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CLOSED, TYPE-I

U.S. District Court District of Columbia (Washington, DC) CIVIL DOCKET FOR CASE #: 1:94-cv-00017-RMU

PUBLIC CITIZEN HEAL. v. FDA Assigned to: Judge Ricardo M. Urbina

Demand: \$0

Cause: 05:552 Freedom of Information Act

Date Filed: 01/05/1994 Date Terminated: 01/06/1997

Jury Demand: None

Nature of Suit: 895 Freedom of

Information Act

Jurisdiction: U.S. Government Defendant

Plaintiff

PUBLIC CITIZEN HEALTH RESEARCH GROUP

represented by Brian Wolfman

1735 20th Street NW Washington, DC 20009 (202) 888-1741Fax: (202) 888-7792

Email: bswolfman@yahoo.com LEAD ATTORNEY

ATTORNEY TO BE NOTICED

Lucinda A Sikes

PUBLIC CITIZEN LITIGATION

GROUP

1600 20th Street, NW Washington, DC 20009-1001

 $(202)\ 588-1000$

V.

Defendant

FOOD & DRUG ADMINISTRATION

represented by Marina Utgoff Braswell

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Washington, DC 20530 $(202)\ 252-2561$ Fax: (202) 252-2599

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Susan Ann Nellor

U.S. ATTORNEY'S OFFICE **Judiciary Center Building** 555 Fourth Street, NW Room 10-845

Washington, DC 20530 (202) 514–0065

TERMINATED: 02/23/1994

LEAD ATTORNEY

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V.

Intervenor Defendant

OCLASSEN PHARMACEUTICALS, INC.

represented by **Peter Robert Mathers**

KLEINFELD, KAPLAN & BECKER 1850 M Street, NW

Suite 800

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Intervenor Defendant

ELI LILLY AND COMPANY

represented by Bruce Neil Kuhlik

MERCK & CO., INC One Merck Drive Suite WS 3A–15 Whitehouse Station, NJ 08889 (908) 423–6802 Fax: 908–735–1244 LEAD ATTORNEY ATTORNEY TO BE NOTICED

Laurie H. Gira

COVINGTON & BURLING 1201 Pennsylvania Avenue, NW Washington, DC 20004–2401 (202) 662–6000 LEAD ATTORNEY ATTORNEY TO BE NOTICED

Date Filed	#	Docket Text
01/05/1994	1	COMPLAINT filed (mlp) (Entered: 01/07/1994)
01/05/1994		SUMMONS issued to federal party defendant FDA, and non-parties: U.S. Attorney and U.S. Attorney General. (mlp) (Entered: 01/07/1994)
01/13/1994	2	RETURN OF SERVICE/AFFIDAVIT executed upon defendant FDA on 1/10/94, via certified mail; attachment (dot) (Entered: 01/14/1994)
01/13/1994	3	RETURN OF SERVICE/AFFIDAVIT executed upon U. S. Attorney on 1/5/94, attachment (dot) (Entered: 01/14/1994)
01/13/1994	4	RETURN OF SERVICE/AFFIDAVIT executed upon U. S. Attorney General on 1/10/94, via certified mail; attachment (dot) (Entered: 01/14/1994)
02/04/1994	5	ATTORNEY APPEARANCE for defendant FDA by Susan Ann Nellor (dot) (Entered: 02/07/1994)
02/04/1994	6	MOTION filed by defendant FDA to extend time to answer the complaint [1–1] to 3/4/94. (dot) (Entered: 02/07/1994)
02/08/1994	7	ORDER by Judge Stanley S. Harris: granting motion to extend time to answer the complaint [1–1] to 3/4/94. [6–1] by FDA (N) (emh) (Entered: 02/09/1994)
02/09/1994	8	MOTION filed by plaintiff PUBLIC CITIZEN HEAL. for a Vaughn Index (mlp) (Entered: 02/10/1994)
02/23/1994	9	ATTORNEY APPEARANCE for defendant FDA by Marina Utgoff Braswell (mlp) (Entered: 02/24/1994)

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02/23/1994	10	MOTION filed by defendant FDA to extend time to 3/4/94 in which to file defendant's response to plaintiff's motion for a Vaughn Index. (mlp) (Entered: 02/24/1994)
03/04/1994	11	ANSWER TO COMPLAINT [1–1] by defendant FDA (mlp) (Entered: 03/07/1994)
03/04/1994		CALENDARED (mlp) (Entered: 03/07/1994)
03/04/1994	12	MOTION filed by defendant FDA to extend time to 3/23/94 to respond to plaintiff's motion for a Vaughn Index. (mlp) (Entered: 03/07/1994)
03/04/1994	13	MOTION filed by movant ELI LILLY & COMPANY to intervene as a defendant; EXHIBIT: Answer of defendant–intervenor to complaint. (mlp) (Entered: 03/07/1994)
03/04/1994	14	ATTORNEY APPEARANCE for movant ELI LILLY & COMPANY by Bruce N. Kuhlik, Esquire of Covington and Burling. (mlp) (Entered: 03/07/1994)
03/17/1994	15	ORDER by Judge Stanley S. Harris: granting nunc pro tunc motion to extend time to 3/4/94 in which to file defendant's response to plaintiff's motion for a Vaughn Index. [10–1] by FDA (N) (emh) (Entered: 03/21/1994)
03/22/1994	19	ORDER by Judge Stanley S. Harris: granting motion to extend time to 3/23/94 to respond to plaintiff's motion for a Vaughn Index. [12–1] by FDA (N) (emh) (Entered: 03/25/1994)
03/22/1994	20	ORDER by Judge Stanley S. Harris: granting motion to intervene as a defendant [13–1] by ELI LILLY & COMPANY; allowing Eli Lilly and Company leave to intervene as a defendant in this action; directing the Clerk to file the answer of Eli Lilly and Company. (N) (emh) (Entered: 03/25/1994)
03/22/1994	21	ANSWER TO COMPLAINT [1–1] by intervenor–defendant ELI LILLY & COMPANY (mlp) (Entered: 03/28/1994)
03/23/1994	16	RESPONSE by defendant FDA to motion for a Vaughn Index [8–1] by PUBLIC CITIZEN HEAL. (mlp) (Entered: 03/24/1994)
03/24/1994	17	MOTION filed by movant OCLASSEN for leave to intervene as a defendant; EXHIBITS: ANSWER TO COMPLAINT, RULE 109 CERTIFICATE (mlp) Modified on 03/25/1994 (Entered: 03/25/1994)
03/24/1994	18	ATTORNEY APPEARANCE for movant OCLASSEN by Peter R. Mathers and Daniel R. Dwyer. (mlp) (Entered: 03/25/1994)
03/28/1994	22	ORDER by Judge Stanley S. Harris: granting motion for leave to intervene as a defendant [17–1] by OCLASSEN; directing the Clerk to file the answer of Oclassen Pharmaceuticals. (N) (emh) (Entered: 03/29/1994)
03/28/1994	23	ANSWER TO COMPLAINT [1–1] by intervenor–defendant OCLASSEN (mlp) (Entered: 03/29/1994)
03/28/1994	24	RULE 109 Certificate of disclosure of corporate affiliations and financial interests by intervenor–defendant OCLASSEN (mlp) (Entered: 03/29/1994)
04/21/1994	25	ORDER by Judge Stanley S. Harris: granting in part motion for a Vaughn Index [8–1] by PUBLIC CITIZEN HEAL; directing defendant to respond within 60 days to Vaughn Index. (N) (emh) (Entered: 04/26/1994)
04/26/1994	26	RULE 109 Certificate of disclosure of corporate affiliations and financial interests by intervenor–defendant ELI LILLY & COMPANY (kmk) (Entered: 05/02/1994)
06/20/1994	27	MOTION filed by defendant FDA to extend time to 6/28/94 to file motion for summary judgment and Vaughn Index (mlp) (Entered: 06/22/1994)
06/28/1994	28	MOTION filed by defendant FDA for summary judgment; declaration of Carolann W. Hooton, exhibits (4) (mlp) (Entered: 06/29/1994)
06/28/1994	29	MOTION filed by intervenor–defendant OCLASSEN PHARM., intervenor–defendant ELI LILLY & COMPANY for summary judgment; declarations of Glenn A. Oclassen and Max W. Talbott, Ph.D., exhibit (1), attachment (1) (mlp) (Entered: 06/29/1994)
06/30/1994	30	ORDER by Judge Stanley S. Harris: granting motion to extend time to 6/28/94 to file motion for summary judgment and Vaughn Index [27–1] by FDA (N) (emh) (Entered:

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		07/03/1994)
07/01/1994	31	REASSIGNMENT OF CIVIL CASE from Judge Harris to Judge Ricardo M. Urbina by direction of the Calendar Committee. Emergency matters will continue to be handled by Judge Harris until Judge Urbina takes the oath of office. (N) (erd) (Entered: 07/05/1994)
07/11/1994	32	MOTION (unopposed) filed by plaintiff(s) PUBLIC CITIZEN HEAL. to extend time to 8/11/94 to oppose defendant's and defendant—intervenors' motions for summary judgment (mlp) (Entered: 07/12/1994)
07/13/1994	33	ORDER by Judge Stanley S. Harris: granting motion to extend time to 8/11/94 to oppose defendant's and defendant–intervenors' motions for summary judgment [32–1] by PUBLIC CITIZEN HEAL. (N) (emh) (Entered: 07/14/1994)
08/09/1994		SCHEDULING NOTICE: status hearing set for 9:00 a.m. 10/8/94 (dbw) (Entered: 08/09/1994)
08/10/1994		CORRECTED SCHEDULING NOTICE: status hearing set for 9:30 10/7/94; (jwd) (Entered: 08/10/1994)
08/11/1994	34	INTERROGATORIES filed by plaintiff PUBLIC CITIZEN HEALTH to defendant FDA (kk) (Entered: 08/12/1994)
08/11/1994	35	REQUEST by plaintiff PUBLIC CITIZEN HEALTH to defendant FDA for production of documents (kk) (Entered: 08/12/1994)
08/11/1994	36	INTERROGATORIES filed by plaintiff PUBLIC CITIZEN HEALTH to intervenor–defendant ELI LILLY & COMPANY (kk) (Entered: 08/12/1994)
08/11/1994	37	REQUEST by plaintiff PUBLIC CITIZEN HEALTH to intervenor–defendant ELI LILLY & COMPANY for production of documents (kk) (Entered: 08/12/1994)
08/11/1994	38	INTERROGATORIES filed by plaintiff PUBLIC CITIZEN HEALTH to intervenor–defendant OCLASSEN PHARM. (kk) (Entered: 08/12/1994)
08/11/1994	39	REQUEST by plaintiff PUBLIC CITIZEN HEALTH to intervenor–defendant OCLASSEN PHARM. for production of documents (kk) (Entered: 08/12/1994)
08/11/1994	40	MEMORANDUM by plaintiff PUBLIC CITIZEN HEALTH in opposition to motion for summary judgment [28–1] by defendant FDA and motion for summary judgment [29–1] by intervenor–defendants ELI LILLY & COMPANY and OCLASSEN PHARM.; Declaration, Exhibits (4) (kk) (Entered: 08/12/1994)
09/01/1994		SCHEDULING NOTICE: status hearing set for 9:30 10/3/94; (confirmation letter will be submitted regarding the rescheduling) (jwd) (Entered: 09/01/1994)
09/13/1994	41	UNOPPOSED MOTION filed by defendant FDA to extend time to 9/30/94 in which to file defendants' response to plaintiff's opposition to defendants' motions for summary judgment and to respond to plaintiff's discovery (dbw) (Entered: 09/14/1994)
09/19/1994	42	ORDER by Judge Ricardo M. Urbina: granting motion to extend time to 9/30/94 in which to file defendants' response to plaintiff's opposition to defendants' motions for summary judgment and to respond to plaintiff's discovery [41–1] by FDA reply to dispositive motions due by 9/30/94; (N) (jwd) (Entered: 09/20/1994)
09/30/1994	43	MOTION filed by defendant FDA for protective order; Attachment (1) (dbw) (Entered: 10/03/1994)
09/30/1994	44	MEMORANDUM by defendant FDA in reply to plaintiff's opposition to motion for summary judgment [28–1] by FDA (dbw) (Entered: 10/03/1994)
09/30/1994	45	MOTION filed by intervenor–defendant OCLASSEN PHARM., intervenor–defendant ELI LILLY & COMPANY for protective order against plaintiff's requests for discovery; Exhibits (7) (dbw) (Entered: 10/03/1994)
09/30/1994	46	REPLY MEMORANDUM by intervenor–defendant OCLASSEN PHARM., intervenor–defendant ELI LILLY & COMPANY in support of motion for summary judgment [29–1] by ELI LILLY & COMPANY, OCLASSEN PHARM.; Declaration (1) (dbw) (Entered: 10/03/1994)

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10/03/1994	47	STATUS HEARING before Judge Ricardo M. Urbina: plaintiff given until 11/14/94 to file a reply; motion for summary judgment will be decided on the pleadings. If a hearing is necessary, parties will be contacted by telephone; attorney Ann Meredith and Laurie H. Gira admitted pro hac vice. Reporter: William McAllister (jwd) Modified on 10/26/1994 (Entered: 10/03/1994)
10/14/1994	47	
		MOTION filed by plaintiff(s) PUBLIC CITIZEN HEAL. to extend time to $10/18/94$ in which to file opposition to defendants' motions for protective order (dbw) (Entered: $10/17/1994$)
10/18/1994		MEMORANDUM by plaintiff(s) PUBLIC CITIZEN HEAL. in opposition to motion for protective order against plaintiff's requests for discovery [45–1] by ELI LILLY & COMPANY, OCLASSEN PHARM., motion for protective order [43–1] by FDA (dbw) (Entered: 10/19/1994)
10/20/1994	49	ORDER by Judge Ricardo M. Urbina: granting motion to extend time to 10/18/94 in which to file opposition to defendants' motions for protective order [47–1] by PUBLIC CITIZEN HEAL. (N) (jwd) (Entered: 10/21/1994)
10/25/1994 5		MOTION filed by defendant FDA, intervenor—defendant OCLASSEN PHARM., intervenor—defendant ELI LILLY & COMPANY to extend time to 11/4/94 in which to file response to plaintiff's opposition to the motions of federal defendant and the defendant—intervenors for a protective order (dbw) (Entered: 10/26/1994)
10/27/1994 5	51	ORDER by Judge Ricardo M. Urbina: granting motion to extend time to 11/4/94 in which to file response to plaintiff's opposition to the motions of federal defendant and the defendant–intervenors for a protective order [50–1] by ELI LILLY & COMPANY, OCLASSEN PHARM., FDA (N) (jwd) (Entered: 10/28/1994)
11/04/1994 5	52	REPLY by defendant FDA to response to motion for protective order [43–1] by FDA (lpp) (Entered: 11/10/1994)
11/09/1994 5		REPLY by intervenor–defendant OCLASSEN PHARM., intervenor–defendant ELI LILLY & COMPANY to response to motion for protective order against plaintiff's requests for discovery [45–1] by ELI LILLY & COMPANY, OCLASSEN PHARM. (lpp) (Entered: 11/10/1994)
02/17/1995 5		MEMORANDUM by intervenor–defendant OCLASSEN PHARM. and intervenor–defendant ELI LILLY & COMPANY concerning recently issued authority in support of their motion for summary judgment [29–1]; Exhibits (2) (kk) (Entered: 02/22/1995)
02/27/1995 5		RESPONSE by plaintiff PUBLIC CITIZEN HEAL. to memorandum by intervenor—defendant OCLASSEN PHARM. and intervenor—defendant ELI LILLY & COMPANY concerning recently issued authority in support of their motion for summary judgment (29–1); Exhibits (2); [54–1] by ELI LILLY & COMPANY, OCLASSEN PHARM. (bjsp) (Entered: 02/28/1995)
04/26/1995 5	56	MEMORANDUM AND ORDER by Judge Ricardo M. Urbina: granting in part defendants' and defendant–intervenors' motion for summary judgment (N) (jwd) (Entered: 04/26/1995)
04/26/1995	57	ORDER by Judge Ricardo M. Urbina: denying as moot motion for protective order against plaintiff's requests for discovery [45–1] by ELI LILLY & COMPANY, OCLASSEN PHARM., denying as moot motion for protective order [43–1] by FDA, granting in denying in part motion for summary judgment [29–1], in part, denying in part motion for summary judgment [28–1]; defendant and defendant—intervenors shall submit supplemental affidavits in support ofthe remaining claims on or before 5/31/95; plaintiffshall file any response tereto on or before 6/16/95 (N) (jwd) (Entered: 04/26/1995)
05/17/1995	58	MOTION filed by plaintiff PUBLIC CITIZEN HEAL. for reconsideration of order of 4/26/95 granting in part defendant's and defendant–intervenors' motions for summary judgment [57–1] exhibits (3); attachments; declaration (1) (bjsp) (Entered: 05/18/1995)
05/31/1995 5		MOTION (UNOPPOSED) filed by defendant FDA to extend time to 6/6/95 in which to file defendant's response to plaintiff's motion for reconsideration and to respond to

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		the Court's order dated 4/26/95, ordering the submission of supplemental affidavits (bjsp) Modified on 06/01/1995 (Entered: 06/01/1995)
06/05/1995	60	ORDER by Judge Ricardo M. Urbina: granting motion to extend time to 6/6/95 in which to file defendant's response to plaintiff's motion for reconsideration and to respond to the Court's order dated 4/26/95, ordering the submission of supplemental affidavits [59–1] by FDA (N) (jwd) Modified on 06/06/1995 (Entered: 06/06/1995)
06/06/1995	61	REPORT to the Court by federal defendant FDA; exhibits (6); declaration (1) copy (bjsp) (Entered: 06/07/1995)
06/06/1995	62	MEMORANDUM by defendant FDA in opposition to motion for reconsideration of order of 4/26/95 granting in part defendant's and defendant—intervenors' motions for summary judgment [57–1] [58–1] by PUBLIC CITIZEN HEAL; exhibits (6); supplemental declaration (1) (bjsp) (Entered: 06/07/1995)
06/06/1995	63	RESPONSE by intervenor–defendant OCLASSEN PHARM., intervenor–defendant ELI LILLY & COMPANY to plaintiff's motion for reconsideration of order of 4/26/95 granting in part defendant's and defendant–intervenors' motions for summary judgment [57–1] [58–1] (bjsp) (Entered: 06/07/1995)
06/14/1995	64	REPLY MEMORANDUM by plaintiff PUBLIC CITIZEN HEAL. in support of their motion for reconsideration of order of 4/26/95 granting in part defendant's and defendant—intervenors' motions for summary judgment [57–1] [58–1]; exhibits (3) (bjsp) (Entered: 06/15/1995)
07/13/1995	65	NOTICE OF CHANGE OF ADDRESS by Lucinda A Sikes representing plaintiff PUBLIC CITIZEN HEAL New address: PUBLIC CITIZEN LITIGATION GROUP, 1600 20th Street, N.W., Washington DC 20036 (202) 588 1000. (bjsp) (Entered: 07/17/1995)
09/28/1995	66	NOTICE OF FILING (SUPPLEMENTL FILING) by intervenor—defendant OCLASSEN PHARM., intervenor—defendant ELI LILLY & COMPANY to the Court letting the Court know that they have a pending case before Judge Lambreth 94cv365.(bjsp) Modified on 09/29/1995 (Entered: 09/29/1995)
10/13/1995	67	NOTICE OF FILING by plaintiff PUBLIC CITIZEN HEAL. to the Court in response to defendant—intervenors ELI LILLY and OCLASSEN PHARMACEUTICALS, INC.'s supplemental filing to the Court regarding this case. (bjsp) (Entered: 10/16/1995)
11/16/1995	68	RESPONSE by defendant FDA to motion for reconsideration of order of 4/26/95 granting in part defendant's and defendant–intervenors' motions for summary judgment [57–1] [58–1] by PUBLIC CITIZEN HEAL. (bjsp) (Entered: 11/17/1995)
12/26/1995	69	NOTICE OF FILING by plaintiff PUBLIC CITIZEN HEAL. to the Court RE: a notice plaintiff filed to the Court on 10/13/95 requesting the Court to delay for 60 days ruling on plaintiff's pending motion for reconsideration in light of new facts which were presented (bjsp) (Entered: 12/27/1995)
01/17/1996	70	RESPONSE by defendant FDA to plaintiff's 12/26/95 notice to the Court RE: a request by the plaintiff's that the Court delay ruling on HRG's pending motion for reconsideration of the Court's 4/26/95 order (granting in part defendant's and defendant—intervenors' motion for summary judgment) (April 26 Order) for an additional forty—five days. [69–1] by PUBLIC CITIZEN HEAL.; exhibits (1) (bjsp) (Entered: 01/18/1996)
02/20/1996	71	NOTICE OF FILING by plaintiff PUBLIC CITIZEN HEAL. to the Court RE: their previously filed motion to delay ruling of a pending motion. Plaintiff would like an additional delay on the ruling of the same pending motion for reconsideration. (bjsp) (Entered: 02/21/1996)
04/05/1996	72	NOTICE OF FILING (NOTICE TO THE COURT) by plaintiff PUBLIC CITIZEN HEAL. letting the Court know that some of the IND documents at issue in this case have been made public in product liability litigation involving FIAU. (bjsp) (Entered: 04/08/1996)

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04/26/1996	73	NOTICE OF FILING (SUPPLEMENTAL FILING) by plaintiff PUBLIC CITIZEN HEAL to the Court explaining that some of the IND documents at issue in this case have been made public in product liability litigation involving FIAU.; exhibits (1) (bjsp) (Entered: 04/29/1996)
05/08/1996	74	RESPONSE by intervenor–defendant OCLASSEN PHARM., intervenor–defendant ELI LILLY & COMPANY to supplemental filing dated 4/26/96 by plaintiff [73–1] PUBLIC CITIZEN HEAL. (bjsp) (Entered: 05/08/1996)
05/28/1996	75	RESPONSE by defendant FDA to plaintiff's 4/26/96 supplemental filing to the Court RE: issues in this case [73–1] by PUBLIC CITIZEN HEAL. (bjsp) (Entered: 05/29/1996)
11/18/1996	76	MEMORANDUM AND ORDER by Judge Ricardo M. Urbina: denying motion for reconsideration of order of 4/26/95 granting in part defendant's and defendant—intervenors' motions for summary judgment [57–1] [58–1] by PUBLIC CITIZEN HEAL. (N) (N) (jwd) (Entered: 11/19/1996)