinhong Byun; defendants representative: Sajid Sohail. (This is a text-only entry generated by the court. There is no document associated with this entry.) (pmcS, COURT STAFF) (Date Filed: 6/17/2021) (Entered: 06/21/2021)
06/23/2021	24	MOTION to Dismiss Based Upon Plaintiff's Failure to State a Claim Upon Which a Relief Can Be Granted (FRCP 12(b)(6)) and for Failure to Allege Fraud with Particularity (FRCP 9(B)) filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. Motion Hearing set for 9/9/2021 01:30 PM in San Francisco, Courtroom 05, 17th Floor before Judge Edward M. Chen. Responses due by 7/7/2021. Replies due by 7/14/2021. (Attachments: # 1 Proposed Order)(Nassihi, Amir) (Filed on 6/23/2021) (Entered: 06/23/2021)
06/23/2021	25	Request for Judicial Notice re 24 MOTION to Dismiss Based Upon Plaintiff's Failure to State a Claim Upon Which a Relief Can Be Granted (FRCP 12(b)(6)) and for Failure to Allege Fraud with Particularity (FRCP 9(B)) filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F)(Related document(s) 24) (Nassihi, Amir) (Filed on 6/23/2021) (Entered: 06/23/2021)
06/25/2021	26	STIPULATION WITH PROPOSED ORDER Re: Motion to Dismiss Briefing Schedule filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Nassihi, Amir) (Filed on 6/25/2021) (Entered: 06/25/2021)
06/28/2021	27	ORDER by Judge Edward M. Chen granting 26 Stipulation. Plaintiffs deadline of 7/7/2021 to respond to Sanofis 24 Motion to Dismiss is continued to 7/23/2021. Defendant's deadline of 7/14/2021 to reply is continued to 8/6/2021. (afmS, COURT STAFF) (Filed on 6/28/2021) (Entered: 06/28/2021)
06/28/2021		Set/Reset Deadlines as to 24 MOTION to Dismiss Based Upon Plaintiff's Failure to State a Claim Upon Which a Relief Can Be Granted (FRCP 12(b)(6)) and for Failure to Allege Fraud with Particularity (FRCP 9(B)). Responses due by 7/23/2021. Replies due by 8/5/2021. (afmS, COURT STAFF) (Filed on 6/28/2021) (Entered: 06/28/2021)
07/12/2021	28	CLERK'S NOTICE RESCHEDULING INITIAL CASE MANAGEMENT CONFERENCE FROM 7/22/2021 TO ALONGSIDE MOTION HEARING ON 9/9/2021 AT 1:30PM: Initial Case Management Conference set for 9/9/2021 01:30 PM in San Francisco, - Videoconference Only. This proceeding will be held via a Zoom webinar. Joint Case Management Statement due by 9/2/2021. Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings , including screenshots or other visual copying of a hearing, is absolutely prohibited. Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/ .

		Joint Case Management Statement due by 9/2/2021. Initial Case Management Conference set for 9/9/2021 01:30 PM in San Francisco, - Videoconference Only. (This is a text-only entry generated by the court. There is no document associated with this entry.)(afmS, COURT STAFF) (Filed on 7/12/2021) (Entered: 07/12/2021)
07/13/2021	29	AMENDED COMPLAINT against All Defendants. Filed by Jade Porter. (Paul, Richard) (Filed on 7/13/2021) (Entered: 07/13/2021)
07/16/2021	30	Notice of Withdrawal of 24 Motion to Dismiss Based Upon Plaintiff's Failure to State a Claim Upon Which a Relief Can Be Granted (FRCP 12(b)(6)) and for Failure to Allege Fraud with Particularity (FRCP 9(B)) (Nassih, Amir) (Filed on 7/16/2021) Modified on 7/16/2021 (mcIS, COURT STAFF). (Entered: 07/16/2021)
07/19/2021	31	MOTION for leave to appear in Pro Hac Vice and [Proposed] Order by Harley V. Ratliff (Filing fee \$ 317, receipt number 0971-16191061.) filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Attachments: # 1 Certificate of Good Standing)(Ratliff, Harley) (Filed on 7/19/2021) (Entered: 07/19/2021)
07/19/2021	32	MOTION for leave to appear in Pro Hac Vice and [Proposed] Order by Torrey M. Peterson (Filing fee \$ 317, receipt number 0971-16191155.) filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Attachments: # 1 Certificate of Good Standing)(Peterson, Torrey) (Filed on 7/19/2021) (Entered: 07/19/2021)
07/19/2021	33	MOTION for leave to appear in Pro Hac Vice and [Proposed] Order by Jon Strongman (Filing fee \$ 317, receipt number 0971-16191202.) filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Attachments: # 1 Certificate of Good Standing)(Strongman, Jon) (Filed on 7/19/2021) (Entered: 07/19/2021)
07/20/2021	34	ORDER by Judge Edward M. Chen granting 31 Motion for Pro Hac Vice. (afmS, COURT STAFF) (Filed on 7/20/2021) (Entered: 07/20/2021)
07/20/2021	35	ORDER by Judge Edward M. Chen granting 32 Motion for Pro Hac Vice. (afmS, COURT STAFF) (Filed on 7/20/2021) (Entered: 07/20/2021)
07/20/2021	36	ORDER by Judge Edward M. Chen granting 33 Motion for Pro Hac Vice. (afmS, COURT STAFF) (Filed on 7/20/2021) (Entered: 07/20/2021)
07/20/2021	37	STIPULATION WITH PROPOSED ORDER re 29 Amended Complaint For Extension of Time to Respond to Amended Complaint and Briefing Schedule filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Peterson, Torrey) (Filed on 7/20/2021) (Entered: 07/20/2021)
07/20/2021	38	ORDER by Judge Edward M. Chen granting 37 Stipulation For Extension of Time to Respond to Amended Complaint and Briefing Schedule. Defendant's response to Amended Complaint due 8/10/2021. If defendant files a pleading challenge, the deadline for plaintiff's opposition is 9/9/2021; reply due 9/23/2021. (afmS, COURT STAFF) (Filed on 7/20/2021) (Entered: 07/20/2021)
08/10/2021	39	CLERK'S NOTICE RESCHEDULING INITIAL CASE MANAGEMENT CONFERENCE FROM 9/9/2021 TO 11/16/2021 AT 1:30PM: Initial Case Management Conference set for 9/9/2021 is vacated and rescheduled for 11/16/2021 01:30 PM in San Francisco, - Videoconference Only. This proceeding will be held via a Zoom webinar. Joint Case Management Statement due by 11/9/2021. Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited. Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/. Joint Case Management Statement due by 11/9/2021. Initial Case Management Conference set for 11/16/2021 01:30 PM in San Francisco, - Videoconference Only. (This is a text-only entry generated by the court. There is no document associated with this entry.)(afmS, COURT STAFF) (Filed on 8/10/2021) (Entered: 08/10/2021)
08/10/2021	40	MOTION to Dismiss Plaintiff's First Amended Complaint filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. Motion Hearing set for 10/14/2021 01:30 PM in San Francisco, Courtroom 05, 17th Floor before Judge Edward M. Chen. Responses due by 9/9/2021. Replies due by 9/23/2021. (Attachments: # 1 Proposed Order)(Nassih, Amir) (Filed on 8/10/2021) (Entered: 08/10/2021)
08/10/2021	41	Request for Judicial Notice re 40 MOTION to Dismiss Plaintiff's First Amended Complaint filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J, # 11 Exhibit K, # 12 Exhibit L)(Related document(s) 40) (Nassih, Amir) (Filed on 8/10/2021) (Entered: 08/10/2021)
09/09/2021	42	OPPOSITION/RESPONSE (re 40 MOTION to Dismiss Plaintiff's First Amended Complaint) filed by Jade Porter. (Paul, Richard) (Filed on 9/9/2021) (Entered: 09/09/2021)
09/09/2021	43	Request for Judicial Notice filed by Jade Porter. (Attachments: # 1 Exhibit)(Paul, Richard) (Filed on 9/9/2021) (Entered: 09/09/2021)
09/09/2021	44	Proposed Order re 43 Request for Judicial Notice by Jade Porter. (Paul, Richard) (Filed on 9/9/2021) (Entered: 09/09/2021)
09/10/2021	45	CLERK'S NOTICE RESCHEDULING HEARING ON 40 MOTION TO DISMISS AND INITIAL CASE MANAGEMENT CONFERENCE TO 11/18/2021 AT 1:30PM. Hearing re: 40 MOTION to Dismiss Plaintiff's First Amended Complaint scheduled for 10/14/2021 is vacated and rescheduled for 11/18/2021 at 1:30PM. Motion briefing deadlines remain unchanged. Initial Case Management Conference reset for 11/18/2021 01:30 PM in San Francisco, - Videoconference Only. Joint Case Management Statement due by 11/10/2021. San Francisco, - Videoconference Only before Judge Edward M. Chen. This proceeding will be held via a Zoom webinar. Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited. Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/. Joint Case Management Statement due by 11/10/2021. Initial Case Management Conference set for 11/18/2021 01:30 PM in San Francisco, - Videoconference Only. Motion Hearing set for 11/18/2021 01:30 PM in San Francisco, - Videoconference Only before Judge

		Edward M. Chen. <i>(This is a text-only entry generated by the court. There is no document associated with this entry.)</i> (afmS, COURT STAFF) (Filed on 9/10/2021) (Entered: 09/10/2021)
09/23/2021	46	REPLY (re 40 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i>) filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Nassih, Amir) (Filed on 9/23/2021) (Entered: 09/23/2021)
10/08/2021	47	NOTICE of Change of Address by Richard M. Paul, III (Paul, Richard) (Filed on 10/8/2021) (Entered: 10/08/2021)
10/20/2021	48	<p>CLERK'S NOTICE RESCHEDULING HEARING RE: 40 MOTION TO DISMISS AND INITIAL CASE MANAGEMENT CONFERENCE FROM 11/18/2021 TO SPECIALLY SET DATE 11/22/2021 AT 1:30PM: Hearing re 40 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> and Initial Case Management Conference specially reset for 11/22/2021 01:30 PM in San Francisco, - Videoconference Only. Joint Case Management Statement due by 11/15/2021. Motion Hearing set for 11/22/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. This proceeding will be held via a Zoom webinar.</p> <p>Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc</p> <p>General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.</p> <p>Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/.</p> <p>Joint Case Management Statement due by 11/15/2021. Initial Case Management Conference set for 11/22/2021 01:30 PM in San Francisco, - Videoconference Only. Motion Hearing set for 11/22/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. <i>(This is a text-only entry generated by the court. There is no document associated with this entry.)</i>(afmS, COURT STAFF) (Filed on 10/20/2021) (Entered: 10/20/2021)</p>
10/25/2021	49	STIPULATION WITH PROPOSED ORDER <i>To Continue Hearing Date for Sanofi's Motion to Dismiss</i> filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC and Jade Porter. (Nassih, Amir) (Filed on 10/25/2021) Modified on 10/26/2021 (jml, COURT STAFF). (Entered: 10/25/2021)
10/27/2021	50	<p>CLERK'S NOTICE RESCHEDULING HEARING RE: 40 MOTION TO DISMISS AND INITIAL CASE MANAGEMENT CONFERENCE TO 12/16/2021 AT 1:30PM: Hearing re 40 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> and Initial Case Management Conference RESCHEDULED for 12/16/2021 01:30 PM in San Francisco, - Videoconference Only. Motion Hearing set for 12/16/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. This proceeding will be held via a Zoom webinar. Joint Case Management Statement due by 12/9/2021.</p> <p>Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc</p> <p>General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.</p> <p>Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/.</p> <p>Joint Case Management Statement due by 12/9/2021. Initial Case Management Conference set for 12/16/2021 01:30 PM in San Francisco, - Videoconference Only. Motion Hearing set for 12/16/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. <i>(This is a text-only entry generated by the court. There is no document associated with this entry.)</i>(afm, COURT STAFF) (Filed on 10/27/2021) (Entered: 10/27/2021)</p>
11/12/2021	51	<p>CLERK'S NOTICE ADVANCING HEARING RE: 40 MOTION TO DISMISS AND INITIAL CASE MANAGEMENT CONFERENCE FROM 12/16/2021 TO SPECIALLY SET DATE 12/14/2021 AT 10:00AM: Hearing re 40 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> and Initial Case Management Conference reset for 12/14/2021 10:00 AM in San Francisco, - Videoconference Only. Motion Hearing set for 12/14/2021 10:00 AM in San Francisco, - Videoconference Only before Judge Edward M. Chen. This proceeding will be held via a Zoom webinar. Joint Case Management Statement due by 12/7/2021.</p> <p>Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc</p> <p>General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.</p> <p>Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/.</p> <p>Joint Case Management Statement due by 12/7/2021. Initial Case Management Conference set for 12/14/2021 10:00 AM in San Francisco, - Videoconference Only. Motion Hearing set for 12/14/2021 10:00 AM in San Francisco, - Videoconference Only before Judge Edward M. Chen. <i>(This is a text-only entry generated by the court. There is no document associated with this entry.)</i>(afm, COURT STAFF) (Filed on 11/12/2021) (Entered: 11/14/2021)</p>
11/24/2021	52	<p>CLERK'S NOTICE ADVANCING 40 MOTION HEARING AND INITIAL CASE MANAGEMENT CONFERENCE FROM 12/14/2021 TO 12/9/2021 AT 1:30PM: Motion hearing re 40 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> and Initial Case Management Conference set for hearing on 12/14/2021 is vacated and ADVANCED to 12/9/2021 01:30 PM in San Francisco, - Videoconference Only. Motion Hearing set for 12/9/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. Joint Case Management Statement due by 12/2/2021. This proceeding will be held via a Zoom webinar.</p> <p>Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc</p> <p>General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.</p> <p>Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/.</p>

	<p>Joint Case Management Statement due by 12/2/2021. Initial Case Management Conference set for 12/9/2021 01:30 PM in San Francisco, - Videoconference Only. Motion Hearing set for 12/9/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. (This is a text-only entry generated by the court. There is no document associated with this entry.)(afm, COURT STAFF) (Filed on 11/24/2021) (Entered: 11/25/2021)</p>
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PACER Service Center			
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12/01/2021 13:23:47			
PACER Login:	RickPaul	Client Code:	Tax Eyes
Description:	Docket Report	Search Criteria:	3:21-cv-01891-EMC
Billable Pages:	8	Cost:	0.80

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25
26
27
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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA

JADE PORTER,

Plaintiff,

v.

SANOFI US SERVICES, INC. f/k/a
SANOFI-AVENTIS U.S., INC.; and
SANOFI-AVENTIS U.S., LLC,

Defendants.

Case No. 3:21-CV-01891-EMC

FIRST AMENDED COMPLAINT

JURY TRIAL DEMANDED

1 Plaintiff Jade Porter, for her First Amended Complaint against Defendants SANOFI US
2 SERVICES, INC., f/k/a SANOFI-AVENTIS U.S., INC. and SANOFI-AVENTIS U.S., LLC
3 (collectively “Sanofi”), alleges:

4 **INTRODUCTION**

5 1. Sanofi manufactures and sells a chemotherapy drug named Taxotere (generic
6 name docetaxel), which is administered to many who suffer primarily from breast cancer. While
7 it is one of many drugs effective at treating breast cancer, Sanofi has known for years that the
8 drug carries a significant risk of causing permanent and irreversible damage to the lacrimal
9 system, including punctal and canalicular stenosis.

10 2. A simple preventative procedure at the onset of chemotherapy-induced tearing,
11 involving the temporary placement of silicone stents, allows a patient to continue her Taxotere
12 regimen while removing the likelihood of permanent and irreversible damage to the lacrimal
13 system. Although Sanofi warns that “excessive tearing which may be attributable to lacrimal
14 duct obstruction has been reported”, Sanofi failed to warn patients and oncologists of the risk
15 that the damage can occur quickly and can be **permanent and irreversible**. Further, Sanofi
16 failed to report the severity and frequency of this risk to the Food and Drug Administration
17 (“FDA”). Worse, Sanofi misled patients and oncologists about the severity and frequency of this
18 devastating side effect even though this condition can be entirely preventable with early
19 intervention and treatment during chemotherapy. As a result, Mrs. Porter suffers from permanent
20 injuries because she used Taxotere.

21 3. Plaintiff is grateful for the chemotherapy that helped to save her life; however,
22 that gratitude is diminished by the fact that she now must endure a permanent and life-altering
23 condition that could have been prevented with an adequate warning to her physicians. Plaintiff’s
24 permanent injuries to her lacrimal system, specifically punctal and canalicular stenosis, cause
25 daily disruption to her life due to excessive tearing, or epiphora. For those who have never
26 experienced epiphora, the condition might seem like a minor annoyance. However, for cancer
27 survivors like Mrs. Porter, the irritated, swollen, watering eyes and the ongoing medical
28 management of the condition affect their work, their self-esteem, interpersonal relationships,

1 daily activities like driving or reading a book, and their general ability to return to a normal life
2 after defeating cancer.

3 **PARTIES**

4 **A. Plaintiff**

5 4. Plaintiff Jade Porter is an individual residing in Pacifica, California who received
6 Taxotere as part of a chemotherapy regimen after being diagnosed with breast cancer. She was
7 administered Taxotere at Kaiser Permanente in South San Francisco, California. She was
8 prescribed once weekly treatment and received a total of 9 rounds of chemotherapy with
9 Taxotere. Since completing chemotherapy, she has been diagnosed with permanent and
10 irreversible punctal and canalicular stenosis, and has undergone two corrective surgeries in an
11 effort to reverse her condition, and yet, the side effects of Taxotere remain.

12 **B. Sanofi Defendants**

13 5. Defendant Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. is a Delaware
14 corporation, with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey
15 08807. Sanofi US Services Inc. is a wholly owned subsidiary of Sanofi S.A. Sanofi S.A. is
16 engaged in research and development, testing, manufacturing, labeling, advertising, marketing,
17 promoting, selling and/or distributing of prescription drugs, including Taxotere. Defendant
18 Sanofi US Services Inc. engages in research and development, testing, manufacturing, labeling,
19 advertising, marketing, promoting, selling and/or distributing of prescription drugs, including
20 Taxotere.

21 6. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, with
22 a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-
23 Aventis U.S. LLC is a wholly owned subsidiary of Defendant Sanofi S.A., and Sanofi S.A. is
24 Sanofi-Aventis U.S., LLC's sole member. Defendant Sanofi-Aventis U.S. LLC engages in
25 research and development, testing, manufacturing, labeling, advertising, marketing, promoting,
26 selling and/or distributing of prescription drugs, including Taxotere.

27 7. Since 2006, defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc.
28 have collectively served as the U.S. operational front for Sanofi S.A. in the U.S. prescription

1 drug market.

2 **JURISDICTION AND VENUE**

3 8. Federal subject matter jurisdiction is based on 28 U.S.C. §1332(a) due to the
4 complete diversity of Mrs. Porter and Defendants and the amount in controversy exceeds
5 \$75,000.

6 9. A substantial part of the acts and omissions giving rise to this cause of action
7 occurred in this district and therefore venue is proper here pursuant to 28 U.S.C. §1391(a).

8 10. The Sanofi Defendants are subject to personal jurisdiction in this Court due to
9 their ongoing and substantial contacts in this forum.

10 **FACTUAL ALLEGATIONS**

11 **I. Development and Approval of Taxotere (Docetaxel)**

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

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

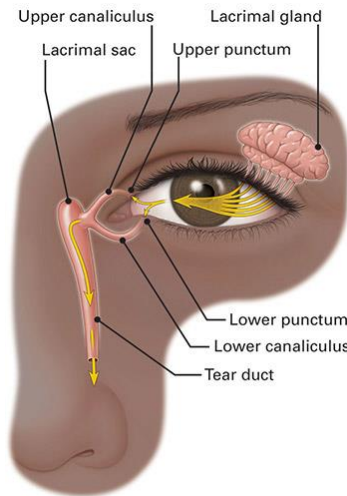
22 13. In August 2004, Sanofi obtained FDA approval for an expanded use of Taxotere
23 “in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients
24 with operable node-positive breast cancer.” This resulted in a greater number of patients being
25 treated with Taxotere.

26 14. As the universe of patients taking Taxotere expanded to include those with a
27 higher survivability, more cancer survivors taking Taxotere would now experience a permanent
28 disabling (but preventable) condition.

1 15. Taxotere is not purchased by patients at a pharmacy; rather, patients' use of these
2 drugs occurs via administration through injection and/or intravenously at a physician's office or
3 medical treatment facility.

4 **II. Anatomy of the Lacrimal System**

5 16. The following image depicts the anatomy of the lacrimal system:



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14 17. Taxotere is secreted in the tear film, thereby causing fibrosis in areas of the
15 lacrimal system, including the puncta and canaliculi¹. This scarring can cause permanent and
16 irreversible occlusion, resulting in the failure of tears to drain naturally through the lacrimal
17 system. Because the eyes are constantly producing tears, this results in persistent epiphora.

18 **III. Taxotere's Labeling**

19 18. Taxotere's labeling information at the time relevant to this lawsuit, states in
20 relevant part:

21 **Post-Marketing Experiences**

22 **Ophthalmologic**

23 Conjunctivitis, lacrimation or lacrimation with or without
24 conjunctivitis. *Excessive tearing which may be attributable to
25 lacrimal duct obstruction has been reported.* Rare cases of transient
26 visual disturbances (flashes, flashing lights, scotomata) typically
occurring during drug infusion and in association with
hypersensitivity reactions have been reported. *These were reversible
upon discontinuation of the infusion.* Cases of cystoid macular
edema (CME) have been reported in patients treated with
TAXOTERE.

27 ¹ For the Court's ease of reference, Plaintiff will use the term "lacrimal duct obstruction" as it is identified in
28 Sanofi's label; however, as the image demonstrates, obstruction of the lacrimal ducts is not the mechanism
generally causing the epiphora. Rather, most cases involve stenosis, or hardening, of the puncta and/or the
canaliculi.

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...
Patient Counseling Information
Explain to patients that side effects such as nausea, vomiting, diarrhea, constipation, fatigue, *excessive tearing*, infusion site reactions, and hair loss are associated with docetaxel administration

(emphasis added)

19. Under the Patient Information section, Sanofi informed patients that “redness of eye, excess tearing” were among the most common side effects of Taxotere but did not advise patients of the rapid onset, permanency of stenosis and, therefore, the critical need to seek immediate medical treatment from an appropriately qualified physician. This representation thereby deterred oncologists from ensuring that their patients were monitored by an appropriately qualified lacrimal specialist upon the presentation of these conditions.

20. Sanofi’s labeling information at all times relevant to this lawsuit, and even to date, does not adequately identify the nature of the risk of lacrimal duct obstruction due to punctal and/or canalicular stenosis; *i.e.*, the rapid onset at which stenosis can occur, the potentially permanent and irreversible nature of the injury, the need to immediately refer patients to a lacrimal specialist, nor does it identify the condition as preventable with timely intervention during chemotherapy.

21. Given the widespread use of Taxotere, it is crucial that the label not only inform oncologists of excessive tearing due to “lacrimal duct obstruction”, but that without treatment, the obstruction can become permanent. Only timely diagnosis and treatment can prevent this from happening.

22. Sanofi did not provide such adequate notice to oncologists. To the contrary, the labeling leads oncologists, like Mrs. Porter’s, to believe that excessive tearing is merely a transitory side effect and will end upon the cessation of chemotherapy. This failure to provide notice resulted in thousands of women, like Mrs. Porter, suffering daily from a permanent condition that could have easily been prevented with adequate warning.

IV. Sanofi’s Duty to Monitor and Update Labeling

23. The primary responsibility for timely communicating complete, accurate, and current safety and efficacy information related to Taxotere rests with Sanofi as it has superior,

1 and in many cases exclusive, access to the relevant safety and efficacy information, including
2 post-market complaints and data.

3 24. To fulfill its essential responsibilities, Sanofi must vigilantly monitor all
4 reasonably available information. It must closely evaluate the post-market clinical experience
5 of its drugs and timely provide updated safety and efficacy information to the healthcare
6 community and to consumers.

7 25. When monitoring and reporting adverse events, as required by both federal
8 regulations and state law, time is of the essence. The purpose of monitoring a product's post-
9 market experience is to detect potential safety signals that could indicate to drug sponsors and
10 the medical community that a public safety problem exists.

11 26. If, for example, a manufacturer was to delay reporting post-market information,
12 that delay could mean that researchers, FDA, and the medical community are years behind in
13 identifying a public safety issue associated with the drug.

14 27. In the meantime, more patients are harmed by using the product without knowing,
15 understanding, and accepting its true risks, which is why drug sponsors must not only
16 completely and accurately monitor, investigate and report post-market experiences, but must
17 also report the data in a timely fashion.

18 28. A drug is "misbranded" in violation of the FDCA when its labeling is false and
19 misleading or does not provide adequate directions for use and adequate warnings. See 21
20 U.S.C. §§ 321(n); 331(a), (b), (k); 352(a), (f). A drug's labeling satisfies federal requirements if
21 it gives physicians and pharmacists sufficient information—including indications for use and
22 "any relevant hazards, contraindications, side effects, and precautions"—to allow those
23 professionals "to use the drug safely and for the purposes for which it is intended." 21 C.F.R. §
24 201.100(c)(1).

25 29. As part of their responsibility to monitor post-market clinical experiences with the
26 drug and provide updated safety and efficacy information to the healthcare community and to
27 consumers, each approved NDA applicant "must promptly review all adverse drug experience
28 information obtained or otherwise received by the applicant from any source, foreign or

1 domestic, including information derived from commercial marketing experience, post
2 marketing clinical investigations, post marketing epidemiological/surveillance studies, reports
3 in the scientific literature, and unpublished scientific papers.” 21 C.F.R. § 314.80(b).

4 30. Any report of a “serious and unexpected” drug experience, whether foreign or
5 domestic, must be reported to the FDA within 15 days and must be promptly investigated by the
6 manufacturer. 21 C.F.R. § 314.80(c)(1)(i-ii).

7 31. Most other adverse event reports must be submitted quarterly for three years after
8 the application is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic
9 reports must include a “history of actions taken since the last report because of adverse drug
10 experiences (for example, labeling changes or studies initiated).” 21 C.F.R. § 314.80(c)(2)(ii).

11 32. Federal law requires labeling to be updated as information accumulates: “labeling
12 must be revised to include a warning about a clinically significant hazard as soon as there is
13 reasonable evidence of a causal association with a drug; a causal relationship need not have been
14 definitely established.” 21 C.F.R. § 201.57(c)(6)(i). Thus, for example, drug manufacturers must
15 warn of an adverse effect where there is “some basis to believe there is a causal relationship
16 between the drug and the occurrence of the adverse event.” 21 C.F.R. § 201.57(c)(7).

17 33. Brand-name drug sponsors may seek to change their approved labels by filing a
18 supplemental application to obtain FDA assent. 21 C.F.R. § 314.70.

19 34. One regulation, the “Changes Being Effected” (CBE) regulation, permits a
20 manufacturer to unilaterally change a drug label to reflect “newly acquired information,” subject
21 to later FDA review and approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information
22 includes “new analyses of previously submitted data.” 21 C.F.R. § 314.3(b).

23 35. Thus, for instance, if a drug sponsor determined that a warning was insufficient
24 based on a new analysis of previously existing data, it could submit a CBE and change its
25 labeling.

26 36. The longer a drug sponsor delays updating its labeling to reflect current safety
27 information, the more likely it is that medical professionals will prescribe drugs without advising
28 patients of harmful side effects, and the more likely it is that patients will suffer harmful side

1 effects without the opportunity to evaluate risks for themselves.

2 **V. Sanofi Knew That Taxotere Causes Permanent and Irreversible Lacrimal Injury**

3 37. Since 2002 Sanofi’s Taxotere label has advised that “excessive tearing which may
4 be attributable due to lacrimal obstruction has been reported”². Despite this language, medical
5 literature has continued to accumulate and raise concerns that oncologists are not being properly
6 warned of the severity of this permanent and irreversible side effect – and in response, Sanofi
7 has done nothing to notify oncologists or patients.

8 38. The following studies, published after 2002, highlight concerns of the increased
9 frequency and severity of permanent stenosis in cancer patients taking Taxotere, the increased
10 need for monitoring, and the lack of awareness among oncologists and their patients regarding
11 the true nature of the damage caused:

12 a) From the American Society of Ophthalmic Plastic and Reconstructive Surgery:

13 *Better education of oncologists who prescribe docetaxel is
14 needed as we continue to encounter new cases of advanced
canalicular blockage.*³

15 b) From the American Cancer Society

16 *Despite the previous publication of several articles by our
17 group regarding canalicular stenosis and lacrimal
18 obstruction resulting from docetaxel therapy, we still
19 frequently encounter advanced cases of this condition
because of delayed diagnosis. Thus it appears that
oncologists need to become better educated regarding this
side effect.*

20 *All patients receiving weekly docetaxel should be monitored
21 closely by an ophthalmologist so that the timely management
of canalicular stenosis can be offered.*

22 *We recommend silicone intubation [stents] in all
23 symptomatic patients who are receiving weekly docetaxel if
they ae to continue receiving the drug.*⁴

24
25 ² https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20449slr022_taxotere_lbl.pdf

26 ³ Bitá Esmali, et al., Docetaxel-Induced Histologic Changes in the Lacrimal Sac and Nasal
27 Mucosa, 19 Ophthalmic Plastic and Reconstructive Surgery 4, pp. 305-308 (2003)

28 ⁴ Bitá Esmali, et al., Blockage of the Lacrimal Drainage Apparatus as a Side Effect of
Docetaxel Therapy, 98 Cancer 504-7 (2003)

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c) From Pharmacotherapy:

Moreover, epiphora may be an underrecognized adverse effect of docetaxel because excess tearing after chemotherapy administration is not as stringently monitored as life-threatening toxicities . . . This adverse effect warrants evaluation because weekly administration is being used more commonly for the treatment of advanced solid tumors, and epiphora can interfere with the activities and quality of daily life.⁵

d) From the Journal of Clinical Oncology:

Despite substantial literature documenting canaliculular stenosis as an adverse effect of docetaxel, the exact incidence of this important adverse effect is unknown. All previous publications were based on retrospective studies at tertiary ophthalmology practices, and only patients who symptoms of epiphora were evaluated. We report the finding of prospective, single-center study designed to determine the incidence and severity of epiphora and its anatomic correlate, canaliculular stenosis, in patients receiving docetaxel weekly or every 3 weeks.

Previous retrospective studies and our clinical experience suggested that the incidence of epiphora might be as high as 50% in patients treated with weekly docetaxel and less than 10% in patients who receive docetaxel every 3 weeks.

In this prospective, observational study, epiphora was seen in 64% of patients in the weekly docetaxel group and in 39% of the docetaxel every 3 weeks group.

Patients who experience epiphora associated with docetaxel should be promptly referred to an ophthalmologist familiar with this adverse effect. Frequent [approximately every 4-6 weeks] probing and irrigation in the office and judicious use of topical steroids on a tapering dose can eliminate the need for silicone intubation or other lacrimal procedures in approximately 80% of patients taking docetaxel every 3 weeks and in approximately 50% of patients taking docetaxel weekly.⁶

39. Prominent medical researchers have described this side effect as follows:

⁵ Polly Kintzel, et al., Docetaxel-related Epiphora, 26 PHARMACOTHERAPY 6 (2006).

⁶ Bitu Esmali, et al., Prospective Study of Incidence and Severity of Epiphora and Canaliculular Stenosis in Patients With Metastatic Breast Cancer Receiving Docetaxel, 24 Journal of Clinical Oncology 22 (2006).

1 “canalicular stenosis may be the most important side effect of weekly docetaxel⁷”; “cancer
2 patients . . . view epiphora as one of the worst side effects because of their inability to read,
3 drive, or wear make-up⁸”; “visually disabling⁹”; “misleading appearance of emotional tears¹⁰”;
4 “canalicular stenosis can negatively impact the quality of life . . . and should be considered when
5 choosing the chemotherapy regimen¹¹”; “epiphora may be a major disability. It interferes with
6 daily activities and causes emotional disturbances¹²”; “the potential risk of this complication
7 should be carefully weighed¹³”; “epiphora may be an underrecognized adverse effect¹⁴”; and
8 “the high incidence of this adverse effect has an impact on several aspects of daily living.¹⁵”

9 40. Medical literature is clear that: (1) the onset of damage to the lacrimal system can
10 be rapid upon beginning Taxotere, (2) referral to a lacrimal specialist for monitoring is essential,
11 (3) damage to the lacrimal system can be permanent and irreversible, (4) this side effect is
12 preventable, and (5) oncologists are not aware of the severity of this side effect. Unfortunately,
13 this lack of awareness often results in oncologists counseling their patients that their tearing is
14 temporary and will cease after chemotherapy ends.

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17 ⁷ Bitá Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

18 ⁸ *Id.*

19 ⁹ Bitá Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly versus Every-3-Weeks Docetaxel in Patients with Metastatic Breast Cancer*, 109 AM ACAD. OF OPHTHALMOLOGY, 1188 (2002).

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21 ¹⁰ Bitá Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly Docetaxel: A Potentially Preventable Side Effect*, 13 EUROPEAN SOC'Y. FOR MED. ONCOLOGY, 218 (2001).

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23 ¹¹ Bitá Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

24 ¹² Medy Tsalic., et al., *Epiphora (Excessive Tearing) and Other Ocular Manifestations Related to Weekly Docetaxel*, 23 MEDICAL ONCOLOGY (2005)

25 ¹³ *Id.*

26 ¹⁴ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

27
28 ¹⁵ Arlene Chan, et al., *Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving Adjuvant Docetaxel-based Chemotherapy*, 31 JOURNAL OF CLINICAL ONCOLOGY, 17 (2013)

1 **VI. Taxotere Caused Mrs. Porter’s Permanent Punctal and Canalicular Stenosis**

2 41. Mrs. Porter was diagnosed with breast cancer and received weekly infusions of
3 Taxotere, receiving a total of nine infusions over the course of three months.

4 42. After her sixth Taxotere infusion, Mrs. Porter complained to her oncologist of
5 itchy, watery eyes and vision problems. At that time, her oncologist recommended that she
6 administer eye drops and use cold compresses for relief. There was no referral to a lacrimal
7 specialist for further evaluation. Following her eighth Taxotere infusion, she continued to
8 complain of tearing and her oncologist referred her to an ophthalmologist. The evaluation by
9 her ophthalmologist indicated punctal and canalicular stenosis.

10 43. Due to the severity of her reactions to her chemotherapy, including tearing and
11 skin rashes, her oncologist decided to stop Mrs. Porter’s regimen after her ninth infusion.

12 44. At no time during her Taxotere treatment did Mrs. Porter’s oncologist, or any
13 healthcare provider, inform her that her tearing might be permanent. To the contrary, in Mrs.
14 Porter’s progress notes, her oncologist noted the half-life and diminishing effects of Taxotere
15 with regard to the time frame for the placement of temporary stents to alleviate the tearing. Her
16 oncologist indicated that the tearing may persist for some time after surgery but did not indicate
17 that Mrs. Porter may have a permanent condition.

18 45. Mrs. Porter’s ophthalmologist performed an irrigation procedure confirming a
19 diagnosis of punctal and canalicular stenosis. With this diagnosis, Mrs. Porter was referred to
20 an oculoplastic surgeon, who noted that her tearing was “severe” and recommended surgical
21 implantation of Monoka stents in both eyes in an attempt to re-open her puncta and canaliculi.

22 46. Within a week of surgery, Mrs. Porter’s upper left stent came out spontaneously,
23 and Mrs. Porter returned for placement of a plug in her upper left punctum. The plug fell out
24 shortly thereafter, and the stent in her right upper eye began hanging into her eye, so she pulled
25 it out.

26 47. At her follow up with her oculoplastic surgeon, Mrs. Porter noted that despite the
27 complications, her tearing and pain improved and was hopeful that she would be cured.

28 48. Two months following surgical implantation of the stents, they were removed.

1 49. The surgery successfully resolved the tearing in Mrs. Porter’s left eye; however
2 she continued to suffer from the persistent tearing, swelling and irritation in her right eye. Her
3 oculoplastic surgeon recommended another surgical stent implantation in her right eye to resolve
4 the issue.

5 50. A second surgery was performed on Mrs. Porter’s right eye and the stents
6 remained in place for five months.

7 51. Unfortunately in the months following the removal of the stents from her right
8 eye, Mrs. Porter continued to suffer from tearing in her right eye. When Mrs. Porter informed
9 her oculoplastic surgeon, he advised her that an operation to insert glass Jones tubes “may be
10 more problems than solutions.” He advised her to see how things go and she responded that the
11 tearing seemed to be improving and she was fine to wait it out and see if it resolved on its own.

12 52. Given the fact that the stenosis on her left side ultimately healed, Mrs. Porter was
13 optimistic that the right eye would eventually resolve as well. Unfortunately, the tearing did not
14 resolve and she continues to suffer to this day.

15 53. Mrs. Porter completed chemotherapy and was excited to be cancer free and rid of
16 all of the side effects she suffered as a result of the cancer treatment. Among these, Mrs. Porter
17 looked forward to no longer suffering from constantly irritated, watering eyes. But as the effects
18 of chemotherapy wore off, her watery eyes remained.

19 54. Despite two surgeries, plugs, and stents, Mrs. Porter continues to experience
20 persistent tearing and a disruption of her life. As a direct and proximate result of Sanofi’s
21 conduct in connection with the design, development, manufacture, testing, packaging,
22 promotion, advertising, marketing, distribution, labeling, warning, and sale of Taxotere, Mrs.
23 Porter suffers from irreversible punctal and canalicular stenosis, resulting in permanent
24 epiphora. Each of these conditions is a side effect of taking Taxotere.

25 55. As a result of the undisclosed true nature of this side effect, Mrs. Porter has
26 struggled to return to normalcy, even after surviving cancer, because she continues to suffer
27 from persistent tearing on a daily basis, interfering with her ability to perform basic activities
28 and enjoy life. This permanent change has altered Mrs. Porter’s self-image, negatively impacted

1 her relationships, and others' perceptions of her, leading to social isolation and depression even
2 long after fighting cancer.

3 56. Mrs. Porter began her battle with Stage II breast cancer with a plan to undergo
4 chemotherapy, radiation, a double mastectomy and multiple reconstruction surgeries over the
5 course of two years. The multiple eye appointments and eye surgeries added unneeded suffering
6 during an already exceptionally difficult time. Throughout her ordeal, Mrs. Porter was advised
7 that, like other chemotherapy side effects, the epiphora would eventually resolve and was
8 reassured that the treatments would work. Mrs. Porter was repeatedly advised by her healthcare
9 providers that the epiphora could be fixed and no one advised this may be a condition she would
10 have to live with the rest of life.

11 57. Mrs. Porter's tearing is much more than a minor annoyance – it impacts all aspects
12 of her daily life. Prior to developing permanent punctal and canalicular stenosis, Mrs. Porter
13 was self-confident and had a successful career in sales. Now she lacks the confidence she has
14 been accustomed to and her work suffers because she works remotely on the phone to avoid face
15 to face meetings with clients. She is painfully aware that any sales pitch to new clients would
16 be ruined by tears streaming down her face and she avoids video conferences with her
17 colleagues. Her tears prevent her from achieving her pre-cancer successes at work.

18 58. Mrs. Porter is anxious not only about interactions with new faces, but also with
19 her childrens' teachers and coaches whom she fears will perceive her as sad and crying. Her
20 glasses are constantly wet and fogged up from moisture and she is unable to keep makeup on
21 her face. She is aware of the concerned looks from well-intentioned friends, colleagues and
22 strangers who perceive her to be emotional and upset.

23 59. Mrs. Porter's injuries could have been prevented had Sanofi simply warned that
24 permanent or irreversible punctal and canalicular stenosis is a common but preventable side
25 effect of Taxotere. Specifically, had Sanofi properly warned Mrs. Porter's oncologist of the
26 rapid onset of permanent damage, her oncologist would have referred her to lacrimal specialist
27 immediately at the onset of her symptoms. Mrs. Porter thus seeks recovery for her mental and
28 physical suffering stemming from permanent, but easily preventable, punctal and canalicular

1 stenosis.

2 **VII. Tolling of the Statute of Limitations**

3 60. Mrs. Porter files this lawsuit within the applicable statute of limitations period of
4 first suspecting that Sanofi’s wrongful conduct caused the appreciable harm she sustained. Due
5 to Sanofi’s fraudulent concealment of the true nature of “excessive tearing which may be
6 attributable to lacrimal duct obstruction,” Mrs. Porter could not, by the exercise of reasonable
7 diligence, have discovered that Sanofi wrongfully caused her injuries as she was unaware of the
8 severity and permanency of her injury. Specifically in its warning label, Sanofi fraudulently
9 concealed (1) the rapid onset at which stenosis can occur, (2) the potentially permanent and
10 irreversible nature of the injury, (3) the need to immediately refer patients to a lacrimal specialist
11 and (4) that the condition is highly preventable with timely intervention during chemotherapy.
12 As a result, Mrs. Porter was unaware that Sanofi knew of the devastating and permanent
13 consequences of stenosis, or that Sanofi concealed this information from her oncologist.
14 Because Mrs. Porter’s oncologist was unaware of the permanent nature of this side effect, Mrs.
15 Porter was unaware that her condition was permanent and irreversible.

16 61. Sanofi to this day does not warn that Taxotere can cause permanent and
17 irreversible obstruction of the lacrimal system. Therefore Mrs. Porter did not suspect, nor did
18 she have reason to suspect, that she had been permanently injured. Furthermore, Mrs. Porter
19 did not – and could not --r suspect the tortious nature of the conduct causing her injuries until a
20 date before filing this action that is less than the applicable limitations period for filing suit.

21 62. Upon presentation of tearing, Mrs. Porter was advised that tearing was a common
22 side effect of Taxotere chemotherapy that, like most other side effects of chemotherapy, would
23 resolve. Indeed, through the insertion of temporary stents, she did find improvement in her left
24 eye. When her oculoplastic surgeon mentioned Jones tubes, she responded she preferred to
25 wait it out to see if the condition would improve.

26 63. However, as her right eye continued to bother her, she sought some answers from
27 the internet, trying to find more information regarding persistent tearing after chemotherapy. On
28 March 21, 2019, Mrs. Porter read a blog post in which she discovered for the first time, that the

1 manufacturers of Taxotere were aware of permanent and irreversible canalicular stenosis, but
2 they intentionally withheld this information from healthcare practitioners and consumers. The
3 blog post was on the website of Hotze Runkle, PLLC, a law firm in Austin, Texas, so she reached
4 out to the firm for more information. For the first time, based on the information she read on the
5 law firm’s website, she appreciated that the manufacturer of her chemotherapy drug failed to
6 inform her and her oncologist of the risk of permanent damage to her lacrimal system, as well
7 as its knowledge that her injury could have been prevented. Mrs. Porter could not have
8 discovered Sanofi’s wrongdoing earlier, because to this date, Sanofi’s warning fails to fully
9 advise of the nature of the injury, resulting in oncologists and their patients remaining in the
10 dark. Mrs. Porter was only able to discover that her tearing was never going to go away after
11 Hotze Runkle put the information out on the internet.

12 64. Additionally, Mrs. Porter was prevented from discovering this information at an
13 earlier date because Sanofi: (1) misrepresented to the public, the FDA, and the medical
14 profession that Taxotere was free from permanent side effects; (2) failed to disclose to the public,
15 the FDA, and the medical profession its knowledge of the risk of permanent but reversible side
16 effects; (3) failed to disclose to the public, the FDA, and the medical profession its knowledge
17 that these side effects were preventable with early intervention during chemotherapy; (4)
18 fraudulently concealed facts and information that could have led Mrs. Porter to discover Sanofi’s
19 liability; and (5) still has not disclosed to the public, the FDA, and the medical profession that
20 Taxotere can cause permanent punctal and canalicular stenosis which can be prevented with
21 early intervention during chemotherapy.

22 **COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)**

23 65. Mrs. Porter incorporates by reference the above paragraphs as if set forth herein.

24 66. At all relevant times, Sanofi was in the business of designing, researching,
25 manufacturing, testing, promoting, marketing, selling, and/or distributing pharmaceutical
26 products, including the Taxotere used by Mrs. Porter.

27 67. The Taxotere designed, formulated, produced, manufactured, sold, marketed,
28 distributed, supplied and/or placed into the stream of commerce by Sanofi failed to provide

1 adequate warnings to users and their healthcare providers, including Mrs. Porter and her
2 healthcare providers, of the risk of side effects associated with the use of Taxotere, particularly
3 the risk of developing disfiguring, permanent punctal and canalicular stenosis, or the measures
4 that could have been taken to prevent it.

5 68. The Taxotere designed, formulated, produced, manufactured, sold, marketed,
6 distributed, supplied and/or placed into the stream of commerce by Sanofi and ultimately
7 administered to Mrs. Porter lacked such warnings when it left Sanofi's control.

8 69. The risks of developing disfiguring, permanent punctal and canalicular stenosis
9 were known to or reasonably knowable by Sanofi at the time the Taxotere left Sanofi's control
10 because of "newly acquired information" available to Sanofi after the 2002 label change.

11 70. A reasonably prudent company in the same or similar circumstances would have
12 provided an enhanced warning that communicated the dangers and safe use of Taxotere.

13 71. Any warnings actually provided by Sanofi did not sufficiently and/or accurately
14 reflect the symptoms, type, scope, severity, duration, and/or preventable nature of these side
15 effects, particularly the risks of developing disfiguring, permanent punctal and canalicular
16 stenosis or how it could have been prevented during administration of the chemotherapy.

17 72. Without adequate warning of these side effects, Taxotere is not reasonably fit,
18 suitable, or safe for its reasonably anticipated or intended purposes.

19 73. Mrs. Porter was a reasonably foreseeable user of Taxotere who used the drug in a
20 reasonably anticipated manner.

21 74. Mrs. Porter and her physicians would have taken preventative measures during
22 the course of her chemotherapy to prevent punctal and canalicular stenosis had she and her
23 physicians been provided an adequate warning by Sanofi of the risk of these side effects.

24 75. As a direct and proximate result of Sanofi's failure to warn of the potentially
25 severe adverse effects of Taxotere, Mrs. Porter suffered and continues to suffer serious and
26 dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and
27 economic and non-economic damages, harms, and losses, including, but not limited to: past and
28 future medical expenses; past and future loss of earnings; past and future loss and impairment

1 of earning capacity; permanent disfigurement, including permanent canalicular stenosis; mental
2 anguish; severe and debilitating emotional distress; increased risk of future harm; past, present,
3 and future physical and mental pain, suffering, and discomfort; and past, present, and future loss
4 and impairment of the quality and enjoyment of life.

5 WHEREFORE, Plaintiff Jade Porter respectfully requests judgment in her favor and
6 against Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other
7 and further relief this Court deems just and proper.

8 **COUNT II - NEGLIGENCE**

9 76. Mrs. Porter incorporates by reference the above paragraphs as if set forth herein.

10 77. Sanofi had a duty to exercise reasonable care in the design, research, formulation,
11 manufacture, production, marketing, testing, supply, promotion, packaging, sale, and/or
12 distribution of Taxotere, including a duty to assure that the product would not cause users to
13 suffer unreasonable, disfiguring, and dangerous side effects.

14 78. Sanofi breached these duties when it put Taxotere into interstate commerce,
15 unreasonably and without adequate and/or proper warning to Mrs. Porter and her healthcare
16 providers, a product that Sanofi knew or should have known created a high risk of unreasonable,
17 disfiguring, and dangerous side effects.

18 79. The negligence of Sanofi, its agents, servants, and/or employees, included but was
19 not limited to, the following acts and/or omissions:

20 a. Manufacturing, producing, promoting, formulating, creating, and/or
21 designing Taxotere without thoroughly, adequately, and/or sufficiently testing it—including
22 pre-clinical and clinical testing and post-marketing surveillance—for safety and fitness for use
23 and/or its dangers and risks;

24 b. Marketing Taxotere to Mrs. Porter, Mrs. Porter's healthcare providers, the
25 public, and the medical and healthcare professions without adequately and correctly warning
26 and/or disclosing the existence, severity, and duration of known or knowable side effects,
27 including permanent punctal and canalicular stenosis;

28 c. Marketing Taxotere to Mrs. Porter, Mrs. Porter's healthcare providers, the

1 public, and the medical and healthcare professions without providing adequate instructions
2 regarding safety precautions to be observed by users, handlers, and persons who would
3 reasonably and foreseeably come into contact with, and more particularly, use, Taxotere;

4 d. Advertising and recommending the use of Taxotere without sufficient
5 knowledge of its safety profile;

6 e. Designing, manufacturing, producing, and/or assembling Taxotere in a
7 manner that was dangerous to its users;

8 f. Concealing information from Mrs. Porter, Mrs. Porter's healthcare
9 providers, the public, other medical and healthcare professionals, and the FDA that Taxotere
10 was unsafe, dangerous, and/or non-conforming with FDA regulations;

11 g. Concealing from and/or misrepresenting information to Mrs. Porter, Mrs.
12 Porter's healthcare providers, other medical and healthcare professionals, and/or the FDA
13 concerning the existence and severity of risks and dangers of Taxotere; and

14 h. Encouraging the sale of Taxotere, either directly or indirectly, orally or in
15 writing, to Mrs. Porter and Mrs. Porter's healthcare providers without warning about the need
16 for more comprehensive and regular medical monitoring than usual to ensure early discovery of
17 potentially serious side effects such as canalicular stenosis.

18 80. Despite the fact that Sanofi knew or should have known that Taxotere caused
19 unreasonably dangerous side effects, Sanofi continues to market, manufacture, distribute, and/or
20 sell Taxotere to consumers.

21 81. Mrs. Porter and Mrs. Porter's healthcare providers were therefore forced to rely
22 on safety information that did not accurately represent the risks and benefits associated with the
23 use of Taxotere and measures that could have been taken to prevent severe and permanent
24 disfigurement from the use of Taxotere.

25 82. Sanofi knew or should have known that consumers such as Mrs. Porter would use
26 its product and would foreseeably suffer injury as a result of Sanofi's failure to exercise
27 reasonable care, as set forth above.

28 83. Sanofi's negligence was a proximate cause of Mrs. Porter's injuries, harms,

1 damages, and losses, in connection with the use of Taxotere, including but not limited to: past
2 and future medical expenses; past and future loss of earnings; past and future loss and
3 impairment of earning capacity; permanent disfigurement including permanent and irreversible
4 canalicular stenosis; mental anguish; severe and debilitating emotional distress; increased risk
5 of future harm; past, present, and future physical and mental pain, suffering, and discomfort;
6 and past, present, and future loss and impairment of the quality and enjoyment of life.

7 WHEREFORE, Jade Porter respectfully requests judgment in her favor and against
8 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and
9 further relief this Court deems just and proper.

10 **COUNT III – NEGLIGENT MISREPRESENTATION**

11 84. Mrs. Porter incorporates by reference the above paragraphs as if set forth herein.

12 85. Sanofi had a duty to represent to Mrs. Porter, Mrs. Porter’s healthcare providers,
13 the healthcare community, and the public in general that Taxotere had been tested and found to
14 be safe and effective for the treatment of various forms of cancer.

15 86. When warning of safety and risks of Taxotere, Sanofi negligently represented to
16 Mrs. Porter, Mrs. Porter’s healthcare providers, the healthcare community, and the public in
17 general that Taxotere had been tested and was found to be safe and/or effective for its indicated
18 use.

19 87. Sanofi concealed its knowledge of Taxotere defects from Mrs. Porter, Mrs.
20 Porter’s healthcare providers, and the public in general and/or the healthcare community
21 specifically.

22 88. Sanofi concealed this information with the intent of defrauding and deceiving Mrs.
23 Porter, Mrs. Porters’ healthcare providers, the public in general, and the healthcare community
24 in particular, and were made with the intent of inducing Mrs. Porter, Mrs. Porter’s healthcare
25 providers, the public in general, and the healthcare community in particular, to recommend,
26 dispense, and/or purchase Taxotere.

27 89. Sanofi failed to exercise ordinary and reasonable care in its representations of
28 Taxotere in its sale, testing, quality assurance, quality control, and/or distribution into interstate

1 commerce, and Sanofi negligently misrepresented Taxotere’s high risks of unreasonable,
2 dangerous side effects. These side effects were unreasonable because they could have been
3 entirely prevented with adequate warning.

4 90. Sanofi breached its duty in misrepresenting Taxotere’s serious side effects to Mrs.
5 Porter, Mrs. Porter’s healthcare providers, the healthcare community, the FDA, and the public
6 in general.

7 91. Mrs. Porter and Mrs. Porter’s healthcare providers reasonably relied on Sanofi to
8 fulfill its obligations to disclose all facts within its knowledge regarding the serious side effects
9 of Taxotere and the ability to prevent those side effects with appropriate precautionary measures.

10 92. As a direct and proximate result of the foregoing acts and omissions, Sanofi
11 caused Mrs. Porter to suffer serious and dangerous side effects, severe and personal injuries that
12 are permanent and lasting in nature, and economic and non-economic damages, harms, and
13 losses, including, but not limited to: past and future medical expenses; past and future loss of
14 earnings; past and future loss and impairment of earning capacity; permanent disfigurement,
15 including permanent canalicular stenosis; mental anguish; severe and debilitating emotional
16 distress; increased risk of future harm; past, present, and future physical and mental pain,
17 suffering, and discomfort; and past, present, and future loss and impairment of the quality and
18 enjoyment of life.

19 WHEREFORE, Jade Porter respectfully requests that judgment in her favor and against
20 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and
21 further relief this Court deems just and proper.

22 **COUNT IV – FRAUDULENT MISREPRESENTATION**

23 93. Mrs. Porter incorporates by reference the above paragraphs as if set forth herein.

24 94. Sanofi represented to Mrs. Porter, Mrs. Porter’s healthcare providers, the
25 healthcare community, and the public in general that “excessive tearing which may be
26 attributable to lacrimal duct obstruction has been reported” and that excessive is a common side
27 effect. These statements failed to accurately inform oncologists and patients of (1) the rapid
28 onset at which stenosis can occur, (2) the potentially permanent and irreversible nature of the

1 injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the condition
2 is highly preventable with timely intervention during chemotherapy.

3 95. Despite having knowledge of these enhanced side effects, Sanofi fraudulently
4 omitted from these representations information that Taxotere could and did cause these serious
5 side effects, including permanent and irreversible punctal and canalicular stenosis.

6 96. These representations were material and false.

7 97. Sanofi made these representations and omissions:

- 8 a. with knowledge or belief of their falsity, and/or in the case of omissions,
9 with knowledge or belief of falsity of the resulting statements;
- 10 b. positively and recklessly without knowledge of their truth or falsity;
- 11 c. with knowledge that they were made without any basis; and/or
- 12 d. without confidence in the accuracy of the representations or statements
13 resulting from the omissions.

14 98. Sanofi made these false representations with the intention or expectation that Mrs.
15 Porter, Mrs. Porter's healthcare providers, the public in general, and the healthcare community
16 in particular, would recommend, dispense, and/or purchase Taxotere, all of which evidenced a
17 callous, reckless, willful, wanton, and depraved indifference to the health, safety, and welfare
18 of Mrs. Porter.

19 99. At the time Sanofi made the aforesaid representations, and, at the time Mrs. Porter
20 used Taxotere, Mrs. Porter and Mrs. Porter's healthcare providers were unaware of the falsity
21 of Sanofi's representations, statements and/or implications and justifiably and reasonably relied
22 on Sanofi's representations, statements, and implications, believing them to be true.

23 100. In reliance on Sanofi's representations, Mrs. Porter and her healthcare providers
24 were induced to and did use and prescribe Taxotere, which caused Mrs. Porter to suffer serious
25 and dangerous side effects, severe and personal injuries that are permanent and lasting in nature,
26 and economic and non-economic damages, harms, and losses, including, but not limited to: past
27 and future medical expenses; past and future loss of earnings; past and future loss and
28 impairment of earning capacity; permanent disfigurement, including permanent canalicular

1 stenosis; mental anguish; severe and debilitating emotional distress; increased risk of future
2 harm; past, present, and future physical and mental pain, suffering, and discomfort; and past,
3 present, and future loss and impairment of the quality and enjoyment of life.

4 WHEREFORE, Jade Porter respectfully requests judgment in her favor and against
5 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and
6 further relief this Court deems just and proper.

7 **COUNT V – FRAUDULENT CONCEALMENT**

8 101. Mrs. Porter incorporates by reference the above paragraphs as if set forth herein.

9 102. At all times during the course of dealing between Sanofi and Mrs. Porter and Mrs.
10 Porter’s healthcare providers, Sanofi misrepresented the design characteristic and safety of
11 Taxotere for their intended use.

12 103. Sanofi knew or was reckless in not knowing that its representations were false due
13 to Sanofi’s access to ongoing studies and reports that disclosed serious, enhanced side effects of
14 Taxotere to the lacrimal system. In representations made to Mrs. Porter and Mrs. Porter’s
15 healthcare providers, Sanofi fraudulently concealed and intentionally omitted the following
16 material information: (1) the rapid onset at which stenosis can occur, (2) the potentially
17 permanent and irreversible nature of the injury, (3) the need to immediately refer patients to a
18 lacrimal specialist and (4) that the condition is highly preventable with timely intervention
19 during chemotherapy.

20 104. Sanofi had a duty to disclose to Mrs. Porter and Mrs. Porter’s healthcare providers
21 the defective nature of Taxotere, including, but not limited to, the heightened risks of
22 disfiguring, permanent punctal and canalicular stenosis.

23 105. Sanofi had a duty to disclose to Mrs. Porter and Mrs. Porter’s healthcare providers
24 that the disfiguring, permanent punctal and canalicular stenosis caused by the use of Taxotere
25 could have been prevented by early identification and treatment of epiphora during
26 chemotherapy.

27 106. Sanofi had sole access to material facts concerning the defective nature of
28 Taxotere and its propensity to cause serious and dangerous side effects, and therefore cause

1 damage to persons who used the drugs at issue, including Mrs. Porter.

2 107. Sanofi's concealment and omissions of material fact concerning the safety of
3 Taxotere were made purposefully, willfully, wantonly, and/or recklessly to mislead Mrs. Porter
4 and Mrs. Porter's healthcare providers into reliance on the continued use of the drugs and to
5 cause them to purchase, prescribe, and/or dispense Taxotere and/or use it.

6 108. Sanofi knew that Mrs. Porter and her healthcare providers had no way to
7 determine the truth behind its concealment and omissions, including the material omissions of
8 fact surrounding Taxotere set forth herein.

9 109. Mrs. Porter and Mrs. Porter's healthcare providers reasonably relied on
10 information disclosed by Sanofi that negligently, fraudulently, and/or purposefully did not
11 include facts that were concealed and/or omitted by Sanofi.

12 110. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Porter to suffer
13 serious and dangerous side effects, severe and personal injuries that are permanent and lasting
14 in nature, and economic and non-economic damages, harms, and losses, including, but not
15 limited to: past and future medical expenses; past and future loss of earnings; past and future
16 loss and impairment of earning capacity; permanent disfigurement, including permanent
17 canalicular stenosis; mental anguish; severe and debilitating emotional distress; increased risk
18 of future harm; past, present, and future physical and mental pain, suffering, and discomfort;
19 and past, present, and future loss and impairment of the quality and enjoyment of life.

20 WHEREFORE, Jade Porter respectfully requests judgment in her favor and against
21 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and
22 further relief this Court deems just and proper.

23 **JURY DEMAND**

24 Plaintiff hereby requests a trial by jury pursuant to rule 38 of the Federal Rules of Civil
25 Procedure.

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Dated: July 13, 2021

FITZPATRICK & SWANSTON
RMP LAW GROUP LLC
HOTZE RUNKLE PLLC

By: /s/ Richard M. Paul III
B. James Fitzpatrick
Richard M. Paul III (*pro hac vice*)
Patrick O. Hotze (*pro hac vice*)
Attorneys for Plaintiff,
JADE PORTER

U.S. District Court
California Northern District (San Francisco)
CIVIL DOCKET FOR CASE #: 3:21-cv-02749-EMC

Estell v. Sanofi US Services, Inc. et al
Assigned to: Judge Edward M. Chen
Cause: 28:1332 Diversity-Product Liability

Date Filed: 04/16/2021
Jury Demand: Plaintiff
Nature of Suit: 367 Personal Injury: Health Care/Pharmaceutical
Personal Injury Product Liability
Jurisdiction: Diversity

Plaintiff

Cathy Estell

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V.

Defendant

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formerly known as
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Defendant

Sanofi-Aventis U.S., LLC

represented by **Amir M. Nassihi**
 (See above for address)
ATTORNEY TO BE NOTICED

Torrey Peterson
 (See above for address)
ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
04/16/2021	1	COMPLAINT against All Defendants (Filing fee \$ 402, receipt number 0971-15847757.). Filed byCathy Estell. (Attachments: # 1 Civil Cover Sheet, # 2 Summons, # 3 Summons)(Fitzpatrick, Bernard) (Filed on 4/16/2021) (Entered: 04/16/2021)
04/16/2021	2	Proposed Summons. (Fitzpatrick, Bernard) (Filed on 4/16/2021) (Entered: 04/16/2021)
04/16/2021	3	Proposed Summons. (Fitzpatrick, Bernard) (Filed on 4/16/2021) (Entered: 04/16/2021)
04/16/2021	4	Case assigned to Magistrate Judge Sallie Kim. Counsel for plaintiff or the removing party is responsible for serving the Complaint or Notice of Removal, Summons and the assigned judge's standing orders and all other new case documents upon the opposing parties. For information, visit <i>E-Filing A New Civil Case</i> at http://cand.uscourts.gov/ecf/caseopening . Standing orders can be downloaded from the court's web page at www.cand.uscourts.gov/judges . Upon receipt, the summons will be issued and returned electronically. Counsel is required to send chambers a copy of the initiating documents pursuant to L.R. 5-1(e)(7). A scheduling order will be sent by Notice of Electronic Filing (NEF) within two business days. Consent/Declination due by 4/30/2021. (asS, COURT STAFF) (Filed on 4/16/2021) (Entered: 04/16/2021)
04/16/2021	5	Initial Case Management Scheduling Order with ADR Deadlines: Case Management Statement due by 7/12/2021. Initial Case Management Conference set for 7/19/2021 01:30 PM in San Francisco, Courtroom C, 15th Floor. (msrS, COURT STAFF) (Filed on 4/16/2021) (Entered: 04/16/2021)
04/16/2021	6	Summons Issued as to Sanofi US Services, Inc. f/k/a Sanofi-Aventis U.S., Inc.. (msrS, COURT STAFF) (Filed on 4/16/2021) (Entered: 04/16/2021)
04/16/2021	7	Summons Issued as to Sanofi-Aventis U.S. LLC. (msrS, COURT STAFF) (Filed on 4/16/2021) (Entered: 04/16/2021)
04/20/2021	8	CONSENT/DECLINATION to Proceed Before a US Magistrate Judge by Cathy Estell.. (Fitzpatrick, Bernard) (Filed on 4/20/2021) (Entered: 04/20/2021)
04/20/2021	9	CLERK'S NOTICE OF IMPENDING REASSIGNMENT TO A U.S. DISTRICT COURT JUDGE: The Clerk of this Court will now randomly reassign this case to a District Judge because either (1) a party has not consented to the jurisdiction of a Magistrate Judge, or (2) time is of the essence in deciding a pending judicial action for which the necessary consents to Magistrate Judge jurisdiction have not been secured. You will be informed by separate notice of the district judge to whom this case is reassigned. ALL HEARING DATES PRESENTLY SCHEDULED BEFORE THE CURRENT MAGISTRATE JUDGE ARE VACATED AND SHOULD BE RE-NOTICED FOR HEARING BEFORE THE JUDGE TO WHOM THIS CASE IS REASSIGNED. <i>This is a text only docket entry; there is no document associated with this notice.</i> (mkIS, COURT STAFF) (Filed on 4/20/2021) (Entered: 04/20/2021)
04/21/2021	10	ORDER REASSIGNING CASE. Case reassigned using a proportionate, random, and blind system pursuant to General Order No. 44 to Judge Edward M. Chen for all further proceedings. Magistrate Judge Sallie Kim no longer assigned to case, Notice: The assigned judge participates in the Cameras in the Courtroom Pilot Project. See General Order No. 65 and http://cand.uscourts.gov/cameras.. Signed by The Clerk on 4/21/21. (Attachments: # 1 Notice of Eligibility for Video Recording)(haS, COURT STAFF) (Filed on 4/21/2021) (Entered: 04/21/2021)
04/26/2021	11	MOTION for leave to appear in Pro Hac Vice (Filing fee \$ 317, receipt number 0971-15888156.) filed by Cathy Estell. (Hotze, Patrick) (Filed on 4/26/2021) (Entered: 04/26/2021)
04/27/2021	12	ORDER by Judge Edward M. Chen granting 11 Motion for Pro Hac Vice. (afmS, COURT STAFF) (Filed on 4/27/2021) (Entered: 04/27/2021)
04/30/2021	13	CASE MANAGEMENT CONFERENCE ORDER IN REASSIGNED CASE: Initial Case Management Conference set for 8/19/2021 09:30 AM in San Francisco, - Videoconference Only. Joint Case Management Statement due by 8/12/2021. Signed by Judge Edward M.

		Chen on 4/30/2021. (afmS, COURT STAFF) (Filed on 4/30/2021) (Entered: 05/02/2021)
05/07/2021	14	WAIVER OF SERVICE Returned Executed filed by Cathy Estell. Service waived by All Defendants. (Fitzpatrick, Bernard) (Filed on 5/7/2021) (Entered: 05/07/2021)
05/07/2021	15	CERTIFICATE OF SERVICE by Cathy Estell <i>RE APRIL 30, 2021 CASE MANAGEMENT CONFERENCE ORDER AND STANDING ORDERS</i> (Fitzpatrick, Bernard) (Filed on 5/7/2021) (Entered: 05/07/2021)
05/07/2021	16	MOTION for leave to appear in Pro Hac Vice (Filing fee \$ 317, receipt number 0971-15940498.) filed by Cathy Estell. (Attachments: # 1 Exhibit Certificate of Good Standing, # 2 Exhibit Certificate of Good Standing)(Paul, Richard) (Filed on 5/7/2021) (Entered: 05/07/2021)
05/10/2021	17	MOTION for leave to appear in Pro Hac Vice (Filing fee \$ 317, receipt number 0971-15946008.) filed by Cathy Estell. (Shanks, Karen) (Filed on 5/10/2021) (Entered: 05/10/2021)
05/13/2021	18	Order by Judge Edward M. Chen granting 16 Motion for Pro Hac Vice for Richard Paul. (tmiS, COURT STAFF) (Filed on 5/13/2021) (Entered: 05/13/2021)
05/13/2021	19	Order by Judge Edward M. Chen granting 17 Motion for Pro Hac Vice for Karen Shanks. (tmiS, COURT STAFF) (Filed on 5/13/2021) (Entered: 05/13/2021)
06/28/2021	20	NOTICE of Appearance by Amir M. Nassihi (Nassihi, Amir) (Filed on 6/28/2021) (Entered: 06/28/2021)
06/28/2021	21	STIPULATION WITH PROPOSED ORDER re 1 Complaint <i>For Extension of Time to Respond to Complaint and Briefing Schedule</i> filed by Sanofi US Services, Inc. f/k/a Sanofi-Aventis U.S., Inc., Sanofi-Aventis U.S. LLC. (Nassihi, Amir) (Filed on 6/28/2021) (Entered: 06/28/2021)
06/28/2021	22	ORDER by Judge Edward M. Chen granting 21 Stipulation. Defendants Sanofi US Services, Inc. f/k/a Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S., LLCs (Sanofi) response to Plaintiff Cathy Estells Complaint is due on 7/29/2021. If Sanofi files a pleading challenge, the deadline for Ms. Estells opposition is 8/30/2021, and the deadline for Sanofis reply is 9/13/2021. (afmS, COURT STAFF) (Filed on 6/28/2021) (Entered: 06/28/2021)
07/27/2021	23	CLERK'S NOTICE RESCHEDULING INITIAL CASE MANAGEMENT CONFERENCE FROM 8/19/2021 TO 8/31/2021 AT 1:30PM: Initial Case Management Conference set for 8/19/2021 is vacated and rescheduled for 8/31/2021 01:30 PM in San Francisco, - Videoconference Only. This proceeding will be held via a Zoom webinar. Joint Case Management Statement due by 8/24/2021. Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited. Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/. Joint Case Management Statement due by 8/24/2021. Initial Case Management Conference set for 8/31/2021 01:30 PM in San Francisco, - Videoconference Only. (This is a text-only entry generated by the court. There is no document associated with this entry.)(afmS, COURT STAFF) (Filed on 7/27/2021) (Entered: 07/27/2021)
07/28/2021	24	STIPULATION and Consent for Plaintiff to File First Amended Complaint filed by Cathy Estell. (Paul, Richard) (Filed on 7/28/2021) (Entered: 07/28/2021)
07/28/2021	25	FIRST AMENDED COMPLAINT Jury Trial Demanded against All Defendants. Filed by Cathy Estell. (Paul, Richard) (Filed on 7/28/2021) Modified on 7/28/2021 (jlgS, COURT STAFF). (Entered: 07/28/2021)
08/11/2021	26	MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> filed by Sanofi US Services, Inc., Sanofi-Aventis U.S., LLC. Motion Hearing set for 10/14/2021 01:30 PM in San Francisco, Courtroom 05, 17th Floor before Judge Edward M. Chen. Responses due by 8/25/2021. Replies due by 9/1/2021. (Attachments: # 1 Proposed Order)(Nassihi, Amir) (Filed on 8/11/2021) (Entered: 08/11/2021)
08/11/2021	27	Request for Judicial Notice re 26 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> filed by Sanofi US Services, Inc., Sanofi-Aventis U.S., LLC. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J)(Related document(s) 26) (Nassihi, Amir) (Filed on 8/11/2021) (Entered: 08/11/2021)
08/17/2021	28	MOTION for leave to appear in Pro Hac Vice (Filing fee \$ 317, receipt number 0971-16290393.) filed by Sanofi US Services, Inc.. (Attachments: # 1 Exhibit Certificate of Good Standing)(Ratliff, Harley) (Filed on 8/17/2021) (Entered: 08/17/2021)
08/17/2021	29	MOTION for leave to appear in Pro Hac Vice (Filing fee \$ 317, receipt number 0971-16290406.) filed by Sanofi US Services, Inc.. (Attachments: # 1 Exhibit Certificate of Good Standing)(Peterson, Torrey) (Filed on 8/17/2021) (Entered: 08/17/2021)
08/17/2021	30	ORDER by Judge Edward M. Chen granting 28 Motion for Pro Hac Vice. (afmS, COURT STAFF) (Filed on 8/17/2021) (Entered: 08/17/2021)
08/17/2021	31	MOTION for leave to appear in Pro Hac Vice (Filing fee \$ 317, receipt number 0971-16290416.) filed by Sanofi US Services, Inc.. (Attachments: # 1 Exhibit Certificate of Good Standing)(Strongman, Jon) (Filed on 8/17/2021) (Entered: 08/17/2021)
08/17/2021	32	ORDER by Judge Edward M. Chen granting 29 Motion for Pro Hac Vice. (afmS, COURT STAFF) (Filed on 8/17/2021) (Entered: 08/17/2021)
08/17/2021	33	ORDER by Judge Edward M. Chen granting 31 Motion for Pro Hac Vice. (afmS, COURT STAFF) (Filed on 8/17/2021) (Entered: 08/17/2021)
08/24/2021	34	CASE MANAGEMENT STATEMENT filed by Cathy Estell. (Paul, Richard) (Filed on 8/24/2021) (Entered: 08/24/2021)
08/24/2021	35	Corporate Disclosure Statement by Sanofi US Services, Inc., Sanofi-Aventis U.S., LLC identifying Corporate Parent Sanofi for Sanofi US Services, Inc., Sanofi-Aventis U.S., LLC. (Nassihi, Amir) (Filed on 8/24/2021) (Entered: 08/24/2021)
08/25/2021	36	OPPOSITION/RESPONSE (re 26 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i>) filed by Cathy Estell. (Paul, Richard) (Filed on 8/25/2021) (Entered: 08/25/2021)
08/27/2021	37	STIPULATION WITH PROPOSED ORDER <i>Regarding Deadline to File Reply in Support of Sanofi's Motion to Dismiss First Amended Complaint</i> filed by Sanofi US Services, Inc., Sanofi-Aventis U.S., LLC. (Peterson, Torrey) (Filed on 8/27/2021) (Entered: 08/27/2021)
08/27/2021	38	CLERK'S NOTICE CHANGING TIME OF INITIAL CASE MANAGEMENT CONFERENCE SET ON 8/31/2021 FROM 1:30PM TO

		<p>3:30PM: Initial Case Management Conference set for 8/31/2021 03:30 PM in San Francisco, - Videoconference Only. This proceeding will be held via a Zoom webinar.</p> <p>Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc</p> <p>General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.</p> <p>Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/.</p> <p>Initial Case Management Conference set for 8/31/2021 03:30 PM in San Francisco, - Videoconference Only. (This is a text-only entry generated by the court. There is no document associated with this entry.)(afmS, COURT STAFF) (Filed on 8/27/2021) (Entered: 08/27/2021)</p>
08/29/2021	39	ORDER by Judge Edward M. Chen granting 37 Stipulation Regarding Deadline to File Reply in Support of Sanofi's Motion to Dismiss First Amended Complaint. Reply due 9/8/2021. (afmS, COURT STAFF) (Filed on 8/29/2021) (Entered: 08/29/2021)
08/31/2021	40	<p>Minute Entry for proceedings held before Judge Edward M. Chen:</p> <p>Initial Case Management Conference held on 8/31/2021. See pdf image for further details.</p> <p>Total Time in Court: 13 Minutes. Court Reporter: Marla Knox.</p> <p>Plaintiff Attorney: Richard Paul. Defendant Attorneys: Amir Nassihi, Torrey Peterson, Harley Ratliff.</p> <p>Attachment: Minute Order. (afmS, COURT STAFF) (Date Filed: 8/31/2021) (Entered: 09/02/2021)</p>
09/03/2021	41	TRANSCRIPT ORDER for proceedings held on 08/31/2021 before Judge Edward M. Chen by Sanofi US Services, Inc., Sanofi-Aventis U.S., LLC, for Court Reporter Marla Knox. (Peterson, Torrey) (Filed on 9/3/2021) (Entered: 09/03/2021)
09/08/2021	42	REPLY (re 26 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i>) filed by Sanofi US Services, Inc., Sanofi-Aventis U.S., LLC. (Attachments: # 1 Exhibit K, # 2 Exhibit L, # 3 Exhibit M, # 4 Exhibit N)(Nassihi, Amir) (Filed on 9/8/2021) (Entered: 09/08/2021)
09/10/2021	43	<p>CLERK'S NOTICE RESCHEDULING HEARING RE: 26 MOTION TO DISMISS FROM 10/14/2021 TO 11/18/2021 AT 1:30PM: Hearing re 26 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> set for 10/14/2021 is vacated and reset for 11/18/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. Motion briefing deadlines remain unchanged. This proceeding will be held via a Zoom webinar.</p> <p>Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc</p> <p>General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.</p> <p>Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/.</p> <p>Motion Hearing set for 11/18/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. (This is a text-only entry generated by the court. There is no document associated with this entry.)(afmS, COURT STAFF) (Filed on 9/10/2021) (Entered: 09/10/2021)</p>
10/01/2021	44	Transcript of Videoconference Proceedings held on August 31, 2021, before Judge Edward M. Chen. Court Reporter, Marla F. Knox, RPR, CRR, RMR, telephone number (602) 391-6990/email marla_knox@cand.uscourts.gov. Per General Order No. 59 and Judicial Conference policy, this transcript may be viewed only at the Clerk's Office public terminal or may be purchased through the Court Reporter/Transcriber until the deadline for the Release of Transcript Restriction. After that date it may be obtained through PACER. Any Notice of Intent to Request Redaction, if required, is due no later than 5 business days from date of this filing. (Re 41 Transcript Order) Release of Transcript Restriction set for 12/30/2021. (Related documents(s) 41) (mfk, COURT STAFF) (Filed on 10/1/2021) (Entered: 10/01/2021)
10/08/2021	45	NOTICE of Change of Address by Richard M. Paul, III (Paul, Richard) (Filed on 10/8/2021) (Entered: 10/08/2021)
10/20/2021	46	<p>CLERK'S NOTICE RESCHEDULING HEARING RE 26 MOTION TO DISMISS FROM 11/18/2021 TO SPECIALLY SET DATE 11/22/2021 AT 1:30PM: Hearing re 26 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> is specially reset for 11/22/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. This proceeding will be held via a Zoom webinar.</p> <p>Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc</p> <p>General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.</p> <p>Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/.</p> <p>Motion Hearing set for 11/22/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. (This is a text-only entry generated by the court. There is no document associated with this entry.)(afmS, COURT STAFF) (Filed on 10/20/2021) (Entered: 10/20/2021)</p>
10/25/2021	47	STIPULATION WITH PROPOSED ORDER <i>To Continue Hearing Date for Sanofi's Motion to Dismiss</i> filed by Sanofi US Services, Inc., Sanofi-Aventis U.S., LLC. (Nassihi, Amir) (Filed on 10/25/2021) (Entered: 10/25/2021)
10/27/2021	48	CLERK'S NOTICE RESCHEDULING HEARING RE 26 MOTION TO DISMISS TO 12/16/2021 AT 1:30PM: Hearing re 26 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> RESCHEDULED for 12/16/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. This proceeding will be held via a Zoom webinar.

		<p>Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc</p> <p>General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.</p> <p>Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/.</p> <p>Motion Hearing set for 12/16/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. <i>(This is a text-only entry generated by the court. There is no document associated with this entry.)</i>(afm, COURT STAFF) (Filed on 10/27/2021) (Entered: 10/27/2021)</p>
11/12/2021	49	<p>CLERK'S NOTICE ADVANCING HEARING RE: 26 MOTION TO DISMISS FROM 12/16/2021 TO SPECIALLY SET DATE 12/14/2021 AT 10:00AM: Hearing re 26 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> is reset for 12/14/2021 10:00 AM in San Francisco, - Videoconference Only before Judge Edward M. Chen. This proceeding will be held via a Zoom webinar.</p> <p>Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc</p> <p>General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadca sting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.</p> <p>Zoom Guidance and Setup: <a href="https://www.cand.uscourts.gov/zoom/">https://www.cand.uscourts.gov/zoom/.</p> <p>Motion Hearing set for 12/14/2021 10:00 AM in San Francisco, - Videoconference Only before Judge Edward M. Chen. <i>(This is a text-only entry generated by the court. There is no document associated with this entry.)</i>(afm, COURT STAFF) (Filed on 11/12/2021) (Entered: 11/14/2021)</p>
11/24/2021	50	<p>CLERK'S NOTICE ADVANCING MOTION 26 HEARING FROM 12/14/2021 TO 12/9/2021 AT 1:30PM: Hearing re 26 MOTION to Dismiss <i>Plaintiff's First Amended Complaint</i> set for 12/14/2021 is vacated and ADVANCED to 12/9/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. This proceeding will be held via a Zoom webinar.</p> <p>Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc</p> <p>General Order 58. Persons granted access to court proceedings held by telephone or videoconference are reminded that photographing, recording, and rebroadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.</p> <p>Zoom Guidance and Setup: <a href="https://www.cand.uscourts.gov/zoom/</p>">https://www.cand.uscourts.gov/zoom/</p> Motion Hearing set for 12/9/2021 01:30 PM in San Francisco, - Videoconference Only before Judge Edward M. Chen. <i>(This is a text-only entry generated by the court. There is no document associated with this entry.)</i>(afm, COURT STAFF) (Filed on 11/24/2021) (Entered: 11/25/2021)</p>

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27 **UNITED STATES DISTRICT COURT**
28 **DISTRICT OF CALIFORNIA**

29 CATHY ESTELL,
30
31 Plaintiff,
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33 v.
34 SANOFI US SERVICES, INC. f/k/a
35 SANOFI-AVENTIS U.S., INC.; and
36 SANOFI-AVENTIS U.S., LLC,
37
38 Defendants.

Case No. 3:21-CV-2749-EMC

FIRST AMENDED COMPLAINT
JURY TRIAL DEMANDED

1 Plaintiff Cathy Estell, for her First Amended Complaint against defendants SANOFI US
2 SERVICES, INC., f/k/a SANOFI-AVENTIS U.S., INC. and SANOFI-AVENTIS U.S., LLC
3 (collectively “Sanofi”), alleges:

4 **INTRODUCTION**

5 1. Sanofi manufactures and sells a chemotherapy drug named Taxotere (generic
6 name docetaxel), which is administered to many who suffer primarily from breast cancer. While
7 it is one of many drugs effective at treating breast cancer, Sanofi has known for years that the
8 drug carries a significant risk of causing permanent and irreversible damage to the lacrimal
9 system, including punctal and nasolacrimal duct stenosis.

10 2. A simple preventative procedure at the onset of chemotherapy-induced tearing,
11 involving the temporary placement of silicone stents, allows a patient to continue her Taxotere
12 regimen while removing the likelihood of permanent and irreversible damage to the lacrimal
13 system. Although Sanofi warns that “excessive tearing which may be attributable to lacrimal
14 duct obstruction has been reported”, Sanofi failed to warn patients and oncologists of the risk
15 that the damage can occur quickly and can be **permanent and irreversible**. Further, Sanofi
16 failed to report the severity and frequency of this risk to the Food and Drug Administration
17 (“FDA”). Worse, Sanofi misled patients and oncologists about the severity and frequency of this
18 devastating side effect even though this condition can be entirely preventable with early
19 intervention and treatment during chemotherapy. As a result, Mrs. Estell suffers from permanent
20 injuries because she used Taxotere.

21 3. Plaintiff is grateful for the chemotherapy that helped to save her life; however,
22 that gratitude is diminished by the fact that she now must endure a permanent and life-altering
23 condition that could have been prevented with an adequate warning to her physicians. Plaintiff’s
24 permanent injuries to her lacrimal system, specifically punctal stenosis, cause daily disruption
25 to her life due to excessive tearing, or epiphora. For those who have never experienced epiphora,
26 the condition might seem like a minor annoyance. However, for cancer survivors like Mrs.
27 Estell, the irritated, swollen, watering eyes and the ongoing medical management of the
28 condition affect their work, their self-esteem, interpersonal relationships, daily activities like

1 driving or reading a book, and their general ability to return to a normal life after defeating
2 cancer.

3 **PARTIES**

4 **A. Plaintiff**

5 4. Plaintiff Cathy Estell is an individual residing in Oakland, California who received
6 Taxotere as part of a chemotherapy regimen after being diagnosed with breast cancer. She was
7 administered Taxotere at Valley Medical Oncology in Castro Valley, California. She was
8 prescribed tri-weekly treatment and received a total of 6 rounds of chemotherapy with Taxotere.
9 Since completing chemotherapy, she has been diagnosed with permanent and irreversible
10 punctal and nasolacrimal duct stenosis, and her eyes continue to tear on a daily basis.

11 **B. Sanofi Defendants**

12 5. Defendant Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. is a Delaware
13 corporation, with a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey
14 08807. Sanofi US Services Inc. is a wholly owned subsidiary of Sanofi S.A. Sanofi S.A. is
15 engaged in research and development, testing, manufacturing, labeling, advertising, marketing,
16 promoting, selling and/or distributing of prescription drugs, including Taxotere. Defendant
17 Sanofi US Services Inc. engages in research and development, testing, manufacturing, labeling,
18 advertising, marketing, promoting, selling and/or distributing of prescription drugs, including
19 Taxotere.

20 6. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, with
21 a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-
22 Aventis U.S. LLC is a wholly owned subsidiary of Defendant Sanofi S.A., and Sanofi S.A. is
23 Sanofi-Aventis U.S., LLC's sole member. Defendant Sanofi-Aventis U.S. LLC engages in
24 research and development, testing, manufacturing, labeling, advertising, marketing, promoting,
25 selling and/or distributing of prescription drugs, including Taxotere.

26 7. Since 2006, defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc.
27 have collectively served as the U.S. operational front for Sanofi S.A. in the U.S. prescription
28 drug market.

1 **JURISDICTION AND VENUE**

2 8. Federal subject matter jurisdiction is based on 28 U.S.C. §1332(a) due to the
3 complete diversity of Mrs. Estell and Defendants and the amount in controversy exceeds
4 \$75,000.

5 9. A substantial part of the acts and omissions giving rise to this cause of action
6 occurred in this district and therefore venue is proper here pursuant to 28 U.S.C. §1391(a).

7 10. The Sanofi Defendants are subject to personal jurisdiction in this Court due to
8 their ongoing and substantial contacts in this forum.

9 **FACTUAL ALLEGATIONS**

10 **I. Development and Approval of Taxotere (Docetaxel)**

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

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

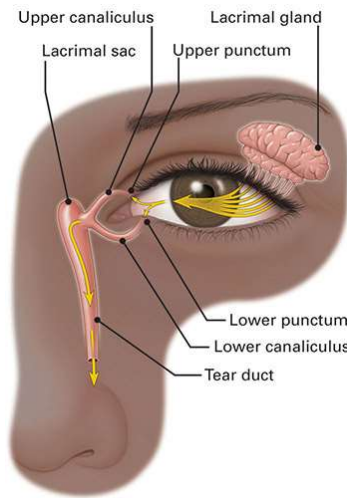
21 13. In August 2004, Sanofi obtained FDA approval for an expanded use of Taxotere
22 “in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients
23 with operable node-positive breast cancer.” This resulted in a greater number of patients being
24 treated with Taxotere.

25 14. As the universe of patients taking Taxotere expanded to include those with a
26 higher survivability, more cancer survivors taking Taxotere would now experience a permanent
27 disabling (but preventable) condition.

1 15. Taxotere is not purchased by patients at a pharmacy; rather, patients’ use of these
2 drugs occurs via administration through injection and/or intravenously at a physician’s office or
3 medical treatment facility.

4 **II. Anatomy of the Lacrimal System**

5 16. The following image depicts the anatomy of the lacrimal system:



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14 17. Taxotere is secreted in the tear film, thereby causing fibrosis in areas of the
15 lacrimal system, including the puncta, canaliculi, and/or the nasolacrimal duct (labeled as tear
16 duct in image).¹ This scarring can cause permanent and irreversible occlusion, resulting in the
17 failure of tears to drain naturally through the lacrimal system. Because the eyes are constantly
18 producing tears, this results in persistent epiphora.

19 **III. Taxotere’s Labeling**

20 18. Taxotere’s labeling information at the time relevant to this lawsuit, states in
21 relevant part:

22 **Patient Information Leaflet**

23 *What are the possible side effects of Taxotere?*

24 Eye Changes – Excessive tearing, which can be related to
25 conjunctivitis or blockage of tear ducts, may occur

26 **Post-Marketing Experiences**

Excessive tearing which may be attributable to lacrimal duct

27 ¹ For the Court’s ease of reference, Plaintiff will use the term “lacrimal duct obstruction” as it is identified in
28 Sanofi’s label; however, as the image demonstrates, obstruction of the lacrimal ducts is not the mechanism
generally causing the epiphora. Rather, most cases involve stenosis, or hardening, of the puncta , the canaliculi
and/or the nasolacrimal ducts

1 *obstruction has been reported. Rare cases of transient visual*
2 *disturbances (flashes, flashing lights, scotomata) typically occurring*
3 *during drug infusion and in association with hypersensitivity*
 reactions have been reported. These were reversible upon
 *discontinuation of the infusion.*²

4 (emphasis added)

5 19. Sanofi’s label informed patients that excessive tearing was a side effect of
6 Taxotere but did not advise patients of the rapid onset, the permanency of stenosis and, therefore,
7 the critical need to seek immediate medical treatment from an appropriately qualified physician.
8 These representations downplay the serious and permanent nature of this side effect by
9 effectively communicating this side effect is transitory. Further, Sanofi represents that these side
10 effects were “reversible upon discontinuation of the infusion.” This affirmatively misrepresents
11 the frequency and severity of this potentially permanent damage to the lacrimal system.

12 20. Sanofi’s labeling information at all times relevant to this lawsuit, and even to date,
13 does not identify the risk of punctal and nasolacrimal duct stenosis as a cause of excessive
14 tearing, the rapid onset at which stenosis can occur, the potentially permanent and irreversible
15 nature of the injury, the need to refer patients to a lacrimal specialist, nor does it identify the
16 condition as preventable with timely intervention during chemotherapy.

17 21. Given the widespread use of Taxotere, it is crucial that the label not only inform
18 oncologists of excessive tearing due to “lacrimal duct obstruction,” but that without prompt
19 treatment, the obstruction can become permanent. Only timely diagnosis and treatment can
20 prevent this from happening.

21 22. Sanofi did not provide such adequate notice to oncologists. To the contrary, the
22 labeling leads oncologists, like Mrs. Estell’s, to believe that excessive tearing is merely a
23 transitory side effect and will end upon the cessation of chemotherapy. This failure to provide
24 notice resulted in thousands of women, like Mrs. Estell, suffering daily from a permanent
25 condition that could have easily been prevented with adequate warning.

26 **IV. Sanofi’s Duty to Monitor and Update Labeling**

27 23. The primary responsibility for timely communicating complete, accurate, and
28

² https://www.accessdata.fda.gov/drugsatfda_docs/label/2006/020449s039lbl.pdf

1 current safety and efficacy information related to Taxotere rests with Sanofi as it has superior,
2 and in many cases exclusive, access to the relevant safety and efficacy information, including
3 post-market complaints and data.

4 24. To fulfill its essential responsibilities, Sanofi must vigilantly monitor all
5 reasonably available information. It must closely evaluate the post-market clinical experience
6 of its drugs and timely provide updated safety and efficacy information to the healthcare
7 community and to consumers.

8 25. When monitoring and reporting adverse events, as required by both federal
9 regulations and state law, time is of the essence. The purpose of monitoring a product's post-
10 market experience is to detect potential safety signals that could indicate to drug sponsors and
11 the medical community that a public safety problem exists.

12 26. If, for example, a manufacturer was to delay reporting post-market information,
13 that delay could mean that researchers, FDA, and the medical community are years behind in
14 identifying a public safety issue associated with the drug.

15 27. In the meantime, more patients are harmed by using the product without knowing,
16 understanding, and accepting its true risks, which is why drug sponsors must not only
17 completely and accurately monitor, investigate and report post-market experiences, but must
18 also report the data in a timely fashion.

19 28. A drug is "misbranded" in violation of the FDCA when its labeling is false and
20 misleading or does not provide adequate directions for use and adequate warnings. See 21
21 U.S.C. §§ 321(n); 331(a), (b), (k); 352(a), (f). A drug's labeling satisfies federal requirements if
22 it gives physicians and pharmacists sufficient information—including indications for use and
23 "any relevant hazards, contraindications, side effects, and precautions"—to allow those
24 professionals "to use the drug safely and for the purposes for which it is intended." 21 C.F.R. §
25 201.100(c)(1).

26 29. As part of their responsibility to monitor post-market clinical experiences with the
27 drug and provide updated safety and efficacy information to the healthcare community and to
28 consumers, each approved NDA applicant "must promptly review all adverse drug experience

1 information obtained or otherwise received by the applicant from any source, foreign or
2 domestic, including information derived from commercial marketing experience, post
3 marketing clinical investigations, post marketing epidemiological/surveillance studies, reports
4 in the scientific literature, and unpublished scientific papers.” 21 C.F.R. § 314.80(b).

5 30. Any report of a “serious and unexpected” drug experience, whether foreign or
6 domestic, must be reported to the FDA within 15 days and must be promptly investigated by the
7 manufacturer. 21 C.F.R. § 314.80(c)(1)(i-ii).

8 31. Most other adverse event reports must be submitted quarterly for three years after
9 the application is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic
10 reports must include a “history of actions taken since the last report because of adverse drug
11 experiences (for example, labeling changes or studies initiated).” 21 C.F.R. § 314.80(c)(2)(ii).

12 32. Federal law requires labeling to be updated as information accumulates: “labeling
13 must be revised to include a warning about a clinically significant hazard as soon as there is
14 reasonable evidence of a causal association with a drug; a causal relationship need not have been
15 definitely established.” 21 C.F.R. § 201.57(c)(6)(i). Thus, for example, drug manufacturers must
16 warn of an adverse effect where there is “some basis to believe there is a causal relationship
17 between the drug and the occurrence of the adverse event.” 21 C.F.R. § 201.57(c)(7).

18 33. Brand-name drug sponsors may seek to change their approved labels by filing a
19 supplemental application to obtain FDA assent. 21 C.F.R. § 314.70.

20 34. One regulation, the “Changes Being Effected” (CBE) regulation, permits a
21 manufacturer to unilaterally change a drug label to reflect “newly acquired information,” subject
22 to later FDA review and approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information
23 includes “new analyses of previously submitted data.” 21 C.F.R. § 314.3(b).

24 35. Thus, for instance, if a drug sponsor determined that a warning was insufficient
25 based on a new analysis of previously existing data, it could submit a CBE and change its
26 labeling.

27 36. The longer a drug sponsor delays updating its labeling to reflect current safety
28 information, the more likely it is that medical professionals will prescribe drugs without advising

1 patients of harmful side effects, and the more likely it is that patients will suffer harmful side
2 effects without the opportunity to evaluate risks for themselves.

3 **V. Sanofi Knew That Taxotere Causes Permanent and Irreversible Lacrimal Injury**

4 37. Since 2002 Sanofi's Taxotere label has advised that "excessive tearing which may
5 be attributable due to lacrimal obstruction has been reported."³ Despite this language, medical
6 literature has continued to accumulate and raise concerns that oncologists are not being properly
7 warned of the severity of this permanent and irreversible side effect – and in response, Sanofi
8 has done nothing to notify oncologists or patients.

9 38. The following studies, published after 2002, highlight concerns of the increased
10 frequency and severity of permanent stenosis in cancer patients taking Taxotere, the increased
11 need for monitoring, and the lack of awareness among oncologists and their patients regarding
12 the true nature of the damage caused:

- 13 a) From the American Society of Ophthalmic Plastic and Reconstructive Surgery:

14 *Better education of oncologists who prescribe*
15 *docetaxel is needed as we continue to encounter new*
*cases of advanced canalicular blockage.*⁴

- 16 b) From the American Cancer Society

17 *Despite the previous publication of several articles*
18 *by our group regarding canalicular stenosis and*
19 *lacrimal obstruction resulting from docetaxel*
20 *therapy, we still frequently encounter advanced*
cases of this condition because of delayed diagnosis.
Thus it appears that oncologists need to become
better educated regarding this side effect.

21 *All patients receiving weekly docetaxel should be*
22 *monitored closely by an ophthalmologist so that the*
23 *timely management of canalicular stenosis can be*
offered.

24 *We recommend silicone intubation [stents] in all*
25 *symptomatic patients who are receiving weekly*

26 ³ https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20449slr022_taxotere_1bl.pdf

27 ⁴ Bitá Esmaeli, et al., *Docetaxel-Induced Histologic Changes in the Lacrimal Sac and Nasal*
28 *Mucosa*, 19 OPTHALMIC PLASTIC AND RECONSTRUCTIVE SURGERY 4, pp. 305-308 (2003)

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docetaxel if they ae to continue receiving the drug.⁵

c) From Pharmacotherapy:

Moreover, epiphora may be an underrecognized adverse effect of docetaxel because excess tearing after chemotherapy administration is not as stringently monitored as life-threatening toxicities . . . This adverse effect warrants evaluation because weekly administration is being used more commonly for the treatment of advanced solid tumors, and epiphora can interfere with the activities and quality of daily life.⁶

d) From the Journal of Clinical Oncology:

Despite substantial literature documenting canalicular stenosis as an adverse effect of docetaxel, the exact incidence of this important adverse effect is unknown. All previous publications were based on retrospective studies at tertiary ophthalmology practices, and only patients who symptoms of epiphora were evaluated. We report the finding of prospective, single-center study designed to determine the incidence and severity of epiphora and its anatomic correlate, canalicular stenosis, in patients receiving docetaxel weekly or every 3 weeks.

Previous retrospective studies and our clinical experience suggested that the incidence of epiphora might be as high as 50% in patients treated with weekly docetaxel and less than 10% in patients who receive docetaxel every 3 weeks.

In this prospective, observational study, epiphora was seen in 64% of patients in the weekly docetaxel group and in 39% of the docetaxel every 3 weeks group.

Patients who experience epiphora associated with docetaxel should be promptly referred to an ophthalmologist familiar with this adverse effect. Frequent [approximately every 4-6 weeks] probing and irrigation in the office and judicious use of topical steroids on a tapering dose can eliminate the need for silicone intubation or other lacrimal procedures in approximately 80% of patients taking docetaxel every 3 weeks and in approximately 50%

⁵ Bita Esmaeli, et al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 *CANCER* 504-7 (2003)

⁶ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 *PHARMACOTHERAPY* 6 (2006).

of patients taking docetaxel weekly.⁷

39. Prominent medical researchers have described this side effect as follows: “canalicular stenosis may be the most important side effect of weekly docetaxel;”⁸ “cancer patients . . . view epiphora as one of the worst side effects because of their inability to read, drive, or wear make-up;”⁹ “visually disabling;”¹⁰ “misleading appearance of emotional tears;”¹¹ “canalicular stenosis can negatively impact the quality of life . . . and should be considered when choosing the chemotherapy regimen;”¹²; “epiphora may be a major disability. It interferes with daily activities and causes emotional disturbances;”¹³; “the potential risk of this complication should be carefully weighed;”¹⁴; “epiphora may be an underrecognized adverse effect;”¹⁵ and “the high incidence of this adverse effect has an impact on several aspects of daily living.”¹⁶

40. Medical literature is clear that: (1) the onset of damage to the lacrimal system can be rapid upon beginning Taxotere, (2) referral to a lacrimal specialist for monitoring is essential,

⁷ Bitá Esmaeli, et al., *Prospective Study of Incidence and Severity of Epiphora and Canalicular Stenosis in Patients With Metastatic Breast Cancer Receiving Docetaxel*, 24 JOURNAL OF CLINICAL ONCOLOGY 22 (2006).

⁸ Bitá Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

⁹ *Id.*

¹⁰ Bitá Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly versus Every-3-Weeks Docetaxel in Patients with Metastatic Breast Cancer*, 109 AM ACAD. OF OPHTHALMOLOGY, 1188 (2002).

¹¹ Bitá Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly Docetaxel: A Potentially Preventable Side Effect*, 13 EUROPEAN SOC'Y. FOR MED. ONCOLOGY, 218 (2001).

¹² Bitá Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

¹³ Medy Tsalic., et al., *Epiphora (Excessive Tearing) and Other Ocular Manifestations Related to Weekly Docetaxel*, 23 MEDICAL ONCOLOGY (2005)

¹⁴ *Id.*

¹⁵ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

¹⁶ Arlene Chan, et al., *Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving Adjuvant Docetaxel-based Chemotherapy*, 31 JOURNAL OF CLINICAL ONCOLOGY, 17 (2013)

1 (3) damage to the lacrimal system can be permanent and irreversible, (4) this side effect is
2 preventable, and (5) oncologists are not aware of the severity of this side effect. Unfortunately
3 this lack of awareness often results in oncologists counseling their patients that their tearing is
4 temporary and will cease after chemotherapy ends.

5 **VI. Taxotere Caused Mrs. Estell's Permanent Punctal and Nasolacrimal Duct Stenosis**

6 41. Mrs. Estell was diagnosed with breast cancer and received weekly infusions of
7 Taxotere, receiving a total of six infusions over the course of three months.

8 42. After completing chemotherapy, Mrs. Estell suffered from itchy, watery eyes and
9 vision problems, which she was told by her treating physicians, was a result of dry eye. In June
10 of 2020, she saw an oculoplastic surgeon who diagnosed her with stenosis of the punctum and
11 nasolacrimal duct. Her doctor attempted to unblock her lacrimal system through probing and
12 irrigation, but was unsuccessful. She continued to use eye drops, but her symptoms persisted.

13 43. Mrs. Estell completed chemotherapy and was excited to be cancer free and rid of
14 all of the side effects she suffered as a result of the cancer treatment. Among these, Mrs. Estell
15 looked forward to no longer suffering from constantly irritated, watering eyes. But as the effects
16 of chemotherapy wore off, her watery eyes remained.

17 44. Mrs. Estell continues to experience persistent tearing and a disruption of her life.
18 As a direct and proximate result of Sanofi's conduct in connection with the design, development,
19 manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling,
20 warning, and sale of Taxotere, Mrs. Estell suffers from permanent epiphora (persistent tearing),
21 due to punctal and nasolacrimal duct stenosis. This condition is a side effect of taking Taxotere.

22 45. As a result of this undisclosed side effect, Mrs. Estell has struggled to return to
23 normalcy, even after surviving cancer, because she continues to suffer from persistent tearing
24 on a daily basis, interfering with her ability to perform basic activities and enjoy life. This
25 permanent change has altered Mrs. Estell's self-image, negatively impacted her relationships,
26 and others' perceptions of her, leading to social isolation and depression even long after fighting
27 cancer .

28 46. Mrs. Estell began her battle with breast cancer with a plan to undergo

1 chemotherapy. After chemotherapy with Taxotere, her eyes unexpectedly became irritated and
2 red and began to tear constantly. Throughout her ordeal, Mrs. Estell remained hopeful that, like
3 other chemotherapy side effects, the epiphora would eventually resolve. To her dismay, it never
4 has.

5 47. Mrs. Estell's tearing is much more than a minor annoyance – it impacts all aspects
6 of her daily life. Prior to developing permanent punctal and nasolacrimal duct stenosis, Mrs.
7 Estell was self-confident and enjoyed engaging with others. Now she lacks the confidence she
8 has been accustomed to and is painfully aware that people see tears streaming down her face
9 and think something is wrong

10 48. Mrs. Estell is anxious about face-to-face interactions with others because she fears
11 people will perceive her as sad and crying. She is unable to keep makeup on her face. She is
12 aware of the concerned looks from well-intentioned friends, colleagues and strangers who
13 perceive her to be emotional and upset.

14 49. Mrs. Estell's injuries could have been prevented had Sanofi simply warned that
15 permanent or irreversible punctal and nasolacrimal duct stenosis is a common but preventable
16 side effect of Taxotere. Mrs. Estell thus seeks recovery for her mental and physical suffering
17 stemming from permanent, but easily preventable, punctal and nasolacrimal duct stenosis.

18 50. Mrs. Estell files this lawsuit within the applicable statute of limitations.

19 **VII. Tolling of the Statute of Limitations**

20 51. Alternatively, Mrs. Estell files this lawsuit within the applicable statute of
21 limitations period of first suspecting that Sanofi's wrongful conduct caused the appreciable harm
22 she sustained. Due to Sanofi's fraudulent concealment of this known side effect, Mrs. Estell
23 could not, by the exercise of reasonable diligence, have discovered that Sanofi wrongfully
24 caused her injuries as she was unaware of the severity of her injury. Specifically, Mrs. Estell did
25 not suspect, nor did she have reason to suspect, that her lacrimal system had been permanently
26 damaged, or suspect the tortious nature of the conduct causing her injuries until a date before
27 filing this action that is less than the applicable limitations period for filing suit.

28 52. Mrs. Estell was advised that tearing was a common side effect of Taxotere

1 chemotherapy that, like most other side effects of chemotherapy, would resolve upon cessation
2 of treatment. However after completion of chemotherapy, Mrs. Estell's tearing persisted, so she
3 sought treatment from an optometrist who diagnosed her with dry eye and gave her eye drops
4 to treat her symptoms. She returned again to her optometrist a year later and again was advised
5 that her excessive tearing was due to dry eyes. It was only in April of 2020 that Mrs. Estell
6 became aware of the facts giving rise to this cause of action when she saw a law firm
7 advertisement explaining that Taxotere was known to cause permanent damage to the lacrimal
8 system. It was then that she discovered that the manufacturers of Taxotere also knew that this
9 permanent damage could easily be prevented with a simple warning to physicians and their
10 patients, yet they inexplicably failed to provide this important information.

11 53. After speaking with the law firm of Hotze Runkle, Mrs. Estell was examined by a
12 lacrimal specialist who conducted a probing and irrigation procedure and was subsequently
13 diagnosed with punctal and nasolacrimal duct stenosis. Due to the severity of her damage, the
14 oculoplastic surgeon recommended that Mrs. Estell be scheduled for a more invasive procedure
15 (either a dacryocystorhinostomy "DCR" or a conjunctivodacryocystorhinostomy "CDCR").
16 Because of the pain she experienced during the probing and irrigation procedure, Mrs. Estell has
17 been anxious and hesitant to follow through with either of these surgeries.

18 54. Mrs. Estell was prevented from discovering the cause of her injury at an earlier
19 date because Sanofi: (1) misrepresented to the public, the FDA, and the medical profession that
20 Taxotere was free from permanent side effects; (2) failed to disclose to the public, the FDA, and
21 the medical profession its knowledge of the risk of permanent but reversible side effects; (3)
22 failed to disclose to the public, the FDA, and the medical profession its knowledge that these
23 side effects were preventable with early intervention during chemotherapy; (4) fraudulently
24 concealed facts and information that could have led Mrs. Estell to discover Sanofi's liability;
25 and (5) still has not disclosed to the public, the FDA, and the medical profession that Taxotere
26 can cause permanent punctal, canalicular and nasolacrimal duct stenosis which can be prevented
27 with early intervention during chemotherapy.

28

COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

1 55. Mrs. Estell incorporates by reference the above paragraphs as if set forth herein.

2 56. At all relevant times, Sanofi was in the business of designing, researching,
3 manufacturing, testing, promoting, marketing, selling, and/or distributing pharmaceutical
4 products, including the Taxotere used by Mrs. Estell.

5 57. The Taxotere designed, formulated, produced, manufactured, sold, marketed,
6 distributed, supplied and/or placed into the stream of commerce by Sanofi failed to provide
7 adequate warnings to users and their healthcare providers, including Mrs. Estell and her
8 healthcare providers, of the risk of side effects associated with the use of Taxotere, particularly
9 the risk of developing disfiguring, permanent punctal and nasolacrimal duct stenosis, or the
10 measures that could have been taken to prevent it.

11 58. The Taxotere designed, formulated, produced, manufactured, sold, marketed,
12 distributed, supplied and/or placed into the stream of commerce by Sanofi and ultimately
13 administered to Mrs. Estell lacked such warnings when it left Sanofi’s control.

14 59. The risks of developing disfiguring, permanent punctal and nasolacrimal duct
15 stenosis were known to or reasonably knowable by Sanofi at the time the Taxotere left Sanofi’s
16 control because of “newly acquired information” available to Sanofi after the 2002 label change.

17 60. A reasonably prudent company in the same or similar circumstances would have
18 provided an enhanced warning that communicated the dangers and safe use of Taxotere.

19 61. Any warnings actually provided by Sanofi did not sufficiently and/or accurately
20 reflect the symptoms, type, scope, severity, duration, and/or preventable nature of these side
21 effects, particularly the risks of developing disfiguring, permanent punctal and nasolacrimal duct
22 stenosis or how it could have been prevented during administration of the chemotherapy.

23 62. Without adequate warning of these side effects, Taxotere is not reasonably fit,
24 suitable, or safe for its reasonably anticipated or intended purposes.

25 63. Mrs. Estell was a reasonably foreseeable user of Taxotere who used the drug in a
26 reasonably anticipated manner.

27 64. Mrs. Estell and her physicians would have taken preventative measures during the
28

1 course of her chemotherapy to prevent punctal and nasolacrimal duct stenosis had she (and her
2 physicians) been provided an adequate warning by Sanofi of the risk of these side effects.

3 65. As a direct and proximate result of Sanofi's failure to warn of the potentially
4 severe adverse effects of Taxotere, Mrs. Estell suffered and continues to suffer serious and
5 dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and
6 economic and non-economic damages, harms, and losses, including, but not limited to: past and
7 future medical expenses; past and future loss of earnings; past and future loss and impairment
8 of earning capacity; permanent disfigurement, including permanent punctal and nasolacrimal
9 duct stenosis; mental anguish; severe and debilitating emotional distress; increased risk of future
10 harm; past, present, and future physical and mental pain, suffering, and discomfort; and past,
11 present, and future loss and impairment of the quality and enjoyment of life.

12 WHEREFORE, Plaintiff Cathy Estell respectfully requests judgment in her favor and
13 against Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any
14 other and further relief this Court deems just and proper.

15 **COUNT II - NEGLIGENCE**

16 66. Mrs. Estell incorporates by reference the above paragraphs as if set forth herein.

17 67. Sanofi had a duty to exercise reasonable care in the design, research, formulation,
18 manufacture, production, marketing, testing, supply, promotion, packaging, sale, and/or
19 distribution of Taxotere, including a duty to assure that the product would not cause users to
20 suffer unreasonable, disfiguring, and dangerous side effects.

21 68. Sanofi breached these duties when it put Taxotere into interstate commerce,
22 unreasonably and without adequate and/or proper warning to Mrs. Estell and her healthcare
23 providers, a product that Sanofi knew or should have known created a high risk of unreasonable,
24 disfiguring, and dangerous side effects.

25 69. The negligence of Sanofi, its agents, servants, and/or employees, included but was
26 not limited to, the following acts and/or omissions:

27 a. Manufacturing, producing, promoting, formulating, creating, and/or
28 designing Taxotere without thoroughly, adequately, and/or sufficiently testing it—including

1 pre- clinical and clinical testing and post-marketing surveillance—for safety and fitness for use
2 and/or its dangers and risks;

3 b. Marketing Taxotere to Mrs. Estell, her healthcare providers, the public,
4 and the medical and healthcare professions without adequately and correctly warning and/or
5 disclosing the existence, severity, and duration of known or knowable side effects, including
6 permanent punctal and nasolacrimal duct stenosis;

7 c. Marketing Taxotere to Mrs. Estell, her healthcare providers, the public,
8 and the medical and healthcare professions without providing adequate instructions regarding
9 safety precautions to be observed by users, handlers, and persons who would reasonably and
10 foreseeably come into contact with, and more particularly, use, Taxotere;

11 d. Advertising and recommending the use of Taxotere without sufficient
12 knowledge of its safety profile;

13 e. Designing, manufacturing, producing, and/or assembling Taxotere in a
14 manner that was dangerous to its users;

15 f. Concealing information from Mrs. Estell, her healthcare providers, the
16 public, other medical and healthcare professionals, and the FDA that Taxotere was unsafe,
17 dangerous, and/or non-conforming with FDA regulations;

18 g. Concealing from and/or misrepresenting information to Mrs. Estell, her
19 healthcare providers, other medical and healthcare professionals, and/or the FDA concerning
20 the existence and severity of risks and dangers of Taxotere; and

21 h. Encouraging the sale of Taxotere, either directly or indirectly, orally or in
22 writing, to Mrs. Estell and her healthcare providers without warning about the need for more
23 comprehensive and regular medical monitoring than usual to ensure early discovery of
24 potentially serious side effects such as punctal and nasolacrimal duct stenosis.

25 70. Despite the fact that Sanofi knew or should have known that Taxotere caused
26 unreasonably dangerous side effects, Sanofi continues to market, manufacture, distribute, and/or
27 sell Taxotere to consumers.

28 71. Mrs. Estell and her healthcare providers were therefore forced to rely on safety

1 information that did not accurately represent the risks and benefits associated with the use of
2 Taxotere and measures that could have been taken to prevent severe and permanent
3 disfigurement from the use of Taxotere.

4 72. Sanofi knew or should have known that consumers such as Mrs. Estell would use
5 its product and would foreseeably suffer injury as a result of Sanofi's failure to exercise
6 reasonable care, as set forth above.

7 73. Sanofi's negligence was a proximate cause of Mrs. Estell's injuries, harms,
8 damages, and losses, in connection with the use of Taxotere, including but not limited to: past
9 and future medical expenses; past and future loss of earnings; past and future loss and
10 impairment of earning capacity; permanent disfigurement including permanent and irreversible
11 punctal and nasolacrimal duct stenosis; mental anguish; severe and debilitating emotional
12 distress; increased risk of future harm; past, present, and future physical and mental pain,
13 suffering, and discomfort; and past, present, and future loss and impairment of the quality and
14 enjoyment of life.

15 WHEREFORE, Cathy Estell respectfully requests judgment in her favor and against
16 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and
17 further relief this Court deems just and proper.

18 **COUNT III – NEGLIGENT MISREPRESENTATION**

19 74. Mrs. Estell incorporates by reference the above paragraphs as if set forth herein.

20 75. Sanofi had a duty to represent to Mrs. Estell, Mrs. Estell's healthcare providers,
21 the healthcare community, and the public in general that Taxotere had been tested and found to
22 be safe and effective for the treatment of various forms of cancer.

23 76. When warning of safety and risks of Taxotere, Sanofi negligently represented to
24 Mrs. Estell, Mrs. Estell's healthcare providers, the healthcare community, and the public in
25 general that Taxotere had been tested and was found to be safe and/or effective for its indicated
26 use.

27 77. Sanofi concealed its knowledge of Taxotere defects from Mrs. Estell, Mrs. Estell's
28 healthcare providers, and the public in general and/or the healthcare community specifically.

1 78. Sanofi concealed this information with the intent of defrauding and deceiving Mrs.
2 Estell, Mrs. Estells' healthcare providers, the public in general, and the healthcare community
3 in particular, and were made with the intent of inducing Mrs. Estell, Mrs. Estell's healthcare
4 providers, the public in general, and the healthcare community in particular, to recommend,
5 dispense, and/or purchase Taxotere.

6 79. Sanofi failed to exercise ordinary and reasonable care in its representations of
7 Taxotere in its sale, testing, quality assurance, quality control, and/or distribution into interstate
8 commerce, and Sanofi negligently misrepresented Taxotere's high risks of unreasonable,
9 dangerous side effects. These side effects were unreasonable because they could have been
10 entirely prevented with adequate warning.

11 80. Sanofi breached its duty in misrepresenting Taxotere's serious side effects to Mrs.
12 Estell, Mrs. Estell's healthcare providers, the healthcare community, the FDA, and the public in
13 general.

14 81. Mrs. Estell and Mrs. Estell's healthcare providers reasonably relied on Sanofi to
15 fulfill its obligations to disclose all facts within its knowledge regarding the serious side effects
16 of Taxotere and the ability to prevent those side effects with appropriate precautionary measures.

17 82. As a direct and proximate result of the foregoing acts and omissions, Sanofi
18 caused Mrs. Estell to suffer serious and dangerous side effects, severe and personal injuries that
19 are permanent and lasting in nature, and economic and non-economic damages, harms, and
20 losses, including, but not limited to: past and future medical expenses; past and future loss of
21 earnings; past and future loss and impairment of earning capacity; permanent disfigurement,
22 including permanent punctal and nasolacrimal duct stenosis; mental anguish; severe and
23 debilitating emotional distress; increased risk of future harm; past, present, and future physical
24 and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of
25 the quality and enjoyment of life.

26 WHEREFORE, Cathy Estell respectfully requests that judgment in her favor and against
27 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and
28 further relief this Court deems just and proper.

COUNT IV – FRAUDULENT MISREPRESENTATION

83. Mrs. Estell incorporates by reference the above paragraphs as if set forth herein.

84. Sanofi represented to Mrs. Estell, Mrs. Estell’s healthcare providers, the healthcare community, and the public in general that “excessive tearing which may be attributable to lacrimal duct obstruction has been reported” and that excessive is a common side effect. These statements failed to accurately inform oncologists and patients of (1) the rapid onset at which stenosis can occur, (2) the potentially permanent and irreversible nature of the injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the condition is highly preventable with timely intervention during chemotherapy.

85. Despite having knowledge of these enhanced side effects, Sanofi fraudulently omitted from these representations information that Taxotere could and did cause these serious side effects, including permanent and irreversible punctal and nasolacrimal duct stenosis.

86. These representations were material and false.

87. Sanofi made these representations and omissions:

- a. with knowledge or belief of their falsity, and/or in the case of omissions, with knowledge or belief of falsity of the resulting statements;
- b. positively and recklessly without knowledge of their truth or falsity;
- c. with knowledge that they were made without any basis; and/or
- d. without confidence in the accuracy of the representations or statements resulting from the omissions.

88. Sanofi made these false representations with the intention or expectation that Mrs. Estell, Mrs. Estell’s healthcare providers, the public in general, and the healthcare community in particular, would recommend, dispense, and/or purchase Taxotere, all of which evidenced a callous, reckless, willful, wanton, and depraved indifference to the health, safety, and welfare of Mrs. Estell.

89. At the time Sanofi made the aforesaid representations, and, at the time Mrs. Estell used Taxotere, Mrs. Estell and Mrs. Estell’s healthcare providers were unaware of the falsity of Sanofi’s representations, statements and/or implications and justifiably and reasonably relied on

1 Sanofi's representations, statements, and implications, believing them to be true.

2 90. In reliance on Sanofi's representations, Mrs. Estell and her healthcare providers
3 were induced to and did use and prescribe Taxotere, which caused Mrs. Estell to suffer serious
4 and dangerous side effects, severe and personal injuries that are permanent and lasting in nature,
5 and economic and non-economic damages, harms, and losses, including, but not limited to: past
6 and future medical expenses; past and future loss of earnings; past and future loss and
7 impairment of earning capacity; permanent disfigurement, including permanent punctal and
8 nasolacrimal duct stenosis; mental anguish; severe and debilitating emotional distress; increased
9 risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort;
10 and past, present, and future loss and impairment of the quality and enjoyment of life.

11 WHEREFORE, Cathy Estell respectfully requests judgment in her favor and against
12 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and
13 further relief this Court deems just and proper.

14 **COUNT V – FRAUDULENT CONCEALMENT**

15 91. Mrs. Estell incorporates by reference the above paragraphs as if set forth herein.

16 92. At all times during the course of dealing between Sanofi and Mrs. Estell and Mrs.
17 Estell's healthcare providers, Sanofi misrepresented the design characteristic and safety of
18 Taxotere for their intended use.

19 93. Sanofi knew or was reckless in not knowing that its representations were false due
20 to Sanofi's access to ongoing studies and reports that disclosed serious, enhanced side effects of
21 Taxotere to the lacrimal system. 93. In representations made to Mrs. Estell and Mrs. Estell's
22 healthcare providers, Sanofi fraudulently concealed and intentionally omitted the following
23 material information: (1) the rapid onset at which stenosis can occur, (2) the potentially
24 permanent and irreversible nature of the injury, (3) the need to immediately refer patients to a
25 lacrimal specialist and (4) that the condition is highly preventable with timely intervention
26 during chemotherapy.

27 94. Sanofi had a duty to disclose to Mrs. Estell and Mrs. Estell's healthcare providers
28 the defective nature of Taxotere, including, but not limited to, the heightened risks of

1 disfiguring, permanent punctal and nasolacrimal duct stenosis.

2 95. Sanofi had a duty to disclose to Mrs. Estell and Mrs. Estell’s healthcare providers
3 that the disfiguring, permanent punctal and nasolacrimal duct stenosis caused by the use of
4 Taxotere could have been prevented by early identification and treatment of epiphora during
5 chemotherapy.

6 96. Sanofi had sole access to material facts concerning the defective nature of
7 Taxotere and its propensity to cause serious and dangerous side effects, and therefore cause
8 damage to persons who used the drugs at issue, including Mrs. Estell.

9 97. Sanofi’s concealment and omissions of material fact concerning the safety of
10 Taxotere were made purposefully, willfully, wantonly, and/or recklessly to mislead Mrs. Estell
11 and Mrs. Estell’s healthcare providers into reliance on the continued use of the drugs and to
12 cause them to purchase, prescribe, and/or dispense Taxotere and/or use it.

13 98. Sanofi knew that Mrs. Estell and her healthcare providers had no way to determine
14 the truth behind its concealment and omissions, including the material omissions of fact
15 surrounding Taxotere set forth herein.

16 99. Mrs. Estell and Mrs. Estell’s healthcare providers reasonably relied on
17 information disclosed by Sanofi that negligently, fraudulently, and/or purposefully did not
18 include facts that were concealed and/or omitted by Sanofi.

19 100. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Estell to suffer
20 serious and dangerous side effects, severe and personal injuries that are permanent and lasting
21 in nature, and economic and non-economic damages, harms, and losses, including, but not
22 limited to: past and future medical expenses; past and future loss of earnings; past and future
23 loss and impairment of earning capacity; permanent disfigurement, including permanent punctal
24 and nasolacrimal duct stenosis; mental anguish; severe and debilitating emotional distress;
25 increased risk of future harm; past, present, and future physical and mental pain, suffering, and
26 discomfort; and past, present, and future loss and impairment of the quality and enjoyment of
27 life.

28 WHEREFORE, Cathy Estell respectfully requests judgment in her favor and against

1 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and
2 further relief this Court deems just and proper.

3 **JURY DEMAND**

4 Plaintiff has requested a trial by jury pursuant to rule 38 of the Federal Rules of Civil
5 Procedure.

6 Dated: July 28, 2021

FITZPATRICK & SWANSTON
RMP LAW GROUP LLC
HOTZE RUNKLE PLLC

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10 By: /s/ Richard M. Paul
11 B. James Fitzpatrick
12 Richard M. Paul (*admitted pro hac vice*)
13 Patrick O. Hotze (*admitted pro hac vice*)
14 Attorneys for Plaintiff,
15 CATHY ESTELL
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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA (Eastern Division - Riverside)
CIVIL DOCKET FOR CASE #: 5:21-cv-00718-JWH-KK

Jeannie Hamilton-Moews v. Sanofi US Services Inc., et al
Assigned to: Judge John W. Holcomb
Referred to: Magistrate Judge Kenly Kiya Kato
Demand: \$75,000
Related Case: 2:21-cv-08964-JWH-KK
Cause: 28:1332 Diversity-Personal Injury

Date Filed: 04/21/2021
Jury Demand: Plaintiff
Nature of Suit: 367 Personal Injury: Health Care/Pharmaceutical
Personal Injury Product Liability
Jurisdiction: Diversity

Plaintiff

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V.

Defendant

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ATTORNEY TO BE NOTICED

Defendant

Sanofi-Aventis, U.S. LLC

represented by Amir M Nassihi
(See above for address)
ATTORNEY TO BE NOTICED

Table with 3 columns: Date Filed, #, Docket Text. Row 1: 04/21/2021, 1, COMPLAINT Receipt No: ACACDC-31160585 - Fee: \$402, filed by Plaintiff Jeannie Hamilton-Moews. (Attorney Bernard James Fitzpatrick added to party Jeannie Hamilton-Moews(pty:pla))(Fitzpatrick, Bernard) (Entered: 04/21/2021). Row 2: 04/21/2021, 2, CIVIL COVER SHEET filed by Plaintiff Jeannie Hamilton-Moews. (Fitzpatrick, Bernard) (Entered: 04/21/2021).

04/21/2021	3	Request for Clerk to Issue Summons on Complaint (Attorney Civil Case Opening) 1 filed by Plaintiff Jeannie Hamilton-Moews. (Fitzpatrick, Bernard) (Entered: 04/21/2021)
04/22/2021	4	NOTICE OF ASSIGNMENT to District Judge John W. Holcomb and Magistrate Judge Kenly Kiya Kato. (esa) (Entered: 04/22/2021)
04/22/2021	5	NOTICE TO PARTIES OF COURT-DIRECTED ADR PROGRAM filed. (esa) (Entered: 04/22/2021)
04/22/2021	6	21 DAY Summons issued re Complaint 1 as to defendants Sanofi US Services, Inc., Sanofi-Aventis, U.S. LLC. (esa) (Entered: 04/22/2021)
04/22/2021	7	NOTICE OF DEFICIENCIES in Attorney Case Opening. The following error(s) was found: No Notice of Interested Parties has been filed. A Notice of Interested Parties must be filed with every partys first appearance. See Local Rule 7.1-1. Counsel must file a Notice of Interested Parties immediately. Failure to do so may be addressed by judicial action, including sanctions. See Local Rule 83-7. (esa) (Entered: 04/22/2021)
04/22/2021	8	NOTICE OF PRO HAC VICE APPLICATION DUE for Non-Resident Attorney Richard M Paul III. A document recently filed in this case lists you as an out-of-state attorney of record. However, the Court has not been able to locate any record that you are admitted to the Bar of this Court, and you have not filed an application to appear Pro Hac Vice in this case. Accordingly, within 5 business days of the date of this notice, you must either (1) have your local counsel file an application to appear Pro Hac Vice (Form G-64) and pay the applicable fee, or (2) complete the next section of this form and return it to the court at cacd_attyadm@cacd.uscourts.gov . You have been removed as counsel of record from the docket in this case, and you will not be added back to the docket until your Pro Hac Vice status has been resolved. (esa) (Entered: 04/22/2021)
04/22/2021	9	NOTICE OF PRO HAC VICE APPLICATION DUE for Non-Resident Attorney Patrick O Hotze. A document recently filed in this case lists you as an out-of-state attorney of record. However, the Court has not been able to locate any record that you are admitted to the Bar of this Court, and you have not filed an application to appear Pro Hac Vice in this case. Accordingly, within 5 business days of the date of this notice, you must either (1) have your local counsel file an application to appear Pro Hac Vice (Form G-64) and pay the applicable fee, or (2) complete the next section of this form and return it to the court at cacd_attyadm@cacd.uscourts.gov . You have been removed as counsel of record from the docket in this case, and you will not be added back to the docket until your Pro Hac Vice status has been resolved. (esa) (Entered: 04/22/2021)
04/23/2021	10	APPLICATION of Non-Resident Attorney Patrick O. Hotze to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-31172489) filed by Plaintiff Jeannie Hamilton-Moews. (Attachments: # 1 Proposed Order) (Fitzpatrick, Bernard) (Entered: 04/23/2021)
04/23/2021	11	NOTICE of Interested Parties filed by Plaintiff Jeannie Hamilton-Moews, (Fitzpatrick, Bernard) (Entered: 04/23/2021)
04/23/2021	12	NOTICE of Deficiency in Electronically Filed Pro Hac Vice Application RE: APPLICATION of Non-Resident Attorney Patrick O. Hotze to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-31172489) 10 . The following error(s) was/were found: Local Rule 83-2.1.3.4 Local counsel does not maintain an office within the District. (lt) (Entered: 04/23/2021)
04/26/2021	13	STANDING ORDER by Judge John W. Holcomb. (iva) (Entered: 04/26/2021)
04/28/2021	14	ORDER by Judge John W. Holcomb: Denying Application of Non-Resident Attorney Patrick Hotze to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews. IT IS HEREBY FURTHER ORDERED that the pro hac vice application fee, if paid, be refunded 10 . (iv) (Entered: 04/28/2021)
04/29/2021	15	APPLICATION of Non-Resident Attorney Richard M. Paul III to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-31210899) filed by Plaintiff Jeannie Hamilton-Moews. (Attachments: # 1 Proposed Order) (Fitzpatrick, Bernard) (Entered: 04/29/2021)
04/30/2021	16	NOTICE of Deficiency in Electronically Filed Pro Hac Vice Application RE: APPLICATION of Non-Resident Attorney Richard M. Paul III to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-31210899) 15 . The following error(s) was/were found: Local Rule 83-2.1.3.4 Local counsel does not maintain an office within the District. (sbou) (Entered: 04/30/2021)
05/03/2021	17	ORDER by Judge John W. Holcomb: denying 15 Non-Resident Attorney Richard M Paul, III APPLICATION to Appear Pro Hac Vice on behalf of Jeannie Hamilton-Moew. (lom) (Entered: 05/03/2021)
05/07/2021	18	WAIVER OF SERVICE Returned Executed filed by Plaintiff Jeannie Hamilton-Moews. upon All Defendants. Waiver of Service signed by Torrey Michelle Peterson, Esq.. (Fitzpatrick, Bernard) (Entered: 05/07/2021)
06/28/2021	19	NOTICE of Appearance filed by attorney Amir M Nassihi on behalf of Defendants Sanofi US Services, Inc., Sanofi-Aventis, U.S. LLC (Attorney Amir M Nassihi added to party Sanofi US Services, Inc.(pty:dft), Attorney Amir M Nassihi added to party Sanofi-Aventis, U.S. LLC(pty:dft))(Nassihi, Amir) (Entered: 06/28/2021)
06/28/2021	20	STIPULATION Extending Time to Answer the complaint as to Sanofi-Aventis, U.S. LLC answer now due 7/29/2021; Sanofi US Services, Inc. answer now due 7/29/2021, re Complaint (Attorney Civil Case Opening) 1 filed by Defendants Sanofi-Aventis, U.S. LLC; Sanofi US Services, Inc..(Nassihi, Amir) (Entered: 06/28/2021)
07/28/2021	21	STIPULATION for Leave to File First Amended Complaint filed by Plaintiff Jeannie Hamilton-Moews. (Attachments: # 1 Proposed Order) (Fitzpatrick, Bernard) (Entered: 07/28/2021)
08/02/2021	22	ORDER FOR PLAINTIFF TO FILE FIRST AMENDED COMPLAINT 21 by Judge John W. Holcomb that Plaintiff Jeannie Hamilton-Moews shall have leave to file her First Amended Complaint in this action, per the stipulation of the parties and the written consent of Defendants Sanofi US Services, Inc., and Sanofi-Aventis US LLC. Plaintiff's deadline to file her amended pleading is 8/16/2021. (jp) (Entered: 08/02/2021)
08/03/2021	23	First AMENDED COMPLAINT All Defendants amending Complaint (Attorney Civil Case Opening) 1 , filed by Plaintiff Jeannie Hamilton-Moews(Fitzpatrick, Bernard) (Entered: 08/03/2021)
08/03/2021	24	NOTICE of Change of Attorney Business or Contact Information: for attorney Bernard James Fitzpatrick counsel for Plaintiff Jeannie Hamilton-Moews. Changing Address to 515 S. FIGUEROA STREET, SUITE 1250, LOS ANGELES, CA 90071. Changing Fax number to (213) 488-6554. Filed by Plaintiff Jeannie Hamilton-Moews. (Fitzpatrick, Bernard) (Entered: 08/03/2021)
08/04/2021	25	NOTICE TO FILER OF DEFICIENCIES in Electronically Filed Documents RE: Notice of Change of Attorney Business or Contact Information (G-06), 24 . The following error(s) was/were found: Information missing from Section 1 of Notice of Change of Attorney Business or Contact Information G6. In response to this notice, the Court may: (1) order an amended or correct document to be filed; (2) order the document stricken; or (3) take other action as the Court deems appropriate. You need not take any action in response to this notice unless and until the Court directs you to do so. (ak) (Entered: 08/04/2021)

08/17/2021	26	NOTICE OF MOTION AND MOTION to Dismiss Plaintiff's First Amended Complaint filed by Defendants Sanofi US Services, Inc., Sanofi-Aventis, U.S. LLC. Motion set for hearing on 10/22/2021 at 09:00 AM before Judge John W. Holcomb. (Attachments: # 1 Proposed Order) (Nassih, Amir) (Entered: 08/17/2021)
08/17/2021	27	REQUEST FOR JUDICIAL NOTICE re NOTICE OF MOTION AND MOTION to Dismiss Plaintiff's First Amended Complaint 26 filed by Defendants Sanofi US Services, Inc., Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J, # 11 Exhibit K)(Nassih, Amir) (Entered: 08/17/2021)
08/17/2021	28	NOTICE of Interested Parties filed by Defendants Sanofi US Services, Inc., Sanofi-Aventis, U.S. LLC, identifying Sanofi. (Nassih, Amir) (Entered: 08/17/2021)
09/10/2021	29	Second APPLICATION of Non-Resident Attorney Patrick O. Hotze to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-31958701) filed by Plaintiff Jeannie Hamilton-Moews. (Attachments: # 1 Proposed Order) (Fitzpatrick, Bernard) (Entered: 09/10/2021)
09/10/2021	30	NOTICE of Deficiency in Electronically Filed Pro Hac Vice Application RE: Second APPLICATION of Non-Resident Attorney Patrick O. Hotze to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-31958701) 29 . The following error(s) was/were found: Local Rule 5-4.3.4 Application not hand-signed. Other error(s) with document(s): The attorney seeking to appear pro hac vice must complete Section I of this Application, personally sign, in ink, the certification in Section II, and have the designated Local Counsel sign in Section III. ELECTRONIC SIGNATURES ARE NOT ACCEPTED. See Instructions for Applicants (1) (G-64). (lt) (Entered: 09/10/2021)
09/13/2021	31	ORDER by Judge John W. Holcomb: denying 29 Non-Resident Attorney Hotze, Patrick O. APPLICATION to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews. IT IS HEREBY FURTHER ORDERED that the pro hac vice application fee, if paid, be refunded. Termining Attorney Patrick O. Hotze. (yl) (Entered: 09/13/2021)
09/14/2021	32	Third APPLICATION of Non-Resident Attorney Patrick O. Hotze to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-31977494) filed by Plaintiff Jeannie Hamilton-Moews. (Attachments: # 1 Proposed Order) (Fitzpatrick, Bernard) (Entered: 09/14/2021)
09/14/2021	33	Second APPLICATION of Non-Resident Attorney Richard M. Paul to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-31983274) filed by Plaintiff Jeannie Hamilton-Moews. (Attachments: # 1 Proposed Order) (Fitzpatrick, Bernard) (Entered: 09/14/2021)
09/17/2021	34	ORDER by Judge John W. Holcomb: granting 32 Non-Resident Attorney Patrick O. Hotze APPLICATION to Appear Pro Hac Vice on behalf of Jeannie Hamilton-Moews, designating B James Fitzpatrick as local counsel. (lom) (Entered: 09/20/2021)
09/21/2021	35	ORDER by Judge John W. Holcomb: granting 33 Non-Resident Attorney Richard M. Paul APPLICATION to Appear Pro Hac Vice on behalf of Jeannie Hamilton-Moews, designating B James Fitzpatrick as local counsel. (lom) (Entered: 09/21/2021)
09/24/2021	36	OPPOSITION to NOTICE OF MOTION AND MOTION to Dismiss Plaintiff's First Amended Complaint 26 filed by Plaintiff Jeannie Hamilton-Moews. (Attachments: # 1 Exhibit)(Fitzpatrick, Bernard) (Entered: 09/24/2021)
09/24/2021	37	REQUEST FOR JUDICIAL NOTICE re NOTICE OF MOTION AND MOTION to Dismiss Plaintiff's First Amended Complaint 26 filed by Plaintiff Jeannie Hamilton-Moews. (Fitzpatrick, Bernard) (Entered: 09/24/2021)
09/24/2021	38	[PROPOSED] ORDER RE PLAINTIFF'S REQUEST FOR JUDICIAL NOTICE re NOTICE OF MOTION AND MOTION to Dismiss Plaintiff's First Amended Complaint 26 filed by Plaintiff Jeannie Hamilton-Moews. (Fitzpatrick, Bernard) (Entered: 09/24/2021)
10/08/2021	39	REPLY In Support Of NOTICE OF MOTION AND MOTION to Dismiss Plaintiff's First Amended Complaint 26 filed by Defendants Sanofi US Services, Inc., Sanofi-Aventis, U.S. LLC. (Nassih, Amir) (Entered: 10/08/2021)
10/15/2021	40	STIPULATION to Continue Hearing Date for Sanofi's Motion to Dismiss (Dkt. 26) from October 22, 2021 to December 10, 2021 Re: NOTICE OF MOTION AND MOTION to Dismiss Plaintiff's First Amended Complaint 26 filed by Defendants Sanofi US Services, Inc., Sanofi-Aventis, U.S. LLC. (Attachments: # 1 Proposed Order)(Nassih, Amir) (Entered: 10/15/2021)
10/18/2021	41	ORDER FOR MODIFICATION OF MOTION TO DISMISS HEARING DEADLINE by Judge John W. Holcomb 40 Defendants Sanofi US Services, Inc. f/k/a Sanofi-Aventis U.S., Inc. and Sanofi-Aventis U.S., LLCs and Plaintiff Jeannie Hamilton-Moews's Motion to Dismiss oral argument hearing date is CONTINUED from October 22,2021, to December 10, 2021, at 9:00 a.m. IT IS SO ORDERED. (yl) (Entered: 10/18/2021)
10/20/2021	42	NOTICE of Change of firm name and address by Richard M Paul, III attorney for Plaintiff Jeannie Hamilton-Moews. Changing firm name to Paul LLP and address to 601 Walnut Street, Suite 300, Kansas City, MO 64106. Filed by Plaintiff Jeannie Hamilton-Moews. (Paul, Richard) (Entered: 10/20/2021)
11/23/2021	43	APPLICATION of Non-Resident Attorney Karen C. Shanks to Appear Pro Hac Vice on behalf of Plaintiff Jeannie Hamilton-Moews (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-32378399) filed by Plaintiff Jeannie Hamilton-Moews. (Attachments: # 1 Proposed Order) (Fitzpatrick, Bernard) (Entered: 11/23/2021)

PACER Service Center			
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12/01/2021 13:47:41			
PACER Login:	RickPaul	Client Code:	Tax Eyes
Description:	Docket Report	Search Criteria:	5:21-cv-00718-JWH-KK End date: 12/1/2021
Billable Pages:	6	Cost:	0.60

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14 rick@rmplawgroup.com

15 Patrick O. Hotze (*pro hac vice* forthcoming)
16 Karen Cannon Shanks (*pro hac*
17 *viceforthcoming*)
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26 *Counsel for Plaintiff*

27 **UNITED STATES DISTRICT COURT FOR THE**
28 **CENTRAL DISTRICT OF CALIFORNIA**

JEANNIE HAMILTON-MOEWS,

Plaintiff,

v.

SANOFI US SERVICES, INC. f/k/a
SANOFI-AVENTIS U.S., INC., and
SANOFI-AVENTIS U.S., LLC,

Defendants.

Case No. 5:21-cv-00718

FIRST AMENDED COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Jeannie Hamilton-Moews, for her First Amended Complaint against defendants SANOFI US SERVICES, INC., f/k/a SANOFI-AVENTIS U.S., INC. and SANOFI-AVENTIS U.S., LLC

1 (collectively “Sanofi”), alleges:

2 **INTRODUCTION**

3 1. Sanofi manufactures and sells a chemotherapy drug named Taxotere (generic name docetaxel),
4 which is administered to many who suffer primarily from breast cancer. While it is one of many drugs
5 effective at treating breast cancer, Sanofi has known for years that the drug carries a significant risk of
6 causing permanent and irreversible damage to the lacrimal system, including punctal stenosis.

7 2. A simple preventative procedure at the onset of chemotherapy-induced tearing, involving the
8 temporary placement of silicone stents, allows a patient to continue her Taxotere regimen while removing
9 the likelihood of permanent and irreversible damage to the lacrimal system. Although Sanofi warns that
10 “excessive tearing which may be attributable to lacrimal duct obstruction has been reported”, Sanofi
11 failed to warn patients and oncologists of the risk that the damage can occur quickly and can be
12 **permanent and irreversible**. Further, Sanofi failed to report the severity and frequency of this risk to
13 the Food and Drug Administration (“FDA”). Worse, Sanofi misled patients and oncologists about the
14 severity and frequency of this devastating side effect even though this condition can be entirely
15 preventable with early intervention and treatment during chemotherapy. As a result, Mrs. Hamilton-
16 Moews suffers from permanent injuries because she used Taxotere.

17 3. Plaintiff is grateful for the chemotherapy that helped to save her life; however, that gratitude is
18 diminished by the fact that she now must endure a permanent and life-altering condition that could have
19 been prevented with an adequate warning to her physicians. Plaintiff’s permanent injuries to her lacrimal
20 system, specifically punctal stenosis, cause daily disruption to her life due to excessive tearing, or
21 epiphora. For those who have never experienced epiphora, the condition might seem like a minor
22 annoyance. However, for cancer survivors like Mrs. Hamilton-Moews, the irritated, swollen, watering
23 eyes and the ongoing medical management of the condition affect their work, their self-esteem,
24 interpersonal relationships, daily activities like driving or reading a book, and their general ability to
25 return to a normal life after defeating cancer.

26 **PARTIES**

27 **A. Plaintiff**

28 4. Plaintiff Jeannie Hamilton-Moews is an individual residing in Eastvale, California who received

1 Taxotere as part of a chemotherapy regimen after being diagnosed with breast cancer in January of 2019.
2 She was administered Taxotere at Kaiser Permanente in Riverside, California. She was prescribed tri-
3 weekly treatment and received a total of 4 rounds of chemotherapy with Taxotere. During chemotherapy,
4 she complained of red, watery eyes, but was told that the symptoms were common with chemotherapy
5 and should subside once she completed her course of treatment. Unfortunately, the epiphora remained
6 and she has since been diagnosed with permanent and irreversible punctal stenosis.

7 **B. Sanofi Defendants**

8 5. Defendant Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. is a Delaware corporation, with
9 a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services
10 Inc. is a wholly owned subsidiary of Sanofi S.A. Sanofi S.A. is engaged in research and development,
11 testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of
12 prescription drugs, including Taxotere. Defendant Sanofi US Services Inc. engages in research and
13 development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or
14 distributing of prescription drugs, including Taxotere.

15 6. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, with a principal
16 place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi- Aventis U.S. LLC
17 is a wholly owned subsidiary of Defendant Sanofi S.A., and Sanofi S.A. is Sanofi-Aventis U.S., LLC's
18 sole member. Defendant Sanofi-Aventis U.S. LLC engages in research and development, testing,
19 manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription
20 drugs, including Taxotere.

21 7. Since 2006, defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. have collectively
22 served as the U.S. operational front for Sanofi S.A. in the U.S. prescription drug market.

23 **JURISDICTION AND VENUE**

24 8. Federal subject matter jurisdiction is based on 28 U.S.C. §1332(a) due to the complete diversity of
25 Mrs. Hamilton-Moews and Defendants and the amount in controversy exceeds \$75,000.

26 9. A substantial part of the acts and omissions giving rise to this cause of action occurred in this
27 district and therefore venue is proper here pursuant to 28 U.S.C. §1391(a).

28 10. The Sanofi Defendants are subject to personal jurisdiction in this Court due to their ongoing and

1 substantial contacts in this forum.

2 **FACTUAL ALLEGATIONS**

3 **I. Development and Approval of Taxotere (Docetaxel)**

4 11. Taxotere is a drug used in the treatment of various forms of cancer, including breast cancer, and
5 is a part of a family of cytotoxic drugs referred to as taxanes. Taxanes are derived from yew trees, and
6 unlike other cytotoxic drugs, taxanes inhibit the multiplication of cancer cells by over-stabilizing the
7 structure of a cancer cell, which prevents the cell from breaking down and reorganizing for cell
8 reproduction. They are widely used as chemotherapy agents.

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

12 13. In August 2004, Sanofi obtained FDA approval for an expanded use of Taxotere “in combination
13 with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-
14 positive breast cancer.” This resulted in a greater number of patients being treated with Taxotere.

15 14. As the universe of patients taking Taxotere expanded to include those with a higher survivability,
16 more cancer survivors taking Taxotere would now experience a permanent disabling (but preventable)
17 condition – namely, permanent and irreversible damage to the lacrimal system.

18 15. Taxotere is not purchased by patients at a pharmacy; rather, patients’ use of these drugs occurs
19 via administration through injection and/or intravenously at a physician’s office or medical treatment
20 facility.

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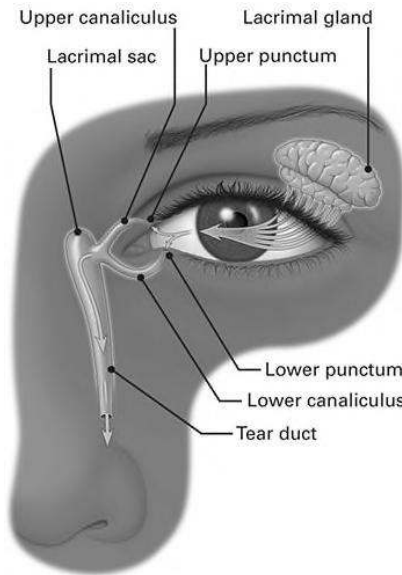
1 **II. Anatomy of Lacrimal System**

2 16. The following image depicts the anatomy of the lacrimal system.

3 17. Taxotere is secreted in the tear film, thereby causing fibrosis in areas of the lacrimal system,
4 including the puncta and canaliculi.¹ This scarring can cause permanent and irreversible occlusion,
5 resulting in the failure of tears to drain naturally through the lacrimal system. Because the eyes are
6 constantly producing tears, this results in persistent epiphora.

7 **III. Taxotere’s Labeling**

8 18. Taxotere’s labeling information at the time relevant to this lawsuit, states in relevant part:



20 **Post-Marketing Experiences**

21 **Ophthalmologic**

22 Conjunctivitis, lacrimation or lacrimation with or without conjunctivitis.
23 *Excessive tearing which may be attributable to lacrimal duct obstruction*
24 *has been reported.* Rare cases of transient visual disturbances (flashes,
25 flashing lights, scotomata) typically occurring during drug infusion and
26 in association with hypersensitivity reactions have been reported. *These*
27 *were reversible upon discontinuation of the infusion.*

28 **Patient Counseling Information:**

Gastrointestinal Events, Eye Disorders

¹ For the Court’s ease of reference, Plaintiff will use the term “lacrimal duct obstruction” as it is identified in Sanofi’s label; however, as the image demonstrates, obstruction of the lacrimal ducts is not the mechanism generally causing the epiphora. Rather, most cases involve stenosis, or hardening, of the puncta and/or the canaliculi.

1 Advise patients that side effects such as nausea, vomiting, diarrhea,
2 constipation, excessive tearing and/or vision disturbances are associated
3 with docetaxel administration. Tell patients to immediately report any
4 abdominal pain or tenderness, and/or diarrhea, with or without fever, any
5 vision changes.

6 **What are the possible side effects of Taxotere?**

7 The most common side effects of Taxotere include: redness of the eye,
8 excess tearing . . .²

9 (emphasis added)

10 19. Sanofi’s label informed patients that “redness of eye, excess tearing” were among the “most
11 common side effects of Taxotere” but did not advise patients of the rapid onset, the permanency of
12 stenosis and, therefore, the critical need to seek immediate medical treatment from an appropriately
13 qualified physician. These representations downplay the serious and permanent nature of this side effect
14 by effectively communicating this side effect is transitory. In the section of the label regarding
15 “Ophthalmologic” side effects, Sanofi represents that these side effects were “reversible upon
16 discontinuation of the infusion.” This affirmatively misrepresents the frequency and severity of this
17 potentially permanent damage to the lacrimal system.

18 20. Sanofi’s labeling information at all times relevant to this lawsuit, and even to date, does not
19 identify the risk of punctal stenosis as a cause of excessive tearing, the rapid onset at which stenosis can
20 occur, the potentially permanent and irreversible nature of the injury, the need to refer patients to a
21 lacrimal specialist, nor does it identify the condition as preventable with timely intervention during
22 chemotherapy.

23 21. Given the widespread use of Taxotere, it is crucial that the label not only inform oncologists of
24 excessive tearing due to “lacrimal duct obstruction,” but that without prompt treatment, the obstruction
25 can become permanent. Only timely diagnosis and treatment can prevent this from happening.

26 22. Sanofi did not provide such adequate notice to oncologists. To the contrary, the labeling leads
27 oncologists, like Mrs. Hamilton-Moews’s, to believe that excessive tearing is merely a transitory side
28 effect and will end upon the cessation of chemotherapy. This failure to provide notice resulted in
thousands of women, like Mrs. Hamilton-Moews, suffering daily from a permanent condition that could

² https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020449s079lbl.pdf

1 have easily been prevented with adequate warning.

2 **IV. Sanofi’s Duty to Monitor and Update Labeling**

3 23. The primary responsibility for timely communicating complete, accurate, and current safety and
4 efficacy information related to Taxotere rests with Sanofi as it has superior, and in many cases exclusive,
5 access to the relevant safety and efficacy information, including post-market complaints and data.

6 24. To fulfill its essential responsibilities, Sanofi must vigilantly monitor all reasonably available
7 information. It must closely evaluate the post-market clinical experience of its drugs and timely provide
8 updated safety and efficacy information to the healthcare community and to consumers.

9 25. When monitoring and reporting adverse events, as required by both federal regulations and state
10 law, time is of the essence. The purpose of monitoring a product’s post-market experience is to detect
11 potential safety signals that could indicate to drug sponsors and the medical community that a public
12 safety problem exists.

13 26. If, for example, a manufacturer was to delay reporting post-market information, that delay could
14 mean that researchers, FDA, and the medical community are years behind in identifying a public safety
15 issue associated with the drug.

16 27. In the meantime, more patients are harmed by using the product without knowing, understanding,
17 and accepting its true risks, which is why drug sponsors must not only completely and accurately monitor,
18 investigate and report post-market experiences, but must also report the data in a timely fashion.

19 28. A drug is “misbranded” in violation of the FDCA when its labeling is false and misleading or
20 does not provide adequate directions for use and adequate warnings. *See* 21 U.S.C. §§ 321(n); 331(a),
21 (b), (k); 352(a), (f). A drug’s labeling satisfies federal requirements if it gives physicians and pharmacists
22 sufficient information—including indications for use and “any relevant hazards, contraindications, side
23 effects, and precautions”—to allow those professionals “to use the drug safely and for the purposes for
24 which it is intended.” 21 C.F.R. § 201.100(c)(1).

25 29. As part of their responsibility to monitor post-market clinical experiences with the drug and
26 provide updated safety and efficacy information to the healthcare community and to consumers, each
27 approved NDA applicant “must promptly review all adverse drug experience information obtained or
28 otherwise received by the applicant from any source, foreign or domestic, including information derived

1 from commercial marketing experience, post marketing clinical investigations, post marketing
2 epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific
3 papers.” 21 C.F.R. § 314.80(b).

4 30. Any report of a “serious and unexpected” drug experience, whether foreign or domestic, must be
5 reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. §
6 314.80(c)(1)(i-ii).

7 31. Most other adverse event reports must be submitted quarterly for three years after the application
8 is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic reports must include a
9 “history of actions taken since the last report because of adverse drug experiences (for example, labeling
10 changes or studies initiated).” 21 C.F.R. § 314.80(c)(2)(ii).

11 32. Federal law requires labeling to be updated as information accumulates: “labeling must be revised
12 to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a
13 causal association with a drug; a causal relationship need not have been definitely established.” 21 C.F.R.
14 § 201.57(c)(6)(i). Thus, for example, drug manufacturers must warn of an adverse effect where there is
15 “some basis to believe there is a causal relationship between the drug and the occurrence of the adverse
16 event.” 21 C.F.R. § 201.57(c)(7).

17 33. All changes to drug labels require FDA assent. 21 C.F.R. § 314.70(b)(2)(v)(A). Brand-name drug
18 sponsors may seek to change their approved labels by filing a supplemental application. 21 C.F.R. §
19 314.70.

20 34. One regulation, the “Changes Being Effected” (CBE) regulation, permits a manufacturer to
21 unilaterally change a drug label to reflect “newly acquired information,” subject to later FDA review and
22 approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information includes “new analyses of previously
23 submitted data.” 21 C.F.R. § 314.3(b).

24 35. Thus, for instance, if a drug sponsor determined that a warning was insufficient based on a new
25 analysis of previously existing data, it could submit a CBE and change its labeling.

26 36. The longer a drug sponsor delays updating its labeling to reflect current safety information, the
27 more likely it is that medical professionals will prescribe drugs without advising patients of harmful
28 adverse reactions, and the more likely it is that patients will suffer harmful side effects without the

1 opportunity to evaluate risks for themselves.

2 **V. Sanofi Knew That Taxotere Can Cause Permanent Punctal Stenosis.**

3 37. Since 2002 Sanofi’s Taxotere label has advised that “excessive tearing which may be attributable
4 due to lacrimal obstruction has been reported.”³ Despite this language, medical literature has continued
5 to accumulate and raise concerns that oncologists are not being properly warned of the severity of this
6 permanent and irreversible side effect – and in response, Sanofi has done nothing to notify oncologists
7 or patients.

8 38. The following studies, published after 2002, highlight concerns of the increased frequency and
9 severity of permanent stenosis in cancer patients taking Taxotere, the increased need for monitoring,
10 and the lack of awareness among oncologists and their patients regarding the true nature of the damage
11 caused:

- 12 a) From the American Society of Ophthalmic Plastic and Reconstructive Surgery:

13 *Better education of oncologists who prescribe docetaxel is
14 needed as we continue to encounter new cases of advanced
15 canalicular blockage.*⁴

- 16 b) From the American Cancer Society:

17 *Despite the previous publication of several articles by our
18 group regarding canalicular stenosis and lacrimal
19 obstruction resulting from docetaxel therapy, we still
20 frequently encounter advanced cases of this condition
21 because of delayed diagnosis. Thus it appears that
22 oncologists need to become better educated regarding this
23 side effect.*

24 *All patients receiving weekly docetaxel should be monitored
25 closely by an ophthalmologist so that the timely management
26 of canalicular stenosis can be offered.*

27 *We recommend silicone intubation [stents] in all
28 symptomatic patients who are receiving weekly docetaxel if*

³ https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20449slr022_taxotere_lbl.pdf

⁴ Bitá Esmali, et al., *Docetaxel-Induced Histologic Changes in the Lacrimal Sac and Nasal Mucosa*, 19 OPTHALMIC PLASTIC AND RECONSTRUCTIVE SURGERY 4, pp. 305-308 (2003)

they ae to continue receiving the drug.⁵

c) From Pharmacotherapy

Moreover, epiphora may be an underrecognized adverse effect of docetaxel because excess tearing after chemotherapy administration is not as stringently monitored as life-threatening toxicities . . . This adverse effect warrants evaluation because weekly administration is being used more commonly for the treatment of advanced solid tumors, and epiphora can interfere with the activities and quality of daily life.⁶

d) From the Journal of Clinical Oncology

Despite substantial literature documenting canalicular stenosis as an adverse effect of docetaxel, the exact incidence of this important adverse effect is unknown. All previous publications were based on retrospective studies at tertiary ophthalmology practices, and only patients who symptoms of epiphora were evaluated. We report the finding of prospective, single-center study designed to determine the incidence and severity of epiphora and its anatomic correlate, canalicular stenosis, in patients receiving docetaxel weekly or every 3 weeks.

Previous retrospective studies and our clinical experience suggested that the incidence of epiphora might be as high as 50% in patients treated with weekly docetaxel and less than 10% in patients who receive docetaxel every 3 weeks.

In this prospective, observational study, epiphora was seen in 64% of patients in the weekly docetaxel group and in 39% of the docetaxel every 3 weeks group.

Patients who experience epiphora associated with docetaxel should be promptly referred to an ophthalmologist familiar with this adverse effect. Frequent [approximately every 4-6 weeks] probing and irrigation in the office and judicious use of topical steroids on a tapering dose can eliminate the need for silicone intubation or other lacrimal procedures in approximately 80% of patients taking docetaxel every 3 weeks and in approximately 50% of patients taking

⁵ Bitá Esmaeli, et al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 CANCER 504-7 (2003)

⁶ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

*docetaxel weekly.*⁷

1
2 39. Prominent medical researchers have described this side effect as follows: “canalicular stenosis
3 may be the most important side effect of weekly docetaxel;”⁸ “cancer patients . . . view epiphora as one
4 of the worst side effects because of their inability to read, drive, or wear make-up;”⁹ “visually
5 disabling;”¹⁰ “misleading appearance of emotional tears;”¹¹ “canalicular stenosis can negatively impact
6 the quality of life . . . and should be considered when choosing the chemotherapy regimen;”¹² “epiphora
7 may be a major disability. It interferes with daily activities and causes emotional disturbances;”¹³ “the
8 potential risk of this complication should be carefully weighed;”¹⁴ “epiphora may be an underrecognized
9 adverse effect;”¹⁵ and “the high incidence of this adverse effect has an impact on several aspects of daily
10 living.”¹⁶

11 40. Medical literature is clear that: (1) the onset of damage to the lacrimal system can be rapid upon
12 beginning Taxotere, (2) immediate referral to a lacrimal specialist for monitoring is essential, (3)

13
14 ⁷ Bita Esmaeli, et al., *Prospective Study of Incidence and Severity of Epiphora and Canalicular Stenosis*
15 *in Patients With Metastatic Breast Cancer Receiving Docetaxel*, 24 JOURNAL OF CLINICAL ONCOLOGY
16 22 (2006).

17 ⁸ Bita Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel*
18 *Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

19 ⁹ *Id.*

20 ¹⁰ Bita Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly versus Every-3-Weeks Docetaxel in*
21 *Patients with Metastatic Breast Cancer*, 109 AM ACAD. OF OPHTHALMOLOGY, 1188 (2002).

22 ¹¹ Bita Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly Docetaxel: A Potentially Preventable*
23 *Side Effect*, 13 EUROPEAN SOC'Y. FOR MED. ONCOLOGY, 218 (2001).

24 ¹² Bita Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel*
25 *Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

26 ¹³ Medy Tsalic., et al., *Epiphora (Excessive Tearing) and Other Ocular Manifestations Related to*
27 *Weekly Docetaxel*, 23 MEDICAL ONCOLOGY (2005)

28 ¹⁴ *Id.*

¹⁵ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

¹⁶ Arlene Chan, et al., *Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving*
Adjuvant Docetaxel-based Chemotherapy, 31 JOURNAL OF CLINICAL ONCOLOGY, 17 (2013)

1 damage to the lacrimal system can be permanent and irreversible, (4) this side effect is preventable, and
2 (5) oncologists are not aware of the severity of this side effect. Unfortunately this lack of awareness
3 often results in oncologists counseling their patients that their tearing is temporary and will cease after
4 chemotherapy ends.

5 **VI. Taxotere Caused Mrs. Hamilton-Moews's Permanent Punctal Stenosis**

6 41. Mrs. Hamilton-Moews was diagnosed with breast cancer and was given chemotherapy with
7 Taxotere, receiving a total of four infusions over the course of two months.

8 42. In a communication two weeks after the completion of her Taxotere infusions, Mrs. Hamilton-
9 Moews emailed her oncologist that she had red, swollen and watery eyes after every chemo treatment
10 and that the watery eyes seems to last anywhere from a week to two weeks. Her oncologist informed her
11 that the condition should get better as chemotherapy is gradually out of her system. Her oncologist
12 recommended she continue artificial tears to treat her discomfort.

13 43. However, by February 2020, due to the severity of her tearing and her inability to get relief from
14 the eye drops, Mrs. Hamilton-Moews saw an oculoplastic surgeon, who performed an irrigation
15 procedure and confirmed a diagnosis of punctal stenosis.

16 44. Mrs. Hamilton-Moews completed chemotherapy and was excited to be cancer free and rid of all
17 of the side effects she suffered as a result of the cancer treatment. Among these, Mrs. Hamilton-Moews
18 looked forward to no longer suffering from constantly irritated, watering eyes. But as the effects of
19 chemotherapy wore off, her watery eyes remained.

20 45. Mrs. Hamilton-Moews continues to experience persistent tearing and a disruption of her life. As
21 a direct and proximate result of Sanofi's conduct in connection with the design, development,
22 manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and
23 sale of Taxotere, Mrs. Hamilton-Moews suffers from permanent epiphora, due to punctal stenosis. This
24 condition is a known permanent side effect of taking Taxotere.

25 46. As a result of this permanent side effect, Mrs. Hamilton-Moews has struggled to return to
26 normalcy, even after surviving cancer, because she continues to suffer from persistent tearing on a daily
27 basis, interfering with her ability to perform basic activities and enjoy life. This permanent change has
28 altered Mrs. Hamilton-Moews's self-image, negatively impacted her relationships, and others'

1 perceptions of her, leading to social isolation and depression even long after fighting cancer.

2 47. When Mrs. Hamilton-Moews she underwent chemotherapy with Taxotere, and her eyes
3 unexpectedly became irritated and red and began to tear constantly. Throughout her ordeal, Mrs.
4 Hamilton-Moews remained hopeful that, like other chemotherapy side effects, the epiphora would
5 eventually resolve. To her dismay, it never has.

6 48. Mrs. Hamilton-Moews’s tearing is much more than a minor annoyance – it impacts all aspects of
7 her daily life. Prior to developing permanent punctal stenosis, Mrs. Hamilton-Moews was self-confident
8 and enjoyed social and professional interactions with other people. Now she lacks the confidence she
9 previously enjoyed.

10 49. Mrs. Hamilton-Moews is anxious about social interactions because she fears people will perceive
11 her as sad and crying. Her tears spill out over her cheeks, making her skin irritated and she is unable to
12 keep makeup on her face. She is aware of the concerned looks from well-intentioned friends, colleagues
13 and strangers who perceive her to be emotional and upset.

14 50. Mrs. Hamilton-Moews’s injuries could have been prevented had Sanofi simply warned that
15 permanent or irreversible punctal, canalicular and nasolacrimal duct stenosis is a common but preventable
16 side effect of Taxotere. Specifically, had Sanofi properly warned Mrs. Hamilton-Moews’ oncologist of
17 the rapid onset of permanent damage, her oncologist would have referred her to lacrimal specialist
18 immediately at the onset of her symptoms, rather than advising her that the symptoms would go away
19 when she completed her chemotherapy. Mrs. Hamilton-Moews thus seeks recovery for her mental and
20 physical suffering stemming from permanent, but easily preventable, punctal stenosis.

21 51. Mrs. Hamilton-Moews files this lawsuit within the applicable statute of limitations.

22 **VII. Tolling of the Statute of Limitations.**

23 52. Alternatively, Mrs. Hamilton-Moews files this lawsuit within the applicable statute of limitations
24 period of first suspecting that Sanofi’s wrongful conduct caused the appreciable harm she sustained. Due
25 to Sanofi’s fraudulent concealment of the true nature of “excessive tearing which may be attributable to
26 lacrimal duct obstruction,” Mrs. Hamilton-Moews could not, by the exercise of reasonable diligence,
27 have discovered that Sanofi wrongfully caused her injuries as she was unaware of the severity and
28 permanency of her injury. Specifically in its warning label, Sanofi fraudulently concealed (1) the rapid

1 onset at which stenosis can occur, (2) the potentially permanent and irreversible nature of the injury, (3)
2 the need to immediately refer patients to a lacrimal specialist and (4) that the condition is highly
3 preventable with timely intervention during chemotherapy. As a result, Mrs. Hamilton-Moews was
4 unaware that Sanofi knew of the devastating and permanent consequences of stenosis, or that Sanofi
5 concealed this information from her oncologist. Because Mrs. Hamilton-Moews' oncologist was unaware
6 of the permanent nature of this side effect, Mrs. Hamilton-Moews was unaware that her condition was
7 permanent and irreversible.

8 53. Sanofi to this day does not warn that Taxotere can cause permanent and irreversible obstruction
9 of the lacrimal system. Therefore Mrs. Hamilton-Moews did not suspect, nor did she have reason to
10 suspect, that she had been permanently injured. Furthermore, Mrs. Hamilton-Moews did not and could
11 not suspect the tortious nature of the conduct causing her injuries until a date before filing this action that
12 is less than the applicable limitations period for filing suit.

13 54. Additionally, Mrs. Hamilton-Moews was prevented from discovering this information at an
14 earlier date because Sanofi: (1) misrepresented to the public, the FDA, and the medical profession that
15 Taxotere was free from permanent side effects; (2) failed to disclose to the public, the FDA, and the
16 medical profession its knowledge of the risk of permanent but reversible side effects; (3) failed to disclose
17 to the public, the FDA, and the medical profession its knowledge that these side effects were preventable
18 with early intervention during chemotherapy; (4) fraudulently concealed facts and information that could
19 have led Mrs. Hamilton-Moews to discover Sanofi's liability; and (5) still has not disclosed to the public,
20 the FDA, and the medical profession that Taxotere can cause permanent punctal, canalicular and
21 nasolacrimal duct stenosis which can be prevented with early intervention during chemotherapy.

22 **COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)**

23 55. Mrs. Hamilton-Moews incorporates by reference the above paragraphs as if set forth herein.

24 56. At all relevant times, Sanofi was in the business of designing, researching, manufacturing, testing,
25 promoting, marketing, selling, and/or distributing pharmaceutical products, including the Taxotere used
26 by Mrs. Hamilton-Moews.

27 57. The Taxotere designed, formulated, produced, manufactured, sold, marketed, distributed,
28 supplied and/or placed into the stream of commerce by Sanofi failed to provide adequate warnings to

1 users and their healthcare providers, including Mrs. Hamilton-Moews and her healthcare providers, of
2 the risk of side effects associated with the use of Taxotere, particularly the risk of developing disfiguring,
3 permanent punctal stenosis, or the measures that could have been taken to prevent it. The Taxotere
4 designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into
5 the stream of commerce by Sanofi and ultimately administered to Mrs. Hamilton-Moews lacked such
6 warnings when it left Sanofi's control.

7 58. The risks of developing disfiguring, permanent punctal stenosis were known to or reasonably
8 knowable by Sanofi at the time the Taxotere left Sanofi's control, because of "newly acquired
9 information" available to Sanofi after the 2002 label change.

10 59. A reasonably prudent company in the same or similar circumstances would have provided a
11 warning that communicated the dangers and safe use of Taxotere.

12 60. Any warnings actually provided by Sanofi did not sufficiently and/or accurately reflect the
13 symptoms, type, scope, severity, and/or duration of these side effects, particularly the risks of developing
14 disfiguring, permanent punctal stenosis or how it could have been prevented during administration of the
15 chemotherapy.

16 61. Without adequate warning of these side effects, Taxotere is not reasonably fit, suitable, or safe
17 for its reasonably anticipated or intended purposes.

18 62. Mrs. Hamilton-Moews was a reasonably foreseeable user of Taxotere who used the drug in a
19 reasonably anticipated manner.

20 63. Mrs. Hamilton-Moews and her physicians would have taken preventative measures during the
21 course of her chemotherapy to prevent punctal stenosis had she and her physicians been provided an
22 adequate warning by Sanofi of the risk of these side effects.

23 64. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse
24 effects of Taxotere, Mrs. Hamilton-Moews suffered and continues to suffer serious and dangerous side
25 effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-
26 economic damages, harms, and losses, including, but not limited to: past and future medical expenses;
27 past and future loss of earnings; past and future loss and impairment of earning capacity; permanent
28 disfigurement, including punctal stenosis; mental anguish; severe and debilitating emotional distress;

1 increased risk of future harm; past, present, and future physical and mental pain, suffering, and
2 discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

3 WHEREFORE, Plaintiff Jeannie Hamilton-Moews respectfully requests judgment in her favor and
4 against Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further
5 relief this Court deems just and proper.

6 **COUNT II - NEGLIGENCE**

7 65. Mrs. Hamilton-Moews incorporates by reference the above paragraphs as if set forth herein.

8 66. Sanofi had a duty to exercise reasonable care in the design, research, formulation, manufacture,
9 production, marketing, testing, supply, promotion, packaging, sale, and/or distribution of Taxotere,
10 including a duty to assure that the product would not cause users to suffer unreasonable, disfiguring, and
11 dangerous side effects.

12 67. Sanofi breached these duties when it put Taxotere into interstate commerce, unreasonably and
13 without adequate and/or proper warning to Mrs. Hamilton-Moews and her healthcare providers, a product
14 that Sanofi knew or should have known created a high risk of unreasonable, disfiguring, and dangerous
15 side effects.

16 68. The negligence of Sanofi, its agents, servants, and/or employees, included but was not limited to,
17 the following acts and/or omissions:

- 18 (a) Manufacturing, producing, promoting, formulating, creating, and/or designing Taxotere
19 without thoroughly, adequately, and/or sufficiently testing it—including pre- clinical and
20 clinical testing and post-marketing surveillance—for safety and fitness for use and/or its
21 dangers and risks;
- 22 (b) Marketing Taxotere to Mrs. Hamilton-Moews, Mrs. Hamilton-Moews’s healthcare providers,
23 the public, and the medical and healthcare professions without adequately and correctly
24 warning and/or disclosing the existence, severity, and duration of known or knowable side
25 effects, including permanent punctal stenosis;
- 26 (c) Marketing Taxotere to Mrs. Hamilton-Moews, Mrs. Hamilton-Moews’s healthcare providers,
27 the public, and the medical and healthcare professions without providing adequate instructions
28 regarding safety precautions to be observed by users, handlers, and persons who would
reasonably and foreseeably come into contact with, and more particularly, use, Taxotere;
- (d) Advertising and recommending the use of Taxotere without sufficient knowledge of its safety
profile;
- (e) Designing, manufacturing, producing, and/or assembling Taxotere in a manner that was

dangerous to its users;

- (f) Concealing information from Mrs. Hamilton-Moews, Mrs. Hamilton-Moews’s healthcare providers, the public, other medical and healthcare professionals, and the FDA that Taxotere was unsafe, dangerous, and/or non-conforming with FDA regulations;
- (g) Concealing from and/or misrepresenting information to Mrs. Hamilton-Moews, Mrs. Hamilton-Moews’s healthcare providers, other medical and healthcare professionals, and/or the FDA concerning the existence and severity of risks and dangers of Taxotere; and
- (h) Encouraging the sale of Taxotere, either directly or indirectly, orally or in writing, to Mrs. Hamilton-Moews and Mrs. Hamilton-Moews’s healthcare providers without warning about the need for more comprehensive and regular medical monitoring than usual to ensure early discovery of potentially serious side effects such as punctal, canalicular and nasolacrimal duct stenosis.

69. Despite the fact that Sanofi knew or should have known that Taxotere caused unreasonably dangerous side effects, Sanofi continues to market, manufacture, distribute, and/or sell Taxotere to consumers.

70. Mrs. Hamilton-Moews and her healthcare providers were therefore forced to rely on safety information that did not accurately represent the risks and benefits associated with the use of Taxotere and measures that could have been taken to prevent severe and permanent disfigurement from the use of Taxotere.

71. Sanofi knew or should have known that consumers such as Mrs. Hamilton-Moews would use its product and would foreseeably suffer injury as a result of Sanofi’s failure to exercise reasonable care, as set forth above.

72. Sanofi’s negligence was a proximate cause of Mrs. Hamilton-Moews’s injuries, harms, damages, and losses, in connection with the use of Taxotere, including but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent and irreversible punctal stenosis; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Jeannie Hamilton-Moews respectfully requests judgment in her favor and against Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief

1 this Court deems just and proper.

2 **COUNT III – NEGLIGENT MISREPRESENTATION**

3 73. Mrs. Hamilton-Moews incorporates by reference the above paragraphs as if set forth herein.

4 74. Sanofi had a duty to represent to Mrs. Hamilton-Moews, Mrs. Hamilton-Moews’s healthcare
5 providers, the healthcare community, and the public in general that Taxotere had been tested and found
6 to be safe and effective for the treatment of various forms of cancer.

7 75. When warning of safety and risks of Taxotere, Sanofi negligently represented to Mrs. Hamilton-
8 Moews, Mrs. Hamilton-Moews’s healthcare providers, the healthcare community, and the public in
9 general that Taxotere had been tested and was found to be safe and/or effective for its indicated use.

10 76. Sanofi concealed its knowledge of Taxotere defects from Mrs. Hamilton-Moews, Mrs. Hamilton-
11 Moews’s healthcare providers, and the public in general and/or the healthcare community specifically.

12 77. Sanofi concealed this information with the intent of defrauding and deceiving Mrs. Hamilton-
13 Moews, Mrs. Hamilton-Moewss’ healthcare providers, the public in general, and the healthcare
14 community in particular, and were made with the intent of inducing Mrs. Hamilton-Moews, Mrs.
15 Hamilton-Moews’s healthcare providers, the public in general, and the healthcare community in
16 particular, to recommend, dispense, and/or purchase Taxotere.

17 78. Sanofi failed to exercise ordinary and reasonable care in its representations of Taxotere in its sale,
18 testing, quality assurance, quality control, and/or distribution into interstate commerce, and Sanofi
19 negligently misrepresented Taxotere’s high risks of unreasonable, dangerous side effects. These side
20 effects were unreasonable because they could have been entirely prevented with adequate warning.

21 79. Sanofi breached its duty in misrepresenting Taxotere’s serious side effects to Mrs. Hamilton-
22 Moews, Mrs. Hamilton-Moews’s healthcare providers, the healthcare community, the FDA, and the
23 public in general.

24 80. Mrs. Hamilton-Moews and Mrs. Hamilton-Moews’s healthcare providers reasonably relied on
25 Sanofi to fulfill its obligations to disclose all facts within its knowledge regarding the serious side effects
26 of Taxotere and the ability to prevent those side effects with appropriate precautionary measures.

27 81. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs.
28 Hamilton-Moews to suffer serious and dangerous side effects, severe and personal injuries that are

1 permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including,
2 but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss
3 and impairment of earning capacity; permanent disfigurement, including permanent punctal stenosis;
4 mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present,
5 and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and
6 impairment of the quality and enjoyment of life.

7 WHEREFORE, Jeannie Hamilton-Moews respectfully requests that judgment in her favor and
8 against Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further
9 relief this Court deems just and proper.

10 **COUNT IV – FRAUDULENT MISREPRESENTATION**

11 82. Mrs. Hamilton-Moews incorporates by reference the above paragraphs as if set forth herein.

12 83. Sanofi represented to Mrs. Hamilton-Moews, her healthcare providers, the healthcare community,
13 and the public in general that “excessive tearing which may be attributable to lacrimal duct obstruction
14 has been reported” and that excessive is a common side effect. These statements failed to accurately
15 inform oncologists and patients of (1) the rapid onset at which stenosis can occur, (2) the potentially
16 permanent and irreversible nature of the injury, (3) the need to immediately refer patients to a lacrimal
17 specialist and (4) that the condition is highly preventable with timely intervention during chemotherapy.

18 84. Despite having knowledge of these enhanced side effects, Sanofi fraudulently omitted from these
19 representations information that Taxotere could and did cause these serious side effects, including
20 permanent and irreversible punctal stenosis.

21 85. These representations were material and false.

22 86. Sanofi made these representations and omissions:

- 23 (a) with knowledge or belief of their falsity, and/or in the case of omissions, with knowledge or
- 24 belief of falsity of the resulting statements;
- 25 (b) positively and recklessly without knowledge of their truth or falsity;
- 26 (c) with knowledge that they were made without any basis; and/or
- 27 (d) without confidence in the accuracy of the representations or statements resulting from the
- 28 omissions.

1 87. Sanofi made these false representations with the intention or expectation that Mrs. Hamilton-
2 Moews, Mrs. Hamilton-Moews’s healthcare providers, the public in general, and the healthcare
3 community in particular, would recommend, dispense, and/or purchase Taxotere, all of which evidenced
4 a callous, reckless, willful, wanton, and depraved indifference to the health, safety, and welfare of Mrs.
5 Hamilton-Moews.

6 88. At the time Sanofi made the aforesaid representations, and, at the time Mrs. Hamilton-Moews
7 used Taxotere, Mrs. Hamilton-Moews and Mrs. Hamilton-Moews’s healthcare providers were unaware
8 of the falsity of Sanofi’s representations, statements and/or implications and justifiably and reasonably
9 relied on Sanofi’s representations, statements, and implications, believing them to be true.

10 89. In reliance on Sanofi’s representations, Mrs. Hamilton-Moews and her healthcare providers were
11 induced to and did use and prescribe Taxotere, which caused Mrs. Hamilton-Moews to suffer serious and
12 dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and
13 economic and non-economic damages, harms, and losses, including, but not limited to: past and future
14 medical expenses; past and future loss of earnings; past and future loss and impairment of earning
15 capacity; permanent disfigurement, including permanent punctal stenosis; mental anguish; severe and
16 debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental
17 pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and
18 enjoyment of life.

19 WHEREFORE, Jeannie Hamilton-Moews respectfully requests judgment in her favor and against
20 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief
21 this Court deems just and proper.

22 **COUNT V – FRAUDULENT CONCEALMENT**

23 90. Mrs. Hamilton-Moews incorporates by reference the above paragraphs as if set forth herein.

24 91. At all times during the course of dealing between Sanofi and Mrs. Hamilton-Moews and Mrs.
25 Hamilton-Moews’ healthcare providers, Sanofi misrepresented the design characteristic and safety of
26 Taxotere for their intended use.

27 92. Sanofi knew or was reckless in not knowing that its representations were false due to Sanofi’s
28 access to ongoing studies and reports that disclosed serious, enhanced side effects of Taxotere to the

1 lacrimal system. In representations made to Mrs. Hamilton-Moews and her healthcare providers, Sanofi
2 fraudulently concealed and intentionally omitted the following material information: (1) the rapid onset
3 at which stenosis can occur, (2) the potentially permanent and irreversible nature of the injury, (3) the
4 need to immediately refer patients to a lacrimal specialist and (4) that the condition is highly preventable
5 with timely intervention during chemotherapy.

6 93. Sanofi had a duty to disclose to Mrs. Hamilton-Moews and her healthcare providers the defective
7 nature of Taxotere, including, but not limited to, the heightened risks of disfiguring, permanent punctal
8 stenosis.

9 94. Sanofi had a duty to disclose to Mrs. Hamilton-Moews and Mrs. her healthcare providers that the
10 disfiguring, permanent punctal stenosis caused by the use of Taxotere could have been prevented by early
11 identification and treatment of epiphora during chemotherapy.

12 95. Sanofi had sole access to material facts concerning the defective nature of Taxotere and its
13 propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used
14 the drugs at issue, including Mrs. Hamilton-Moews.

15 96. Sanofi's concealment and omissions of material fact concerning the safety of Taxotere were made
16 purposefully, willfully, wantonly, and/or recklessly to mislead Mrs. Hamilton-Moews and her healthcare
17 providers into reliance on the continued use of the drugs and to cause them to purchase, prescribe, and/or
18 dispense Taxotere and/or use it.

19 97. Sanofi knew that Mrs. Hamilton-Moews and her healthcare providers had no way to determine
20 the truth behind its concealment and omissions, including the material omissions of fact surrounding
21 Taxotere set forth herein.

22 98. Mrs. Hamilton-Moews and Mrs. Hamilton-Moews's healthcare providers reasonably relied on
23 information disclosed by Sanofi that negligently, fraudulently, and/or purposefully did not include facts
24 that were concealed and/or omitted by Sanofi.

25 99. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Hamilton-Moews to suffer
26 serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature,
27 and economic and non-economic damages, harms, and losses, including, but not limited to: past and
28 future medical expenses; past and future loss of earnings; past and future loss and impairment of earning

1 capacity; permanent disfigurement, including permanent punctal stenosis; mental anguish; severe and
2 debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental
3 pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and
4 enjoyment of life.

5 WHEREFORE, Jeannie Hamilton-Moews respectfully requests judgment in her favor and against
6 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief
7 this Court deems just and proper.

8 **VI. JURY DEMAND**

9 Plaintiff has requested a trial by jury pursuant to rule 38 of the Federal Rules of Civil Procedure.

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Dated: July 28, 2021

FITZPATRICK & SWANSTON

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**U.S. District Court
DISTRICT OF ARIZONA (Phoenix Division)
CIVIL DOCKET FOR CASE #: 2:21-cv-00689-DJH**

Cone v. Sanofi US Services Incorporated et al
Assigned to: Judge Diane J Humetewa
Cause: 28:1331 Fed. Question: Personal Injury

Date Filed: 04/21/2021
Jury Demand: Plaintiff
Nature of Suit: 367 Personal Injury: Health Care/Pharmaceutical
Personal Injury Product Liability
Jurisdiction: Federal Question

Plaintiff**Deenen Cone**

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V.

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Laura Elizabeth Sixkiller
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ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
04/21/2021	1	COMPLAINT. Filing fee received: \$ 402.00, receipt number 0970-19382747 filed by Deenen Cone. (Runkle, Ryan) (Attachments: # 1 Civil Cover Sheet)(JAM) (Entered: 04/21/2021)
04/21/2021	2	SUMMONS Submitted by Deenen Cone. (Runkle, Ryan) (Attachments: # 1 Summons)(JAM) (Entered: 04/21/2021)
04/21/2021	3	Filing fee paid, receipt number 0970-19382747. This case has been assigned to the Honorable Diane J Humetewa. All future pleadings or documents should bear the correct case number: CV-21-689-PHX-DJH. Notice of Availability of Magistrate Judge to Exercise Jurisdiction form attached. (JAM) (Entered: 04/21/2021)
04/21/2021	4	Summons Issued as to Sanofi US Services Incorporated, Sanofi-Aventis U.S. LLC. (Attachments: # 1 Summons)(JAM). *** IMPORTANT: When printing the summons, select "Document and stamps" or "Document and comments" for the seal to appear on the document. (Entered: 04/21/2021)
04/21/2021	5	NOTICE TO FILER OF DEFICIENCY re: 1 Complaint filed by Deenen Cone. Document not in compliance with LRCiv 7.1(a)(3) - Party names must be capitalized using proper upper and lower case type. No further action is required. This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (JAM) (Entered: 04/21/2021)
04/21/2021		Remark: Pro hac vice motion(s) granted for Ryan Christopher Runkle on behalf of Plaintiff Deenen Cone. This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (WLP) (Entered: 04/21/2021)
04/22/2021		Remark: Pro hac vice motion(s) granted for Ryan Christopher Runkle on behalf of Plaintiff Deenen Cone. This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (BAS) (Entered: 04/22/2021)
04/22/2021	6	ORDER that motions pursuant to Fed. R. Civ. P. 12(b) are discouraged if the defect can be cured by filing an amended pleading. The parties must meet and confer prior to the filing of such motions to determine whether it can be avoided. ORDERED that Plaintiff(s) serve a copy of this Order upon Defendant(s) and file a notice of service. See Order for details. Signed by Judge Diane J Humetewa on 4/22/2021. (LFIG) (Entered: 04/22/2021)
05/20/2021	7	SERVICE EXECUTED filed by Deenen Cone: Rule 4 Waiver of Service of Summons. Waiver sent on 5/18/2021 to Sanofi-Aventis US, LLC. (Runkle, Ryan) (Entered: 05/20/2021)
05/20/2021	8	SERVICE EXECUTED filed by Deenen Cone: Rule 4 Waiver of Service of Summons. Waiver sent on 5/18/2021 to Sanofi US Services, Inc. (Runkle, Ryan) (Entered: 05/20/2021)

05/20/2021	9	ORDER setting a Rule 16 Scheduling Conference for 8/3/2021 at 10:30 AM in Courtroom 605, 401 West Washington Street, Phoenix, AZ 85003 before Judge Diane J Humetewa. Signed by Judge Diane J Humetewa on 5/20/2021. (See Order for details.) (LFIG) (Entered: 05/20/2021)
07/09/2021	10	STIPULATION FOR EXTENSION OF TIME TO ANSWER COMPLAINT re: 1 Complaint (<i>First Request</i>) by Sanofi US Services Incorporated, Sanofi-Aventis U.S. LLC. (Attachments: # 1 Text of Proposed Order Proposed Order)(Montecuallo, Peter) (Entered: 07/09/2021)
07/12/2021	11	ORDER: Before the Court is the Stipulation for Extension of Time to Answer Complaint (Doc. 10). The parties provide no cause for the extension requested. Because it is unopposed, the Court will reluctantly grant the request for a 30-day extension of time to respond to the Complaint. The remaining requests are denied without prejudice. Accordingly, IT IS ORDERED the Stipulation (Doc. 10) is APPROVED in part. Defendants shall have until August 11, 2021 to answer or otherwise respond to the Complaint. The remaining requests are denied. ORDERED by Judge Diane J Humetewa on 7/12/2021. This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (LFIG) (Entered: 07/12/2021)
07/27/2021	12	REPORT of Rule 26(f) Planning Meeting by Deenen Cone. (Runkle, Ryan) (Entered: 07/27/2021)
07/28/2021	13	*Document filed in the incorrect case. All docket text associated with the entry has been removed on 7/28/2021. (LFIG) (Entered: 07/28/2021)
07/28/2021	14	RULE 16 SCHEDULING ORDER: Discovery due by 4/29/2022. Dispositive motions due by 10/28/2022. ORDERED vacating the Rule 16 Scheduling Conference set for 8/3/2021. Signed by Judge Diane J Humetewa on 7/28/2021. (See Order for details.) (LFIG) (Entered: 07/28/2021)
07/30/2021		Remark: Pro hac vice motion(s) granted for Torrey Peterson, Harley V Ratliff on behalf of Defendants Sanofi US Services Incorporated, Sanofi-Aventis U.S. LLC. This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (BAS) (Entered: 07/30/2021)
08/10/2021	15	NOTICE of Filing Amended Pleading pursuant to LRCiv 15.1(b) by Deenen Cone re: <i>First Amended Complaint</i> . (Attachments: # 1 Exhibit Def Sanofi's Consent to File Amended Complaint, # 2 Exhibit First Amended Complaint_Redlined)(Runkle, Ryan) (Entered: 08/10/2021)
08/10/2021	16	*AMENDED COMPLAINT (<i>First Amended Petition</i>) against All Defendants filed by Deenen Cone.(Runkle, Ryan) *Modified to reflect document not in compliance with the local rule; attorney notified on 8/11/2021 (MFR). (Entered: 08/10/2021)
08/12/2021		Remark: Pro hac vice motion(s) granted for Patrick OConnor Hotze on behalf of Plaintiff Deenen Cone. This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (BAS) (Entered: 08/12/2021)
08/24/2021	17	NOTICE of Appearance by Laura Elizabeth Sixkiller on behalf of Sanofi US Services Incorporated, Sanofi-Aventis U.S. LLC. (Sixkiller, Laura) (Entered: 08/24/2021)
08/24/2021	18	MOTION to Dismiss Case <i>MOTION TO DISMISS PLAINTIFFS FIRST AMENDED COMPLAINT</i> by Sanofi US Services Incorporated, Sanofi-Aventis U.S. LLC. (Attachments: # 1 Exhibit Exhibit A, # 2 Exhibit Exhibit B, # 3 Exhibit Exhibit C, # 4 Exhibit Exhibit D, # 5 Exhibit Exhibit E, # 6 Exhibit Exhibit F, # 7 Exhibit Exhibit G, # 8 Exhibit Exhibit H, # 9 Exhibit Exhibit I, # 10 Exhibit Exhibit J, # 11 Exhibit Exhibit K, # 12 Supplement Corporate Disclosure Statement)(Montecuallo, Peter) (Entered: 08/24/2021)
08/24/2021	19	REQUEST re: REQUEST FOR JUDICIAL NOTICE by Defendants Sanofi US Services Incorporated, Sanofi-Aventis U.S. LLC. (Attachments: # 1 Proposed Order PROPOSED ORDER GRANTING REQUEST FOR JUDICIAL NOTICE)(Montecuallo, Peter) (Entered: 08/24/2021)
08/24/2021	20	NOTICE re: DEFENDANTS SANOFI-AVENTIS US LLC AND SANOFI US SERVICES INCS CERTIFICATE OF CONFERRAL by Sanofi US Services Incorporated, Sanofi-Aventis U.S. LLC re: 18 MOTION to Dismiss Case <i>MOTION TO DISMISS PLAINTIFFS FIRST AMENDED COMPLAINT</i> . (Montecuallo, Peter) (Entered: 08/24/2021)
08/31/2021	21	NOTICE of Service of Discovery filed by Sanofi US Services Incorporated, Sanofi-Aventis U.S. LLC. (Sixkiller, Laura) (Entered: 08/31/2021)
09/01/2021	22	NOTICE of Service of Discovery filed by Deenen Cone. (Runkle, Ryan) (Entered: 09/01/2021)
09/02/2021	23	NOTICE TO FILER OF DEFICIENCY re: 22 Notice of Service of Discovery filed by Deenen Cone. Document not in compliance with LRCiv 5.5(g) - Documents signed by an attorney shall be filed using that attorney's ECF log-in and password and shall not be filed using a log-in and password belonging to another attorney. Document(s) signed by attorney Patrick Hotze but submitted using the log-in and password belonging to attorney Ryan Runkle. <i>No further action is required.</i> This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (KAH) (Entered: 09/02/2021)
09/07/2021	24	RESPONSE in Opposition re: 18 MOTION to Dismiss Case <i>MOTION TO DISMISS PLAINTIFFS FIRST AMENDED COMPLAINT</i> filed by Deenen Cone. (Hotze, Patrick) (Entered: 09/07/2021)
09/07/2021	25	REQUEST re: Request for Judicial Notice by Plaintiff Deenen Cone. (Attachments: # 1 Exhibit Exhibit A, # 2 Proposed Order Proposed Order Granting Request for Judicial Notice)(Hotze, Patrick) (Entered: 09/07/2021)
09/14/2021	26	REPLY to Response to Motion re: 18 MOTION to Dismiss Case <i>MOTION TO DISMISS PLAINTIFFS FIRST AMENDED COMPLAINT REPLY IN SUPPORT OF SANOFIS MOTION TO DISMISS PLAINTIFFS FIRST AMENDED COMPLAINT</i> filed by Sanofi US Services Incorporated, Sanofi-Aventis U.S. LLC. (Sixkiller, Laura) (Entered: 09/14/2021)
09/15/2021		Remark: Pro hac vice motion(s) granted for Karen Cannon Shanks on behalf of Plaintiff Deenen Cone. This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (BAS) (Entered: 09/15/2021)
10/01/2021		Remark: Pro hac vice motion(s) granted for Richard M Paul, III on behalf of Plaintiff Deenen Cone. This is a TEXT ENTRY ONLY. There is no PDF document associated with this entry. (BAS) (Entered: 10/01/2021)
10/21/2021	27	NOTICE OF ATTORNEY'S CHANGE OF ADDRESS/FIRM NAME by Richard M Paul, III. (Paul, Richard) (Entered: 10/21/2021)

PACER Service Center			
Transaction Receipt			
12/01/2021 14:50:49			
PACER Login:	RickPaul:4634292:4634266	Client Code:	Tax Eyes
Description:	Docket Report	Search Criteria:	2:21-cv-00689-DJH
Billable	4	Cost:	0.40

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

DEENEN CONE,

Plaintiff,

v.

SANOFI US SERVICES, INC. f/k/a
SANOFI-AVENTIS U.S., INC., and
SANOFI-AVENTIS U.S., LLC,

Defendants.

Case No. _____

COMPLAINT
(TORT – PRODUCT LIABILITY)

JURY TRIAL DEMANDED

Plaintiff Deenen Cone, for her Complaint against defendants SANOFI US SERVICES, INC., f/k/a SANOFI-AVENTIS U.S., INC. And SANOFI-AVENTIS U.S., LLC (collectively “Sanofi”), alleges:

INTRODUCTION

1. Sanofi manufactures and sells a chemotherapy drug named Taxotere (generic name docetaxel), which is administered to many who suffer primarily from breast cancer. While it is one of many drugs effective at treating breast cancer, Sanofi has known for years that the drug carries a significant risk of causing permanent punctal, canalicular and nasolacrimal duct stenosis. Despite this, Sanofi failed to warn patients and healthcare providers of the risk of permanent bilateral permanent punctal, canalicular and nasolacrimal duct stenosis and report this risk to the Food and Drug Administration (“FDA”). Worse, Sanofi hid this devastating side effect even though this condition is entirely preventable with early intervention and treatment during chemotherapy. As a result, Mrs. Cone suffers from permanent injuries because she used Taxotere.

Plaintiff is grateful for the chemotherapy that helped to save her life; however, that gratitude is diminished by the fact that she now must endure a permanent and life-altering condition that could have

1 been prevented with an adequate warning to her physicians. Plaintiff's permanent punctal stenosis causes
2 daily disruption to her life due to excessive tearing, or epiphora. For those who have never experienced
3 epiphora, the condition might seem like a minor annoyance. However, for cancer survivors like Mrs.
4 Cone, the irritated, swollen, watering eyes affect their work, their self-esteem, interpersonal relationships,
5 daily activities like driving or reading a book, and their general ability to return to a normal life after
6 defeating cancer.

7 **PARTIES**

8 **A. Plaintiff**

9 2. Plaintiff Deenen Cone is an individual residing in Yarnell, Arizona, who received Taxotere as part
10 of a chemotherapy regimen after being diagnosed with breast cancer. She was administered Taxotere
11 through the Honor Health Virginia C. Piper Cancer Care Network in Wickenburg, Arizona. She was
12 prescribed tri-weekly treatment and received a total of 4 rounds of chemotherapy with Taxotere. Since
13 completing chemotherapy, she has been diagnosed with permanent and irreversible bilateral punctal
14 stenosis, and her eyes continue to tear on a daily basis.

15 **B. Sanofi Defendants**

16 3. Defendant Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. is a Delaware corporation, with
17 a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services
18 Inc. is a wholly owned subsidiary of Sanofi S.A. Sanofi S.A. is engaged in research and development,
19 testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of
20 prescription drugs, including Taxotere. Defendant Sanofi US Services Inc. engages in research and
21 development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or
22 distributing of prescription drugs, including Taxotere.

23 4. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, with a principal
24 place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC
25 is a wholly owned subsidiary of Defendant Sanofi S.A., and Sanofi S.A. is Sanofi-Aventis U.S., LLC's
26 sole member. Defendant Sanofi-Aventis U.S. LLC engages in research and development, testing,
27 manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription
28 drugs, including Taxotere.

1 5. Since 2006, defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. have collectively
2 served as the U.S. operational front for Sanofi S.A. in the U.S. prescription drug market.

3 **JURISDICTION AND VENUE**

4 6. This Court has subject matter jurisdiction is based on 28 U.S.C. §1332(a) because complete
5 diversity of citizenship exists since Plaintiff and Defendants are citizens of different states and the amount
6 in controversy exceeds \$75,000 exclusive of interest and costs.

7 7. A substantial part of the acts and omissions giving rise to this cause of action occurred in this
8 district and therefore venue is proper here pursuant to 28 U.S.C. §1391(a).

9 8. The Sanofi Defendants are subject to personal jurisdiction in this Court due to their continuous and
10 systemic contacts in this forum. Defendants are present and doing business in this State.

11 **FACTUAL ALLEGATIONS**

12 **I. Development and Approval of Taxotere (Docetaxel)**

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

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

21 11. Taxotere is not purchased by patients at a pharmacy; rather, patients' use of these drugs occurs
22 via administration through injection and/or intravenously at a physician's office or medical treatment
23 facility.

24 **II. Taxotere's Labeling**

25 12. Taxotere's labeling information at the time pertinent to this lawsuit, states in relevant part:

26 **Post-Marketing Experiences**

27 **Ophthalmologic**

28 Conjunctivitis, lacrimation or lacrimation with or without conjunctivitis. Excessive
tearing which may be attributable to lacrimal duct obstruction has been reported. Rare

1 cases of transient visual disturbances (flashes, flashing lights, scotomata) typically
2 occurring during drug infusion and in association with hypersensitivity reactions
3 have been reported. These were reversible upon discontinuation of the infusion.

4 **Patient Counseling Information:**

5 Explain to patients that side effects such as nausea, vomiting, diarrhea, constipation, fatigue,
6 excessive tearing, infusion site reactions, and hair loss are associated with docetaxel
7 administration.

8 **What are the possible side effects of Taxotere?**

9 The most common side effects of Taxotere include: redness of the eye, excessive tearing
10 ...

11 13. Sanofi's labeling information at all times relevant to this lawsuit, and even to date, does not
12 identify the risk of permanent punctal, canalicular and nasolacrimal duct stenosis as a cause of excessive
13 tearing, the rapid onset at which this stenosis can occur, the potentially permanent and irreversible nature
14 of the injury, the need to refer patients to a lacrimal specialist, nor does it identify the condition as
15 preventable with timely intervention during chemotherapy.

16 14. At no time has Sanofi's prescribing information contained any mention that once anatomic
17 narrowing of the punctum, canaliculi or nasolacrimal duct secondary to Taxotere reaches a critical
18 threshold, it can be irreversible without appropriate surgical intervention.

19 15. Given the widespread use of Taxotere, it is crucial that the label inform oncologists that permanent
20 punctal, canalicular and/or nasolacrimal duct stenosis is a possible side effect of its use. Only timely
21 diagnosis and treatment of the punctum, canaliculi and/or nasolacrimal duct can prevent complete and
22 permanent closure.

23 16. Sanofi did not provide such adequate notice to oncologists. This failure to provide notice resulted
24 in thousands of women, like Mrs. Cone, suffering daily from a permanent condition that could have easily
25 been prevented with adequate warning.

26 **III. Sanofi's Duty to Monitor and Update Labeling**

27 17. The primary responsibility for timely communicating complete, accurate, and current safety and
28 efficacy information related to Taxotere rests with Sanofi as it has superior, and in many cases exclusive,
access to the relevant safety and efficacy information, including post-market complaints and data.

18. To fulfill its essential responsibilities, Sanofi must vigilantly monitor all reasonably available

1 information. It must closely evaluate the post-market clinical experience of its drugs and timely provide
2 updated safety and efficacy information to the healthcare community and to consumers.

3 19. When monitoring and reporting adverse events, as required by both federal regulations and state
4 law, time is of the essence. The purpose of monitoring a product’s post-market experience is to detect
5 potential safety signals that could indicate to drug sponsors and the medical community that a public
6 safety problem exists.

7 20. If, for example, a manufacturer was to delay reporting post-market information, that delay could
8 mean that researchers, FDA, and the medical community are years behind in identifying a public safety
9 issue associated with the drug.

10 21. In the meantime, more patients are harmed by using the product without knowing, understanding,
11 and accepting its true risks, which is why drug sponsors must not only completely and accurately monitor,
12 investigate and report post-market experiences, but must also report the data in a timely fashion.

13 22. A drug is “misbranded” in violation of the FDCA when its labeling is false and misleading or
14 does not provide adequate directions for use and adequate warnings. *See* 21 U.S.C. §§ 321(n); 331(a),
15 (b), (k); 352(a), (f). A drug’s labeling satisfies federal requirements if it gives physicians and pharmacists
16 sufficient information—including indications for use and “any relevant hazards, contraindications, side
17 effects, and precautions”—to allow those professionals “to use the drug safely and for the purposes for
18 which it is intended.” 21 C.F.R. § 201.100(c)(1).

19 23. As part of their responsibility to monitor post-market clinical experiences with the drug and
20 provide updated safety and efficacy information to the healthcare community and to consumers, each
21 approved NDA applicant “must promptly review all adverse drug experience information obtained or
22 otherwise received by the applicant from any source, foreign or domestic, including information derived
23 from commercial marketing experience, post marketing clinical investigations, post marketing
24 epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific
25 papers.” 21 C.F.R. § 314.80(b).

26 24. Any report of a “serious and unexpected” drug experience, whether foreign or domestic, must be
27 reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. §
28 314.80(c)(1)(i-ii).

1 25. Most other adverse event reports must be submitted quarterly for three years after the application
2 is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic reports must include a
3 “history of actions taken since the last report because of adverse drug experiences (for example, labeling
4 changes or studies initiated).” 21 C.F.R. § 314.80(c)(2)(ii).

5 26. Federal law requires labeling to be updated as information accumulates: “labeling must be revised
6 to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a
7 causal association with a drug; a causal relationship need not have been definitely established.” 21 C.F.R.
8 § 201.57(c)(6)(i). The labeling “must describe significant adverse reactions . . . and steps that should be
9 taken if they occur.” *Id.* Thus, for example, drug manufacturers must warn of an adverse effect where
10 there is “some basis to believe there is a causal relationship between the drug and the occurrence of the
11 adverse event.” 21 C.F.R. § 201.57(c)(7).

12 27. All changes to drug labels require FDA assent. 21 C.F.R. § 314.70(b)(2)(v)(A). Brand-name drug
13 sponsors may seek to change their approved labels by filing a supplemental application. 21 C.F.R. §
14 314.70.

15 28. One regulation, the “Changes Being Effected” (CBE) regulation, permits a manufacturer to
16 unilaterally change a drug label to reflect “newly acquired information,” subject to later FDA review and
17 approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information includes “new analyses of previously
18 submitted data.” 21 C.F.R. § 314.3(b).

19 29. If a drug sponsor determined that a warning was insufficient based on a new analysis of previously
20 existing data, it could submit a CBE and change its labeling. For example, if a drug manufacturer is aware
21 of an adverse reaction that can be prevented, it has an obligation to update the label to not only include a
22 warning of the side effect, but also the steps that can be taken to mitigate, prevent, or treat the side effect.
23 The longer a drug sponsor delays updating its labeling to reflect current safety information, the more
24 likely it is that medical professionals will prescribe drugs without advising patients of harmful adverse
25 reactions, and the more likely it is that patients will suffer harmful adverse reactions without the
26 opportunity to evaluate risks for themselves and/or seek appropriate treatment if adverse reactions occur.

27 **IV. Sanofi Knew That Taxotere Causes Permanent Punctal Stenosis.**

28 30. From 2001 until present day, medical literature has documented and concluded that docetaxel is

1 secreted in the tear film, thereby causing fibrosis of the lacrimal system, including the puncta, canaliculi
 2 and nasolacrimal duct. Medical literature has concluded that this scarring can cause permanent and
 3 irreversible occlusion, resulting in the failure of tears to drain naturally through the lacrimal system.
 4 Because the eyes are constantly producing tears, this results in persistent epiphora and further lacrimal
 5 complications.

6 31. Prominent medical researchers have described this side effect as follows: “canalicular stenosis
 7 may be the most important side effect of weekly docetaxel¹”; “cancer patients . . . view epiphora as one
 8 of the worst side effects because of their inability to read, drive, or wear make-up²”; “visually
 9 disabling³”; “misleading appearance of emotional tears⁴”; “canalicular stenosis can negatively impact
 10 the quality of life . . . and should be considered when choosing the chemotherapy regimen⁵”; “epiphora
 11 may be a major disability. It interferes with daily activities and causes emotional disturbances⁶”; “the
 12 potential risk of this complication should be carefully weighed⁷”; “epiphora may be an underrecognized
 13 adverse effect⁸”; and “the high incidence of this adverse effect has an impact on several aspects of daily
 14 living.⁹”

15 _____
 16 ¹ Bitá Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel*
Therapy, 98 AM. CANCER SOC'Y., 504 (2003).

17 ² *Id.*

18 ³ Bitá Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly versus Every-3-Weeks Docetaxel in*
 19 *Patients with Metastatic Breast Cancer*, 109 AM ACAD. OF OPHTHALMOLOGY, 1188 (2002).

20 ⁴ Bitá Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly Docetaxel: A Potentially Preventable*
 21 *Side Effect*, 13 EUROPEAN SOC'Y. FOR MED. ONCOLOGY, 218 (2001).

22 ⁵ Bitá Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel*
 23 *Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

24 ⁶ Medy Tsalic., et al., *Epiphora (Excessive Tearing) and Other Ocular Manifestations Related to*
 25 *Weekly Docetaxel*, 23 MEDICAL ONCOLOGY (2005)

26 ⁷ *Id.*

27 ⁸ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

28 ⁹ Arlene Chan, et al., *Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving*
Adjuvant Docetaxel-based Chemotherapy, 31 JOURNAL OF CLINICAL ONCOLOGY, 17 (2013)

1 32. Medical literature is clear that: (1) the onset of punctal, canalicular and/or nasolacrimal duct
2 stenosis can be rapid, (2) referral to a lacrimal specialist for evaluation is essential, (3) punctal,
3 canalicular and/or nasolacrimal duct stenosis can be permanent and irreversible, (4) punctal, canalicular
4 and nasolacrimal duct stenosis is preventable, and (5) oncologists are not aware of the severity of this
5 issue.

6 **V. Taxotere Caused Mrs. Cone’s Permanent Bilateral Punctal Stenosis.**

7 33. Mrs. Cone was diagnosed with breast cancer and received weekly infusions of Taxotere, receiving
8 a total of four infusions over the course of three months.

9 34. Almost immediately after completing her first infusion of Taxotere, Mrs. Cone began tearing.
10 Mrs. Cone informed her oncologist of the excessive tearing, and was informed that it was a normal side
11 effect of Taxotere that should get better. Mrs. Cone resumed chemotherapy with the belief that her
12 tearing, like other chemotherapy adverse effects, was temporary and would resolve upon completion of
13 treatment.

14 35. In April of 2019, a month after her last chemotherapy infusion, Mrs. Cone visited an optometrist
15 who evaluated her tearing and referred Mrs. Cone to an oculoplastic surgeon. In June of 2019, Mrs. Cone
16 consulted a surgeon who diagnosed her with punctal stenosis and epiphora due to insufficient drainage,
17 recommending that she undergo a punctoplasty surgery.

18 36. On October 1, 2019, Mrs. Cone arrived for her punctoplasty surgery complaining that her eyes
19 were “still watering like crazy.” Mrs. Cone proceeded with the punctoplasty surgery in an attempt to
20 repair her damaged lacrimal system.

21 37. Despite surgical intervention, Mrs. Cone’s epiphora did not improve.

22 38. On February 24, 2020 Mrs. Cone met again with her oculoplastic surgeon with concerns that she
23 was still experiencing excessive tearing in both eyes, with tears spilling over so frequently, the skin on
24 her cheeks had become raw and chapped, and she was constantly having to wipe her face to keep it dry.
25 She complained to her surgeon that “something is not right” despite the invasive surgery. At her
26 physician’s recommendation, she continued to use artificial tears and warm compresses in attempt to
27 alleviate the symptoms, despite the fact that these interventions had little to no effect.

28 39. Mrs. Cone completed chemotherapy and was excited to be cancer free and rid of all of the side

1 effects she suffered as a result of the cancer treatment. Among these, Mrs. Cone looked forward to no
2 longer suffering from constantly irritated, watering eyes. But as the effects of chemotherapy wore off,
3 her watery eyes remained.

4 40. Mrs. Cone’s ability to work has been diminished because, as a forest fire dispatcher, a large part
5 of her job is spent working on a computer. Her vision disturbances and watery eyes prevent her from
6 clearly seeing her computer screen. She is unable to read, fill out forms, drive or perform other basic
7 tasks that require clear vision. She is devastated by the fact that, as an artist, her craft suffers due to the
8 fact that she cannot clearly see her work as she visualizes each project.

9 41. Mrs. Cone continues to experience persistent tearing and a disruption of her life. As a direct and
10 proximate result of Sanofi’s conduct in connection with the design, development, manufacture, testing,
11 packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of Taxotere, Mrs.
12 Cone suffers from permanent epiphora (persistent tearing), due to punctal stenosis. This condition is a
13 side effect of taking Taxotere.

14 42. As a result of this undisclosed side effect, Mrs. Cone has struggled to return to normalcy, even
15 after surviving cancer, because she continues to suffer from persistent tearing on a daily basis, interfering
16 with her ability to perform basic activities and enjoy life. This permanent change has altered Mrs. Cone’s
17 self-image, negatively impacted her relationships, and others’ perceptions of her, leading to social
18 isolation and depression even long after fighting cancer.

19 43. Mrs. Cone began her battle with Stage II breast cancer with a plan to undergo chemotherapy.
20 After chemotherapy with Taxotere, her eyes unexpectedly became irritated and red and began to tear
21 constantly. Throughout her ordeal, Mrs. Cone remained hopeful that, like other chemotherapy side
22 effects, the epiphora would eventually resolve. To her dismay, it never has.

23 44. Mrs. Cone’s tearing is much more than a minor annoyance – it impacts all aspects of her daily
24 life. Prior to developing permanent punctal stenosis, Mrs. Cone was self-confident and enjoyed engaging
25 with others. Now she lacks the confidence she has been accustomed to and is painfully aware that people
26 see tears streaming down her face and think something is wrong.

27 45. Mrs. Cone is anxious about face-to-face interactions with others because she fears people will
28 perceive her as sad and crying. She is unable to keep makeup on her face. She is aware of the concerned

1 looks from well-intentioned friends, colleagues and strangers who perceive her to be emotional and upset.

2 46. Mrs. Cone's injuries could have been prevented had Sanofi simply warned that permanent or
3 irreversible punctal stenosis is a common but preventable side effect of Taxotere. Mrs. Cone thus seeks
4 recovery for her mental and physical suffering stemming from permanent, but easily preventable, punctal
5 stenosis.

6 47. To this day, Mrs. Cone continues to suffer from epiphora but has found no relief.

7 **VI. Tolling of the Statute of Limitations.**

8 48. Mrs. Cone files this lawsuit within the applicable statute of limitations period of first suspecting
9 that Taxotere's wrongful conduct caused the appreciable harm she sustained. Due to Sanofi's fraudulent
10 concealment of this known side effect, Mrs. Cone could not, by the exercise of reasonable diligence, have
11 discovered that Sanofi wrongfully caused her injuries as she was unaware of the severity of her injury.
12 Specifically, Mrs. Cone did not suspect, nor did she have reason to suspect, that she had been permanently
13 injured, or suspect the tortious nature of the conduct causing her injuries until a date before filing this
14 action that is less than the applicable limitations period for filing suit.

15 49. Mrs. Cone was advised that tearing was a common side effect of Taxotere chemotherapy that,
16 like most other side effects of chemotherapy, would resolve.

17 50. Additionally, Mrs. Cone was prevented from discovering this information at an earlier date
18 because Sanofi: (1) misrepresented to the public, the FDA, and the medical profession that Taxotere was
19 free from permanent side effects; (2) failed to disclose to the public, the FDA, and the medical profession
20 its knowledge of the risk of permanent but reversible side effects; (3) failed to disclose to the public, the
21 FDA, and the medical profession its knowledge that these side effects were preventable with early
22 intervention during chemotherapy; (4) fraudulently concealed facts and information that could have led
23 Mrs. Cone to discover Sanofi's liability; and (5) still has not disclosed to the public, the FDA, and the
24 medical profession that Taxotere can cause permanent punctal, canalicular and nasolacrimal duct stenosis
25 which can be prevented with early intervention during chemotherapy.

26 **COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)**

27 51. Mrs. Cone incorporates by reference the above paragraphs as if set forth herein.

28 52. At all relevant times, Sanofi was in the business of designing, researching, manufacturing, testing,

1 promoting, marketing, selling, and/or distributing pharmaceutical products, including the Taxotere used
2 by Mrs. Cone.

3 53. The Taxotere designed, formulated, produced, manufactured, sold, marketed, distributed,
4 supplied and/or placed into the stream of commerce by Sanofi failed to provide adequate warnings to
5 users and their healthcare providers, including Mrs. Cone and her healthcare providers, of the risk of side
6 effects associated with the use of Taxotere, particularly the risk of developing disfiguring, permanent
7 punctal, canalicular and nasolacrimal duct stenosis, or the measures that could have been taken to prevent
8 it.

9 54. The Taxotere designed, formulated, produced, manufactured, sold, marketed, distributed,
10 supplied and/or placed into the stream of commerce by Sanofi and ultimately administered to Mrs. Cone
11 lacked such warnings when it left Sanofi's control.

12 55. The risks of developing disfiguring, permanent bilateral punctal, canalicular and nasolacrimal
13 duct stenosis were known to or reasonably knowable by Sanofi at the time the Taxotere left Sanofi's
14 control.

15 56. A reasonably prudent company in the same or similar circumstances would have provided a
16 warning that communicated the dangers and safe use of Taxotere.

17 57. Any warnings actually provided by Sanofi did not sufficiently and/or accurately reflect the
18 symptoms, type, scope, severity, and/or duration of these side effects, particularly the risks of developing
19 disfiguring, permanent punctal, canalicular and nasolacrimal duct stenosis or how it could have been
20 prevented during administration of the chemotherapy.

21 58. Without adequate warning of these side effects, Taxotere is not reasonably fit, suitable, or safe
22 for its reasonably anticipated or intended purposes.

23 59. Mrs. Cone was a reasonably foreseeable user of Taxotere who used the drug in a reasonably
24 anticipated manner.

25 60. Mrs. Cone would have taken preventative measures during the course of her chemotherapy to
26 prevent punctal stenosis had she (and her physicians) been provided an adequate warning by Sanofi of
27 the risk of these side effects.

28 61. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse

1 effects of Taxotere, Mrs. Cone suffered and continues to suffer serious and dangerous side effects, severe
2 and personal injuries that are permanent and lasting in nature, and economic and non-economic damages,
3 harms, and losses, including, but not limited to: past and future medical expenses; past and future loss of
4 earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including
5 permanent punctal stenosis; mental anguish; severe and debilitating emotional distress; increased risk of
6 future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past,
7 present, and future loss and impairment of the quality and enjoyment of life.

8 WHEREFORE, Plaintiff Deenen Cone respectfully requests judgment in her favor and against
9 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief
10 this Court deems just and proper.

11 **COUNT II – STRICT PRODUCTS LIABILITY (MISREPRESENTATION)**

12 62. Mrs. Cone incorporates by reference the above paragraphs as if set forth herein.

13 63. Sanofi sold the Taxotere that Mrs. Cone’s healthcare providers prescribed for Mrs. Cone and that
14 Mrs. Cone used.

15 64. Sanofi was engaged in the business of selling the Taxotere for resale, use, or consumption.

16 65. Sanofi misrepresented facts as set forth herein concerning the character or quality of the Taxotere
17 that would be material to potential prescribers and purchasers or users of the product.

18 66. Sanofi’s misrepresentations were made to potential prescribers and/or purchasers or users as
19 members of the public at large.

20 67. As purchasers or users, Mrs. Cone and/or her healthcare providers reasonably relied on the
21 misrepresentations.

22 68. Mrs. Cone was a person who would reasonably be expected to use, consume, or be affected by
23 the Taxotere.

24 69. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Cone to
25 suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in
26 nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past
27 and future medical expenses; past and future loss of earnings; past and future loss and impairment of
28 earning capacity; permanent disfigurement, including permanent punctal stenosis; mental anguish; severe

1 and debilitating emotional distress; increased risk of future harm; past, present, and future physical and
 2 mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality
 3 and enjoyment of life.

4 WHEREFORE, Deenen Cone respectfully requests judgment in her favor and against Defendants in
 5 an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
 6 deems just and proper.

7 **COUNT III - NEGLIGENCE**

8 70. Mrs. Cone incorporates by reference the above paragraphs as if set forth herein.

9 71. Sanofi had a duty to exercise reasonable care in the design, research, formulation, manufacture,
 10 production, marketing, testing, supply, promotion, packaging, sale, and/or distribution of Taxotere,
 11 including a duty to assure that the product would not cause users to suffer unreasonable, disfiguring, and
 12 dangerous side effects.

13 72. Sanofi breached these duties when it put Taxotere into interstate commerce, unreasonably and
 14 without adequate and/or proper warning to Mrs. Cone and her healthcare providers, a product that Sanofi
 15 knew or should have known created a high risk of unreasonable, disfiguring, and dangerous side effects.

16 73. The negligence of Sanofi, its agents, servants, and/or employees, included but was not limited to,
 17 the following acts and/or omissions:

- 18 (a) Manufacturing, producing, promoting, formulating, creating, and/or designing Taxotere
 19 without thoroughly, adequately, and/or sufficiently testing it—including pre- clinical and
 20 clinical testing and post-marketing surveillance—for safety and fitness for use and/or its
 21 dangers and risks;
- 22 (b) Marketing Taxotere to Mrs. Cone, Mrs. Cone’s healthcare providers, the public, and the
 23 medical and healthcare professions without adequately and correctly warning and/or
 24 disclosing the existence, severity, and duration of known or knowable side effects, including
 25 permanent punctal stenosis;
- 26 (c) Marketing Taxotere to Mrs. Cone, Mrs. Cone’s healthcare providers, the public, and the
 27 medical and healthcare professions without providing adequate instructions regarding safety
 28 precautions to be observed by users, handlers, and persons who would reasonably and
 foreseeably come into contact with, and more particularly, use, Taxotere;
- (d) Advertising and recommending the use of Taxotere without sufficient knowledge of its safety
 profile;
- (e) Designing, manufacturing, producing, and/or assembling Taxotere in a manner that was

dangerous to its users;

- (f) Concealing information from Mrs. Cone, Mrs. Cone’s healthcare providers, the public, other medical and healthcare professionals, and the FDA that Taxotere was unsafe, dangerous, and/or non-conforming with FDA regulations;
- (g) Concealing from and/or misrepresenting information to Mrs. Cone, Mrs. Cone’s healthcare providers, other medical and healthcare professionals, and/or the FDA concerning the existence and severity of risks and dangers of Taxotere; and
- (h) Encouraging the sale of Taxotere, either directly or indirectly, orally or in writing, to Mrs. Cone and Mrs. Cone’s healthcare providers without warning about the need for more comprehensive and regular medical monitoring than usual to ensure early discovery of potentially serious side effects such as punctal stenosis.

74. Despite the fact that Sanofi knew or should have known that Taxotere caused unreasonably dangerous side effects, Sanofi continues to market, manufacture, distribute, and/or sell Taxotere to consumers.

75. Mrs. Cone and Mrs. Cone’s healthcare providers were therefore forced to rely on safety information that did not accurately represent the risks and benefits associated with the use of Taxotere and measures that could have been taken to prevent severe and permanent disfigurement from the use of Taxotere.

76. Sanofi knew or should have known that consumers such as Mrs. Cone would use its product and would foreseeably suffer injury as a result of Sanofi’s failure to exercise reasonable care, as set forth above.

77. Sanofi’s negligence was a proximate cause of Mrs. Cone’s injuries, harms, damages, and losses, in connection with the use of Taxotere, including but not limited to: past and future medical expenses; past and future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement including permanent and irreversible punctal stenosis; mental anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

WHEREFORE, Deenen Cone respectfully requests judgment in her favor and against Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court deems just and proper.

COUNT IV – NEGLIGENT MISREPRESENTATION

1
2 78. Mrs. Cone incorporates by reference the above paragraphs as if set forth herein.

3 79. Sanofi had a duty to represent to Mrs. Cone, Mrs. Cone’s healthcare providers, the healthcare
4 community, and the public in general that Taxotere had been tested and found to be safe and effective for
5 the treatment of various forms of cancer.

6 80. When warning of safety and risks of Taxotere, Sanofi negligently represented to Mrs. Cone, Mrs.
7 Cone’s healthcare providers, the healthcare community, and the public in general that Taxotere had been
8 tested and was found to be safe and/or effective for its indicated use.

9 81. Sanofi concealed its knowledge of Taxotere defects from Mrs. Cone, Mrs. Cone’s healthcare
10 providers, and the public in general and/or the healthcare community specifically.

11 82. Sanofi concealed this information with the intent of defrauding and deceiving Mrs. Cone, Mrs.
12 Cones’ healthcare providers, the public in general, and the healthcare community in particular, and were
13 made with the intent of inducing Mrs. Cone, Mrs. Cone’s healthcare providers, the public in general, and
14 the healthcare community in particular, to recommend, dispense, and/or purchase Taxotere.

15 83. Sanofi failed to exercise ordinary and reasonable care in its representations of Taxotere in its sale,
16 testing, quality assurance, quality control, and/or distribution into interstate commerce, and Sanofi
17 negligently misrepresented Taxotere’s high risks of unreasonable, dangerous side effects. These side
18 effects were unreasonable because they could have been entirely prevented with adequate warning.

19 84. Sanofi breached its duty in misrepresenting Taxotere’s serious side effects to Mrs. Cone, Mrs.
20 Cone’s healthcare providers, the healthcare community, the FDA, and the public in general.

21 85. Mrs. Cone and Mrs. Cone’s healthcare providers reasonably relied on Sanofi to fulfill its
22 obligations to disclose all facts within its knowledge regarding the serious side effects of Taxotere and
23 the ability to prevent those side effects with appropriate precautionary measures.

24 86. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Cone to
25 suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in
26 nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past
27 and future medical expenses; past and future loss of earnings; past and future loss and impairment of
28 earning capacity; permanent disfigurement, including permanent punctal stenosis; mental anguish; severe

1 and debilitating emotional distress; increased risk of future harm; past, present, and future physical and
 2 mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality
 3 and enjoyment of life.

4 WHEREFORE, Deenen Cone respectfully requests that judgment in her favor and against Defendants
 5 in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
 6 deems just and proper.

7 **COUNT V – FRAUDULENT MISREPRESENTATION**

8 87. Mrs. Cone incorporates by reference the above paragraphs as if set forth herein.

9 88. Sanofi represented to Mrs. Cone, Mrs. Cone’s healthcare providers, the healthcare community,
 10 and the public in general that Taxotere had been tested and was found to be safe and effective for the
 11 treatment of certain forms of cancer and was free of defects that could and would cause serious side
 12 effects, including permanent and irreversible punctal stenosis.

13 89. Sanofi fraudulently omitted from these representations information that Taxotere could and did
 14 cause serious side effects, including permanent and irreversible punctal stenosis.

15 90. These representations were material and false.

16 91. Sanofi made these representations and omissions:

- 17 (a) with knowledge or belief of their falsity, and/or in the case of omissions, with knowledge or
 18 belief of falsity of the resulting statements;
- 19 (b) positively and recklessly without knowledge of their truth or falsity;
- 20 (c) with knowledge that they were made without any basis; and/or
- 21 (d) without confidence in the accuracy of the representations or statements resulting from the
 22 omissions.

23 92. Sanofi made these false representations with the intention or expectation that Mrs. Cone, Mrs.
 24 Cone’s healthcare providers, the public in general, and the healthcare community in particular, would
 25 recommend, dispense, and/or purchase Taxotere, all of which evidenced a callous, reckless, willful,
 26 wanton, and depraved indifference to the health, safety, and welfare of Mrs. Cone.

27 93. At the time Sanofi made the aforesaid representations, and, at the time Mrs. Cone used Taxotere,
 28 Mrs. Cone and Mrs. Cone’s healthcare providers were unaware of the falsity of Sanofi’s representations,

1 statements and/or implications and justifiably and reasonably relied on Sanofi’s representations,
2 statements, and implications, believing them to be true.

3 94. In reliance on Sanofi’s representations, Mrs. Cone and her healthcare providers were induced to
4 and did use and prescribe Taxotere, which caused Mrs. Cone to suffer serious and dangerous side effects,
5 severe and personal injuries that are permanent and lasting in nature, and economic and non-economic
6 damages, harms, and losses, including, but not limited to: past and future medical expenses; past and
7 future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement,
8 including permanent punctal stenosis; mental anguish; severe and debilitating emotional distress;
9 increased risk of future harm; past, present, and future physical and mental pain, suffering, and
10 discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

11 WHEREFORE, Deenen Cone respectfully requests judgment in her favor and against Defendants in
12 an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
13 deems just and proper.

14 **COUNT VI – FRAUDULENT CONCEALMENT**

15 95. Mrs. Cone incorporates by reference the above paragraphs as if set forth herein.

16 96. At all times during the course of dealing between Sanofi and Mrs. Cone and Mrs. Cone’s
17 healthcare providers, Sanofi misrepresented the design characteristic and safety of Taxotere for their
18 intended use.

19 97. Sanofi knew or was reckless in not knowing that its representations were false.

20 98. In representations made to Mrs. Cone and Mrs. Cone’s healthcare providers, Sanofi fraudulently
21 concealed and intentionally omitted the following material information:

- 22 (a) that Taxotere was not as safe as other forms of treatment for which they were marketed and
23 sold to cancer patients;
- 24 (b) that the risks of adverse events with Taxotere was higher than those with other forms of
25 treatment for which they were marketed and sold to cancer patients;
- 26 (c) that the risks of adverse events with Taxotere was not adequately tested and/or known by
27 Sanofi;
- 28 (d) that Sanofi was aware of dangers in Taxotere, in addition to and above and beyond those
associated with other forms of treatment for cancer patients; and

1 (e) that Taxotere was defective in that it caused dangerous side effects as well as other severe and
2 permanent health consequences at a much more significant rate than other forms of treatment
3 for cancer patients.

4 99. Sanofi had a duty to disclose to Mrs. Cone and Mrs. Cone's healthcare providers the defective
5 nature of Taxotere, including, but not limited to, the heightened risks of disfiguring, permanent punctal,
6 canalicular and nasolacrimal stenosis.

7 100. Sanofi had a duty to disclose to Mrs. Cone and Mrs. Cone's healthcare providers that the
8 disfiguring, permanent punctal, canalicular and nasolacrimal stenosis caused by the use of Taxotere could
9 have been prevented by early identification and treatment of epiphora during chemotherapy.

10 101. Sanofi had sole access to material facts concerning the defective nature of Taxotere and its
11 propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used
12 the drugs at issue, including Mrs. Cone.

13 102. Sanofi's concealment and omissions of material fact concerning the safety of Taxotere were
14 made purposefully, willfully, wantonly, and/or recklessly to mislead Mrs. Cone and Mrs. Cone's
15 healthcare providers into reliance on the continued use of the drugs and to cause them to purchase,
16 prescribe, and/or dispense Taxotere and/or use it.

17 103. Sanofi knew that Mrs. Cone and her healthcare providers had no way to determine the truth
18 behind its concealment and omissions, including the material omissions of fact surrounding Taxotere set
19 forth herein.

20 104. Mrs. Cone and Mrs. Cone's healthcare providers reasonably relied on information disclosed by
21 Sanofi that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or
22 omitted by Sanofi.

23 105. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Cone to suffer serious and
24 dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and
25 economic and non-economic damages, harms, and losses, including, but not limited to: past and future
26 medical expenses; past and future loss of earnings; past and future loss and impairment of earning
27 capacity; permanent disfigurement, including permanent punctal stenosis; mental anguish; severe and
28 debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental
pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and

1 enjoyment of life.

2 WHEREFORE, Deenen Cone respectfully requests judgment in her favor and against Defendants in
3 an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
4 deems just and proper.

5 **VII. JURY DEMAND**

6 Plaintiff hereby requests a trial by jury pursuant to rule 38 of the Federal Rules of Civil
7 Procedure.

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Dated: April 21, 2021

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HOTZE RUNKLE, PLLC

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By: /s/ Ryan Runkle _____
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**U.S. District Court
Eastern District of California - Live System (Sacramento)
CIVIL DOCKET FOR CASE #: 2:21-cv-00730-TLN-DB**

Vega v. Sanofi US Services, Inc., et al
Assigned to: District Judge Troy L. Nunley
Referred to: Magistrate Judge Deborah Barnes
Cause: 28:1332 Diversity-Product Liability

Date Filed: 04/23/2021
Jury Demand: Plaintiff
Nature of Suit: 367 Personal Injury: Health Care/Pharmaceutical
Personal Injury Product Liability
Jurisdiction: Diversity

Plaintiff

Teresa Vega

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V.

Defendant

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Amir M. Nassihi
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Date Filed	#	Docket Text
04/23/2021	1	COMPLAINT against All Defendants by Teresa Vega. Attorney Fitzpatrick, B. James added. (Filing fee \$ 402, receipt number 0972-9562157) (Attachments: # 1 Civil Cover Sheet)(Fitzpatrick, B.) (Entered: 04/23/2021)
04/23/2021	2	PRO HAC VICE APPLICATION and PROPOSED ORDER submitted by Teresa Vega. (Filing fee \$ 225, receipt number 0972-9562223) (Fitzpatrick, B.) (Entered: 04/23/2021)
04/23/2021	3	SUMMONS ISSUED as to *Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC* with answer to complaint due within *21* days. Attorney *B. James Fitzpatrick* *Fitzpatrick & Swanston* *555 S. Main Street* *Salinas, CA 93901*. (Zignago, K.) (Entered: 04/23/2021)
04/23/2021	4	CIVIL NEW CASE DOCUMENTS ISSUED; (Attachments: # 1 Consent Form, # 2 VDRP) (Zignago, K.) (Entered: 04/23/2021)
04/29/2021	5	PRO HAC VICE ORDER signed by District Judge Troy L. Nunley on 4/28/2021 GRANTING 2 Application for Pro Hac Vice, Attorney Patrick O. Hotze, to appear for Teresa Vega. (Reader, L) (Entered: 04/29/2021)
05/07/2021	6	PRO HAC VICE APPLICATION and PROPOSED ORDER submitted by Teresa Vega for attorney Richard M. Paul, III to appear Pro Hac Vice. (Filing fee \$ 225, receipt number 0972-9589696) (Fitzpatrick, Bernard) (Entered: 05/07/2021)
05/07/2021	7	WAIVER of SERVICE RETURNED EXECUTED: Waiver sent to All Defendants (Fitzpatrick, Bernard) (Entered: 05/07/2021)
05/12/2021	8	PRO HAC VICE ORDER signed by District Judge Troy L. Nunley on 5/11/21 ADDING Attorney Richard M. Paul, III, PHV for Teresa Vega. (Kastilahn, A) (Entered: 05/12/2021)
06/28/2021	9	NOTICE of APPEARANCE by Amir M. Nassihi on behalf of Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. Attorney Nassihi, Amir M. added. (Nassihi, Amir) (Entered: 06/28/2021)
06/28/2021	10	STIPULATION and PROPOSED ORDER for Extension of Time to Respond to Complaint and Briefing Schedule re 1 Complaint by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Nassihi, Amir) (Entered: 06/28/2021)
06/28/2021	11	ORDER signed by District Judge Troy L. Nunley on 6/28/2021 CONTINUING defendants Sanofi US Services, Inc., Inc. and Sanofi-Aventis U.S., LLC's deadline to file a response to the Complaint to 8/2/2021. If Sanofi files a pleading challenge, the deadline for Plaintiff's opposition is 9/1/2021, and the deadline for Sanofi's reply is due by 9/15/2021. (Coll, A) Modified on 7/6/2021 (Krueger, M). (Entered: 06/28/2021)
07/30/2021	12	STIPULATION and PROPOSED ORDER for Plaintiff to File First Amended Complaint by Teresa Vega. Attorney Paul, Richard added. (Paul, Richard) (Entered: 07/30/2021)
07/30/2021	13	FIRST AMENDED COMPLAINT against All Defendants by Teresa Vega.(Paul, Richard) (Entered: 07/30/2021)
08/02/2021	14	STIPULATION and ORDER signed by District Judge Troy L. Nunley on 7/30/2021 ORDERING that Plaintiff Teresa Vega shall have leave to file her First Amended Complaint in this action. (Huang, H) (Entered: 08/02/2021)
08/13/2021	15	MOTION to DISMISS by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. Motion Hearing set for 10/28/2021 at 02:00 PM in Courtroom 2 (TLN) before District Judge Troy L. Nunley. (Attachments: # 1 Proposed Order)(Nassihi, Amir) (Entered: 08/13/2021)
08/13/2021	16	REQUEST for JUDICIAL NOTICE by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC in re 15 Motion to Dismiss. (Attachments: # 1 Exhibit A, # 2 Exhibit B, # 3 Exhibit C, # 4 Exhibit D, # 5 Exhibit E, # 6 Exhibit F, # 7 Exhibit G, # 8 Exhibit H, # 9 Exhibit I, # 10 Exhibit J, # 11 Exhibit K)(Nassihi, Amir) (Entered: 08/13/2021)
08/24/2021	17	CORPORATE DISCLOSURE STATEMENT by Defendants Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Nassihi, Amir) (Entered: 08/24/2021)
08/27/2021	18	PRO HAC VICE APPLICATION and PROPOSED ORDER submitted by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC for attorney Torrey Peterson to appear Pro Hac Vice. (Filing fee \$ 225, receipt number ACAEDC-9789742) (Attachments: # 1 Certificate of Good Standing) (Nassihi, Amir) (Entered: 08/27/2021)
08/27/2021	19	PRO HAC VICE APPLICATION and PROPOSED ORDER submitted by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC for attorney Harley V. Ratliff to appear Pro Hac Vice. (Filing fee \$ 225, receipt number ACAEDC-9789842) (Attachments: # 1 Certificate of Good Standing) (Nassihi, Amir) (Entered: 08/27/2021)
09/14/2021	20	ORDER GRANTING 18 Application for Pro Hac Vice signed by District Judge Troy L. Nunley on 09/13/21. Added attorney Torrey Peterson, PHV for Sanofi US Services, Inc. and Sanofi-Aventis U.S. LLC. The Pro Hac Vice attorney is directed to request electronic filing access through PACER. (Benson, A.) (Entered: 09/14/2021)
09/14/2021	21	ORDER GRANTING 19 Application for Pro Hac Vice signed by District Judge Troy L. Nunley on 09/13/21. Added attorney Harley V. Ratliff, PHV for Sanofi US Services, Inc. and Sanofi-Aventis U.S. LLC. The Pro Hac Vice attorney is directed to request electronic filing access through PACER. (Benson, A.) (Entered: 09/14/2021)
10/07/2021	22	RESPONSE by Teresa Vega in OPPOSITION to 15 Motion to Dismiss. (Attachments: # 1 Exhibit A)(Paul, Richard) Modified on 10/8/2021

		(Mena-Sanchez, L). (Entered: 10/07/2021)
10/07/2021	23	REQUEST for Judicial Notice by Teresa Vega re 15 Motion to Dismiss. (Attachments: # 1 Exhibit A)(Paul, Richard) Modified on 10/8/2021 (Mena-Sanchez, L). (Entered: 10/07/2021)
10/07/2021	24	PROPOSED ORDER re Request for Judicial Notice by Teresa Vega. (Paul, Richard) (Entered: 10/07/2021)
10/08/2021	25	NOTICE of CHANGE of ADDRESS by Richard Paul, PHV. (Paul, Richard) (Entered: 10/08/2021)
10/18/2021	26	STIPULATION and PROPOSED ORDER for Continuance of Hearing Date for Sanofi's Motion to Dismiss by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Nassih, Amir) (Entered: 10/18/2021)
10/18/2021	27	MINUTE ORDER issued by Courtroom Deputy M. Krueger for District Judge Troy L. Nunley on 10/18/2021: On the Court's own motion, Defendants' Motion to Dismiss (ECF No. 15) is hereby SUBMITTED without oral argument. Accordingly, the hearing set for 10/28/2021 is VACATED. If the Court determines oral argument is necessary, it will be scheduled at a later date. Defendants may still file a reply brief on or before 10/21/2021. The parties' Stipulation to Extend Time (ECF No. 26) is DENIED as MOOT. (Text Only Entry) (Krueger, M) (Entered: 10/18/2021)
10/21/2021	28	REPLY by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC in support of 15 Motion to Dismiss. (Nassih, Amir) Modified on 10/22/2021 (Coll, A). (Entered: 10/21/2021)

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24 Attorneys for Plaintiff,
25 TERESA VEGA

26
27
28
**UNITED STATES DISTRICT COURT FOR THE
EASTERN DISTRICT OF CALIFORNIA
SACRAMENTO DIVISION**

TERESA VEGA,

Plaintiff,

v.

SANOFI US SERVICES, INC. f/k/a
SANOFI-AVENTIS U.S., INC., and
SANOFI-AVENTIS U.S., LLC,

Defendants.

Case No. 2:21-cv-00730- TLN -DB

FIRST AMENDED COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Teresa Vega, for her First Amended Complaint against defendants SANOFI US SERVICES,

1 INC., f/k/a SANOFI-AVENTIS U.S., INC. and SANOFI-AVENTIS U.S., LLC (collectively “Sanofi”),
2 alleges:

3 INTRODUCTION

4 1. Sanofi manufactures and sells a chemotherapy drug named Taxotere (generic name docetaxel),
5 which is administered to many who suffer primarily from breast cancer. While it is one of many drugs
6 effective at treating breast cancer, Sanofi has known for years that the drug carries a significant risk of
7 causing permanent and irreversible damage to the lacrimal system, including nasolacrimal duct stenosis.

8 2. A simple preventative procedure at the onset of chemotherapy-induced tearing, involving the
9 temporary placement of silicone stents, allows a patient to continue her Taxotere regimen while removing
10 the likelihood of permanent and irreversible damage to the lacrimal system. Although Sanofi warns that
11 “excessive tearing which may be attributable to lacrimal duct obstruction has been reported”, Sanofi
12 failed to warn patients and oncologists of the risk that the damage can occur quickly and can be
13 **permanent and irreversible**. Further, Sanofi failed to report the severity and frequency of this risk to
14 the Food and Drug Administration (“FDA”). Worse, Sanofi misled patients and oncologists about the
15 severity and frequency of this devastating side effect even though this condition can be entirely
16 preventable with early intervention and treatment during chemotherapy. As a result, Ms. Vega suffers
17 from permanent injuries because she used Taxotere.

18 3. Plaintiff is grateful for the chemotherapy that helped to save her life; however, that gratitude is
19 diminished by the fact that she now must endure a permanent and life-altering condition that could have
20 been prevented with an adequate warning to her physicians. Plaintiff’s permanent injuries to her lacrimal
21 system, specifically punctal stenosis, cause daily disruption to her life due to excessive tearing, or
22 epiphora. For those who have never experienced epiphora, the condition might seem like a minor
23 annoyance. However, for cancer survivors like Ms. Vega, the irritated, swollen, watering eyes and the
24 ongoing medical management of the condition affect their work, their self-esteem, interpersonal
25 relationships, daily activities like driving or reading a book, and their general ability to return to a normal
26 life after defeating cancer.

27 PARTIES

28 A. Plaintiff

1 4. Plaintiff Teresa Vega is an individual residing in Citrus Heights, California who received Taxotere
2 as part of a chemotherapy regimen after being diagnosed with breast cancer in March of 2019. She was
3 administered Taxotere at Kaiser Permanente in Roseville, California. She was prescribed tri- weekly
4 treatment and received a total of 4 rounds of chemotherapy with Taxotere. During chemotherapy, she
5 complained of red, watery eyes, but was told that the symptoms were common with chemotherapy and
6 should subside once she completed her course of treatment. Unfortunately, the epiphora remained and
7 she has since been diagnosed with permanent and irreversible bilateral nasolacrimal duct obstruction.

8 **B. Sanofi Defendants**

9 5. Defendant Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. is a Delaware corporation, with
10 a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services
11 Inc. is a wholly owned subsidiary of Sanofi S.A. Sanofi S.A. is engaged in research and development,
12 testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of
13 prescription drugs, including Taxotere. Defendant Sanofi US Services Inc. engages in research and
14 development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or
15 distributing of prescription drugs, including Taxotere.

16 6. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, with a principal
17 place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi- Aventis U.S. LLC
18 is a wholly owned subsidiary of Defendant Sanofi S.A., and Sanofi S.A. is Sanofi-Aventis U.S., LLC's
19 sole member. Defendant Sanofi-Aventis U.S. LLC engages in research and development, testing,
20 manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription
21 drugs, including Taxotere.

22 7. Since 2006, Defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. have collectively
23 served as the U.S. operational front for Sanofi S.A. in the U.S. prescription drug market.

24 **JURISDICTION AND VENUE**

25 8. Federal subject matter jurisdiction is based on 28 U.S.C. §1332(a) due to the complete diversity of
26 Ms. Vega and Defendants and the amount in controversy exceeds \$75,000.

27 9. A substantial part of the acts and omissions giving rise to this cause of action occurred in this
28 district and therefore venue is proper here pursuant to 28 U.S.C. §1391(a).

1 10. The Sanofi Defendants are subject to personal jurisdiction in this Court due to their ongoing and
2 substantial contacts in this forum.

3 **FACTUAL ALLEGATIONS**

4 **I. Development and Approval of Taxotere (Docetaxel)**

5 11. Taxotere is a drug used in the treatment of various forms of cancer, including breast cancer, and
6 is a part of a family of cytotoxic drugs referred to as taxanes. Taxanes are derived from yew trees, and
7 unlike other cytotoxic drugs, taxanes inhibit the multiplication of cancer cells by over-stabilizing the
8 structure of a cancer cell, which prevents the cell from breaking down and reorganizing for cell
9 reproduction. They are widely used as chemotherapy agents.

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

13 13. In August 2004, Sanofi obtained FDA approval for an expanded use of Taxotere “in combination
14 with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-
15 positive breast cancer.” This resulted in a greater number of patients being treated with Taxotere.

16 14. As the universe of patients taking Taxotere expanded to include those with a higher survivability,
17 more cancer survivors taking Taxotere would now experience a permanent disabling (but preventable)
18 condition.

19 15. Taxotere is not purchased by patients at a pharmacy; rather, patients’ use of these drugs occurs
20 via administration through injection and/or intravenously at a physician’s office or medical treatment
21 facility.

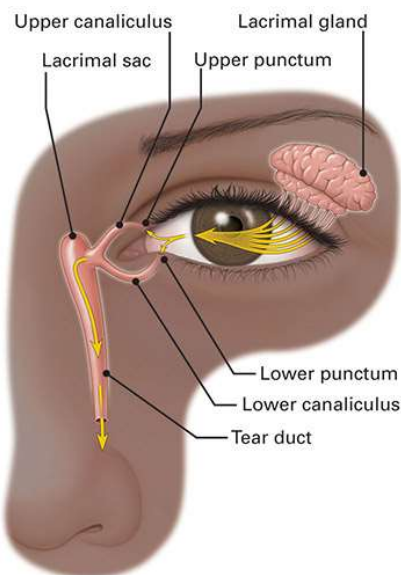
II. Anatomy of Lacrimal System

16. The following image depicts the anatomy of the lacrimal system.

17. Taxotere is secreted in the tear film, thereby causing fibrosis in areas of the lacrimal system, including the puncta, the canaliculi and the nasolacrimal duct.¹ This scarring can cause permanent and irreversible occlusion, resulting in the failure of tears to drain naturally through the lacrimal system. Because the eyes are constantly producing tears, this results in persistent epiphora.

III. Taxotere's Labeling

18. Taxotere's labeling information at the time relevant to this lawsuit, states in relevant part:



Post-Marketing Experiences

Ophthalmologic

Conjunctivitis, lacrimation or lacrimation with or without conjunctivitis. *Excessive tearing which may be attributable to lacrimal duct obstruction has been reported.* Rare cases of transient visual disturbances (flashes, flashing lights, scotomata) typically occurring during drug infusion and in association with hypersensitivity reactions have been reported. *These were reversible upon discontinuation of the infusion.*

Patient Counseling Information:

Gastrointestinal Events, Eye Disorders

¹ For the Court's ease of reference, Plaintiff will use the term "lacrimal duct obstruction" as it is identified in Sanofi's label; however, as the image demonstrates, obstruction of the lacrimal ducts is not the mechanism generally causing the epiphora. Rather, most cases involve stenosis, or hardening, of the puncta and/or the canaliculi.

1 Explain to patients that side effects such as nausea, vomiting, diarrhea,
2 constipation, excessive tearing and/or vision disturbances are associated
3 with docetaxel administration. Tell patients to immediately report any
4 abdominal pain or tenderness, and/or diarrhea, with or without fever, any
5 vision changes.

6 **What are the possible side effects of Taxotere?**

7 The most common side effects of Taxotere include: redness of the eye,
8 excess tearing . . .²

9 (emphasis added)

10 19. Sanofi's label informed patients that "redness of eye, excess tearing" were among the "most
11 common side effects of Taxotere" but did not advise patients of the rapid onset, permanency of stenosis
12 and, therefore, the critical need to seek immediate medical treatment from an appropriately qualified
13 physician. These representations downplay the serious and permanent nature of this side effect by
14 effectively communicating this side effect is transitory. In the section of the label regarding
15 "Ophthalmologic" side effects, Sanofi represents that these side effects were "reversible upon
16 discontinuation of the infusion." This affirmatively misrepresents the frequency and severity of this
17 potentially permanent damage to the lacrimal system.

18 20. Sanofi's labeling information at all times relevant to this lawsuit, and even to date, does not
19 identify the risk of punctal and canalicular stenosis as a cause of excessive tearing, the rapid onset at
20 which stenosis can occur, the potentially permanent and irreversible nature of the injury, the need to refer
21 patients to a lacrimal specialist, nor does it identify the condition as preventable with timely intervention
22 during chemotherapy.

23 21. Given the widespread use of Taxotere, it is crucial that the label not only inform oncologists of
24 excessive tearing due to "lacrimal duct obstruction", but that without treatment, the obstruction can
25 become permanent. Only timely diagnosis and treatment can prevent this from happening.

26 22. Sanofi did not provide such adequate notice to oncologists. To the contrary, the labeling leads
27 oncologists, like Ms. Vega's, to believe that excessive tearing is merely a transitory side effect and will
28 end upon the cessation of chemotherapy. This failure to provide notice resulted in thousands of women,
like Ms. Vega, suffering daily from a permanent condition that could have easily been prevented with

² https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020449s079lbl.pdf

1 adequate warning.

2 **IV. Sanofi's Duty to Monitor and Update Labeling**

3 23. The primary responsibility for timely communicating complete, accurate, and current safety and
4 efficacy information related to Taxotere rests with Sanofi as it has superior, and in many cases exclusive,
5 access to the relevant safety and efficacy information, including post-market complaints and data.

6 24. To fulfill its essential responsibilities, Sanofi must vigilantly monitor all reasonably available
7 information. It must closely evaluate the post-market clinical experience of its drugs and timely provide
8 updated safety and efficacy information to the healthcare community and to consumers.

9 25. When monitoring and reporting adverse events, as required by both federal regulations and state
10 law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect
11 potential safety signals that could indicate to drug sponsors and the medical community that a public
12 safety problem exists.

13 26. If, for example, a manufacturer was to delay reporting post-market information, that delay could
14 mean that researchers, FDA, and the medical community are years behind in identifying a public safety
15 issue associated with the drug.

16 27. In the meantime, more patients are harmed by using the product without knowing, understanding,
17 and accepting its true risks, which is why drug sponsors must not only completely and accurately monitor,
18 investigate and report post-market experiences, but must also report the data in a timely fashion.

19 28. A drug is "misbranded" in violation of the FDCA when its labeling is false and misleading or
20 does not provide adequate directions for use and adequate warnings. *See* 21 U.S.C. §§ 321(n); 331(a),
21 (b), (k); 352(a), (f). A drug's labeling satisfies federal requirements if it gives physicians and pharmacists
22 sufficient information—including indications for use and "any relevant hazards, contraindications, side
23 effects, and precautions"—to allow those professionals "to use the drug safely and for the purposes for
24 which it is intended." 21 C.F.R. § 201.100(c)(1).

25 29. As part of their responsibility to monitor post-market clinical experiences with the drug and
26 provide updated safety and efficacy information to the healthcare community and to consumers, each
27 approved NDA applicant "must promptly review all adverse drug experience information obtained or
28 otherwise received by the applicant from any source, foreign or domestic, including information derived

1 from commercial marketing experience, post marketing clinical investigations, post marketing
2 epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific
3 papers.” 21 C.F.R. § 314.80(b).

4 30. Any report of a “serious and unexpected” drug experience, whether foreign or domestic, must be
5 reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. §
6 314.80(c)(1)(i-ii).

7 31. Most other adverse event reports must be submitted quarterly for three years after the application
8 is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic reports must include a
9 “history of actions taken since the last report because of adverse drug experiences (for example, labeling
10 changes or studies initiated).” 21 C.F.R. § 314.80(c)(2)(ii).

11 32. Federal law requires labeling to be updated as information accumulates: “labeling must be revised
12 to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a
13 causal association with a drug; a causal relationship need not have been definitely established.” 21 C.F.R.
14 § 201.57(c)(6)(i). Thus, for example, drug manufacturers must warn of an adverse effect where there is
15 “some basis to believe there is a causal relationship between the drug and the occurrence of the adverse
16 event.” 21 C.F.R. § 201.57(c)(7).

17 33. All changes to drug labels require FDA assent. 21 C.F.R. § 314.70(b)(2)(v)(A). Brand-name drug
18 sponsors may seek to change their approved labels by filing a supplemental application. 21 C.F.R. §
19 314.70.

20 34. One regulation, the “Changes Being Effected” (CBE) regulation, permits a manufacturer to
21 unilaterally change a drug label to reflect “newly acquired information,” subject to later FDA review and
22 approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information includes “new analyses of previously
23 submitted data.” 21 C.F.R. § 314.3(b).

24 35. Thus, for instance, if a drug sponsor determined that a warning was insufficient based on a new
25 analysis of previously existing data, it could submit a CBE and change its labeling.

26 36. The longer a drug sponsor delays updating its labeling to reflect current safety information, the
27 more likely it is that medical professionals will prescribe drugs without advising patients of harmful
28 adverse reactions, and the more likely it is that patients will suffer harmful side effects without the

1 opportunity to evaluate risks for themselves.

2 **V. Sanofi Knew That Taxotere Can Cause Permanent and Irreversible Lacrimal Injury**

3 37. Since 2002 Sanofi's Taxotere label has advised that "excessive tearing which may be attributable
4 due to lacrimal duct obstruction has been reported."³ Despite this language, medical literature has
5 continued to accumulate and raise concerns that oncologists are not being properly warned of the
6 severity of this permanent and irreversible side effect – and in response, Sanofi has done nothing to
7 notify oncologists or patients.

8 38. The following studies, published after 2002, highlight concerns of the increased frequency and
9 severity of permanent stenosis in cancer patients taking Taxotere, the increased need for monitoring,
10 and the lack of awareness among oncologists and their patients regarding the true nature of the damage
11 caused:

- 12 a) From the American Society of Ophthalmic Plastic and Reconstructive Surgery

13 *Better education of oncologists who prescribe docetaxel is
14 needed as we continue to encounter new cases of advanced
15 canalicular blockage.*⁴

- 16 b) From the American Cancer Society:

17 *Despite the previous publication of several articles by our
18 group regarding canalicular stenosis and lacrimal
19 obstruction resulting from docetaxel therapy, we still
20 frequently encounter advanced cases of this condition
21 because of delayed diagnosis. Thus it appears that
22 oncologists need to become better educated regarding this
23 side effect.*

24 *All patients receiving weekly docetaxel should be monitored
25 closely by an ophthalmologist so that the timely management
26 of canalicular stenosis can be offered.*

27 *We recommend silicone intubation [stents] in all
28 symptomatic patients who are receiving weekly docetaxel if*

3 https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20449slr022_taxotere_lbl.pdf

4 Bitá Esmali, et al., *Docetaxel-Induced Histologic Changes in the Lacrimal Sac and Nasal Mucosa*,
19 OPTHALMIC PLASTIC AND RECONSTRUCTIVE SURGERY 4, pp. 305-308 (2003)

1 *they are to continue receiving the drug.*⁵

2 c) From Pharmacotherapy

3 *Moreover, epiphora may be an underrecognized adverse*
4 *effect of docetaxel because excess tearing after*
5 *chemotherapy administration is not as stringently monitored*
6 *as life-threatening toxicities . . . This adverse effect warrants*
7 *evaluation because weekly administration is being used*
8 *more commonly for the treatment of advanced solid tumors,*
9 *and epiphora can interfere with the activities and quality of*
10 *daily life.*⁶

11 d) From the Journal of Clinical Oncology

12 *Despite substantial literature documenting canalicular*
13 *stenosis as an adverse effect of docetaxel, the exact*
14 *incidence of this important adverse effect is unknown. All*
15 *previous publications were based on retrospective studies at*
16 *tertiary ophthalmology practices, and only patients whose*
17 *symptoms of epiphora were evaluated. We report the finding*
18 *of prospective, single-center study designed to determine the*
19 *incidence and severity of epiphora and its anatomic*
20 *correlate, canalicular stenosis, in patients receiving*
21 *docetaxel weekly or every 3 weeks.*

22 *Previous retrospective studies and our clinical experience*
23 *suggested that the incidence of epiphora might be as high as*
24 *50% in patients treated with weekly docetaxel and less than*
25 *10% in patients who receive docetaxel every 3 weeks.*

26 *In this prospective, observational study, epiphora was seen*
27 *in 64% of patients in the weekly docetaxel group and in 39%*
28 *of the docetaxel every 3 weeks group.*

Patients who experience epiphora associated with docetaxel
 should be promptly referred to an ophthalmologist familiar
 with this adverse effect. Frequent [approximately every 4-6
 weeks] probing and irrigation in the office and judicious use
 of topical steroids on a tapering dose can eliminate the need
 for silicone intubation or other lacrimal procedures in
 approximately 80% of patients taking docetaxel every 3
 weeks and in approximately 50% of patients taking

⁵ Bitá Esmaeli, et al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 *CANCER* 504-7 (2003)

⁶ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 *PHARMACOTHERAPY* 6 (2006).

*docetaxel weekly.*⁷

1
2 39. Prominent medical researchers have described this side effect as follows: “canalicular stenosis
3 may be the most important side effect of weekly docetaxel;”⁸ “cancer patients . . . view epiphora as one
4 of the worst side effects because of their inability to read, drive, or wear make-up;”⁹ “visually
5 disabling;”¹⁰ “misleading appearance of emotional tears;”¹¹ “canalicular stenosis can negatively impact
6 the quality of life . . . and should be considered when choosing the chemotherapy regimen;”¹² “epiphora
7 may be a major disability. It interferes with daily activities and causes emotional disturbances;”¹³ “the
8 potential risk of this complication should be carefully weighed;”¹⁴ “epiphora may be an underrecognized
9 adverse effect;”¹⁵ and “the high incidence of this adverse effect has an impact on several aspects of daily
10 living.”¹⁶

11 40. Medical literature is clear that: (1) the onset of damage to the lacrimal system can be rapid upon
12 beginning Taxotere, (2) immediate referral to a lacrimal specialist for monitoring is essential, (3)

13
14 ⁷ Bita Esmaeli, et al., *Prospective Study of Incidence and Severity of Epiphora and Canalicular Stenosis*
15 *in Patients With Metastatic Breast Cancer Receiving Docetaxel*, 24 JOURNAL OF CLINICAL ONCOLOGY
16 22 (2006).

17 ⁸ Bita Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel*
18 *Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

19 ⁹ *Id.*

20 ¹⁰ Bita Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly versus Every-3-Weeks Docetaxel in*
21 *Patients with Metastatic Breast Cancer*, 109 AM ACAD. OF OPHTHALMOLOGY, 1188 (2002).

22 ¹¹ Bita Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly Docetaxel: A Potentially Preventable*
23 *Side Effect*, 13 EUROPEAN SOC'Y. FOR MED. ONCOLOGY, 218 (2001).

24 ¹² Bita Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel*
25 *Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

26 ¹³ Medy Tsalic., et al., *Epiphora (Excessive Tearing) and Other Ocular Manifestations Related to*
27 *Weekly Docetaxel*, 23 MEDICAL ONCOLOGY (2005)

28 ¹⁴ *Id.*

¹⁵ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

¹⁶ Arlene Chan, et al., *Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving*
Adjuvant Docetaxel-based Chemotherapy, 31 JOURNAL OF CLINICAL ONCOLOGY, 17 (2013)

1 damage to the lacrimal system can be permanent and irreversible, (4) this side effect is preventable, and
2 (5) oncologists are not aware of the severity of this side effect. Unfortunately this lack of awareness
3 often results in oncologists counseling their patients that their tearing is temporary and will cease after
4 chemotherapy ends.

5 **VI. Taxotere Caused Ms. Vega's Permanent Nasolacrimal Duct Obstruction**

6 41. Ms. Vega was diagnosed with breast cancer and received infusions of Taxotere, receiving a total
7 of four infusions over the course of approximately two months.

8 42. After beginning chemotherapy with Taxotere, Ms. Vega complained to her oncologist of tearing.
9 Ms. Vega had not experienced persistent tearing prior to her chemotherapy with Taxotere. Her oncologist
10 informed her that the condition was normal and should improve once chemotherapy was completed and
11 recommended that she continue to use artificial tears.

12 43. After completion of chemotherapy the tearing persisted and Ms. Vega was seen by an optometrist
13 who diagnosed her with dry eye. Again, the use of artificial tears did not resolve this adverse reaction.

14 44. Due to this debilitating, ongoing side effect, Ms. Vega was referred to an oculoplastic surgeon for
15 further evaluation. On March 12, 2021, the oculoplastic surgeon performed an irrigation procedure and
16 confirmed a diagnosis of nasolacrimal duct obstruction which resulted in insufficient drainage. Ms. Vega
17 was told that if her tearing persists, the next course of treatment would be a dacryocystorhinostomy.

18 45. The oculoplastic surgeon told Ms. Vega that this surgery was successful 50% of the time. At the
19 time of this filing, Ms. Vega still suffers from persistent tearing and has decided not to proceed with
20 surgery.

21 46. Ms. Vega completed chemotherapy and was excited to be cancer free and rid of all of the side
22 effects she suffered as a result of the cancer treatment. Among these, Ms. Vega looked forward to no
23 longer suffering from constantly irritated, watering eyes. But as the effects of the chemotherapy wore
24 off, her watery eyes remained.

25 47. Ms. Vega continues to experience persistent tearing and a disruption of her life. As a direct and
26 proximate result of Sanofi's conduct in connection with the design, development, manufacture, testing,
27 packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of Taxotere, Ms.
28 Vega suffers from permanent epiphora (persistent tearing), due to nasolacrimal duct stenosis. This

1 condition is a side effect of taking Taxotere.

2 48. As a result of this permanent side effect, Ms. Vega has struggled to return to normalcy, even after
3 surviving cancer, because she continues to suffer from persistent tearing on a daily basis, interfering with
4 her ability to perform basic activities and enjoy life. This permanent change has altered Ms. Vega's self-
5 image, negatively impacted her relationships, and others' perception of her, leading to social isolation
6 and depression even long after fighting cancer.

7 49. Throughout her ordeal, Ms. Vega remained hopeful that, like other chemotherapy side effects, the
8 epiphora would eventually resolve. To her dismay, it never has.

9 50. Ms. Vega's tearing is much more than a minor annoyance—it impacts all aspects of her daily life.
10 Prior to developing permanent nasolacrimal duct stenosis, Ms. Vega was self-confident and enjoyed
11 social and professional interactions with other people. Now she lacks the confidence she previously
12 enjoyed.

13 51. Ms. Vega is anxious about social interactions because she fears people will perceive her as sad
14 and crying. Her tears spill out over her cheeks, making her skin irritated and she is unable to keep makeup
15 on her face. She also no longer has eyelashes as a result of the constant tearing. She is aware of the
16 concerned looks from well-intentioned friends, colleagues and strangers who perceive her to be emotional
17 and upset. Additionally, Ms. Vega no longer feels comfortable working because of the impression that
18 her constant tearing would give to colleagues and customers. In short, Ms. Vega no longer feels like
19 herself and is self-conscious around others because of the constant tearing.

20 52. Ms. Vega's injuries could have been prevented had Sanofi simply warned that permanent or
21 irreversible nasolacrimal duct stenosis is a common but preventable side effect of Taxotere. Ms. Vega
22 thus seeks recovery for her mental and physical suffering stemming from permanent, but easily
23 preventable, nasolacrimal duct stenosis.

24 53. Mrs. Vega files this lawsuit within the applicable statute of limitations.

25 **VII. Tolling of the Statute of Limitations.**

26 54. Alternatively, Ms. Vega files this lawsuit within the applicable statute of limitations period of
27 first suspecting that Taxotere's wrongful conduct caused the appreciable harm she sustained. Due to
28 Sanofi's fraudulent concealment of the true nature of "excessive tearing which may be attributable to

1 lacrimal duct obstruction,” Ms. Vega could not, by the exercise of reasonable diligence, have discovered
2 that Sanofi wrongfully caused her injuries as she was unaware of the severity and permanency of her
3 injury. Specifically in its warning label, Sanofi fraudulently concealed (1) the rapid onset at which
4 stenosis can occur, (2) the potentially permanent and irreversible nature of the injury, (3) the need to
5 immediately refer patients to a lacrimal specialist and (4) that the condition is highly preventable with
6 timely intervention during chemotherapy. As a result, Ms. Vega was unaware that Sanofi knew of the
7 devastating and permanent consequences of stenosis, or that Sanofi concealed this information from her
8 oncologist. Because Ms. Vega’s oncologist was unaware of the permanent nature of this side effect, Ms.
9 Vega was unaware that her condition was permanent and irreversible.

10 55. Sanofi to this day does not warn that Taxotere can cause permanent and irreversible
11 obstruction of the lacrimal system. Therefore, Ms. Vega did not suspect, nor did she have reason to
12 suspect, that she had been permanently injured. Furthermore, Ms. Vega did not and could not suspect
13 the tortious nature of the conduct causing her injuries until a date before filing this action that is less than
14 the applicable limitations period for filing suit.

15 56. Additionally, Ms. Vega was prevented from discovering this information at an earlier date
16 because Sanofi: (1) misrepresented to the public, the FDA, and the medical profession that Taxotere was
17 free from permanent side effects; (2) failed to disclose to the public, the FDA, and the medical profession
18 its knowledge of the risk of permanent but reversible side effects; (3) failed to disclose to the public, the
19 FDA, and the medical profession its knowledge that these side effects were preventable with early
20 intervention during chemotherapy; (4) fraudulently concealed facts and information that could have led
21 Ms. Vega to discover Sanofi’s liability; and (5) still has not disclosed to the public, the FDA, and the
22 medical profession that Taxotere can cause permanent punctal, canalicular and nasolacrimal duct stenosis
23 which can be prevented with early intervention during chemotherapy.

24 **COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)**

25 57. Ms. Vega incorporates by reference the above paragraphs as if set forth herein.

26 58. At all relevant times, Sanofi was in the business of designing, researching, manufacturing, testing,
27 promoting, marketing, selling, and/or distributing pharmaceutical products, including the Taxotere used
28 by Ms. Vega.

1 59. The Taxotere designed, formulated, produced, manufactured, sold, marketed, distributed,
2 supplied and/or placed into the stream of commerce by Sanofi failed to provide adequate warnings to
3 users and their healthcare providers, including Ms. Vega and her healthcare providers, of the risk of side
4 effects associated with the use of Taxotere, particularly the risk of developing disfiguring, permanent
5 punctal, canalicular and/or nasolacrimal duct stenosis, or the measures that could have been taken to
6 prevent it.

7 60. The Taxotere designed, formulated, produced, manufactured, sold, marketed, distributed,
8 supplied and/or placed into the stream of commerce by Sanofi and ultimately administered to Ms. Vega
9 lacked such warnings when it left Sanofi's control.

10 61. The risks of developing disfiguring, permanent punctal, canalicular and/or nasolacrimal duct
11 stenosis were known to or reasonably knowable by Sanofi at the time the Taxotere left Sanofi's control.

12 62. A reasonably prudent company in the same or similar circumstances would have provided a
13 warning that communicated the dangers and safe use of Taxotere.

14 63. Any warnings actually provided by Sanofi did not sufficiently and/or accurately reflect the
15 symptoms, type, scope, severity, and/or duration of these side effects, particularly the risks of developing
16 disfiguring, permanent punctal, canalicular and/or nasolacrimal duct stenosis or how it could have been
17 prevented during administration of the chemotherapy.

18 64. Without adequate warning of these side effects, Taxotere is not reasonably fit, suitable, or safe
19 for its reasonably anticipated or intended purposes.

20 65. Ms. Vega was a reasonably foreseeable user of Taxotere who used the drug in a reasonably
21 anticipated manner.

22 66. Ms. Vega and her physicians would have taken preventative measures during the course of her
23 chemotherapy to prevent nasolacrimal duct stenosis had she (and her physicians) been provided an
24 adequate warning by Sanofi of the risk of these side effects.

25 67. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse
26 effects of Taxotere, Ms. Vega suffered and continues to suffer serious and dangerous side effects, severe
27 and personal injuries that are permanent and lasting in nature, and economic and non-economic damages,
28 harms, and losses, including, but not limited to: past and future medical expenses; past and future loss of

1 earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including
2 nasolacrimal duct stenosis; mental anguish; severe and debilitating emotional distress; increased risk of
3 future harm; past, present, and future physical and mental pain, suffering, and discomfort; and past,
4 present, and future loss and impairment of the quality and enjoyment of life.

5 WHEREFORE, Plaintiff Teresa Vega respectfully requests judgment in her favor and against
6 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief
7 this Court deems just and proper.

8 **COUNT II - NEGLIGENCE**

9 68. Ms. Vega incorporates by reference the above paragraphs as if set forth herein.

10 69. Sanofi had a duty to exercise reasonable care in the design, research, formulation, manufacture,
11 production, marketing, testing, supply, promotion, packaging, sale, and/or distribution of Taxotere,
12 including a duty to assure that the product would not cause users to suffer unreasonable, disfiguring, and
13 dangerous side effects.

14 70. Sanofi breached these duties when it put Taxotere into interstate commerce, unreasonably and
15 without adequate and/or proper warning to Ms. Vega and her healthcare providers, a product that Sanofi
16 knew or should have known created a high risk of unreasonable, disfiguring, and dangerous side effects.

17 71. The negligence of Sanofi, its agents, servants, and/or employees, included but was not limited to,
18 the following acts and/or omissions:

- 19 (a) Manufacturing, producing, promoting, formulating, creating, and/or designing Taxotere
20 without thoroughly, adequately, and/or sufficiently testing it—including pre-clinical and
21 clinical testing and post-marketing surveillance—for safety and fitness for use and/or its
22 dangers and risks;
- 23 (b) Marketing Taxotere to Ms. Vega, Ms. Vega's healthcare providers, the public, and the medical
24 and healthcare professions without adequately and correctly warning and/or disclosing the
25 existence, severity, and duration of known or knowable side effects, including permanent
26 punctal, canalicular and nasolacrimal duct stenosis;
- 27 (c) Marketing Taxotere to Ms. Vega, Ms. Vega's healthcare providers, the public, and the medical
28 and healthcare professions without providing adequate instructions regarding safety
precautions to be observed by users, handlers, and persons who would reasonably and
foreseeably come into contact with, and more particularly, use, Taxotere;
- (d) Advertising and recommending the use of Taxotere without sufficient knowledge of its safety
profile;

- 1 (e) Designing, manufacturing, producing, and/or assembling Taxotere in a manner that was
2 dangerous to its users;
- 3 (f) Concealing information from Ms. Vega, Ms. Vega's healthcare providers, the public, other
4 medical and healthcare professionals, and the FDA that Taxotere was unsafe, dangerous,
5 and/or non-conforming with FDA regulations;
- 6 (g) Concealing from and/or misrepresenting information to Ms. Vega, Ms. Vega's healthcare
7 providers, other medical and healthcare professionals, and/or the FDA concerning the
8 existence and severity of risks and dangers of Taxotere; and
- 9 (h) Encouraging the sale of Taxotere, either directly or indirectly, orally or in writing, to Ms.
10 Vega and Ms. Vega's healthcare providers without warning about the need for more
11 comprehensive and regular medical monitoring than usual to ensure early discovery of
12 potentially serious side effects such as punctal, canalicular and nasolacrimal duct stenosis.

13 72. Despite the fact that Sanofi knew or should have known that Taxotere caused unreasonably
14 dangerous side effects, Sanofi continues to market, manufacture, distribute, and/or sell Taxotere to
15 consumers.

16 73. Ms. Vega and Ms. Vega's healthcare providers were therefore forced to rely on safety information
17 that did not accurately represent the risks and benefits associated with the use of Taxotere and measures
18 that could have been taken to prevent severe and permanent disfigurement from the use of Taxotere.

19 74. Sanofi knew or should have known that consumers such as Ms. Vega would use its product and
20 would foreseeably suffer injury as a result of Sanofi's failure to exercise reasonable care, as set forth
21 above.

22 75. Sanofi's negligence was a proximate cause of Ms. Vega's injuries, harms, damages, and losses,
23 in connection with the use of Taxotere, including but not limited to: past and future medical expenses;
24 past and future loss of earnings; past and future loss and impairment of earning capacity; permanent
25 disfigurement including permanent and irreversible nasolacrimal duct stenosis; mental anguish; severe
26 and debilitating emotional distress; increased risk of future harm; past, present, and future physical and
27 mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality
28 and enjoyment of life.

WHEREFORE, Teresa Vega respectfully requests judgment in her favor and against Defendants in
an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
deems just and proper.

COUNT III – NEGLIGENT MISREPRESENTATION

1
2 76. Ms. Vega incorporates by reference the above paragraphs as if set forth herein.

3 77. Sanofi had a duty to represent to Ms. Vega, Ms. Vega’s healthcare providers, the healthcare
4 community, and the public in general that Taxotere had been tested and found to be safe and effective for
5 the treatment of various forms of cancer.

6 78. When warning of safety and risks of Taxotere, Sanofi negligently represented to Ms. Vega, Ms.
7 Vega’s healthcare providers, the healthcare community, and the public in general that Taxotere had been
8 tested and was found to be safe and/or effective for its indicated use.

9 79. Sanofi concealed its knowledge of Taxotere defects from Ms. Vega, Ms. Vega’s healthcare
10 providers, and the public in general and/or the healthcare community specifically.

11 80. Sanofi concealed this information with the intent of defrauding and deceiving Ms. Vega, Ms.
12 Vega’s healthcare providers, the public in general, and the healthcare community in particular, and were
13 made with the intent of inducing Ms. Vega, Ms. Vega’s healthcare providers, the public in general, and
14 the healthcare community in particular, to recommend, dispense, and/or purchase Taxotere.

15 81. Sanofi failed to exercise ordinary and reasonable care in its representations of Taxotere in its sale,
16 testing, quality assurance, quality control, and/or distribution into interstate commerce, and Sanofi
17 negligently misrepresented Taxotere’s high risks of unreasonable, dangerous side effects. These side
18 effects were unreasonable because they could have been entirely prevented with adequate warning.

19 82. Sanofi breached its duty in misrepresenting Taxotere’s serious side effects to Ms. Vega, Ms.
20 Vega’s healthcare providers, the healthcare community, the FDA, and the public in general.

21 83. Ms. Vega and Ms. Vega’s healthcare providers reasonably relied on Sanofi to fulfill its
22 obligations to disclose all facts within its knowledge regarding the serious side effects of Taxotere and
23 the ability to prevent those side effects with appropriate precautionary measures.

24 84. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Ms. Vega to
25 suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in
26 nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past
27 and future medical expenses; past and future loss of earnings; past and future loss and impairment of
28 earning capacity; permanent disfigurement, including permanent nasolacrimal duct stenosis; mental

1 anguish; severe and debilitating emotional distress; increased risk of future harm; past, present, and future
2 physical and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of
3 the quality and enjoyment of life.

4 WHEREFORE, Teresa Vega respectfully requests that judgment in her favor and against Defendants
5 in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
6 deems just and proper.

7 **COUNT IV – FRAUDULENT MISREPRESENTATION**

8 85. Ms. Vega incorporates by reference the above paragraphs as if set forth herein.

9 Sanofi represented to Ms. Vega, her healthcare providers, the healthcare community, and the public in
10 general that “excessive tearing which may be attributable to lacrimal duct obstruction has been reported”
11 and that excessive tearing is a common side effect. These statements failed to accurately inform
12 oncologists and patients of (1) the rapid onset at which stenosis can occur, (2) the potentially permanent
13 and irreversible nature of the injury, (3) the need to immediately refer patients to a lacrimal specialist and
14 (4) that the condition is highly preventable with timely intervention during chemotherapy.

15 86. Despite having knowledge of these enhanced side effects, Sanofi fraudulently omitted from these
16 representations information that Taxotere could and did cause these serious side effects, including
17 permanent and irreversible nasolacrimal duct stenosis.

18 87. These representations were material and false.

19 88. Sanofi made these representations and omissions:

- 20 (a) with knowledge or belief of their falsity, and/or in the case of omissions, with knowledge or
21 belief of falsity of the resulting statements;
- 22 (b) positively and recklessly without knowledge of their truth or falsity;
- 23 (c) with knowledge that they were made without any basis; and/or
- 24 (d) without confidence in the accuracy of the representations or statements resulting from the
25 omissions.

26 89. Sanofi made these false representations with the intention or expectation that Ms. Vega, Ms.
27 Vega’s healthcare providers, the public in general, and the healthcare community in particular, would
28 recommend, dispense, and/or purchase Taxotere, all of which evidenced a callous, reckless, willful,

1 wanton, and depraved indifference to the health, safety, and welfare of Ms. Vega.

2 90. At the time Sanofi made the aforesaid representations, and, at the time Ms. Vega used Taxotere,
3 Ms. Vega and Ms. Vega's healthcare providers were unaware of the falsity of Sanofi's representations,
4 statements and/or implications and justifiably and reasonably relied on Sanofi's representations,
5 statements, and implications, believing them to be true.

6 91. In reliance on Sanofi's representations, Ms. Vega and her healthcare providers were induced to
7 and did use and prescribe Taxotere, which caused Ms. Vega to suffer serious and dangerous side effects,
8 severe and personal injuries that are permanent and lasting in nature, and economic and non-economic
9 damages, harms, and losses, including, but not limited to: past and future medical expenses; past and
10 future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement,
11 including permanent nasolacrimal duct stenosis; mental anguish; severe and debilitating emotional
12 distress; increased risk of future harm; past, present, and future physical and mental pain, suffering, and
13 discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

14 WHEREFORE, Teresa Vega respectfully requests judgment in her favor and against Defendants in
15 an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
16 deems just and proper.

17 **COUNT V – FRAUDULENT CONCEALMENT**

18 92. Ms. Vega incorporates by reference the above paragraphs as if set forth herein.

19 93. At all times during the course of dealings between Sanofi and Ms. Vega and Ms. Vega's
20 healthcare providers, Sanofi misrepresented the design characteristic and safety of Taxotere for their
21 intended use.

22 94. Sanofi knew or was reckless in not knowing that its representations were false due to Sanofi's
23 access to ongoing studies and reports that disclosed serious, enhanced side effects of Taxotere to the
24 lacrimal system. In representations made to Ms. Vega and her healthcare providers, Sanofi fraudulently
25 concealed and intentionally omitted the following material information: (1) the rapid onset at which
26 stenosis can occur, (2) the potentially permanent and irreversible nature of the injury, (3) the need to
27 immediately refer patients to a lacrimal specialist and (4) that the condition is highly preventable with
28 timely intervention during chemotherapy.

1 95. Sanofi had a duty to disclose to Ms. Vega and her healthcare providers the defective nature of
2 Taxotere, including, but not limited to, the heightened risks of disfiguring, permanent nasolacrimal duct
3 stenosis.

4 96. Sanofi had a duty to disclose to Ms. Vega and her healthcare providers that the disfiguring,
5 permanent punctal, canalicular and/or nasolacrimal duct stenosis caused by the use of Taxotere could
6 have been prevented by early identification and treatment of epiphora during chemotherapy.

7 97. Sanofi had sole access to material facts concerning the defective nature of Taxotere and its
8 propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used
9 the drugs at issue, including Ms. Vega.

10 98. Sanofi's concealment and omissions of material fact concerning the safety of Taxotere were made
11 purposefully, willfully, wantonly, and/or recklessly to mislead Ms. Vega and her healthcare providers
12 into reliance on the continued use of the drugs and to cause them to purchase, prescribe, and/or dispense
13 Taxotere and/or use it.

14 99. Sanofi knew that Ms. Vega and her healthcare providers had no way to determine the truth behind
15 its concealment and omissions, including the material omissions of fact surrounding Taxotere set forth
16 herein.

17 100. Ms. Vega and Ms. Vega's healthcare providers reasonably relied on information disclosed by
18 Sanofi that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or
19 omitted by Sanofi.

20 101. As a result of the foregoing acts and omissions, Sanofi caused Ms. Vega to suffer serious and
21 dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and
22 economic and non-economic damages, harms, and losses, including, but not limited to: past and future
23 medical expenses; past and future loss of earnings; past and future loss and impairment of earning
24 capacity; permanent disfigurement, including permanent nasolacrimal duct stenosis; mental anguish;
25 severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical
26 and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the
27 quality and enjoyment of life.

28 WHEREFORE, Teresa Vega respectfully requests judgment in her favor and against Defendants in

1 an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
2 deems just and proper.

3 **VI. JURY DEMAND**

4 Plaintiff has requested a trial by jury pursuant to rule 38 of the Federal Rules of Civil Procedure.

5 Dated: July 30, 2021

6 **FITZPATRICK & SWANSTON**

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28 **ATTORNEYS FOR PLAINTIFF**

**UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA (Western Division - Los Angeles)
CIVIL DOCKET FOR CASE #: 2:21-cv-08964-JWH-KK**

Jennifer Burns v. Sanofi US Services Inc. et al
Assigned to: Judge John W. Holcomb
Referred to: Magistrate Judge Kenly Kiya Kato
Demand: \$75,000
Related Case: [5:21-cv-00718-JWH-KK](#)
Cause: 28:1332 Diversity-Product Liability

Date Filed: 11/15/2021
Jury Demand: Plaintiff
Nature of Suit: 367 Personal Injury: Health Care/Pharmaceutical
Personal Injury Product Liability
Jurisdiction: Diversity

Plaintiff**Jennifer Burns**

represented by **Bernard James Fitzpatrick**
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V.

Defendant

Sanofi US Services, Inc.
also known as
Sanofi-Aventis U.S., Inc.

Defendant**Sanofi-Aventis U.S., LLC**

Date Filed	#	Docket Text
11/15/2021	1	COMPLAINT Receipt No: ACACDC-32327671 - Fee: \$402, filed by Plaintiff Jennifer Burns. (Attorney Bernard James Fitzpatrick added to party Jennifer Burns(pty:pla))(Fitzpatrick, Bernard) (Entered: 11/15/2021)
11/15/2021	2	CIVIL COVER SHEET filed by Plaintiff Jennifer Burns. (Fitzpatrick, Bernard) (Entered: 11/15/2021)
11/16/2021	3	NOTICE OF ASSIGNMENT to District Judge Andre Birotte Jr and Magistrate Judge Pedro V. Castillo. (ghap) (Entered: 11/16/2021)
11/16/2021	4	NOTICE TO PARTIES OF COURT-DIRECTED ADR PROGRAM filed. (ghap) (Entered: 11/16/2021)
11/16/2021	5	Notice to Counsel Re Consent to Proceed Before a United States Magistrate Judge. (ghap) (Entered: 11/16/2021)
11/16/2021	6	NOTICE OF PRO HAC VICE APPLICATION DUE for Non-Resident Attorney Richard M Paul III on behalf on Plaintiff. A document recently

		filed in this case lists you as an out-of-state attorney of record. However, the Court has not been able to locate any record that you are admitted to the Bar of this Court, and you have not filed an application to appear Pro Hac Vice in this case. Accordingly, within 5 business days of the date of this notice, you must either (1) have your local counsel file an application to appear Pro Hac Vice (Form G-64) and pay the applicable fee, or (2) complete the next section of this form and return it to the court at caed_attyadm@caed.uscourts.gov . You have been removed as counsel of record from the docket in this case, and you will not be added back to the docket until your Pro Hac Vice status has been resolved. (ghap) (Entered: 11/16/2021)
11/16/2021	7	NOTICE OF PRO HAC VICE APPLICATION DUE for Non-Resident Attorney Patrick O Hotze on behalf on Plaintiff. A document recently filed in this case lists you as an out-of-state attorney of record. However, the Court has not been able to locate any record that you are admitted to the Bar of this Court, and you have not filed an application to appear Pro Hac Vice in this case. Accordingly, within 5 business days of the date of this notice, you must either (1) have your local counsel file an application to appear Pro Hac Vice (Form G-64) and pay the applicable fee, or (2) complete the next section of this form and return it to the court at caed_attyadm@caed.uscourts.gov . You have been removed as counsel of record from the docket in this case, and you will not be added back to the docket until your Pro Hac Vice status has been resolved. (ghap) (Entered: 11/16/2021)
11/16/2021	8	NOTICE OF PRO HAC VICE APPLICATION DUE for Non-Resident Attorney Karen Cannon Shanks on behalf on Plaintiff. A document recently filed in this case lists you as an out-of-state attorney of record. However, the Court has not been able to locate any record that you are admitted to the Bar of this Court, and you have not filed an application to appear Pro Hac Vice in this case. Accordingly, within 5 business days of the date of this notice, you must either (1) have your local counsel file an application to appear Pro Hac Vice (Form G-64) and pay the applicable fee, or (2) complete the next section of this form and return it to the court at caed_attyadm@caed.uscourts.gov . You have been removed as counsel of record from the docket in this case, and you will not be added back to the docket until your Pro Hac Vice status has been resolved. (ghap) (Entered: 11/16/2021)
11/16/2021	9	NOTICE OF DEFICIENCIES in Attorney Case Opening RE: Complaint (Attorney Civil Case Opening) 1 . The following error(s) was found: No Notice of Interested Parties has been filed. A Notice of Interested Parties must be filed with every partys first appearance. See Local Rule 7.1-1. Counsel must file a Notice of Interested Parties immediately. Failure to do so may be addressed by judicial action, including sanctions. See Local Rule 83-7. (ghap) (Entered: 11/16/2021)
11/17/2021	10	ORDER RE TRANSFER PURSUANT TO GENERAL ORDER 21-01-Related Case- filed. Related Case No: 5:21-cv-00718 JWH(KKx). Case transferred from Judge Andre Birotte Jr and Magistrate Judge Pedro V. Castillo to Judge John W. Holcomb and Magistrate Judge Kenly Kiya Kato for all further proceedings. The case number will now reflect the initials of the transferee Judge 2:21-cv-08964 JWH(KKx). Signed by Judge John W. Holcomb (rn) (Entered: 11/17/2021)
11/19/2021	11	This action has been reassigned to the Honorable John W. Holcomb, United States District Judge. Judge Holcomb is located in Courtroom 2, on the 2nd Floor of the George E. Brown, Jr. Federal Building and United States Courthouse at 3470 Twelfth Street, Riverside, California 92501. Additional information regarding Judge Holcomb's procedures and schedules is available on the court's website at www.caed.uscourts.gov . THERE IS NO PDF DOCUMENT ASSOCIATED WITH THIS ENTRY. (iva) TEXT ONLY ENTRY (Entered: 11/19/2021)
11/22/2021	12	CERTIFICATE of Interested Parties filed by Plaintiff Jennifer Burns, identifying Jennifer Burns, Sanofi US Services, Inc. (f/k/a Sanofi-Aventis US, Inc.), and Sanofi-Aventis US, LLC. (Fitzpatrick, Bernard) (Entered: 11/22/2021)
11/23/2021	13	APPLICATION of Non-Resident Attorney Richard M. Paul, III to Appear Pro Hac Vice on behalf of Plaintiff Jennifer Burns (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-32378073) filed by Plaintiff Jennifer Burns. (Attachments: # 1 Proposed Order) (Fitzpatrick, Bernard) (Entered: 11/23/2021)
11/23/2021	14	APPLICATION of Non-Resident Attorney Patrick O. Hotze to Appear Pro Hac Vice on behalf of Plaintiff Jennifer Burns (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-32378187) filed by Plaintiff Jennifer Burns. (Attachments: # 1 Proposed Order) (Fitzpatrick, Bernard) (Entered: 11/23/2021)
11/23/2021	15	APPLICATION of Non-Resident Attorney Karen C. Shanks to Appear Pro Hac Vice on behalf of Plaintiff Jennifer Burns (Pro Hac Vice Fee - \$500 Fee Paid, Receipt No. ACACDC-32378259) filed by Plaintiff Jennifer Burns. (Attachments: # 1 Proposed Order) (Fitzpatrick, Bernard) (Entered: 11/23/2021)
11/29/2021	16	STANDING ORDER by Judge John W. Holcomb. (iva) (Entered: 11/29/2021)

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12/01/2021 13:48:19			
PACER Login:	RickPaul	Client Code:	Tax Eyes
Description:	Docket Report	Search Criteria:	2:21-cv-08964-JWH-KK End date: 12/1/2021
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25 Attorneys for Plaintiff,
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27 **UNITED STATES DISTRICT COURT FOR THE**
28 **CENTRAL DISTRICT OF CALIFORNIA**

JENNIFER BURNS,

Plaintiff,

v.

SANOFI US SERVICES, INC. f/k/a
SANOFI-AVENTIS U.S., INC., and
SANOFI-AVENTIS U.S., LLC,

Defendants.

Case No.

COMPLAINT

JURY TRIAL DEMANDED

Plaintiff Jennifer Burns, for her Original Complaint against Defendants SANOFI US SERVICES, INC., f/k/a SANOFI-AVENTIS U.S., INC. and SANOFI-AVENTIS U.S., LLC (collectively “Sanofi”), alleges:

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I. INTRODUCTION

1. Sanofi manufactures and sells a chemotherapy drug named Taxotere (generic name docetaxel), which is administered to many who suffer primarily from breast cancer. While it is one of many drugs effective at treating breast cancer, Sanofi has known for years that the drug carries a significant risk of causing permanent damage to the lacrimal system, including canalicular stenosis.

2. A simple preventative procedure at the onset of chemotherapy-induced tearing, involving the temporary placement of silicone stents, allows a patient to continue her Taxotere regimen while removing the likelihood of permanent damage to the lacrimal system. Although Sanofi warns that “excessive tearing which may be attributable to lacrimal duct obstruction has been reported,” Sanofi failed to warn patients and oncologists of the risk that the damage can occur quickly and can be **permanent**. Further, Sanofi failed to report the severity and frequency of this risk to the Food and Drug Administration (“FDA”). Worse, Sanofi misled patients and oncologists about the severity and frequency of this devastating side effect even though this condition can be entirely preventable with early intervention and treatment during chemotherapy. As a result, Mrs. Burns suffers from permanent injuries because she used Taxotere.

3. Plaintiff is grateful for the chemotherapy that helped to save her life; however, that gratitude is diminished by the fact that she now must endure a permanent and life-altering condition that could have been prevented with an adequate warning to her physicians. Plaintiff’s permanent injuries to her lacrimal system, specifically canalicular stenosis, cause daily disruption to her life due to excessive tearing, or epiphora. For those who have never experienced epiphora, the condition might seem like a minor annoyance. However, for cancer survivors like Mrs. Burns, the irritated, swollen, watering eyes and the ongoing medical management of the condition affect their work, their self-esteem, interpersonal relationships, daily activities like driving or reading a book, and their general ability to return to a normal life after defeating cancer.

II. PARTIES

A. Plaintiff

4. Plaintiff Jennifer Burns is an individual residing in Woodland Hills, California who received Taxotere as part of a chemotherapy regimen after being diagnosed with breast cancer. She was

1 administered Taxotere at Kaiser Permanente in Woodland Hills, California. She was prescribed weekly
2 treatment and received a total of twelve rounds of chemotherapy with Taxotere. During chemotherapy,
3 she complained of excessively watery eyes. Mrs. Burns was told that her watery eyes were a side effect
4 of the chemotherapy. Unfortunately, because no measures were taken to intervene, the epiphora
5 continued and she was ultimately diagnosed with permanent canalicular stenosis.

6 **B. Sanofi Defendants**

7 5. Defendant Sanofi US Services Inc. f/k/a Sanofi-Aventis U.S. Inc. is a Delaware corporation, with
8 a principal place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi US Services
9 Inc. is a wholly owned subsidiary of Sanofi S.A. Sanofi S.A. is engaged in research and development,
10 testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of
11 prescription drugs, including Taxotere. Defendant Sanofi US Services Inc. engages in research and
12 development, testing, manufacturing, labeling, advertising, marketing, promoting, selling and/or
13 distributing of prescription drugs, including Taxotere.

14 6. Defendant Sanofi-Aventis U.S. LLC is a Delaware limited liability company, with a principal
15 place of business at 55 Corporate Drive, Bridgewater, New Jersey 08807. Sanofi-Aventis U.S. LLC
16 is a wholly owned subsidiary of Defendant Sanofi S.A., and Sanofi S.A. is Sanofi-Aventis U.S., LLC's
17 sole member. Defendant Sanofi-Aventis U.S. LLC engages in research and development, testing,
18 manufacturing, labeling, advertising, marketing, promoting, selling and/or distributing of prescription
19 drugs, including Taxotere.

20 7. Since 2006, defendants Sanofi-Aventis U.S. LLC and Sanofi US Services Inc. have collectively
21 served as the U.S. operational front for Sanofi S.A. in the U.S. prescription drug market.

22 **III. JURISDICTION AND VENUE**

23 8. Federal subject matter jurisdiction is based on 28 U.S.C. §1332(a) due to the complete diversity of
24 Mrs. Burns and Defendants and the amount in controversy exceeds \$75,000.

25 9. A substantial part of the acts and omissions giving rise to this cause of action occurred in this
26 district and therefore venue is proper here pursuant to 28 U.S.C. §1391(a).

27 10. The Sanofi Defendants are subject to personal jurisdiction in this Court due to their ongoing and
28 substantial contacts in this forum.

1 **IV. FACTUAL ALLEGATIONS**

2 **A. Development and Approval of Taxotere (Docetaxel)**

3 11. Taxotere is a drug used in the treatment of various forms of cancer, including breast cancer, and
4 is a part of a family of cytotoxic drugs referred to as taxanes. Taxanes are derived from yew trees, and
5 unlike other cytotoxic drugs, taxanes inhibit the multiplication of cancer cells by over-stabilizing the
6 structure of a cancer cell, which prevents the cell from breaking down and reorganizing for cell
7 reproduction. They are widely used as chemotherapy agents.

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

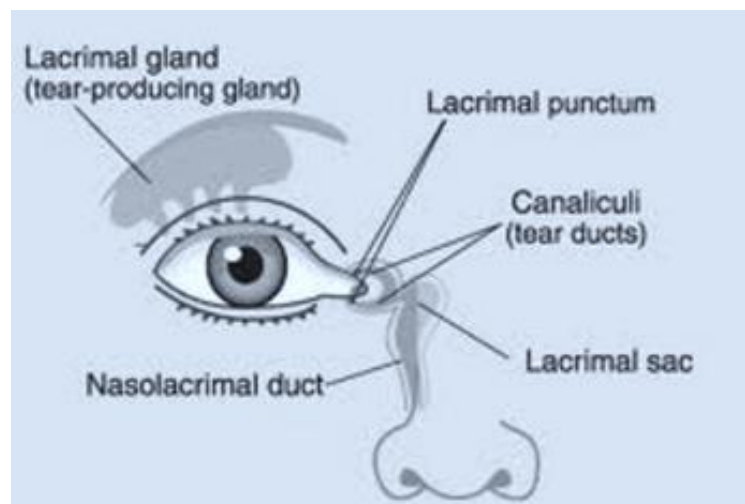
11 13. In August 2004, Sanofi obtained FDA approval for an expanded use of Taxotere “in combination
12 with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-
13 positive breast cancer.” This resulted in a greater number of patients being treated with Taxotere.

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

17 15. Taxotere is not purchased by patients at a pharmacy; rather, patients’ use of this drug occurs via
18 administration through injection and/or intravenously at a physician’s office or medical treatment facility.

19 **B. Anatomy of Lacrimal System**

20 16. The following image depicts the anatomy of the lacrimal system.



1 17. Taxotere is secreted in the tear film, thereby causing fibrosis in areas of the lacrimal system,
2 including the puncta, canaliculus and/or nasolacrimal duct. This scarring can cause permanent occlusion,
3 causing an inability for tears to drain naturally through the lacrimal system. Because the eyes are
4 constantly producing tears, this results in persistent epiphora.

5 **C. Taxotere's Labeling**

6 18. At the time Mrs. Burns was administered Taxotere, its labeling information stated in relevant part
7 under **Post-Marketing Experiences:**

8 **Ophthalmologic:** conjunctivitis, lacrimation or lacrimation with or without conjunctivitis. Excessive tearing which may be
9 attributable to lacrimal duct obstruction has been reported. Rare cases of transient visual disturbances (flashes, flashing lights,
10 scotomata) typically occurring during drug infusion and in association with hypersensitivity reactions have been reported. These were
11 reversible upon discontinuation of the infusion.

12 and under **Patient Counseling Information:**¹

13 • Explain to patients that side effects such as nausea, vomiting, diarrhea, constipation, fatigue, excessive tearing, infusion site
14 reactions, and hair loss are associated with docetaxel administration.

15 19. Additionally, in the *Patient Information* section of the label, Sanofi includes “redness of the eye,
16 excess tearing” among “the most common side effects of Taxotere.” *Id.* Sanofi’s inclusion of this
17 potentially permanent side effect in a laundry list of common but notably transitory side effects
18 effectively misrepresents the risk of harm associated with tearing. By failing to fully inform patients and
19 physicians of the potential for serious permanent damage to the lacrimal system, Sanofi downplays the
20 significance of the underlying injury causing the patient to tear.

21 20. Sanofi’s labeling information at all times relevant to this lawsuit, and even to date, does not
22 identify the risk of stenosis as a cause of excessive tearing, the rapid onset at which stenosis can occur,
23 the potentially permanent nature of the injury, the need to refer patients to a lacrimal specialist, nor does
24 it identify the condition as preventable with timely intervention during chemotherapy.

25 21. Sanofi did not provide such adequate notice to oncologists. To the contrary, the labeling leads
26 oncologists, like Mrs. Burns’s, to believe that excessive tearing is merely a transitory side effect and will
27

28 ¹ https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020449s0631bl.pdf

1 end after the cessation of chemotherapy. This failure to provide notice resulted in thousands of women,
2 like Mrs. Burns, suffering daily from a permanent condition that could have easily been prevented with
3 adequate warning.

4 **D. Sanofi's Duty to Monitor and Update Labeling**

5 22. The primary responsibility for timely communicating complete, accurate, and current safety and
6 efficacy information related to Taxotere rests with Sanofi because it has superior, and in many cases
7 exclusive, access to the relevant safety and efficacy information, including post-market complaints and
8 data.

9 23. To fulfill its essential responsibilities, Sanofi must vigilantly monitor all reasonably available
10 information. It must closely evaluate the post-market clinical experience of its drugs and timely provide
11 updated safety and efficacy information to the healthcare community and to consumers.

12 24. When monitoring and reporting adverse events, as required by both federal regulations and state
13 law, time is of the essence. The purpose of monitoring a product's post-market experience is to detect
14 potential safety signals that could indicate to drug sponsors and the medical community that a public
15 safety problem exists.

16 25. If, for example, a manufacturer was to delay reporting post-market information, that delay could
17 mean that researchers, FDA, and the medical community are years behind in identifying a public safety
18 issue associated with the drug.

19 26. In the meantime, more patients are harmed by using the product without knowing, understanding,
20 and accepting its true risks, which is why drug sponsors must not only completely and accurately monitor,
21 investigate and report post-market experiences, but must also report the data in a timely fashion.

22 27. A drug is "misbranded" in violation of the FDCA when its labeling is false and misleading or
23 does not provide adequate directions for use and adequate warnings. *See* 21 U.S.C. §§ 321(n); 331(a),
24 (b), (k); 352(a), (f). A drug's labeling satisfies federal requirements if it gives physicians and pharmacists
25 sufficient information—including indications for use and "any relevant hazards, contraindications, side
26 effects, and precautions"—to allow those professionals "to use the drug safely and for the purposes for
27 which it is intended." 21 C.F.R. § 201.100(c)(1).

28 28. As part of their responsibility to monitor post-market clinical experiences with the drug and

1 provide updated safety and efficacy information to the healthcare community and to consumers, each
2 approved NDA applicant “must promptly review all adverse drug experience information obtained or
3 otherwise received by the applicant from any source, foreign or domestic, including information derived
4 from commercial marketing experience, post marketing clinical investigations, post marketing
5 epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific
6 papers.” 21 C.F.R. § 314.80(b).

7 29. Any report of a “serious and unexpected” drug experience, whether foreign or domestic, must be
8 reported to the FDA within 15 days and must be promptly investigated by the manufacturer. 21 C.F.R. §
9 314.80(c)(1)(i-ii).

10 30. Most other adverse event reports must be submitted quarterly for three years after the application
11 is approved and annually thereafter. 21 C.F.R. § 314.80(c)(2)(i). These periodic reports must include a
12 “history of actions taken since the last report because of adverse drug experiences (for example, labeling
13 changes or studies initiated).” 21 C.F.R. § 314.80(c)(2)(ii).

14 31. Federal law requires labeling to be updated as information accumulates: “labeling must be revised
15 to include a warning about a clinically significant hazard as soon as there is reasonable evidence of a
16 causal association with a drug; a causal relationship need not have been definitely established.” 21 C.F.R.
17 § 201.57(c)(6)(i). Thus, for example, drug manufacturers must warn of an adverse effect where there is
18 “some basis to believe there is a causal relationship between the drug and the occurrence of the adverse
19 event.” 21 C.F.R. § 201.57(c)(7).

20 32. All changes to drug labels require FDA assent. 21 C.F.R. § 314.70(b)(2)(v)(A). Brand-name drug
21 sponsors may seek to change their approved labels by filing a supplemental application. 21 C.F.R. §
22 314.70.

23 33. One regulation, the “Changes Being Effected” (CBE) regulation, permits a manufacturer to
24 unilaterally change a drug label to reflect “newly acquired information,” subject to later FDA review and
25 approval. 21 C.F.R. § 314.70(c)(6)(iii). Newly acquired information includes “new analyses of previously
26 submitted data.” 21 C.F.R. § 314.3(b).

27 34. Thus, for instance, if a drug sponsor determined that a warning was insufficient based on a new
28 analysis of previously existing data, it could submit a CBE and change its labeling.

1 35. The longer a drug sponsor delays updating its labeling to reflect current safety information, the
2 more likely it is that medical professionals will prescribe the drug without advising patients of harmful
3 adverse reactions, and the more likely it is that patients will suffer harmful side effects without the
4 opportunity to evaluate risks for themselves.

5 **E. Sanofi Knew That Taxotere Can Cause Permanent Canalicular Stenosis.**

6 36. Since 2002, Sanofi's Taxotere label has advised that "excessive tearing which may be
7 attributable due to lacrimal obstruction has been reported."² Despite this language, medical literature
8 has continued to accumulate and raise concerns that oncologists are not being properly warned of the
9 severity of this permanent side effect – and in response, Sanofi has done nothing to notify oncologists
10 or patients.

11 37. The following studies, published after 2002, highlight concerns of the increased frequency and
12 severity of permanent stenosis in cancer patients taking Taxotere, the increased need for monitoring,
13 and the lack of awareness among oncologists and their patients regarding the true nature of the damage
14 caused:

15 a) From *American Society of Ophthalmic Plastic and Reconstructive Surgery*:

16 Better education of oncologists who prescribe docetaxel is
17 needed as we continue to encounter new cases of advanced
18 canalicular blockage.³

19 b) From *American Cancer Society*:

20 Despite the previous publication of several articles by our
21 group regarding canalicular stenosis and lacrimal
22 obstruction resulting from docetaxel therapy, we still
23 frequently encounter advanced cases of this condition
24 because of delayed diagnosis. Thus it appears that
25 oncologists need to become better educated regarding this
26 side effect.

All patients receiving weekly docetaxel should be monitored
27 closely by an ophthalmologist so that the timely
28 management of canalicular stenosis can be offered.

² https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020449s0631bl.pdf

³ Bita Esmaeli, et al., *Docetaxel-Induced Histologic Changes in the Lacrimal Sac and Nasal Mucosa*,
19 OPTHALMIC PLASTIC AND RECONSTRUCTIVE SURGERY 4, pp. 305-308 (2003)

1 We recommend silicone intubation [stents] in all
2 symptomatic patients who are receiving weekly docetaxel if
3 they are to continue receiving the drug.⁴

4 c) From *Pharmacotherapy*:

5 Moreover, epiphora may be an underrecognized adverse
6 effect of docetaxel because excess tearing after
7 chemotherapy administration is not as stringently monitored
8 as life-threatening toxicities . . . This adverse effect warrants
9 evaluation because weekly administration is being used
10 more commonly for the treatment of advanced solid tumors,
11 and epiphora can interfere with the activities and quality of
12 daily life.⁵

13 d) From the *Journal of Clinical Oncology*:

14 Despite substantial literature documenting canalicular
15 stenosis as an adverse effect of docetaxel, the exact
16 incidence of this important adverse effect is unknown. All
17 previous publications were based on retrospective studies at
18 tertiary ophthalmology practices, and only patients whose
19 symptoms of epiphora were evaluated. We report the finding
20 of prospective, single-center study designed to determine the
21 incidence and severity of epiphora and its anatomic
22 correlate, canalicular stenosis, in patients receiving
23 docetaxel weekly or every 3 weeks.

24 Previous retrospective studies and our clinical experience
25 suggested that the incidence of epiphora might be as high as
26 50% in patients treated with weekly docetaxel and less than
27 10% in patients who receive docetaxel every 3 weeks.

28 In this prospective, observational study, epiphora was seen
in 64% of patients in the weekly docetaxel group and in 39%
of the docetaxel every 3 weeks group.

Patients who experience epiphora associated with docetaxel
should be promptly referred to an ophthalmologist familiar
with this adverse effect. Frequent [approximately every 4-6
weeks] probing and irrigation in the office and judicious use
of topical steroids on a tapering dose can eliminate the need
for silicone intubation or other lacrimal procedures in

⁴ Bitá Esmaeli, et al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy*, 98 *CANCER* 504-7 (2003)

⁵ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 *PHARMACOTHERAPY* 6 (2006).

1 approximately 80% of patients taking docetaxel every 3
2 weeks and in approximately 50% of patients taking
3 docetaxel weekly.⁶

38. Prominent medical researchers have described this side effect as follows: “canalicular stenosis
4 may be the most important side effect of weekly docetaxel;”⁷ “cancer patients . . . view epiphora as one
5 of the worst side effects because of their inability to read, drive, or wear make-up;”⁸ “visually
6 disabling;”⁹ “misleading appearance of emotional tears;”¹⁰ “canalicular stenosis can negatively impact
7 the quality of life . . . and should be considered when choosing the chemotherapy regimen;”¹¹ “epiphora
8 may be a major disability. It interferes with daily activities and causes emotional disturbances;”¹² “the
9 potential risk of this complication should be carefully weighed;”¹³ “epiphora may be an underrecognized
10 adverse effect;”¹⁴ and “the high incidence of this adverse effect has an impact on several aspects of daily
11 living.”¹⁵

12 39. Medical literature is clear that: (1) the onset of damage to the lacrimal system can be rapid upon

13 ⁶ Bitá Esmaeli, et al., *Prospective Study of Incidence and Severity of Epiphora and Canalicular Stenosis*
14 *in Patients With Metastatic Breast Cancer Receiving Docetaxel*, 24 JOURNAL OF CLINICAL ONCOLOGY
15 22 (2006).

16 ⁷ Bitá Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel*
17 *Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

18 ⁸ *Id.*

19 ⁹ Bitá Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly versus Every-3-Weeks Docetaxel in*
20 *Patients with Metastatic Breast Cancer*, 109 AM ACAD. OF OPHTHALMOLOGY, 1188 (2002).

21 ¹⁰ Bitá Esmaeli, et. al., *Canalicular Stenosis Secondary to Weekly Docetaxel: A Potentially Preventable*
22 *Side Effect*, 13 EUROPEAN SOC'Y. FOR MED. ONCOLOGY, 218 (2001).

23 ¹¹ Bitá Esmaeli, et. al., *Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel*
24 *Therapy*, 98 AM. CANCER SOC'Y., 504 (2003).

25 ¹² Medy Tsalic, et al., *Epiphora (Excessive Tearing) and Other Ocular Manifestations Related to*
26 *Weekly Docetaxel*, 23 MEDICAL ONCOLOGY (2005).

27 ¹³ *Id.*

28 ¹⁴ Polly Kintzel, et al., *Docetaxel-related Epiphora*, 26 PHARMACOTHERAPY 6 (2006).

¹⁵ Arlene Chan, et al., *Prevalence of Excessive Tearing in Women with Early Breast Cancer Receiving*
Adjuvant Docetaxel-based Chemotherapy, 31 JOURNAL OF CLINICAL ONCOLOGY, 17 (2013)

1 initiation of Taxotere administration, (2) immediate referral to a lacrimal specialist for monitoring is
2 essential, (3) damage to the lacrimal system can be permanent, (4) this side effect is preventable, and
3 (5) oncologists are not aware of the severity of this side effect. Unfortunately this lack of awareness
4 often results in oncologists counseling their patients that their tearing is a temporary side effect and will
5 eventually subside.

6 **F. Taxotere Caused Mrs. Burns' Permanent Canalicular Stenosis**

7 40. Mrs. Burns was diagnosed with breast cancer and given chemotherapy with Taxotere, receiving
8 a total of twelve infusions over the course of four months.

9 41. At her sixth Taxotere infusion, Mrs. Burns notified her oncologist that she was experiencing
10 severe watery eyes. Although he visited her during her chemotherapy session, he did not advise her to
11 seek treatment from a lacrimal specialist. The next day, she scheduled an appointment with an
12 optometrist who diagnosed her with dry eye and advised her that watery eyes were a side effect of
13 chemotherapy.

14 42. After completing chemotherapy, Mrs. Burns reported to her physician that the persistently tearing
15 eyes were her primary concern, and two weeks after her final Taxotere infusion she was referred to an
16 ophthalmologist. The ophthalmologist inserted punctal plugs in an attempt to alleviate the tearing;
17 however, the near constant tearing continued.

18 43. Three and a half months after her last chemotherapy treatment, Mrs. Burns saw an oculoplastic
19 surgeon, who diagnosed her with canaliculus obstruction in both eyes. She was advised that Taxotere had
20 caused scarring in her tear ducts and was causing her eyes to excessively tear.

21 44. Over the next several months, Mrs. Burns endured multiple surgeries involving tube insertion but
22 the tubes continued to migrate into her nose and the tearing persisted. Subsequently, a left eye tube was
23 removed and was unable to be reinserted after persistent infections in that eye. Her medical records
24 indicate that her right eye continued to tear as well, despite the repeated surgeries.

25 45. Mrs. Burns completed chemotherapy and was excited to be cancer free and rid of all of the side
26 effects she suffered as a result of the cancer treatment. Among these, Mrs. Burns looked forward to no
27 longer suffering from constantly irritated, watering eyes. But as the effects of chemotherapy wore off,
28 her watery eyes remained.

1 46. Mrs. Burns continues to experience persistent tearing and a disruption of her life. As a direct and
2 proximate result of Sanofi's conduct in connection with the design, development, manufacture, testing,
3 packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of Taxotere, Mrs.
4 Burns suffers from epiphora due to permanent canalicular stenosis. This condition is a known permanent
5 side effect of taking Taxotere.

6 47. As a result of this permanent side effect, Mrs. Burns has struggled to return to normalcy, even
7 after surviving cancer, because she continues to suffer from persistent tearing on a daily basis, interfering
8 with her ability to perform basic activities and enjoy life. This permanent change has altered Mrs. Burns's
9 self-image, negatively impacted her relationships, and others' perceptions of her, leading to social
10 isolation and depression even long after fighting cancer.

11 48. When Mrs. Burns underwent chemotherapy with Taxotere, her eyes unexpectedly became
12 irritated and red and began to tear constantly. Throughout her ordeal, Mrs. Burns remained hopeful that,
13 like other chemotherapy side effects, the epiphora would eventually resolve. Indeed, she was advised that
14 the tearing would get better. To her dismay, it never has.

15 49. Mrs. Burns's tearing impacts all aspects of her daily life. Prior to developing permanent
16 canalicular stenosis, Mrs. Burns was self-confident and enjoyed social and professional interactions with
17 other people. Now she lacks the confidence she previously enjoyed.

18 50. Mrs. Burns is anxious about social interactions because she fears people will perceive her as sad
19 and crying. Her tears spill out over her cheeks, making her skin irritated and she is unable to keep makeup
20 on her face. She is aware of the concerned looks from well-intentioned friends, colleagues and strangers
21 who perceive her to be emotional and upset.

22 51. Throughout her ordeal, Mrs. Burns was advised that, like other chemotherapy side effects, the
23 epiphora would eventually resolve and was reassured that the treatments would work. Mrs. Burns was
24 advised by her healthcare providers that the epiphora could be fixed and no one advised this may be a
25 condition she would have to live with the rest of life.

26 52. Mrs. Burns's injuries could have been prevented had Sanofi simply warned that permanent
27 canalicular stenosis is a common but preventable side effect of Taxotere. Specifically, had Sanofi
28 properly warned Mrs. Burns's oncologist of the rapid onset of permanent damage, her oncologist would

1 have referred her to a lacrimal specialist immediately at the onset of her symptoms, rather than advising
2 her that the symptoms would go away when she completed her chemotherapy. Mrs. Burns thus seeks
3 recovery for her mental and physical suffering stemming from permanent, but easily preventable,
4 canalicular stenosis.

5 53. Mrs. Burns files this lawsuit within the applicable statute of limitations.

6 **G. Tolling of the Statute of Limitations.**

7 54. Alternatively, Mrs. Burns files this lawsuit within the applicable statute of limitations period of
8 first suspecting that Sanofi's wrongful conduct caused the appreciable harm she sustained. Due to
9 Sanofi's fraudulent concealment of the true nature of "excessive tearing which may be attributable to
10 lacrimal duct obstruction," Mrs. Burns could not, by the exercise of reasonable diligence, have discovered
11 that Sanofi wrongfully caused her injuries since she was unaware of the severity and permanency of her
12 injury. Specifically in its warning label, which Sanofi intended for oncologists to read and rely on, Sanofi
13 fraudulently concealed (1) the rapid onset at which stenosis can occur, (2) the potentially permanent
14 nature of the injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the
15 condition is highly preventable with timely intervention during chemotherapy. As a result, Mrs. Burns
16 was unaware that Sanofi knew of the devastating and permanent consequences of stenosis, or that Sanofi
17 concealed this information from her oncologist. Because Mrs. Burns's oncologist was unaware of the
18 permanent nature of this side effect, Mrs. Burns was also unaware that her condition was permanent.

19 55. Sanofi to this day does not warn that Taxotere can cause permanent obstruction of the lacrimal
20 system. Therefore Mrs. Burns did not suspect, nor did she have reason to suspect, that she had been
21 permanently injured. Furthermore, Mrs. Burns did not and could not suspect the tortious nature of the
22 conduct causing her injuries until a date before filing this action that is less than the applicable limitations
23 period for filing suit.

24 56. Upon presentation of tearing, Mrs. Burns was advised that tearing was a common side effect of
25 Taxotere chemotherapy that, like most other side effects of chemotherapy, would resolve.

26 57. In February of 2020, a friend reached out to Mrs. Burns after seeing a blog post on the website of
27 the law firm of Hotze Runkle, PLLC regarding Sanofi's negligence in failing to warn of the risk of
28 canalicular stenosis. Only then did Mrs. Burns discover that the manufacturers of Taxotere were aware

1 of permanent canalicular stenosis, but they intentionally withheld this information from healthcare
2 practitioners and consumers. Mrs. Burns felt as though she had an epiphany. For the first time, based on
3 the information she read on the law firm’s website, she appreciated that the manufacturer of her
4 chemotherapy drug failed to inform her and her oncologist of the risk of permanent damage to her
5 lacrimal system, as well as its knowledge that her injury could have been prevented. Mrs. Burns could
6 not have discovered Sanofi’s wrongdoing earlier, because to this date, Sanofi’s warning fails to fully
7 advise of the nature of the injury, resulting in oncologists and their patients remaining in the dark. Mrs.
8 Burns was only able to discover that her tearing was never going to go away after Hotze Runkle published
9 these facts on the internet.

10 58. Additionally, Mrs. Burns was prevented from discovering this information at an earlier date
11 because Sanofi: (1) misrepresented to the public, the FDA, and the medical profession the permanent
12 nature of “lacrimal duct obstruction;” (2) failed to disclose to the public, the FDA, and the medical
13 profession its knowledge of the risk of permanent but reversible side effects; (3) failed to disclose to the
14 public, the FDA, and the medical profession its knowledge that these side effects were preventable with
15 early intervention during chemotherapy; (4) fraudulently concealed facts and information that could have
16 led Mrs. Burns to discover Sanofi’s liability; and (5) still has not disclosed to the public, the FDA, and
17 the medical profession that Taxotere can cause permanent punctal, canalicular and nasolacrimal duct
18 stenosis which can be prevented with early intervention during chemotherapy.

19 **COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)**

20 59. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

21 60. At all relevant times, Sanofi was in the business of designing, researching, manufacturing, testing,
22 promoting, marketing, selling, and/or distributing pharmaceutical products, including the Taxotere used
23 by Mrs. Burns.

24 61. The Taxotere designed, formulated, produced, manufactured, sold, marketed, distributed,
25 supplied and/or placed into the stream of commerce by Sanofi failed to provide adequate warnings to
26 users and their healthcare providers, including Mrs. Burns and her healthcare providers, of the risk of
27 side effects associated with the use of Taxotere, particularly the risk of developing disfiguring, permanent
28 canalicular stenosis, or the measures that could have been taken to prevent it. The Taxotere designed,

1 formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream
2 of commerce by Sanofi and ultimately administered to Mrs. Burns lacked such warnings when it left
3 Sanofi's control.

4 62. The risks of developing disfiguring, permanent canalicular stenosis were known to or reasonably
5 knowable by Sanofi at the time the Taxotere left Sanofi's control, because of "newly acquired
6 information" available to Sanofi after the 2002 label change.

7 63. A reasonably prudent company in the same or similar circumstances would have provided a
8 warning that communicated the dangers and safe use of Taxotere.

9 64. Any warnings actually provided by Sanofi did not sufficiently and/or accurately reflect the
10 symptoms, type, scope, severity, and/or duration of these side effects, particularly the risks of developing
11 disfiguring, permanent canalicular stenosis or how it could have been prevented during administration of
12 the chemotherapy.

13 65. Without adequate warning of these side effects, Taxotere is not reasonably fit, suitable, or safe
14 for its reasonably anticipated or intended purposes.

15 66. Mrs. Burns was a reasonably foreseeable user of Taxotere who used the drug in a reasonably
16 anticipated manner.

17 67. Mrs. Burns would have taken preventative measures during the course of her chemotherapy to
18 prevent canalicular stenosis had she (and her physicians) been provided an adequate warning by Sanofi
19 of the risk of these side effects.

20 68. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse
21 effects of Taxotere, Mrs. Burns suffered and continues to suffer serious and dangerous side effects, severe
22 and personal injuries that are permanent and lasting in nature, and economic and non-economic damages,
23 harms, and losses, including, but not limited to: past and future medical expenses; past and future loss of
24 earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including
25 canalicular stenosis; mental anguish; severe and debilitating emotional distress; increased risk of future
26 harm; past, present, and future physical and mental pain, suffering, and discomfort; and past, present, and
27 future loss and impairment of the quality and enjoyment of life.

28 WHEREFORE, Plaintiff Jennifer Burns respectfully requests judgment in her favor and against

1 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief
2 this Court deems just and proper.

3 **COUNT II - NEGLIGENCE**

4 69. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

5 70. Sanofi had a duty to exercise reasonable care in the design, research, formulation, manufacture,
6 production, marketing, testing, supply, promotion, packaging, sale, and/or distribution of Taxotere,
7 including a duty to assure that the product would not cause users to suffer unreasonable, disfiguring, and
8 dangerous side effects.

9 71. Sanofi breached these duties when it put Taxotere into interstate commerce, unreasonably and
10 without adequate and/or proper warning to Mrs. Burns and her healthcare providers, a product that Sanofi
11 knew or should have known created a high risk of unreasonable, disfiguring, and dangerous side effects.

12 72. The negligence of Sanofi, its agents, servants, and/or employees, included but was not limited to,
13 the following acts and/or omissions:

- 14 (a) Manufacturing, producing, promoting, formulating, creating, and/or designing Taxotere
15 without thoroughly, adequately, and/or sufficiently testing it — including pre-clinical and
16 clinical testing and post-marketing surveillance — for safety and fitness for use and/or its
17 dangers and risks;
- 18 (b) Marketing Taxotere to Mrs. Burns, her healthcare providers, the public, and the medical and
19 healthcare professions without adequately and correctly warning and/or disclosing the
20 existence, severity, and duration of known or knowable side effects, including permanent
21 canalicular stenosis;
- 22 (c) Marketing Taxotere to the public, and the medical and healthcare professions without
23 providing adequate instructions regarding safety precautions to be observed by users,
24 handlers, and persons who would reasonably and foreseeably come into contact with, and
25 more particularly, use, Taxotere;
- 26 (d) Advertising and recommending the use of Taxotere without sufficient knowledge of its safety
27 profile;
- 28 (e) Designing, manufacturing, producing, and/or assembling Taxotere in a manner that was
dangerous to its users;
- (f) Concealing information from Mrs. Burns, her healthcare providers, the public, other medical
and healthcare professionals, and the FDA that Taxotere was unsafe, dangerous, and/or non-
conforming with FDA regulations;
- (g) Concealing from and/or misrepresenting information to Mrs. Burns, her healthcare providers,

1 other medical and healthcare professionals, and/or the FDA concerning the existence and
2 severity of risks and dangers of Taxotere; and

- 3 (h) Encouraging the sale of Taxotere, either directly or indirectly, orally or in writing, to Mrs.
4 Burns and her healthcare providers without warning about the need for more comprehensive
5 and regular medical monitoring than usual to ensure early discovery of potentially serious side
6 effects such as punctal, canalicular and nasolacrimal duct stenosis.

7 73. Despite the fact that Sanofi knew or should have known that Taxotere caused unreasonably
8 dangerous side effects, Sanofi continues to market, manufacture, distribute, and/or sell Taxotere to
9 consumers.

10 74. Mrs. Burns and her healthcare providers were therefore forced to rely on safety information that
11 did not accurately represent the risks and benefits associated with the use of Taxotere and measures that
12 could have been taken to prevent severe and permanent disfigurement from the use of Taxotere.

13 75. Sanofi knew or should have known that consumers such as Mrs. Burns would use its product and
14 would foreseeably suffer injury as a result of Sanofi's failure to exercise reasonable care, as set forth
15 above.

16 76. Sanofi's negligence was a proximate cause of Mrs. Burns's injuries, harms, damages, and losses,
17 in connection with the use of Taxotere, including but not limited to: past and future medical expenses;
18 past and future loss of earnings; past and future loss and impairment of earning capacity; permanent
19 disfigurement including permanent canalicular stenosis; mental anguish; severe and debilitating
20 emotional distress; increased risk of future harm; past, present, and future physical and mental pain,
21 suffering, and discomfort; and past, present, and future loss and impairment of the quality and enjoyment
22 of life.

23 WHEREFORE, Jennifer Burns respectfully requests judgment in her favor and against Defendants
24 in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
25 deems just and proper.

26 **COUNT III – NEGLIGENT MISREPRESENTATION**

27 77. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

28 78. Sanofi had a duty to represent to Mrs. Burns, her healthcare providers, the healthcare community,
and the public in general that Taxotere had been tested and found to be safe and effective for the treatment
of various forms of cancer.

1 79. When warning of safety and risks of Taxotere, Sanofi negligently represented to Mrs. Burns, her
2 healthcare providers, the healthcare community, and the public in general that Taxotere had been tested
3 and was found to be safe and/or effective for its indicated use.

4 80. Sanofi concealed its knowledge of Taxotere defects from Mrs. Burns, her healthcare providers,
5 and the public in general and/or the healthcare community specifically.

6 81. Sanofi concealed this information with the intent of defrauding and deceiving Mrs. Burns, her
7 healthcare providers, the public in general, and the healthcare community in particular, and were made
8 with the intent of inducing Mrs. Burns, her healthcare providers, the public in general, and the healthcare
9 community in particular, to recommend, dispense, and/or purchase Taxotere.

10 82. Sanofi failed to exercise ordinary and reasonable care in its representations of Taxotere in its sale,
11 testing, quality assurance, quality control, and/or distribution into interstate commerce, and Sanofi
12 negligently misrepresented Taxotere's high risks of unreasonable, dangerous side effects. These side
13 effects were unreasonable because they could have been entirely prevented with adequate warning.

14 83. Sanofi breached its duty in misrepresenting Taxotere's serious side effects to Mrs. Burns, her
15 healthcare providers, the healthcare community, the FDA, and the public in general.

16 84. Mrs. Burns and her healthcare providers reasonably relied on Sanofi to fulfill its obligations to
17 disclose all facts within its knowledge regarding the serious side effects of Taxotere and the ability to
18 prevent those side effects with appropriate precautionary measures.

19 85. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Burns
20 to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting
21 in nature, and economic and non-economic damages, harms, and losses, including, but not limited to:
22 past and future medical expenses; past and future loss of earnings; past and future loss and impairment
23 of earning capacity; permanent disfigurement, including permanent canalicular stenosis; mental anguish;
24 severe and debilitating emotional distress; increased risk of future harm; past, present, and future physical
25 and mental pain, suffering, and discomfort; and past, present, and future loss and impairment of the
26 quality and enjoyment of life.

27 WHEREFORE, Jennifer Burns respectfully requests that judgment in her favor and against
28 Defendants in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief

1 this Court deems just and proper.

2 **COUNT IV – FRAUDULENT MISREPRESENTATION**

3 86. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

4 87. In its labeling information, Sanofi communicated to Mrs. Burns, her healthcare providers, the
5 healthcare community, and the public in general that “excessive tearing which may be attributable to
6 lacrimal duct obstruction has been reported” and that excessive tearing is a common side effect. These
7 statements misrepresented the true risk of harm to patients, in that they failed to fully inform oncologists
8 and patients of (1) the rapid onset at which stenosis can occur, (2) the potentially **permanent** nature of
9 the injury, (3) the need to immediately refer patients to a lacrimal specialist and (4) that the condition is
10 highly preventable with timely intervention during chemotherapy.

11 88. Despite having knowledge of this side effect, Sanofi fraudulently omitted from this vague
12 warning of “lacrimal duct obstruction” and/or “excessive tearing” that Taxotere could and did cause
13 **permanent** damage to the lacrimal system, including canalicular stenosis.

14 89. These representations were material and false.

15 90. Sanofi made these representations and omissions:

- 16 (a) with knowledge or belief of their falsity, and/or in the case of omissions, with knowledge or
17 belief of falsity of the resulting statements;
- 18 (b) positively and recklessly without knowledge of their truth or falsity;
- 19 (c) with knowledge that they were made without any basis; and/or
- 20 (d) without confidence in the accuracy of the representations or statements resulting from the
21 omissions.

22 91. Sanofi made these false representations with the intention or expectation that Mrs. Burns, her
23 healthcare providers, the public in general, and the healthcare community in particular, would
24 recommend, dispense, and/or purchase Taxotere, all of which evidenced a callous, reckless, willful,
25 wanton, and depraved indifference to the health, safety, and welfare of Mrs. Burns.

26 92. At the time Sanofi made the aforesaid representations, and, at the time Mrs. Burns used Taxotere,
27 Mrs. Burns and Mrs. Burns’s healthcare providers were unaware of the falsity of Sanofi’s representations,
28 statements and/or implications and justifiably and reasonably relied on Sanofi’s representations,

1 statements, and implications, believing them to be true.

2 93. In reliance on Sanofi's representations, Mrs. Burns and her healthcare providers were induced to
3 and did use and prescribe Taxotere, which caused Mrs. Burns to suffer serious and dangerous side effects,
4 severe and personal injuries that are permanent and lasting in nature, and economic and non-economic
5 damages, harms, and losses, including, but not limited to: past and future medical expenses; past and
6 future loss of earnings; past and future loss and impairment of earning capacity; permanent disfigurement,
7 including permanent canalicular stenosis; mental anguish; severe and debilitating emotional distress;
8 increased risk of future harm; past, present, and future physical and mental pain, suffering, and
9 discomfort; and past, present, and future loss and impairment of the quality and enjoyment of life.

10 WHEREFORE, Jennifer Burns respectfully requests judgment in her favor and against Defendants
11 in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
12 deems just and proper.

13 **COUNT V – FRAUDULENT CONCEALMENT**

14 94. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

15 95. At all times during the course of dealing between Sanofi and Mrs. Burns and her healthcare
16 providers, Sanofi misrepresented the design characteristic and safety of Taxotere for their intended use.

17 96. Sanofi knew or was reckless in not knowing that its representations were false due to Sanofi's
18 access to ongoing studies and reports that disclosed serious, but preventable damage to the lacrimal
19 system caused by Taxotere. In representations made to Mrs. Burns and her healthcare providers, Sanofi
20 fraudulently concealed and intentionally omitted the following material information: (1) the rapid onset
21 at which stenosis can occur, (2) the potentially permanent nature of the injury, (3) the need to immediately
22 refer patients to a lacrimal specialist and (4) that the condition is highly preventable with timely
23 intervention during chemotherapy.

24 97. Sanofi had a duty to disclose to Mrs. Burns and her healthcare providers the defective nature of
25 Taxotere, including, but not limited to, the heightened risks of disfiguring, permanent canalicular
26 stenosis.

27 98. Sanofi had a duty to disclose to Mrs. Burns and her healthcare providers that the disfiguring,
28 permanent canalicular stenosis caused by the use of Taxotere could have been prevented by early

1 identification and treatment of epiphora during chemotherapy.

2 99. Sanofi had sole access to material facts concerning the defective nature of Taxotere and its
3 propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used
4 the drugs at issue, including Mrs. Burns.

5 100. Sanofi's concealment and omissions of material fact concerning the safety of Taxotere were
6 made purposefully, willfully, wantonly, and/or recklessly to mislead Mrs. Burns and her healthcare
7 providers into reliance on the continued use of the drugs and to cause them to purchase, prescribe, and/or
8 dispense Taxotere and/or use it.

9 101. Sanofi knew that Mrs. Burns and her healthcare providers had no way to determine the truth
10 behind its concealment and omissions, including the material omissions of fact surrounding Taxotere set
11 forth herein.

12 102. Mrs. Burns and her healthcare providers reasonably relied on information disclosed by Sanofi
13 that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or
14 omitted by Sanofi.

15 103. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Burns to suffer serious and
16 dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and
17 economic and non-economic damages, harms, and losses, including, but not limited to: past and future
18 medical expenses; past and future loss of earnings; past and future loss and impairment of earning
19 capacity; permanent disfigurement, including permanent canalicular stenosis; mental anguish; severe and
20 debilitating emotional distress; increased risk of future harm; past, present, and future physical and mental
21 pain, suffering, and discomfort; and past, present, and future loss and impairment of the quality and
22 enjoyment of life.

23 WHEREFORE, Jennifer Burns respectfully requests judgment in her favor and against Defendants
24 in an amount that exceeds \$75,000, plus the costs of this suit and any other and further relief this Court
25 deems just and proper.

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V. JURY DEMAND

Plaintiff has requested a trial by jury pursuant to rule 38 of the Federal Rules of Civil Procedure.

Dated: November 15, 2021

FITZPATRICK & SWANSTON
RMP LAW GROUP LLC
HOTZE RUNKLE PLLC

By: /s/ B. James Fitzpatrick _____
B. James Fitzpatrick
Richard M. Paul (*pro hac* forthcoming)
Patrick O. Hotze (*pro hac* forthcoming)
Attorneys for Plaintiff

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