BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

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

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 INJURY CLAIMS	))	MDL Docket No.

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 warming 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

Respectfully submitted,

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BEFORE THE UNITED STATES JUDICIAL PANEL
ON MULTIDISTRICT LITIGATION

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

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 INJURY CLAIMS	))	MDL Docket No.

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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San Francisco, CA 94102

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District of Arizona
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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

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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 *E-Filing A New Civil Case* 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. *This is a text only docket entry; there is no document associated with this notice.* (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)(mbcS, 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 bySanofi 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 Manag ement 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 byJade 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))* (Nassihi, Amir) (Filed on 7/16/2021) Modified on 7/16/2021 (mclS, 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 cou rt proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.** **Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/.** **Jo int 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)(Nassihi, 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 bySanofi 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) (Nassihi, 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 byJade Porter. (Paul, Richard) (Filed on 9/9/2021) (Entered: 09/09/2021)
09/09/2021	43	Request for Judicial Notice filed byJade 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 rebroadc asting 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. ***(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)**
09/23/2021	46	REPLY (re 40 MOTION to Dismiss *Plaintiff's First Amended Complaint*) filed bySanofi US Services, Inc., Sanofi-Aventis U.S. LLC. (Nassihi, 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	**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 *Plaintiff's First Amended Complaint* 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.** **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 Managemen t 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.** ***(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)**
10/25/2021	49	STIPULATION WITH PROPOSED ORDER *To Continue Hearing Date for Sanofi's Motion to Dismiss* filed by Sanofi US Services, Inc., Sanofi-Aventis U.S. LLC adn Jade Porter. (Nassihi, Amir) (Filed on 10/25/2021) Modified on 10/26/2021 (jml, COURT STAFF). (Entered: 10/25/2021)
10/27/2021	50	**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 *Plaintiff's First Amended Complaint* 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.** **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 12/9/2021. Initia l 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.** ***(This is a text-only entry generated by the court. There is no document associated with this entry.)*****(afm, COURT STAFF) (Filed on 10/27/2021) (Entered: 10/27/2021)**
11/12/2021	51	**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 *Plaintiff's First Amended Complaint* 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.** **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 State ment 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.** ***(This is a text-only entry generated by the court. There is no document associated with this entry.)*****(afm, COURT STAFF) (Filed on 11/12/2021) (Entered: 11/14/2021)**
11/24/2021	52	**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 *Plaintiff's First Amended Complaint* 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.** **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 procee dings, 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 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)**

PACER Service Center			
Transaction Receipt			
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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Attorneys for Plaintiff,
JADE PORTER

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**

Plaintiff Jade Porter, 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 (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 and irreversible damage to the lacrimal system, including punctal and 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 and irreversible 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 and irreversible.** 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. Porter 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 punctal and 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. Porter, 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.

PARTIES

A. Plaintiff

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

B. Sanofi Defendants

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

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

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

drug market.

JURISDICTION AND VENUE

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

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

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

FACTUAL ALLEGATIONS

I. Development and Approval of Taxotere (Docetaxel)

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

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

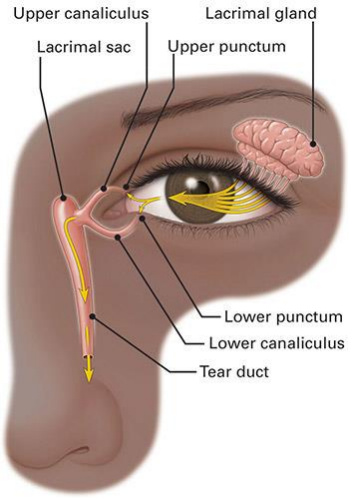
13. In August 2004, Sanofi obtained FDA approval for an expanded use of Taxotere "in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer." This resulted in a greater number of patients being treated with Taxotere.

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

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

II. Anatomy of the 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 and canaliculi[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*. Cases of cystoid macular edema (CME) have been reported in patients treated with TAXOTERE.

[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.

> …
> **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,

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

effects without the opportunity to evaluate risks for themselves.

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

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

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

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

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

b) From the American Cancer Society

> *Despite the previous publication of several articles by our group regarding canalicular stenosis and lacrimal obstruction resulting from docetaxel 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.*
>
> *All patients receiving weekly docetaxel should be monitored closely by an ophthalmologist so that the timely management of canalicular stenosis can be offered.*
>
> *We recommend silicone intubation [stents] in all symptomatic patients who are receiving weekly docetaxel if they ae to continue receiving the drug.*[4]

[2] https://www.accessdata.fda.gov/drugsatfda_docs/label/2003/20449slr022_taxotere_lbl.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)

[4] Bita Esmaeli, et al., Blockage of the Lacrimal Drainage Apparatus as a Side Effect of Docetaxel Therapy, 98 Cancer 504-7 (2003)

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 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 docetaxel weekly.* [6]

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

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

[6] Bita 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).

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

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

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

[8] *Id.*

[9] Bita 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).

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

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

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

[13] *Id.*

[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)

VI. Taxotere Caused Mrs. Porter's Permanent Punctal and Canalicular Stenosis

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

stenosis.

VII. Tolling of the Statute of Limitations

60. Mrs. Porter files this lawsuit within the applicable statute of limitations period of first suspecting that Sanofi's wrongful conduct caused the appreciable harm she sustained. Due to Sanofi's fraudulent concealment of the true nature of "excessive tearing which may be attributable to lacrimal duct obstruction," Mrs. Porter could not, by the exercise of reasonable diligence, have discovered that Sanofi wrongfully caused her injuries as she was unaware of the severity and permanency of her injury. Specifically in its warning label, Sanofi fraudulently concealed (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. As a result, Mrs. Porter was unaware that Sanofi knew of the devastating and permanent consequences of stenosis, or that Sanofi concealed this information from her oncologist. Because Mrs. Porter's oncologist was unaware of the permanent nature of this side effect, Mrs. Porter was unaware that her condition was permanent and irreversible.

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

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

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

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

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

COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

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

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

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

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

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

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

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

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

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

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

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

75. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse effects of Taxotere, Mrs. Porter suffered and continues to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 canalicular 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, Plaintiff Jade Porter 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 II - NEGLIGENCE

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

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

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

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

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

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

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

public, and the medical 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;

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

f. Concealing information from Mrs. Porter, Mrs. Porter'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. Porter, Mrs. Porter'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. Porter and Mrs. Porter'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 canalicular stenosis.

80. 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.

81. Mrs. Porter and Mrs. Porter'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.

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

83. Sanofi's negligence was a proximate cause of Mrs. Porter'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 canalicular 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, Jade Porter 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

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

85. Sanofi had a duty to represent to Mrs. Porter, Mrs. Porter's 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.

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

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

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

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

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

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

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

92. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Porter to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 canalicular 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, Jade Porter respectfully requests that 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 – FRAUDULENT MISREPRESENTATION

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

94. Sanofi represented to Mrs. Porter, Mrs. Porter'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.

95. 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 canalicular stenosis.

96. These representations were material and false.

97. 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.

98. Sanofi made these false representations with the intention or expectation that Mrs. Porter, Mrs. Porter'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. Porter.

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

100. In reliance on Sanofi's representations, Mrs. Porter and her healthcare providers were induced to and did use and prescribe Taxotere, which caused Mrs. Porter to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 canalicular

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, Jade Porter 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 V – FRAUDULENT CONCEALMENT

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

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

103. Sanofi knew or was reckless in not knowing that its representations were false due to Sanofi's access to ongoing studies and reports that disclosed serious, enhanced side effects of Taxotere to the lacrimal system. In representations made to Mrs. Porter and Mrs. Porter's healthcare providers, Sanofi fraudulently concealed and intentionally omitted the following material information: (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.

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

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

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

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

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

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

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

110. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Porter to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 canalicular 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, Jade Porter 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.

JURY DEMAND

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

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

represented by **Bernard James Fitzpatrick**
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V.

Defendant

Sanofi US Services, Inc.
formerly known as
Sanofi-Aventis U.S., Inc.

represented by **Amir M. Nassihi**
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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 *E-Filing A New Civil Case* 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. *This is a text only docket entry; there is no document associated with this notice.* (mklS, 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 *RE APRIL 30, 2021 CASE MANAGEMENT CONFERENCE ORDER AND STANDING ORDERS* (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 *For Extension of Time to Respond to Complaint and Briefing Schedule* 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 co urt proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.** **Zoom Guidance and Setup: https://www.cand.uscourts.gov/zoom/.** **J oint 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 *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 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 *Plaintiff's First Amended Complaint* filed bySanofi 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 *Plaintiff's First Amended Complaint*) filed byCathy Estell. (Paul, Richard) (Filed on 8/25/2021) (Entered: 08/25/2021)
08/27/2021	37	STIPULATION WITH PROPOSED ORDER *Regarding Deadline to File Reply in Support of Sanofi's Motion to Dismiss First Amended Complaint* 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**

		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. **Webinar Access: All counsel, members of the public, and media may access the webinar information at https://www.cand.uscourts.gov/emc** **General Or der 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/.** **Initial Case Management Conference set for 8/31/2021 03:30 PM in San Francisco, - Videocon ference 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)**
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	**Minute Entry for proceedings held before Judge Edward M. Chen:** **Initial Case Management Conference held on 8/31/2021. See pdf image for further details.** **Total Time in Court: 13 Minutes.** **Court Reporter: Marla Knox.** **Plaintiff Attorney: Richard Paul.** **Defendant Attorneys: Amir Nassihi, Torrey Peterson, Harley Ratliff.** **Attachment: Minute Order.** **(afmS, COURT STAFF) (Date Filed: 8/31/2021) (Entered: 09/02/2021)**
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 *Plaintiff's First Amended Complaint*) filed bySanofi 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	**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 *Plaintiff's First Amended Complaint* 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.** **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/.** **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 n o document associated with this entry.)*(afmS, COURT STAFF) (Filed on 9/10/2021) (Entered: 09/10/2021)**
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	**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 *Plaintiff's First Amended Complaint* 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.** **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 rebr oadcasting of court proceedings, including screenshots or other visual copying of a hearing, is absolutely prohibited.** **Zoom Guidance and Setup: https://www.cand.uscourts.gov/z oom/.** **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)**
10/25/2021	47	STIPULATION WITH PROPOSED ORDER *To Continue Hearing Date for Sanofi's Motion to Dismiss* 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 *Plaintiff's First Amended Complaint* 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.**

		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/.** **Motion Hearing set for 12/16/2021 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 10/27/2021) (Entered: 10/27/2021)**
11/12/2021	49	**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 *Plaintiff's First Amended Complaint* 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.** **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 rebroadca sting 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/< /A>.** **Motion Hearing set for 12/14/2021 10:00 AM 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 11/12/2021) (Entered: 11/14/2021)**
11/24/2021	50	**CLERK'S NOTICE ADVANCING MOTION 26 HEARING FROM 12/14/2021 TO 12/9/2021 AT 1:30PM: Hearing re 26 MOTION to Dismiss *Plaintiff's First Amended Complaint* 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.** **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/.< /p> 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)**

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Attorneys for Plaintiff,
CATHY ESTELL

UNITED STATES DISTRICT COURT

DISTRICT OF CALIFORNIA

CATHY ESTELL, 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-2749-EMC **FIRST AMENDED COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiff Cathy Estell, 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 (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 and irreversible damage to the lacrimal system, including punctal and nasolacrimal duct 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 and irreversible 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 and irreversible.** 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. Estell 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 punctal 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. Estell, 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.

PARTIES

A. Plaintiff

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

B. Sanofi Defendants

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

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

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

JURISDICTION AND VENUE

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

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

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

FACTUAL ALLEGATIONS

I. Development and Approval of Taxotere (Docetaxel)

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

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

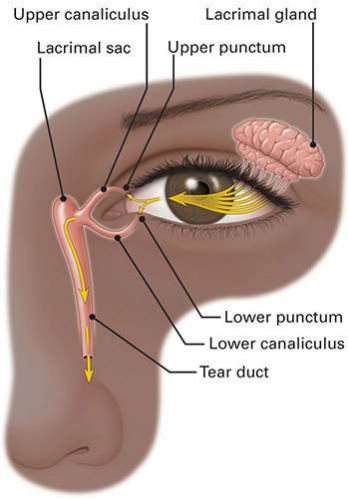
13. In August 2004, Sanofi obtained FDA approval for an expanded use of Taxotere "in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer." This resulted in a greater number of patients being treated with Taxotere.

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

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

II. Anatomy of the 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, canaliculi, and/or the nasolacrimal duct (labeled as tear duct in image).[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:

> **Patient Information Leaflet**
> ***What are the possible side effects of Taxotere?***
> Eye Changes – Excessive tearing, which can be related to conjunctivitis or blockage of tear ducts, may occur
>
> **Post-Marketing Experiences**
>
> *Excessive tearing which may be attributable to lacrimal duct*

[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 , the canaliculi and/or the nasolacrimal ducts

> *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*.[2]
>
> (emphasis added)

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

20. Sanofi's labeling information at all times relevant to this lawsuit, and even to date, does not identify the risk of punctal and nasolacrimal duct stenosis as a cause of excessive tearing, the rapid onset at which stenosis can occur, the potentially permanent and irreversible nature of the injury, the need to 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 prompt 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. Estell'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. Estell, 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

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

current safety and 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.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

b) From the American Cancer Society

> *Despite the previous publication of several articles by our group regarding canalicular stenosis and lacrimal obstruction resulting from docetaxel 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.*
>
> *All patients receiving weekly docetaxel should be monitored closely by an ophthalmologist so that the timely management of canalicular stenosis can be offered.*
>
> *We recommend silicone intubation [stents] in all symptomatic patients who are receiving weekly*

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

[4] 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)

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%

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[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,

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

[12] Bita 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)

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

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

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

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

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

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

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

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

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

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

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

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

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

VII. Tolling of the Statute of Limitations

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

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

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

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

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

COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

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

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

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

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

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

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

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

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

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

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

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

65. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse effects of Taxotere, Mrs. Estell suffered and continues to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 punctal and nasolacrimal duct 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, Plaintiff Cathy Estell 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 II - NEGLIGENCE

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

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

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

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

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

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

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

c. Marketing Taxotere to Mrs. Estell, her healthcare providers, the public, and the medical 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;

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

f. Concealing information from Mrs. Estell, 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. Estell, her 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. Estell and her 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 and nasolacrimal duct stenosis.

70. 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.

71. Mrs. Estell 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.

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

73. Sanofi's negligence was a proximate cause of Mrs. Estell'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 and nasolacrimal duct 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, Cathy Estell respectfully requests judgment in her favor and against Defendantsin 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

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

75. Sanofi had a duty to represent to Mrs. Estell, Mrs. Estell's 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.

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

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

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

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

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

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

82. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Estell to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 punctal and nasolacrimal duct 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, Cathy Estell respectfully requests that 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 – 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

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

90. In reliance on Sanofi's representations, Mrs. Estell and her healthcare providers were induced to and did use and prescribe Taxotere, which caused Mrs. Estell to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 punctal and nasolacrimal duct 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, Cathy Estell 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 V – FRAUDULENT CONCEALMENT

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

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

93. Sanofi knew or was reckless in not knowing that its representations were false due to Sanofi's access to ongoing studies and reports that disclosed serious, enhanced side effects of Taxotere to the lacrimal system. 93. In representations made to Mrs. Estell and Mrs. Estell's healthcare providers, Sanofi fraudulently concealed and intentionally omitted the following material information: (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.

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

disfiguring, permanent punctal and nasolacrimal duct stenosis.

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

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

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

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

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

100. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Estell to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 punctal and nasolacrimal duct 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, Cathy Estell 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.

JURY DEMAND

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

Dated: July 28, 2021

FITZPATRICK & SWANSTON
RMP LAW GROUP LLC
HOTZE RUNKLE PLLC

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

ACCO,(KKx),DISCOVERY,MANADR

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

Jeannie Hamilton-Moews

represented by **Karen C. Shanks**
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ATTORNEY TO BE NOTICED

V.

Defendant

Sanofi US Services, Inc.
formerly known as
Sanofi-Aventis U.S., Inc.

represented by **Amir M Nassihi**
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Email: anassihi@shb.com
ATTORNEY TO BE NOTICED

Defendant

Sanofi-Aventis, U.S. LLC

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

Date Filed	#	Docket Text
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)
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) (Nassihi, 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)(Nassihi, 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. (Nassihi, 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 1 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. Terming 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. (Nassihi, 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)(Nassihi, 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 601Walnut 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)

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UNITED STATES DISTRICT COURT FOR THE 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

(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 and irreversible damage to the lacrimal system, including punctal 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 and irreversible 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 and irreversible.** 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. Hamiton-Moews 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 punctal 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. Hamilton-Moews, 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.

PARTIES

A. Plaintiff

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

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

B. Sanofi Defendants

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

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

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

JURISDICTION AND VENUE

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

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

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

substantial contacts in this forum.

FACTUAL ALLEGATIONS

I. Development and Approval of Taxotere (Docetaxel)

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

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

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

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

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

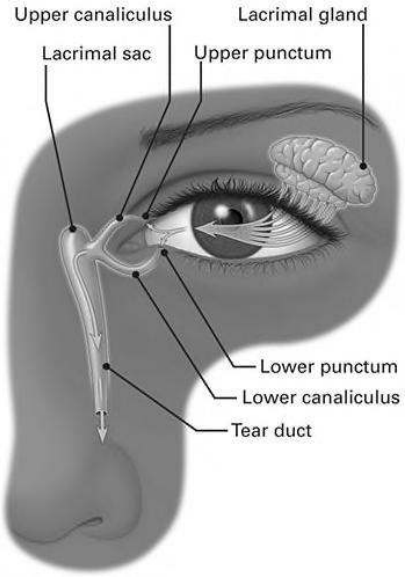
II. Anatomy of Lacrimal System

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 and canaliculi.[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.

> Advise patients that side effects such as nausea, vomiting, diarrhea, constipation, excessive tearing and/or vision disturbances are associated with docetaxel administration. Tell patients to immediately report any abdominal pain or tenderness, and/or diarrhea, with or without fever, any vision changes.
>
> **What are the possible side effects of Taxotere?**
> The most common side effects of Taxotere include: redness of the eye, excess tearing . . . [2]
>
> (emphasis added)

19. Sanofi's label 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, the permanency of stenosis and, therefore, the critical need to seek immediate medical treatment from an appropriately qualified physician. These representations downplay the serious and permanent nature of this side effect by effectively communicating this side effect is transitory. In the section of the label regarding "Ophthalmologic" side effects, Sanofi represents that these side effects were "reversible upon discontinuation of the infusion." This affirmatively misrepresents the frequency and severity of this potentially permanent damage to the lacrimal system.

20. Sanofi's labeling information at all times relevant to this lawsuit, and even to date, does not identify the risk of punctal stenosis as a cause of excessive tearing, the rapid onset at which stenosis can occur, the potentially permanent and irreversible nature of the injury, the need to 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 prompt 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. Hamilton-Moews'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. Hamilton-Moews, suffering daily from a permanent condition that could

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

opportunity to evaluate risks for themselves.

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

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

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

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

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

b) From the American Cancer Society:

> *Despite the previous publication of several articles by our group regarding canalicular stenosis and lacrimal obstruction resulting from docetaxel 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.*
>
> *All patients receiving weekly docetaxel should be monitored closely by an ophthalmologist so that the timely management of canalicular stenosis can be offered.*
>
> *We recommend silicone intubation [stents] in all symptomatic patients who are receiving weekly docetaxel if*

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

[4] 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)

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

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[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).

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) immediate referral to a lacrimal specialist for monitoring is essential, (3)

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

[12] Bita 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)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VII. Tolling of the Statute of Limitations.

52. Alternatively, Mrs. Hamilton-Moews files this lawsuit within the applicable statute of limitations period of first suspecting that Sanofi's wrongful conduct caused the appreciable harm she sustained. Due to Sanofi's fraudulent concealment of the true nature of "excessive tearing which may be attributable to lacrimal duct obstruction," Mrs. Hamilton-Moews could not, by the exercise of reasonable diligence, have discovered that Sanofi wrongfully caused her injuries as she was unaware of the severity and permanency of her injury. Specifically in its warning label, Sanofi fraudulently concealed (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. As a result, Mrs. Hamilton-Moews was unaware that Sanofi knew of the devastating and permanent consequences of stenosis, or that Sanofi concealed this information from her oncologist. Because Mrs. Hamilton-Moews' oncologist was unaware of the permanent nature of this side effect, Mrs. Hamilton-Moews was unaware that her condition was permanent and irreversible.

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

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

COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

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

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

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

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

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

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

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

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

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

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

64. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse effects of Taxotere, Mrs. Hamilton-Moews suffered and continues to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 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, Plaintiff 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 this Court deems just and proper.

COUNT II - NEGLIGENCE

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

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

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

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

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

(b) Marketing Taxotere to Mrs. Hamilton-Moews, Mrs. Hamilton-Moews's healthcare providers, the public, and the medical and healthcare professions without adequately and correctly warning and/or disclosing the existence, severity, and duration of known or knowable side effects, including permanent punctal stenosis;

(c) Marketing Taxotere to Mrs. Hamilton-Moews, Mrs. Hamilton-Moews's healthcare providers, the public, and the medical 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;

(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

this Court deems just and proper.

COUNT III – NEGLIGENT MISREPRESENTATION

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

74. Sanofi had a duty to represent to Mrs. Hamilton-Moews, Mrs. Hamilton-Moews's 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.

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

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

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

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

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

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

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

permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 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 that 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 – FRAUDULENT MISREPRESENTATION

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

83. Sanofi represented to Mrs. Hamilton-Moews, her 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.

84. 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 stenosis.

85. These representations were material and false.

86. 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.

87. Sanofi made these false representations with the intention or expectation that Mrs. Hamilton-Moews, Mrs. Hamilton-Moews'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. Hamilton-Moews.

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

89. In reliance on Sanofi's representations, Mrs. Hamilton-Moews and her healthcare providers were induced to and did use and prescribe Taxotere, which caused Mrs. Hamilton-Moews to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 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 this Court deems just and proper.

COUNT V – FRAUDULENT CONCEALMENT

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

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

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

lacrimal system. In representations made to Mrs. Hamilton-Moews and her healthcare providers, Sanofi fraudulently concealed and intentionally omitted the following material information: (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.

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

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

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

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

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

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

99. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Hamilton-Moews to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 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 this Court deems just and proper.

VI. JURY DEMAND

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

Dated: July 28, 2021

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ATTORNEYS FOR PLAINTIFF

STD

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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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 *(First Request)* by Sanofi US Services Incorporated, Sanofi-Aventis U.S. LLC. (Attachments: # 1 Text of Proposed Order Proposed Order)(Montecuollo, 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: First Amended Complaint*. (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 *(First Amended Petition)* 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 *MOTION TO DISMISS PLAINTIFFS FIRST AMENDED COMPLAINT* 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)(Montecuollo, 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)(Montecuollo, 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 *MOTION TO DISMISS PLAINTIFFS FIRST AMENDED COMPLAINT* . (Montecuollo, 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. ***No further action is required***. 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 *MOTION TO DISMISS PLAINTIFFS FIRST AMENDED COMPLAINT* 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 *MOTION TO DISMISS PLAINTIFFS FIRST AMENDED COMPLAINT REPLY IN SUPPORT OF SANOFIS MOTION TO DISMISS PLAINTIFFS FIRST AMENDED COMPLAINT* 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

been prevented with an adequate warning to her physicians. Plaintiff's permanent punctal stenosis causes 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. Cone, the irritated, swollen, watering eyes 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.

PARTIES

A. Plaintiff

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

B. Sanofi Defendants

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

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

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

JURISDICTION AND VENUE

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

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

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

FACTUAL ALLEGATIONS

I. Development and Approval of Taxotere (Docetaxel)

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

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

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

II. Taxotere's Labeling

12. Taxotere's labeling information at the time pertinent 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**:
> 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.
>
> **What are the possible side effects of Taxotere?**
> The most common side effects of Taxotere include: redness of the eye, excessive tearing . . .

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

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

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

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

III. Sanofi's Duty to Monitor and Update Labeling

17. The primary responsibility for timely communicating complete, accurate, and current safety and 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

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

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

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

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

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

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

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

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

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

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

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

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

IV. Sanofi Knew That Taxotere Causes Permanent Punctal Stenosis.

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

secreted in the tear film, thereby causing fibrosis of the lacrimal system, including the puncta, canaliculi and nasolacrimal duct. Medical literature has concluded that 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 and further lacrimal complications.

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

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

[2] *Id.*

[3]Bita 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).

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

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

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

[7] *Id.*

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

[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)

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

V. Taxotere Caused Mrs. Cone's Permanent Bilateral Punctal Stenosis.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

VI. Tolling of the Statute of Limitations.

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

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

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

COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

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

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

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

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

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

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

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

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

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

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

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

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

effects of Taxotere, Mrs. Cone suffered and continues to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 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, Plaintiff 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 II – STRICT PRODUCTS LIABILITY (MISREPRESENTATION)

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

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

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

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

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

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

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

69. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Cone to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 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 III - NEGLIGENCE

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

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

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

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

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

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

(c) Marketing Taxotere to Mrs. Cone, Mrs. Cone's healthcare providers, the public, and the medical 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;

(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

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

79. Sanofi had a duty to represent to Mrs. Cone, Mrs. Cone's 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.

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

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

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

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

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

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

86. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Cone to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 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 that 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 V – FRAUDULENT MISREPRESENTATION

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

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

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

90. These representations were material and false.

91. 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.

92. Sanofi made these false representations with the intention or expectation that Mrs. Cone, Mrs. Cone'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. Cone.

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

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

94. In reliance on Sanofi's representations, Mrs. Cone and her healthcare providers were induced to and did use and prescribe Taxotere, which caused Mrs. Cone to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 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 VI – FRAUDULENT CONCEALMENT

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

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

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

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

(a) that Taxotere was not as safe as other forms of treatment for which they were marketed and sold to cancer patients;

(b) that the risks of adverse events with Taxotere was higher than those with other forms of treatment for which they were marketed and sold to cancer patients;

(c) that the risks of adverse events with Taxotere was not adequately tested and/or known by Sanofi;

(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

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

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

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

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

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

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

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

105. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Cone to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 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.

VII. JURY DEMAND

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

Dated: April 21, 2021

HOTZE RUNKLE, PLLC

By: /s/ Ryan Runkle
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CIVIL

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.

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Torrey Peterson , PHV
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LEAD ATTORNEY
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Amir M. Nassihi
(See above for address)
ATTORNEY TO BE NOTICED

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. (Nassihi, 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. (Nassihi, Amir) Modified on 10/22/2021 (Coll, A). (Entered: 10/21/2021)

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Attorneys for Plaintiff,
TERESA VEGA

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,

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 and irreversible damage to the lacrimal system, including nasolacrimal duct 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 and irreversible 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 and irreversible.** 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, Ms. Vega 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 punctal 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 Ms. Vega, 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.

PARTIES

A. Plaintiff

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

B. Sanofi Defendants

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

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

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

JURISDICTION AND VENUE

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

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

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

FACTUAL ALLEGATIONS

I. Development and Approval of Taxotere (Docetaxel)

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

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

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

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

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

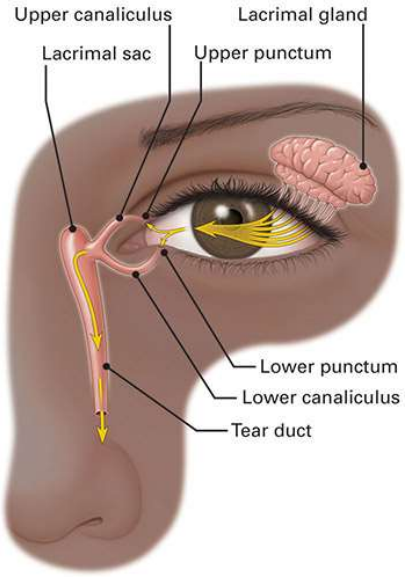
II. Anatomy of Lacrimal System

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.

> Explain to patients that side effects such as nausea, vomiting, diarrhea, constipation, excessive tearing and/or vision disturbances are associated with docetaxel administration. Tell patients to immediately report any abdominal pain or tenderness, and/or diarrhea, with or without fever, any vision changes.
>
> **What are the possible side effects of Taxotere?**
> The most common side effects of Taxotere include: redness of the eye, excess tearing . . . [2]
>
> (emphasis added)

19. Sanofi's label 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. These representations downplay the serious and permanent nature of this side effect by effectively communicating this side effect is transitory. In the section of the label regarding "Ophthalmologic" side effects, Sanofi represents that these side effects were "reversible upon discontinuation of the infusion." This affirmatively misrepresents the frequency and severity of this potentially permanent damage to the lacrimal system.

20. Sanofi's labeling information at all times relevant to this lawsuit, and even to date, does not identify the risk of punctal and canalicular stenosis as a cause of excessive tearing, the rapid onset at which stenosis can occur, the potentially permanent and irreversible nature of the injury, the need to 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 Ms. Vega'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 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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

opportunity to evaluate risks for themselves.

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

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

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

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

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

b) From the American Cancer Society:

> *Despite the previous publication of several articles by our group regarding canalicular stenosis and lacrimal obstruction resulting from docetaxel 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.*
>
> *All patients receiving weekly docetaxel should be monitored closely by an ophthalmologist so that the timely management of canalicular stenosis can be offered.*
>
> *We recommend silicone intubation [stents] in all symptomatic patients who are receiving weekly docetaxel if*

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

[4] 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)

they are 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 whose 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

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[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).

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) immediate referral to a lacrimal specialist for monitoring is essential, (3)

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

[12] Bita 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 Docetaxe*l, 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)

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

VI. Taxotere Caused Ms. Vega's Permanent Nasolacrimal Duct Obstruction

41. Ms. Vega was diagnosed with breast cancer and received infusions of Taxotere, receiving a total of four infusions over the course of approximately two months.

42. After beginning chemotherapy with Taxotere, Ms. Vega complained to her oncologist of tearing. Ms. Vega had not experienced persistent tearing prior to her chemotherapy with Taxotere. Her oncologist informed her that the condition was normal and should improve once chemotherapy was completed and recommended that she continue to use artificial tears.

43. After completion of chemotherapy the tearing persisted and Ms. Vega was seen by an optometrist who diagnosed her with dry eye. Again, the use of artificial tears did not resolve this adverse reaction.

44. Due to this debilitating, ongoing side effect, Ms. Vega was referred to an oculoplastic surgeon for further evaluation. On March 12, 2021, the oculoplastic surgeon performed an irrigation procedure and confirmed a diagnosis of nasolacrimal duct obstruction which resulted in insufficient drainage. Ms. Vega was told that if her tearing persists, the next course of treatment would be a dacryocystorhinostomy.

45. The oculoplastic surgeon told Ms. Vega that this surgery was successful 50% of the time. At the time of this filing, Ms. Vega still suffers from persistent tearing and has decided not to proceed with surgery.

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

47. Ms. Vega continues to experience persistent tearing and a disruption of her life. As a direct and proximate result of Sanofi's conduct in connection with the design, development, manufacture, testing, packaging, promotion, advertising, marketing, distribution, labeling, warning, and sale of Taxotere, Ms. Vega suffers from permanent epiphora (persistent tearing), due to nasolacrimal duct stenosis. This

condition is a side effect of taking Taxotere.

48. As a result of this permanent side effect, Ms. Vega has struggled to return to normalcy, even after surviving cancer, because she continues to suffer from persistent tearing on a daily basis, interfering with her ability to perform basic activities and enjoy life. This permanent change has altered Ms. Vega's self-image, negatively impacted her relationships, and others' perception of her, leading to social isolation and depression even long after fighting cancer.

49. Throughout her ordeal, Ms. Vega remained hopeful that, like other chemotherapy side effects, the epiphora would eventually resolve. To her dismay, it never has.

50. Ms. Vega's tearing is much more than a minor annoyance—it impacts all aspects of her daily life. Prior to developing permanent nasolacrimal duct stenosis, Ms. Vega was self-confident and enjoyed social and professional interactions with other people. Now she lacks the confidence she previously enjoyed.

51. Ms. Vega is anxious about social interactions because she fears people will perceive her as sad and crying. Her tears spill out over her cheeks, making her skin irritated and she is unable to keep makeup on her face. She also no longer has eyelashes as a result of the constant tearing. She is aware of the concerned looks from well-intentioned friends, colleagues and strangers who perceive her to be emotional and upset. Additionally, Ms. Vega no longer feels comfortable working because of the impression that her constant tearing would give to colleagues and customers. In short, Ms. Vega no longer feels like herself and is self-conscious around others because of the constant tearing.

52. Ms. Vega's injuries could have been prevented had Sanofi simply warned that permanent or irreversible nasolacrimal duct stenosis is a common but preventable side effect of Taxotere. Ms. Vega thus seeks recovery for her mental and physical suffering stemming from permanent, but easily preventable, nasolacrimal duct stenosis.

53. Mrs. Vega files this lawsuit within the applicable statute of limitations.

VII. Tolling of the Statute of Limitations.

54. Alternatively, Ms. Vega files this lawsuit within the applicable statute of limitations period of first suspecting that Taxotere's wrongful conduct caused the appreciable harm she sustained. Due to Sanofi's fraudulent concealment of the true nature of "excessive tearing which may be attributable to

lacrimal duct obstruction," Ms. Vega could not, by the exercise of reasonable diligence, have discovered that Sanofi wrongfully caused her injuries as she was unaware of the severity and permanency of her injury. Specifically in its warning label, Sanofi fraudulently concealed (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. As a result, Ms. Vega was unaware that Sanofi knew of the devastating and permanent consequences of stenosis, or that Sanofi concealed this information from her oncologist. Because Ms. Vega's oncologist was unaware of the permanent nature of this side effect, Ms. Vega was unaware that her condition was permanent and irreversible.

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

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

COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

57. Ms. Vega incorporates by reference the above paragraphs as if set forth herein.

58. At all relevant times, Sanofi was in the business of designing, researching, manufacturing, testing, promoting, marketing, selling, and/or distributing pharmaceutical products, including the Taxotere used by Ms. Vega.

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

60. The Taxotere designed, formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Sanofi and ultimately administered to Ms. Vega lacked such warnings when it left Sanofi's control.

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

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

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

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

65. Ms. Vega was a reasonably foreseeable user of Taxotere who used the drug in a reasonably anticipated manner.

66. Ms. Vega and her physicians would have taken preventative measures during the course of her chemotherapy to prevent nasolacrimal duct stenosis had she (and her physicians) been provided an adequate warning by Sanofi of the risk of these side effects.

67. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse effects of Taxotere, Ms. Vega suffered and continues to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, including, but not limited to: past and future mel expenses; past and future loss of

earnings; past and future loss and impairment of earning capacity; permanent disfigurement, including nasolacrimal duct 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, Plaintiff 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 II - NEGLIGENCE

68. Ms. Vega incorporates by reference the above paragraphs as if set forth herein.

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

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

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

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

(b) Marketing Taxotere to Ms. Vega, Ms. Vega's healthcare providers, the public, and the medical and healthcare professions without adequately and correctly warning and/or disclosing the existence, severity, and duration of known or knowable side effects, including permanent punctal, canalicular and nasolacrimal duct stenosis;

(c) Marketing Taxotere to Ms. Vega, Ms. Vega's healthcare providers, the public, and the medical 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;

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

(f) Concealing information from Ms. Vega, Ms. Vega'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 Ms. Vega, Ms. Vega'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 Ms. Vega and Ms. Vega'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.

72. 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.

73. Ms. Vega and Ms. Vega'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.

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

75. Sanofi's negligence was a proximate cause of Ms. Vega'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 nasolacrimal duct 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, 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

76. Ms. Vega incorporates by reference the above paragraphs as if set forth herein.

77. Sanofi had a duty to represent to Ms. Vega, Ms. Vega's 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.

78. When warning of safety and risks of Taxotere, Sanofi negligently represented to Ms. Vega, Ms. Vega's healthcare providers, the healthcare community, and the public in general that Taxotere had been tested and was found to be safe and/or effective for its indicated use.

79. Sanofi concealed its knowledge of Taxotere defects from Ms. Vega, Ms. Vega's healthcare providers, and the public in general and/or the healthcare community specifically.

80. Sanofi concealed this information with the intent of defrauding and deceiving Ms. Vega, Ms. Vega's healthcare providers, the public in general, and the healthcare community in particular, and were made with the intent of inducing Ms. Vega, Ms. Vega's healthcare providers, the public in general, and the healthcare community in particular, to recommend, dispense, and/or purchase Taxotere.

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

82. Sanofi breached its duty in misrepresenting Taxotere's serious side effects to Ms. Vega, Ms. Vega's healthcare providers, the healthcare community, the FDA, and the public in general.

83. Ms. Vega and Ms. Vega's healthcare providers reasonably relied on Sanofi to fulfill its obligations to disclose all facts within its knowledge regarding the serious side effects of Taxotere and the ability to prevent those side effects with appropriate precautionary measures.

84. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Ms. Vega to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 nasolacrimal duct 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, Teresa Vega respectfully requests that 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 – FRAUDULENT MISREPRESENTATION

85. Ms. Vega incorporates by reference the above paragraphs as if set forth herein. Sanofi represented to Ms. Vega, her 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 tearing 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.

86. 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 nasolacrimal duct stenosis.

87. These representations were material and false.

88. 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.

89. Sanofi made these false representations with the intention or expectation that Ms. Vega, Ms. Vega'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 Ms. Vega.

90. At the time Sanofi made the aforesaid representations, and, at the time Ms. Vega used Taxotere, Ms. Vega and Ms. Vega's healthcare providers were unaware of the falsity of Sanofi's representations, statements and/or implications and justifiably and reasonably relied on Sanofi's representations, statements, and implications, believing them to be true.

91. In reliance on Sanofi's representations, Ms. Vega and her healthcare providers were induced to and did use and prescribe Taxotere, which caused Ms. Vega to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 nasolacrimal duct 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, 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 V – FRAUDULENT CONCEALMENT

92. Ms. Vega incorporates by reference the above paragraphs as if set forth herein.

93. At all times during the course of dealings between Sanofi and Ms. Vega and Ms. Vega's healthcare providers, Sanofi misrepresented the design characteristic and safety of Taxotere for their intended use.

94. Sanofi knew or was reckless in not knowing that its representations were false due to Sanofi's access to ongoing studies and reports that disclosed serious, enhanced side effects of Taxotere to the lacrimal system. In representations made to Ms. Vega and her healthcare providers, Sanofi fraudulently concealed and intentionally omitted the following material information: (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.

95. Sanofi had a duty to disclose to Ms. Vega and her healthcare providers the defective nature of Taxotere, including, but not limited to, the heightened risks of disfiguring, permanent nasolacrimal duct stenosis.

96. Sanofi had a duty to disclose to Ms. Vega and her healthcare providers that the disfiguring, permanent punctal, canalicular and/or nasolacrimal duct stenosis caused by the use of Taxotere could have been prevented by early identification and treatment of epiphora during chemotherapy.

97. Sanofi had sole access to material facts concerning the defective nature of Taxotere and its propensity to cause serious and dangerous side effects, and therefore cause damage to persons who used the drugs at issue, including Ms. Vega.

98. Sanofi's concealment and omissions of material fact concerning the safety of Taxotere were made purposefully, willfully, wantonly, and/or recklessly to mislead Ms. Vega and her healthcare providers into reliance on the continued use of the drugs and to cause them to purchase, prescribe, and/or dispense Taxotere and/or use it.

99. Sanofi knew that Ms. Vega and her healthcare providers had no way to determine the truth behind its concealment and omissions, including the material omissions of fact surrounding Taxotere set forth herein.

100. Ms. Vega and Ms. Vega's healthcare providers reasonably relied on information disclosed by Sanofi that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or omitted by Sanofi.

101. As a result of the foregoing acts and omissions, Sanofi caused Ms. Vega to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 nasolacrimal duct 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, 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.

VI. JURY DEMAND

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

Dated: July 30, 2021

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ATTORNEYS FOR PLAINTIFF

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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

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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 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. (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 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. (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 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. (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.cacd.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)

PACER Service Center

Transaction Receipt

12/01/2021 13:48:19

PACER Login:	RickPaul	**Client Code:**	Tax Eyes
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Attorneys for Plaintiff,
Jennifer Burns

UNITED STATES DISTRICT COURT FOR THE 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:

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

administered Taxotere at Kaiser Permanente in Woodland Hills, California. She was prescribed weekly treatment and received a total of twelve rounds of chemotherapy with Taxotere. During chemotherapy, she complained of excessively watery eyes. Mrs. Burns was told that her watery eyes were a side effect of the chemotherapy. Unfortunately, because no measures were taken to intervene, the epiphora continued and she was ultimately diagnosed with permanent canalicular stenosis.

B. Sanofi Defendants

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

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

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

III. JURISDICTION AND VENUE

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

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

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

IV. FACTUAL ALLEGATIONS

A. Development and Approval of Taxotere (Docetaxel)

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

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

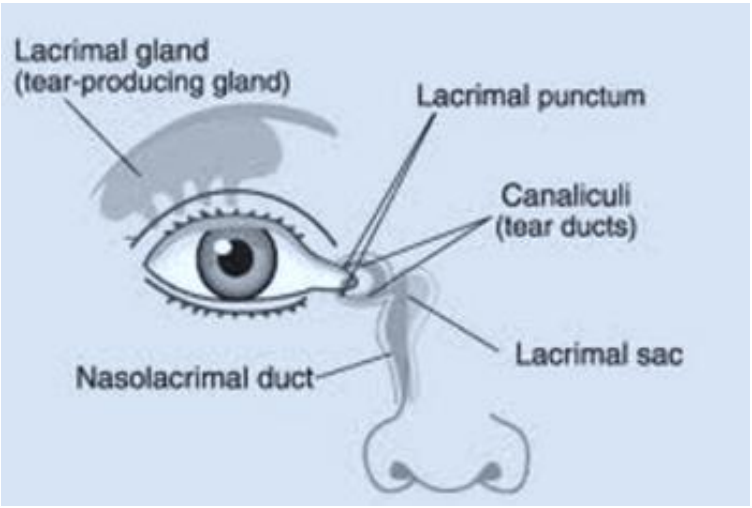
13. In August 2004, Sanofi obtained FDA approval for an expanded use of Taxotere "in combination with doxorubicin and cyclophosphamide for the adjuvant treatment of patients with operable node-positive breast cancer." This resulted in a greater number of patients being treated with Taxotere.

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

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

B. 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, canaliculus and/or nasolacrimal duct. This scarring can cause permanent occlusion, causing an inability for tears to drain naturally through the lacrimal system. Because the eyes are constantly producing tears, this results in persistent epiphora.

C. Taxotere's Labeling

18. At the time Mrs. Burns was administered Taxotere, its labeling information stated in relevant part under **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.

and under **Patient Counseling Information**:[1]

> • 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.

19. Additionally, in the *Patient Information* section of the label, Sanofi includes "redness of the eye, excess tearing" among "the most common side effects of Taxotere." *Id.* Sanofi's inclusion of this potentially permanent side effect in a laundry list of common but notably transitory side effects effectively misrepresents the risk of harm associated with tearing. By failing to fully inform patients and physicians of the potential for serious permanent damage to the lacrimal system, Sanofi downplays the significance of the underlying injury causing the patient to tear.

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

21. Sanofi did not provide such adequate notice to oncologists. To the contrary, the labeling leads oncologists, like Mrs. Burns's, to believe that excessive tearing is merely a transitory side effect and will

[1] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020449s063lbl.pdf

end after the cessation of chemotherapy. This failure to provide notice resulted in thousands of women, like Mrs. Burns, suffering daily from a permanent condition that could have easily been prevented with adequate warning.

D. Sanofi's Duty to Monitor and Update Labeling

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

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

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

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

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

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

28. As part of their responsibility to monitor post-market clinical experiences with the drug and

provide updated safety and efficacy information to the healthcare community and to consumers, each approved NDA applicant "must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, post marketing clinical investigations, post marketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers." 21 C.F.R. § 314.80(b).

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

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

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

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

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

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

35. The longer a drug sponsor delays updating its labeling to reflect current safety information, the more likely it is that medical professionals will prescribe the drug without advising patients of harmful adverse reactions, and the more likely it is that patients will suffer harmful side effects without the opportunity to evaluate risks for themselves.

E. Sanofi Knew That Taxotere Can Cause Permanent Canalicular Stenosis.

36. Since 2002, Sanofi's Taxotere label has advised that "excessive tearing which may be attributable due to lacrimal obstruction has been reported."[2] Despite this language, medical literature has continued to accumulate and raise concerns that oncologists are not being properly warned of the severity of this permanent side effect – and in response, Sanofi has done nothing to notify oncologists or patients.

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

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

> Better education of oncologists who prescribe docetaxel is needed as we continue to encounter new cases of advanced canalicular blockage.[3]

b) From *American Cancer Society*:

> Despite the previous publication of several articles by our group regarding canalicular stenosis and lacrimal obstruction resulting from docetaxel 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.
>
> All patients receiving weekly docetaxel should be monitored closely by an ophthalmologist so that the timely management of canalicular stenosis can be offered.

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[2] https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/020449s063lbl.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)

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

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 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 whose 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

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[4] Bita 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).

> approximately 80% of patients taking docetaxel every 3 weeks and in approximately 50% of patients taking docetaxel weekly. [6]

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

39. Medical literature is clear that: (1) the onset of damage to the lacrimal system can be rapid upon

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[6] Bita 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).

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

[8] *Id.*

[9] Bita 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).

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

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

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

[13] *Id.*

[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)

initiation of Taxotere administration, (2) immediate referral to a lacrimal specialist for monitoring is essential, (3) damage to the lacrimal system can be permanent, (4) this side effect is preventable, and (5) oncologists are not aware of the severity of this side effect. Unfortunately this lack of awareness often results in oncologists counseling their patients that their tearing is a temporary side effect and will eventually subside.

F. Taxotere Caused Mrs. Burns' Permanent Canalicular Stenosis

40. Mrs. Burns was diagnosed with breast cancer and given chemotherapy with Taxotere, receiving a total of twelve infusions over the course of four months.

41. At her sixth Taxotere infusion, Mrs. Burns notified her oncologist that she was experiencing severe watery eyes. Although he visited her during her chemotherapy session, he did not advise her to seek treatment from a lacrimal specialist. The next day, she scheduled an appointment with an optometrist who diagnosed her with dry eye and advised her that watery eyes were a side effect of chemotherapy.

42. After completing chemotherapy, Mrs. Burns reported to her physician that the persistently tearing eyes were her primary concern, and two weeks after her final Taxotere infusion she was referred to an ophthalmologist. The ophthalmologist inserted punctal plugs in an attempt to alleviate the tearing; however, the near constant tearing continued.

43. Three and a half months after her last chemotherapy treatment, Mrs. Burns saw an oculoplastic surgeon, who diagnosed her with canaliculus obstruction in both eyes. She was advised that Taxotere had caused scarring in her tear ducts and was causing her eyes to excessively tear.

44. Over the next several months, Mrs. Burns endured multiple surgeries involving tube insertion but the tubes continued to migrate into her nose and the tearing persisted. Subsequently, a left eye tube was removed and was unable to be reinserted after persistent infections in that eye. Her medical records indicate that her right eye continued to tear as well, despite the repeated surgeries.

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

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

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

48. When Mrs. Burns underwent chemotherapy with Taxotere, her eyes unexpectedly became irritated and red and began to tear constantly. Throughout her ordeal, Mrs. Burns remained hopeful that, like other chemotherapy side effects, the epiphora would eventually resolve. Indeed, she was advised that the tearing would get better. To her dismay, it never has.

49. Mrs. Burns's tearing impacts all aspects of her daily life. Prior to developing permanent canalicular stenosis, Mrs. Burns was self-confident and enjoyed social and professional interactions with other people. Now she lacks the confidence she previously enjoyed.

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

51. Throughout her ordeal, Mrs. Burns was advised that, like other chemotherapy side effects, the epiphora would eventually resolve and was reassured that the treatments would work. Mrs. Burns was advised by her healthcare providers that the epiphora could be fixed and no one advised this may be a condition she would have to live with the rest of life.

52. Mrs. Burns's injuries could have been prevented had Sanofi simply warned that permanent canalicular stenosis is a common but preventable side effect of Taxotere. Specifically, had Sanofi properly warned Mrs. Burns's oncologist of the rapid onset of permanent damage, her oncologist would

have referred her to a lacrimal specialist immediately at the onset of her symptoms, rather than advising her that the symptoms would go away when she completed her chemotherapy. Mrs. Burns thus seeks recovery for her mental and physical suffering stemming from permanent, but easily preventable, canalicular stenosis.

53. Mrs. Burns files this lawsuit within the applicable statute of limitations.

G. Tolling of the Statute of Limitations.

54. Alternatively, Mrs. Burns files this lawsuit within the applicable statute of limitations period of first suspecting that Sanofi's wrongful conduct caused the appreciable harm she sustained. Due to Sanofi's fraudulent concealment of the true nature of "excessive tearing which may be attributable to lacrimal duct obstruction," Mrs. Burns could not, by the exercise of reasonable diligence, have discovered that Sanofi wrongfully caused her injuries since she was unaware of the severity and permanency of her injury. Specifically in its warning label, which Sanofi intended for oncologists to read and rely on, Sanofi fraudulently concealed (1) the rapid onset at which stenosis can occur, (2) the potentially permanent 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. As a result, Mrs. Burns was unaware that Sanofi knew of the devastating and permanent consequences of stenosis, or that Sanofi concealed this information from her oncologist. Because Mrs. Burns's oncologist was unaware of the permanent nature of this side effect, Mrs. Burns was also unaware that her condition was permanent.

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

56. Upon presentation of tearing, Mrs. Burns was advised that tearing was a common side effect of Taxotere chemotherapy that, like most other side effects of chemotherapy, would resolve.

57. In February of 2020, a friend reached out to Mrs. Burns after seeing a blog post on the website of the law firm of Hotze Runkle, PLLC regarding Sanofi's negligence in failing to warn of the risk of canalicular stenosis. Only then did Mrs. Burns discover that the manufacturers of Taxotere were aware

of permanent canalicular stenosis, but they intentionally withheld this information from healthcare practitioners and consumers. Mrs. Burns felt as though she had an epiphany. For the first time, based on the information she read on the law firm's website, she appreciated that the manufacturer of her chemotherapy drug failed to inform her and her oncologist of the risk of permanent damage to her lacrimal system, as well as its knowledge that her injury could have been prevented. Mrs. Burns could not have discovered Sanofi's wrongdoing earlier, because to this date, Sanofi's warning fails to fully advise of the nature of the injury, resulting in oncologists and their patients remaining in the dark. Mrs. Burns was only able to discover that her tearing was never going to go away after Hotze Runkle published these facts on the internet.

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

COUNT I – STRICT PRODUCTS LIABILITY (FAILURE TO WARN)

59. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

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

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

formulated, produced, manufactured, sold, marketed, distributed, supplied and/or placed into the stream of commerce by Sanofi and ultimately administered to Mrs. Burns lacked such warnings when it left Sanofi's control.

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

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

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

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

66. Mrs. Burns was a reasonably foreseeable user of Taxotere who used the drug in a reasonably anticipated manner.

67. Mrs. Burns would have taken preventative measures during the course of her chemotherapy to prevent canalicular stenosis had she (and her physicians) been provided an adequate warning by Sanofi of the risk of these side effects.

68. As a direct and proximate result of Sanofi's failure to warn of the potentially severe adverse effects of Taxotere, Mrs. Burns suffered and continues to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 canalicular 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, Plaintiff Jennifer Burns 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 II - NEGLIGENCE

69. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

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

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

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

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

(b) Marketing Taxotere to Mrs. Burns, her healthcare providers, the public, and the medical and healthcare professions without adequately and correctly warning and/or disclosing the existence, severity, and duration of known or knowable side effects, including permanent canalicular stenosis;

(c) Marketing Taxotere to the public, and the medical 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;

(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,

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. Burns and her 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.

73. 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.

74. Mrs. Burns 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.

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

76. Sanofi's negligence was a proximate cause of Mrs. Burns'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 canalicular 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, Jennifer Burns 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

77. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

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.

79. When warning of safety and risks of Taxotere, Sanofi negligently represented to Mrs. Burns, her healthcare providers, the healthcare community, and the public in general that Taxotere had been tested and was found to be safe and/or effective for its indicated use.

80. Sanofi concealed its knowledge of Taxotere defects from Mrs. Burns, her healthcare providers, and the public in general and/or the healthcare community specifically.

81. Sanofi concealed this information with the intent of defrauding and deceiving Mrs. Burns, her healthcare providers, the public in general, and the healthcare community in particular, and were made with the intent of inducing Mrs. Burns, her healthcare providers, the public in general, and the healthcare community in particular, to recommend, dispense, and/or purchase Taxotere.

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

83. Sanofi breached its duty in misrepresenting Taxotere's serious side effects to Mrs. Burns, her healthcare providers, the healthcare community, the FDA, and the public in general.

84. Mrs. Burns and her healthcare providers reasonably relied on Sanofi to fulfill its obligations to disclose all facts within its knowledge regarding the serious side effects of Taxotere and the ability to prevent those side effects with appropriate precautionary measures.

85. As a direct and proximate result of the foregoing acts and omissions, Sanofi caused Mrs. Burns to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 canalicular 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, Jennifer Burns respectfully requests that 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 – FRAUDULENT MISREPRESENTATION

86. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

87. In its labeling information, Sanofi communicated to Mrs. Burns, her 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 tearing is a common side effect. These statements misrepresented the true risk of harm to patients, in that they failed to fully inform oncologists and patients of (1) the rapid onset at which stenosis can occur, (2) the potentially **permanent** 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.

88. Despite having knowledge of this side effect, Sanofi fraudulently omitted from this vague warning of "lacrimal duct obstruction" and/or "excessive tearing" that Taxotere could and did cause **permanent** damage to the lacrimal system, including canalicular stenosis.

89. These representations were material and false.

90. 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.

91. Sanofi made these false representations with the intention or expectation that Mrs. Burns, her 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. Burns.

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

statements, and implications, believing them to be true.

93. In reliance on Sanofi's representations, Mrs. Burns and her healthcare providers were induced to and did use and prescribe Taxotere, which caused Mrs. Burns to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 canalicular 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, Jennifer Burns 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 V – FRAUDULENT CONCEALMENT

94. Mrs. Burns incorporates by reference the above paragraphs as if set forth herein.

95. At all times during the course of dealing between Sanofi and Mrs. Burns and her healthcare providers, Sanofi misrepresented the design characteristic and safety of Taxotere for their intended use.

96. Sanofi knew or was reckless in not knowing that its representations were false due to Sanofi's access to ongoing studies and reports that disclosed serious, but preventable damage to the lacrimal system caused by Taxotere. In representations made to Mrs. Burns and her healthcare providers, Sanofi fraudulently concealed and intentionally omitted the following material information: (1) the rapid onset at which stenosis can occur, (2) the potentially permanent 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.

97. Sanofi had a duty to disclose to Mrs. Burns and her healthcare providers the defective nature of Taxotere, including, but not limited to, the heightened risks of disfiguring, permanent canalicular stenosis.

98. Sanofi had a duty to disclose to Mrs. Burns and her healthcare providers that the disfiguring, permanent canalicular stenosis caused by the use of Taxotere could have been prevented by early

identification and treatment of epiphora during chemotherapy.

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

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

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

102. Mrs. Burns and her healthcare providers reasonably relied on information disclosed by Sanofi that negligently, fraudulently, and/or purposefully did not include facts that were concealed and/or omitted by Sanofi.

103. As a result of the foregoing acts and omissions, Sanofi caused Mrs. Burns to suffer serious and dangerous side effects, severe and personal injuries that are permanent and lasting in nature, and economic and non-economic damages, harms, and losses, 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 canalicular 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, Jennifer Burns 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.

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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
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