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MEMORANDUM IN SUPPORT

I. FACTUAL AND PROCEDURAL BACKGROUND

On September 11, 2007, FDA's Division of Freedom of Information ("DFOI") received a Freedom of Information Act request dated August 15, 2007, from plaintiff's attorney Kerry Donahue of Bellinger & Donahue.¹ See Declaration of Frederick J. Sadler ("Sadler Decl."), ¶ 9, attached as Exhibit A. Plaintiff's request sought:

A copy of all letters written to the FDA (or prepared by the FDA) and purported to be from Dr. Scher, Dr. Hussain and Doctor Fleming in between March 29th 2007 and April 30th of 2007, regarding the BLA [Biologics License Application] submitted for Provenge also known as Sipuleucel-T including the envelope or other means of communication whereby the FDA received such letters and a copy of any record of those letters then being disclosed to any media or other persons or specifically a publication called "The Cancer Letter," including the means of communication to the Cancer Letter of the Scher, Hussain and Fleming letters from the FDA or its employees to outside persons, publications or companies.

Sadler Decl. ¶ 9. DFOI referred the request to the Access Litigation and Freedom of Information Branch ("ALFOI") of FDA's Center for Biologics Evaluation and Research ("CBER") on September 14, 2007 because the request sought documents relating to Provenge, an unapproved biological product regulated by CBER. See id. at ¶ 12; see also Declaration of Beth Brockner-Ryan ("Brockner-Ryan Decl."), ¶¶ 10-11, attached as Exhibit B. On November 6, 2007, CBER released all responsive documents, without any redactions, to the requester. See Brockner-Ryan Decl. ¶ 14; Sadler Decl. ¶ 12.

DFOI also forwarded plaintiff's request to the Office of the Executive Secretariat ("Exec. Sec.") and the Immediate Office of the Commissioner ("Immediate Office"), both of which

¹ The delay between the date of Bellinger & Donahue's letter and receipt by DFOI occurred because the requester improperly sent the request to the agency's Cincinnati District Office rather than to DFOI. Per 21 CFR 20.40(a), all FOIA requests must be received by DFOI in order to be processed. The request was ultimately forwarded from the Cincinnati District Office to DFOI on or around September 11, 2007.

maintain agency correspondence files, in FDA's Office of the Commissioner. See Sadler Decl. ¶ 13. Exec. Sec. responded to plaintiff, through DFOI, on January 24, 2008, indicating that no responsive records had been located. Id. at ¶ 14. The Immediate Office, through DFOI, produced responsive documents, without any redactions, to plaintiff on February 26, 2008. Id. at ¶ 15.

On October 10, 2007, DFOI forwarded plaintiff's request to the Division of Information Disclosure Policy ("DIDP") in FDA's Center for Drug Evaluation and Research ("CDER"). See Sadler Decl. ¶ 16; see also Declaration of Nancy B. Sager ("Sager Decl.") ¶ 11, attached as Exhibit C. DFOI did so because, after consultation with CBER, it appeared that CDER was also likely to have records relating to Provenge. Id.

Because DIDP uses a "first-in, first-out" queue system to process all requests for documents, and there were many requests for documents ahead of plaintiff's FOIA request, DIDP could not process plaintiff's request within the timeframe required by the FOIA. See Sager Decl. at ¶ 13. When plaintiff became aware of the delay, it filed its complaint (Doc. 1) on January 2, 2008, seeking the immediate production of all documents responsive to its request. See Sadler Decl. ¶ 17. In response to plaintiff's complaint, FDA filed a Motion to Stay Proceedings (Doc. 10).² See id. at ¶ 18.

The Court granted FDA's Motion to Stay Proceedings on May 22, 2008 (Opinion and Order Doc. 23), ordering CDER to provide responsive documents to plaintiff's request no later than May 18, 2009. See Sadler Decl. ¶ 19; see also Sager Decl. ¶ 14. The Court ordered DIDP to update the Court on the progress of the FOIA request in the queue on December 1, 2008, and

² FDA's argument in support of its Motion to Stay Proceedings will be discussed in greater detail below.

to produce all documents responsive to the request no later than May 18, 2009. See Sager Decl. ¶ 14. On December 1, 2008, DIDP informed the Court that plaintiff's request was still on track to rise to the top of the queue in October 2009, but DIDP would provide plaintiff with all responsive documents on or before May 18, 2009 as required by the Court's order. Id.; see also Notice (Doc. 25).

Following a search of all relevant CDER offices, DIDP produced one responsive document, without any redactions, to plaintiff on May 18, 2009. Id. at ¶¶ 17–20.

II. ARGUMENT

A. Standard for Summary Judgment in FOIA cases

Summary judgment is appropriate where there is no genuine issue of material fact in dispute and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56; Celotex Corp. v. Catrett, 477 U.S. 317, 322 (1986). Although a court must view the facts in a light most favorable to the non-moving party, only a fact “that might affect the outcome of the suit under the governing law” will suffice to defeat a motion for summary judgment. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). In FOIA cases, courts have routinely entered summary judgment where the defendant agency has shown that it conducted a reasonable search and that all responsive documents have been produced. See, e.g., Rugiero v. United States Dept. of Justice, 257 F.3d 534, 547–48 (6th Cir. 2001); GMRI, Inc. v. Equal Employment Opportunity Comm'n, 149 F.3d 449, 451 (6th Cir. 1998) (upholding grant of summary judgment where agency had turned over all records responsive to plaintiff's request).

The burden is on the agency to establish the reasonableness of the search. See Rugiero, 257 F.3d at 543. To meet this burden, an agency may rely on detailed affidavits or declarations to show that it has conducted a reasonable search that has led to the production of all responsive

documents. See id.; see also Dayton Newspaper, Inc. v. Dep't of Veteran Affairs, 510 F.Supp.2d 441, 447-8 (S.D. Ohio 2007).

Here, FDA relies on declarations submitted by supervisors of three FOIA divisions within FDA to show in detail the steps that were taken to locate records in every agency office that was likely to have documents responsive to the plaintiff's narrow request. See e.g., Sadler Decl., Sager Decl., and Brocker-Ryan Decl. As a result of the searches performed by the agency, all responsive documents have now been produced to plaintiff, there is no genuine issue as to any material fact, and FDA is entitled to judgment as a matter of law. Thus, FDA is entitled to a grant of summary judgment.

B. FDA Conducted An Adequate Search Within the Narrow Scope of Plaintiff's Request And Produced All Responsive Documents.

1. An Agency's Search for Documents Must Be Reasonable And Can Be Sufficiently Proven Through Detailed Declarations.

An agency's search for documents in response to a FOIA request "is held to a reasonableness standard." Dayton Newspaper, 510 F.Supp.2d at 447-48. To meet the reasonableness standard, an agency need not "search the ends of the earth for the requested documents," Comer, 2002 WL 1058056 at *1, but "must make a good faith effort to conduct a search that is reasonably expected to produce the requested information" and that is "tailored to the nature of the request." Rugiero, 257 F.3d at 547. The search standards under the FOIA do not place upon an agency the requirement that it prove that all responsive documents have been located. Nation Magazine v. United States Customs Serv., 71 F.3d 885, 892 n.7 (D.C. Cir. 1995); see also Rugiero, 257 F.3d at 547. As a result, an agency is not required to search every division or field office in response to a FOIA request when responsive documents are likely to be located in a few places. Marks v. Dep't of Justice, 622 F.Supp. 261, 263 (9th Cir. 1978).

Although the burden is on the agency to “establish the adequacy of its search,” the agency may discharge this burden by “rel[ying] on affidavits or declarations that provide reasonable detail of the scope of the search.” Ruggiero, 257 F.3d at 547; see also Perry, 684 F.2d at 127 (finding that affidavits describing an agency’s search need not “set forth with meticulous documentation the details of an epic search for the requested records”). Indeed, “in the absence of countervailing evidence or apparent inconsistency of proof, [such affidavits] will suffice to demonstrate compliance with the obligations imposed by the FOIA.” Ruggeiro, 257 F.3d at 547. Furthermore, a requester cannot rebut agency affidavits regarding the adequacy of the search with purely speculative claims. SafeCard Servs., Inc. v. SEC, 926 F.2d 1197, 2000 (D.C. Cir. 1991).

2. FDA Has Satisfied Its Burden By Conducting A Reasonable Search.

There is no question that FDA conducted a reasonable and thorough search for all documents responsive to plaintiff’s request. The scope of the search is defined by the scope of the request, and plaintiff’s request was very narrow, seeking only copies of correspondence between FDA and three individuals, and possibly “media or other persons,” during a one month period. See Kowalczyk v. Dep’t of Justice, 73 F.3d 386, 388 (D.C. Cir. 1996); see also Sadler Decl., Attachment 1. As set forth below, both DFOI and the FOIA offices located in CBER and CDER strictly followed detailed procedures in processing plaintiff’s request, and forwarded the request to every office that would likely have a copy of the requested correspondence. As FOIA only requires an agency to search the offices that are likely to have responsive documents, FDA has met its burden under FOIA. See Marks, 578 F.2d at 263.

a. DFOI’s Role In The Search For Plaintiff’s Requested Documents

Under FDA’s regulations at 21 C.F.R. § 20.40(a), all requests for FDA records must be

made in writing to DFOI. See Sadler Decl. ¶ 5. When a FOIA request is received by DFOI, a Freedom of Information technician (“FOI technician”) scans the request into a PDF format, logs and uploads the request into the Agency Information Management Systems (“AIMS”), which stores and keeps track of all of the agency’s FOIA requests, and assigns the request a reference number. Id. at ¶ 6. Once a FOIA request is logged in, DFOI sends a letter to the requester acknowledging FDA’s receipt of the request. Id. at ¶ 8. The FOI technician then forwards the request to the FDA office(s) which, based on a preliminary review of the request, is (are) most likely to possess responsive records. See id. at ¶ 7.

DFOI received plaintiff’s request on September 11, 2007, and on that same day, a FOI technician logged it into AIMS, assigned it a reference number, and sent an acknowledgment letter to plaintiff. See id. at ¶¶ 9-11. On September 14, 2007, DFOI referred plaintiff’s request to CBER’s ALFOI because the request sought documents relating to Provenge, an unapproved biological product regulated by CBER. Id. at ¶ 12. ALFOI’s search for documents is discussed in detail below.

DFOI also forwarded plaintiff’s request to Exec. Sec. and the Immediate Office in FDA’s Office of the Commissioner because the request sought agency correspondence, and both Exec. Sec. and the Immediate Office maintain certain agency correspondence in their files. Id. at ¶ 13. Both offices searched their official agency correspondence files and reported their findings to DFOI. Exec. Sec. responded to plaintiff, through DFOI, on January 24, 2008, indicating that no responsive records had been located. See id. at ¶ 14. On February 26, 2008, DFOI, on behalf of the Immediate Office, produced responsive documents, without any redactions, to plaintiff. See id. at ¶ 15.

On October 10, 2007, DFOI forwarded plaintiff’s request to DIDP in CDER. See id. at

¶ 16. Both DFOI and ALFOI had determined that it was likely that CDER had copies of the requested correspondence, as the addressees on the letters from Dr. Scher, Hussain, and Fleming included CDER employees. See id; see also Sager Decl. at ¶ 11.

b. CBER's Role In The Search For Plaintiff's Requested Documents.

Similar to DFOI, ALFOI has a detailed procedure that it follows in its processing of FOIA requests. Once ALFOI receives a FOIA request from DFOI, it places each request in one (or more) of seven queues of pending requests, based on the complexity and subject matter of the requested documents. See Brockner-Ryan Decl. ¶ 7. ALFOI's queues consist of the Fast, Simple, 510k, Counter-Terrorism-Related, Influenza, Adverse Event, and Complex Tracks. Id. Generally, requests in each queue are assigned to reviewers for processing on a first-in, first-out basis. Id.

For any request, independent of the queue under which it is processed, ALFOI may need to contact many individuals in several CBER offices and direct them to search their files for responsive documents. Id. at ¶ 8. ALFOI then gathers all documents and conducts a preliminary review of the records collected to verify that they are responsive. Id. This is generally followed by a line-by-line, word-by-word review of the responsive documents to determine whether any FOIA exemptions apply. Id. Any exempt material is then redacted. Id. Finally, the employee assigned to the request prepares copies of the responsive documents for delivery to the requester. Id. at ¶ 9.

Plaintiff's request, received by ALFOI on September 14, 2007, was processed in ALFOI's Fast Track. See id. at ¶¶ 11-12. Requests in the Fast Track can be answered with readily available documents that do not need to be redacted. See id. at ¶12. Requests are placed in this track usually because they seek documents that previously were reviewed and redacted

(typically in response to a previous document request) or information that is publicly available (often from documents that were reviewed, redacted and placed on FDA's website). See id. Plaintiff's request was placed in the Fast Track because many of the documents that were responsive to plaintiff's request had been assembled and reviewed for a previous document request. See id. The ALFOI employee who conducted the initial search for responsive documents is no longer employed by the agency. Id. at ¶ 13. However, based on the administrative record in the file, it appears that ALFOI searched for records in the Office of Cellular, Tissue and Gene Therapies, the Office of Communication, Outreach, and Development, the Immediate Office of the Director, and the Office of Management, Division of Scientific Advisors and Consultants, all of which were likely to have the requested correspondence. See id.

The ALFOI staff gathered and reviewed all potentially responsive documents to determine whether they were actually responsive to plaintiff's FOIA request and to determine whether any documents or portions thereof were exempt from disclosure. Id. at ¶ 14. ALFOI identified twelve documents that were responsive to plaintiff's request, and determined that these documents did not contain any information that fell within an exemption to the FOIA. Id. ALFOI provided the responsive documents, without any redactions, to the requesters in a letter dated November 6, 2007. Id. at ¶ 15.

c. CDER's Role In The Search For Plaintiff's Requested Documents.

CDER's DIDP also follows established procedures in responding to FOIA requests. Upon receiving a request, DIDP considers all requests that can be answered quickly with readily available documents, and that require no redacting as "simple" requests, which generally are processed on a fast track (the "Simple Track"), as opposed to "complex" requests, which follow

a slower processing track (the “Complex Track”)³. Sager Decl. ¶ 8. DIDP staff generally process Simple and Complex Tracks requests in queues, on a first-in, first-out basis.

For requests in the Complex Track, DIDP may need to search, or contact individuals and direct them to search, numerous agency files. Id. at ¶ 10. After the search has been carried out and the documents have been sent to DIDP, DIDP conducts a preliminary review of the records collected to verify that they are responsive to the request. Id. DIDP then conducts a page-by-page, line-by-line review of the responsive documents to determine whether any records can be released and whether any FOIA exemptions apply. Id. Any exempt material is redacted. Id. Frequently, a team leader conducts a quality control review to ensure that the responsive documents have been properly prepared for public disclosure. Id. This review ensures that the FOIA exemptions have been properly applied, that no releasable material will be withheld, and that no material meriting protection will be released. Id. Finally, copies of the responsive documents are prepared and delivered to the requester. See id.

When DIDP received plaintiff’s FOIA request in October 2007, DIDP assigned the request to the Complex Track because it requested documents that were not readily available and that would require a search and possible redaction. See id. at ¶ 12. However, DIDP was unable to process plaintiff’s request any further because so many other requests for documents were ahead of plaintiff’s request in the Complex Track queue. At the time it received plaintiff’s request, DIDP estimated that the request would not rise to the top of the Complex Track for processing until October 2009. See id.

³ Simple requests do not require DIDP personnel to redact documents, generally because: 1) DIDP has already reviewed and redacted the responsive documents; 2) the documents requested are publicly available; or 3) it is apparent from the face of the request that the documents do not exist in CDER’s records. Id. at ¶ 9.

When plaintiff learned of this delay, it filed a Complaint against FDA on January 2, 2008, seeking the immediate production of all documents responsive to its FOIA request. See id. FDA filed a Motion to Stay Proceedings on February 18, 2008. See id. at ¶ 14. This Court granted the FDA's request on May 22, 2008 (Opinion and Order, Doc.23), ordering DIDP to update the Court on the progress of the FOIA request in the Complex Track queue on December 1, 2008, and to produce all documents responsive to the request no later than May 18, 2009. See id. On December 1, 2008, as required by the Court's order, DIDP filed in a declaration with the Court stating that the plaintiff's request was still on track and estimating that it would rise to the top of the queue in October 2009. See id. at ¶ 15. However, to comply with the Court's order, DIDP stated that it would provide plaintiff with all responsive documents on or before May 18, 2009. Id.

DIDP pulled plaintiff's request from the Complex Track queue in mid-April 2009. Id. at ¶ 16. A DIDP employee reviewed the documents produced by CBER's ALFOI in response to plaintiff's request in order to identify individuals in CDER that might have responsive documents. See id. at ¶ 17. The DIDP employee identified two CDER employees to which the CBER documents had been addressed or copied, and were therefore likely to have responsive documents: Dr. Janet Woodcock, the Director of CDER, and Dr. Richard Pazdur, a Supervisory Medical Officer in CDER's Office of Oncology. Id. As discussed in detail below, Dr. Pazdur did not have any responsive documents. See id. at ¶ 18. Dr. Woodcock's staff conducted a search of her files, and they were able to locate only one responsive document, a copy of the letter dated April 4, 2007 from Dr. Howard Scher to Dr. Andrew von Eschenbach. Id. The DIDP employee determined that the letter did not contain any information that fell within an exemption to the FOIA. Id. at ¶ 19. The letter, without any redactions, was produced to the

plaintiff on May 18, 2009. Id. & Attachment 1.

In an abundance of caution, the DIDP employee also searched: (i) the CDER electronic databases containing application information on drugs and therapeutic biological products; and (ii) CDER's document room, where CDER stores paper application files for drug and therapeutic biological products, even though CDER ordinarily would not maintain any electronic or paper application files for a vaccine such as Provenge. Id. at ¶ 20. The DIDP employee did not find any responsive documents in CDER's electronic or paper application archives. Id.

As described above, FDA conducted a search reasonably calculated to locate all documents responsive to plaintiff's FOIA request. Even plaintiff admits that their request is "a very simple, basic, and easy request," and FDA's search included every conceivable office and individual that may have had responsive documents. See Plaintiff's Opposition to the Government's Motion for Stay ("Plaintiff's Opposition") (Doc. 18) at p. 6. Thus, all responsive documents have been produced, and summary judgment should be entered on behalf of FDA.

3. Dr. Pazdur's Inability To Produce Responsive Documents Is Not Evidence of Bad Faith.

As is evident in Plaintiff's Opposition, plaintiffs allege that Dr. Richard Pazdur, a Supervisory Medical Officer in CDER's Office of Oncology, has numerous documents that are responsive to their FOIA request. See Plaintiff's Opposition at pp. 2-3, 15 (stating repeatedly that Dr. Pazdur's computer contains files that are responsive to plaintiff's request, including some that plaintiff claims reveal his "improper involvement in the conspiracy to sabotage Provenge"). Plaintiff is mistaken.

Dr. Pazdur is an addressee of Dr. Maha Hussain's April 27, 2007 letter to numerous FDA employees. See Declaration of Dr. Richard Pazdur ("Pazdur Decl.") at ¶ 5, attached as Exhibit

D. He is also listed as a “cc” recipient on the April 5, 2007 letters from Dr. Howard Scher to Dr. Janet Woodcock, Director of CDER, Dr. Celia Witten, Director of CBER, and Andrew von Eschenbach, Commissioner of FDA. See id. Plaintiff has already received copies of these letters in CBER’s response to its FOIA request. See Brockner-Ryan Decl., Attachment 2.

Dr. Pazdur searched both his paper and computer files and could not locate any documents responsive to plaintiff’s request. See id. at ¶ 6. Dr. Pazdur recalls receiving both hard copies and electronic copies of the letters from Drs. Hussain and Scher in April 2007. See id. at ¶ 7. However, as these letters related to a specific regulatory application conducted by a different FDA Center (CBER), did not fall under his direct regulatory supervision, and did not require a response from him, Dr. Pazdur shredded the hard copies of these letters and deleted any electronic copies. See id. The documents were shredded and deleted within a month of receipt. See id. In fact, Dr. Pazdur does not keep personal copies of any regulatory communications. See id. at ¶ 8. Official copies of regulatory correspondence are kept in the official regulatory document room of the specific center assigned to an application. Id.

Contrary to plaintiff’s suspicions, Dr. Pazdur never disclosed Dr. Scher’s or Dr. Hussain’s letters to “any individuals outside of the FDA, or any media outlet, including a publication called ‘The Cancer Letter.’” See id. at ¶ 9. In addition, he did not write any portion of the letters that Drs. Scher, Hussain, or Fleming sent to the FDA. See id. at ¶ 10. He also never received a copy of a letter from Dr. Thomas Fleming to the FDA regarding Provenge. See id. at ¶ 11.

Plaintiff cannot rebut the reasonableness of FDA’s search, as detailed in the attached declarations, or show bad faith on the part of FDA, by making baseless allegations and “speculative claims” regarding documents that plaintiff merely imagines Dr. Pazdur to possess.

See SafeCard Servs., 926 F.2d at 2000. Indeed, Dr. Pazdur only ever possessed duplicates of letters that plaintiff has already received in response to its FOIA request. As plaintiff cannot supply any evidence to show that FDA has purposefully withheld any documents, it must accept FDA's highly detailed descriptions of its reasonable search for responsive documents as proof that the agency has discharged its burden under the FOIA. Id.

III. CONCLUSION

Because FDA has conducted a reasonable search, as set forth in the attached declarations, and all documents responsive to plaintiff's September 11, 2007 FOIA request have been released, there are no genuine issues of material fact and FDA is entitled to judgment as a matter of law. Consequently, FDA's Motion for Summary Judgment should be granted.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I certify that on May 18, 2009, I electronically filed the foregoing Motion for Summary Judgment with the Clerk of the Court using the CM/ECF system, which will send notification to Kerry M. Donahue.

s/John J. Stark
John J. Stark
Assistant United States Attorney