CASE NO. 09-4084

IN THE UNITED STATES COURT OF APPEALS
FOR THE SIXTH CIRCUIT

CareToLive

Plaintiff - Appellant

v.

Food and Drug Administration (FDA)
Defendant - Appellee

On Appeal from the Southern District of Ohio, Eastern Division

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REPLY
BRIEF OF APPELLANT

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TABLE OF CONTENTS

TABLE OF CONTENTS……………………………………..…………………....ii

INDEX OF AUTHORITIES………………………………………………….………...iii

LAW AND ARGUMENT………………..……………………………………….…1

CERTIFICATE OF SERVICE……………………………..……………………..33
.
CERTIFICATE OF COMPLIANCE...34

INDEX OF AUTHORITIES

A. Michael's Piano, Inc. v. FTC, 18 F.3d 138, 141, 143, 146 (2d Cir. 1994).........10

Amnesty Int'l USA v. CIA, No. 07 Civ. 5435 (LAP), 2008 U.S. Dist. LEXIS 47882, 2008 WL 2519908, at * 9 (S.D.N.Y. June 19, 2008)..28

Anderson, 477 U.S. 242, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986).........................24

Baker & Hostetler LLP v. United States DOC, 374 U.S. App. D.C. 172, 473 F.3d 312, 317 (D.C. Cir. 2006)..31

Bryant v. Maffucci, 923 F.2d 979, 982 (2d Cir. 1991)..3

Campbell v. United States Dep't of Justice, 164 F.3d 20, 27, 334 U.S. App. D.C. 20 (D.C. Cir. 1998). 2, 17

Church of Scientology, Int'l, 30 F.3d at 233..2

Coastal States Gas Corp. v. Department of Energy, 644 F.2d 969, 980 (3d Cir. 1981) 12

El Badrawi v. Dep't of Homeland Security, 583 F. Supp. 2d 285, 2008 U.S. Dist..34 LEXIS 76038, 2008 WL 4480363, at *7 (D. Conn. Sept. 30, 2008).......31

Exxon Corp. v. FTC, 466 F. Supp. 1088, 1094 (D.D.C. 1978). See Halpern, 181 F.3d at 295 31

Founding Church of Scientology, 603 F.2d at 950..12

Garcia v. U.S. Dep't of Justice, 181 F. Supp. 2d 356, 366 (S.D.N.Y. 2002) 22

Grand Central P'ship, 166 F.3d at 488-89..29

Halpern v. FBI, 181 F.3d 279 ....14, 31

Hopkins v. United States Dep't of Hous. & Urban Dev., 929 F.2d 81, 84 (2d Cir. 1991). 14

John Doe Agency v. John Doe Corp., 493 U.S. 146, 151, 107 L. Ed. 2d 462, 110 S. Ct. 471 (1989). 1

Judicial Watch II, 185 F. Supp. 2d at 65. 27

Katzman v. CIA, 903 F. Supp. 434, 438 (E.D.N.Y. 1995).......................................30

Massey v. FBI, 3 F.3d 620, 622 (2d Cir. 1993);...10

McCutchen v. Dep't of Health & Human Servs., 30 F.3d 183, 184, 308 U.S. App. D.C. 121 (D.C. Cir. 1994)...13

Moayedi v. U.S. Customs & Border Protection, 510 F. Supp. 2d 73, 78 (D.D.C. 2007) 30

Nation Magazine v. United States Customs Serv., 71 F.3d 885, 892, 315 U.S. App. D.C. 177 (D.C. Cir. 1995). 14

Negley v. FBI, 658 F. Supp. 2d 50...2, 23

Oglesby v. Dep't of the Army, 920 F.2d 57, 68, 287 U.S. App. D.C. 126 (D.C. Cir. 1990). 13

Raulerson v. Ashcroft, 271 F. Supp. 2d 17 (D.D.C. 2002) 14

Ruotolo v. Department of Justice, Tax Div., 53 F.3d 4, 9 (2d Cir. 1995)..............10

SafeCard Servs., Inc. v. SEC, 288 U.S. App. D.C. 324, 926 F.2d 1197, 1201 (D.C. Cir. 1991)...28

Schrecker v. United States Dep't of Justice, 349 F.3d 657, 663, 358 U.S. App. D.C. 334 (D.C. Cir. 2003). 14

Steinberg v. United States Department of Justice, 306 U.S. App. D.C. 240, 23 F.3d 548, 551 (D.C. Cir. 1994) 33

Summers, 140 F.3d at 1080-81 12

Tarullo v. United States DOD, 170 F. Supp. 2d 271 (D. Conn. 2001) 29

Truitt v. Department of State, 283 U.S. App. D.C. 86, 897 F.2d 540, 542 (D.C. Cir. 1990); 28

Weisberg v. United States Dep't of Justice, 705 F.2d 1344, 1351, 227 U.S. App. D.C. 253 (D.C. Cir. 1983)..14

Other Authorities

The Freedom of Information Act (FOIA) 5 USCS § 552 ....5, 15, 36

REPLY

De novo review by the Court is difficult because of the total lack of specificity related to the FDA's Center for Drug Evaluation and Research (CDER) "search" for records. The time expended by CDER, by its own accounting, was virtually zero. The exact locations searched were undisclosed. No computers, e-mail servers, or server farms were searched. No keyword searches were ever made. The locations, where both hardcopy as well as electronic (digital) versions of the sought after documents might be found, were well known, given the personnel and Centers involved. Yet, the Government totally and utterly failed to execute properly even the most basic objective searches demanded by "good practices" and standard operating procedures at these locations. Simply put, there is not enough detail provided by CDER regarding their search of the paper and electronic archives to provide the Court with the basis upon which to draw *any* conclusions and to make *any* determinations based on that record, ostensibly provided by CDER's Richard Pazdur.

"Public access to Government documents" is the "fundamental principle" that instructs the Freedom of Information Act (FOIA). John Doe Agency v. John Doe Corp., 493 U.S. 146, 151, 107 L. Ed. 2d 462, 110 S. Ct. 471 (1989). FOIA requests are construed liberally. *Any doubt about the adequacy of the search*

should be resolved in favor of the requester. Campbell, 164 F.3d at 27; Mack v. Dep't of the Navy, 259 F. Supp. 2d 99, 104 (D.D.C. 2003). Negley v. FBI, 685 F. Supp. 2d 50. The adequacy of the CDER search should be resolved in favor of Appellant, CareToLive. Even though Plaintiff-Appellant had their hands tied behind them by the District Court, Defendant-Appellee, none-the-less, did not sustain the burdens imposed by law upon them, to demonstrate in detail and present that detail in a non-conclusory manner, sufficient to show a reasonable good-faith search. That burden surely is *not* satisfied by mere production of dismissive, cut-and-paste, mostly boilerplate declarations from CDER. Absent a sufficiently specific explanation from an agency, a Court's *de novo* review is not possible, and the adversary process envisioned in FOIA litigation cannot proceed. Church of Scientology, Int'l, 30 F.3d at 233.

This case involves—in fact, goes to the very heart of—numerous disputed facts relative to the issue of bad faith. These include the intentions, motives, and circumstances surrounding the destruction of the requested FDA documents by employee Richard Pazdur. That one of the highest ranking employees of the FDA, the sometimes called “Cancer Czar” and a person who some once trumpeted for Commissioner, just absent mindedly destroyed documents in the middle of a firestorm of controversy, is simply beyond belief. At a minimum, it invites further

inquiry. As long as there were *genuine issues of material fact,* something seemingly admitted in Appellee's brief, it invites a hearing rather than a determination on summary judgment. At a minimum, it suggested, even invited the allowance of some minimal discovery or the granting of Plaintiff-Appellant's request to the District Court to require supplemental responses on the part of CDER, so that Plaintiff-Appellant could have had the opportunity to file its own motion for summary judgment. On an appeal from a grant of summary judgment, the Court also reviews the record *de novo* to determine whether or not there are genuine issues of material fact requiring a trial. See Bryant v. Maffucci, 923 F.2d 979, 982 (2d Cir. 1991). The Government did not sustain even its initial burden by demonstrating that a reasonable good faith search had been made, and therefore, summary judgment was improper.

The District Court could have requested more of an explanation regarding the search performed by CDER's Richard Pazdur or, at a minimum, inquire as to the availability of the sought-after records on the identified computer or e-mail servers. Note that simply because one "deletes" a file from one's computer does not mean that the information still is not resident on that computer's hard drive. "Deleting" a file does nothing more than remove the file name from the computer's directory – something akin to taking a company's name off the Directory on the

first floor of an office building. The company still may or may not occupy the space above; its name just isn't listed in the Directory. Actually, when one "deletes" a file, the computer is free to reuse the memory space once allocated to that file, so whether or not the document still may be on the hard drive is in question. *However,* if the sought-after documents entered the system via e-mails, by Federal Regulation, those e-mails and their attached documents still must reside on that agency's server(s), where they easily can be retrieved by an information technology (IT) technician using a time-constrained keyword search. Thus, the Court could have, as was requested by Plaintiff-Appellant, inquired of the FDA as to the ability to have one of their own IT employees search Dr. Pazdur's computer to determine the retrievability of correspondence over a short 30-day period of time. No proper computer search was done on that computer. Nor was a search made of the e-mail server that provided service to Dr. Pazdur during the period in question. That it can be done is not denied by Appellee. Instead, it is dismissively proclaimed to be burdensome. In reality, this is a simple search that can be accomplished by an FDA IT employee in less than one hour. Once the FDA employee, Dr. Richard Pazdur, admitted receiving correspondence—that is, that the information sought in Appellant's FOIA request was on his computer within a month or so of litigation being filed against the FDA over the lack of due process

provided the Provenge Biologics License Application (BLA), which litigation included allegations of his interference with that process—the FDA had a duty to search his computer and the e-mail server(s) providing service to him. Dr. Richard Pazdur is *not* an IT employee or a computer expert. It is doubtful that he could find documents that an IT person or even a person with just more experience with computers could find, even assuming he possessed the *desire* to find documents that would demonstrate his role in the denial of due process to the Provenge BLA. This of course assuming that since then no steps have been taken to ensure the complete destruction of the sought-after documents (an IT person could see that footprint also). The conclusion is nothing less than the total and utter failure of CDER/DIDP (Division of Information Disclosure Policy) to take those clearly reasonable next steps in the search process—a search of Dr. Pazdur's computer and of the e-mail server(s) providing service to Dr. Pazdur. The minimal "search" described—renders the search *less than reasonable* under the specific facts and circumstances of this case.

According to Dr. Richard Pazdur, he thoughtlessly destroyed the documents because they were supposedly unimportant to him. This statement, when considered under the totality of the circumstances existing at the alleged time of destruction, borders on the absurd. As stated in his declaration,

Dr. Pazdur's justiification for deleting and shredding was:

> However, as these letters related to a specific regulatory application conducted by a different FDA Center (CBER), did not fall under my direct regulatory supervision, and did not require a response from me, I shredded my hard copies of these letters and deleted any electronic copies.

That reasoning is contrary to the statement set forth by the FDA in response to CareToLive's Citizen Petition, wherein the agency stated:

> Also, at CBER's request, Dr. Pazdur from FDA's Office of Oncology Drug Products (OODP), Center for Drug Evaluation and Research (CDER) participated in the advisory committee meeting. Dr. Pazdur has extensive experience in OODP evaluating other prostate cancer therapies.

In addition, 8 days later, the FDA declared on its website:

> Pazdur joined the FDA in 1999 and was named director of the Office of Oncology Drug Products when that office was established in 2005. As part of his duties, Pazdur *coordinates oncology activities across all FDA product centers and ensures collaboration among the FDA, the National Cancer Institute* at the National Institutes of Health, and both public and private cancer organizations.

http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm163025.htm

Importantly, when criticism was in fact directed at the FDA following the controversial decision to delay approval of Provenge, it was often Dr. Richard Pazdur who was espousing arguments for, and defending, the agency's decision to the press and the public. Based on the burdens of proof at the summary judgment stage of proceedings, Plaintiff-Appellant would have thought that this factual

contention would have had to be decided by the District Court in its favor, not contrarily.

A material factual dispute exists regarding the motives, circumstances and timing behind and surrounding the destruction, which purportedly occurred at a time the FDA was receiving relentless criticism from the public. Such criticism included that of prostate cancer advocacy groups, which were incensed over the FDA's May 8, 2007 decision to ignore the agency's own handpicked experts on the Provenge Advisory Committee and instead rely on the opinion of two oncologists who lacked experience with the treatment, or in the field, and who were recruited by Dr. Pazdur. Both of these oncologists were acting as special government employees on the Provenge Advisory Committee and were otherwise consultants to Dr. Richard Pazdur's Center. The timing of the alleged destruction, as set forth by Dr. Richard Pazdur, is about the same time that FDA Commissioner, Dr. Andrew von Eschenbach, was meeting with outraged prostate cancer advocacy group leaders in Washington D.C., and at which advocates, including current CareToLive directors and members, were marching in the streets of D.C.

Importantly, Dr. Pazdur ignores in his affidavit, and the Appellee ignores in its brief, the fact that the FDA's FOIA office left not only the entire search for Dr. Pazdur's e-mails, to Dr. Pazdur, but also, apparently left the interpretation of the

scope of the FOIA request to the very last person at the FDA who should be interpreting it. Dr. Pazdur purposely does not discuss in his affidavit the other e-mails that clearly had to be sent to and/or from Drs. Scher and Hussain, who were members of his own ODAC organization, during the 30 day window as set forth in the FOIA request. It certainly did not go unnoticed that Dr. Richard Pazdur was seen exchanging notes with letter writer Hussain during the Provenge Advisory Committee meeting, and one would have expected, given the uproar within the agency and at the National Cancer Institute (NCI) following that meeting, that such communications continued in the days and weeks that followed. The declaration by Dr. Richard Pazdur indicates that he purposefully and inappropriately used far too narrow of a reading of the FOIA request so as to avoid answering the sensitive question of whether or not he does, or did, have accompanying correspondence. He only addresses the three "cancer letters" themselves. It is properly assumed that the letters were on his computer *because* they were e-mailed to him, which means there had to also be retrievable e-mails, since there is no such thing as a completely blank e-mail with attachment. Whether the claim is that those e-mails were also deleted, or whether they were not deleted, or whether the search included a search for those e-mails, has never been adequately explained by the agency.

There were three "cancer letters"—one ostensibly written by Dr. Scher and sent on Memorial Sloan-Kettering stationery (a copy of which (v.3, with edits) was found on the Government computer belonging to then-National Cancer Institute (NCI) employee Dr. Alison Martin); one written by Dr. Maha Hussain and sent on University of Michigan stationery; and one written by Dr. Thomas Fleming and sent on University of Washington stationery). All three letters were quickly leaked by the FDA—to a non-peer-reviewed newsletter *The Cancer Letter,* which is owned and published by a personal friend of Richard Pazdur's. All three letters were supportive of Dr. Pazdur's position on Provenge. It is noteworthy that this is not the first time that leaks from the FDA to *The Cancer Letter* have occurred. A most notable occurrence is the leak attendant to the issuance of the Refusal to File letter in the case of ImClone in 2001 (*The Cancer Letter,* December 28, 2001) ... a leak that was traced to Dr. Pazdur as discussed at a Congressional hearing, where Dr. Pazdur was, perhaps coincidentally, represented by the same attorney that represented the owner of the *Cancer Letter* in the related case (07-729).

Despite the fact that the "cancer letters" were immediately controversial when quickly published in the *Cancer Letter* in April, 2007 and the FDA came under immediate media scrutiny following the May 8, 2007 decision, Dr. Pazdur claims the letters were just "unimportant to him". Once published in *The Cancer*

Letter, the letters were quickly circulated around the world by the Internet, which ignited a firestorm. There was a flurry of discussion on numerous Web sites and an eventual call for a congressional investigation by three members of Congress.

Per the FDA's own admission, the arguments improperly made by and advocated by the two letter writers—Dr. Scher and Hussain— who were also part of the Provenge AC at the invitation of Dr. Pazdur, affected the FDA decision-making process. Plaintiff-Appellant avers that this resulted in the wrongful delay of a late stage prostate cancer therapy, preventing the treatment from reaching patients, including some now-deceased members of CareToLive.

A pure *de novo* standard is appropriate without further adopting the nuances or lower standard often requested by the Government in FOIA cases. A. Michael's Piano, Inc. v. FTC, 18 F.3d 138, 141, 143, 146 (2d Cir. 1994); Massey v. FBI, 3 F.3d 620, 622 (2d Cir. 1993). Such standard is consistent with Congress' purposes in enacting FOIA. See, Halpern v. FBI, 181 F.3d 279:

> In striking a balance between the incompatible notions of disclosure and privacy when it enacted FOIA in 1966, Congress established -- in the absence of one of that law's clearly delineated exemptions -- a general, *firm philosophy of full agency disclosure,* and provided de novo review by federal courts so that *citizens* and the press *could obtain agency information wrongfully withheld*. De novo review was deemed *essential to prevent courts reviewing agency action from issuing a meaningless judicial imprimatur on agency discretion*. A. Michael's Piano, Inc. v. FTC, 18 F.3d at 141 (citing S. Rep. No. 813, 89th Cong., 1st Sess. 2, 8 (1965)).(emphasis added)

Plaintiff-Appellant avers that the District Court issued a meaningless judicial imprimatur on Agency discretion and allowed a different interpretation to be placed on the request by CDER's Richard Pazdur versus the interpretation that was more properly used by the Center for Biologics Evaluation and Research (CBER) that resulted in disclosure of 10 important e-mails (discussed in more detail below). Consider that when a request demands all agency records *on a given subject,* then the agency is obliged to pursue any "clear and certain" lead it cannot in good faith ignore. 73 F.3d at 389. Although an agency need not conduct a search that *plainly* is unduly burdensome, Ruotolo v. Department of Justice, Tax Div., 53 F.3d 4, 9 (2d Cir. 1995), the CareToLive request was *a very specific and extremely unburdensome request*, covering a very short and very specific period in time. It essentially sought all correspondence between Dr. Richard Pazdur and Drs. Scher/Hussain/Fleming as well as correspondence from Dr. Richard Pazdur to those outside the FDA regarding the immunotherapy called by the marketing name of Provenge, between March 29, 2007 and April 30, 2007. *That is roughly a one-month period of time*. The wrongful interpretation of the FOIA request is but another contested fact that somehow was decided without sufficient basis by the District Court. *See Founding Church of Scientology,* 603 F.2d at 950 ("District Court decisions in FOIA cases must provide statements of law that are both

accurate and sufficiently detailed to establish that the careful *de novo* review prescribed by Congress has in fact taken place."); *Coastal States Gas Corp. v. Department of Energy*, 644 F.2d 969, 980 (3d Cir. 1981) (A district court's obligation to state the legal basis for its resolution of a FOIA summary judgment motion "is, in a sense, implicit in the statutory duty of *de novo* review**.**"). See also, generally, Summers, 140 F.3d at 1080-81 (discussing the difficulties of appellate review unique to FOIA litigation). There were clear and certain leads not followed, essentially that the correspondence sought was, and/or is, on the office computer of Dr. Richard Pazdur—or on the e-mail server(s) providing e-mail support to Dr. Richard Pazdur—and merely requires a reasonable search of that computer and server(s) to properly make that determination. That the sought-after documents were not produced previously could be because they are not there, or could be because the interpretation of the scope of the request was incorrect, or could be just because a person who does not have the knowledge necessary to query a computer or server was given the job of locating the documents.

This case is unlike most FOIA cases because the CDER employee that would be most exposed by disclosure of the documents is the sole person asked to search the most logical location, his office computer. Dr. Richard Pazdur lacks the ability to conduct a proper or real search of his computer and the FDA's e-mail

server(s), or archives, even if he was inclined to do such a thorough search. This FOIA case also is unique in that we have admittance by Appellee that the documents were on a certain specific computer, in a certain location, at a certain time; therefore retrieval of them is a relatively simple process. Yet this simple search has suspiciously been one the Defendant-Appellee has refused to conduct, and one it has unconvincingly labeled as "burdensome".

The very purpose of FOIA is to "facilitate public access to Government documents" and "to pierce the veil of secrecy and to open agency action to the light of public scrutiny." *McCutchen v. Dep't of Health & Human Servs*., 30 F.3d 183, 184, 308 U.S. App. D.C. 121 (D.C. Cir. 1994). In responding to a FOIA request, an agency is under an obligation to conduct a reasonable search for responsive records. *Oglesby v. Dep't of the Army*, 920 F.2d 57, 68, 287 U.S. App. D.C. 126 (D.C. Cir. 1990). *To win summary judgment on the adequacy of a search, the agency must demonstrate beyond material doubt that its search was "reasonably calculated to uncover all relevant documents*." *Weisberg v. United States Dep't of Justice*, 705 F.2d 1344, 1351, 227 U.S. App. D.C. 253 (D.C. Cir. 1983).

The burden is on the agency, which must "show that it made a good faith effort to conduct a search for the requested records, using methods which can be reasonably expected to produce the information requested." *Oglesby*, 920 F.2d at

68. There is no requirement that an agency search *every record system* in which responsive documents might conceivably be found. *Nation Magazine v. United States Customs Serv*., 71 F.3d 885, 892, 315 U.S. App. D.C. 177 (D.C. Cir. 1995). However, the agency cannot limit its search to only one record system if there are others that are likely to turn up the information requested. Id. at 892. Here DIDP knows where the records may be located; they just refuse to properly look where these records most certainly are still located, or archived.

The adequacy of any FOIA search is measured by a standard of "reasonableness" and is *dependent on the circumstances of the case*. *Schrecker v. United States Dep't of Justice*, 349 F.3d 657, 663, 358 U.S. App. D.C. 334 (D.C. Cir. 2003). The adequacy of a search is not determined by its results, but by the method of the search itself. *Weisberg v. United States Dep't of Justice*, 745 F.2d 1476, 1485, 240 U.S. App. D.C. 339 (D.C. Cir. 1984). *Raulerson v. Ashcroft*, 271 F. Supp. 2d 17 (D.D.C. 2002) ("[I]f [the agency] discovers that relevant information might exist in another set of files or a separate record system, the agency must look at those sources as well."). *If the record leaves substantial doubt as to the sufficiency of the search, summary judgment for the agency is not proper*. *Campbell v. United States Dep't of Justice*, 164 F.3d 20, 27, 334 U.S. App. D.C. 20 (D.C. Cir. 1998).

To show reasonableness at the summary judgment phase and to allow the court to determine if the search was adequate, an agency must provide, "[a] reasonably detailed affidavit, *setting forth the search terms* and *the type of search performed*, and *averring that all files likely to contain responsive materials* (if such records exist) *were searched*." *Oglesby*, 920 F.2d at 68. It was improper for CDER/DIDP to neglect to conduct its own search versus relying on the self-serving proclamations of destruction made by Dr. Richard Pazdur. Merely asking the fox to count the chickens, without even allowing Plaintiff-Appellant to subject the answers of the fox to any sort of test of accuracy or truthfulness, was improper. Any search must be reasonably calculated to uncover all relevant documents. The *reasonableness of the search is "dependent upon the circumstances of the case."* Weisberg, *Id.* at 1351. While the FOIA request could admittedly have been better crafted with the 20-20 hindsight now possessed 2 years later, Plaintiff-Appellant avers that the agency also must, at a minimum, have known by the time CDER replied that *all the correspondence regarding Provenge from and to Dr. Richard Pazdur during that very small time frame was sought by CTL*. There was, after all, constant monitoring of the activities of CareToLive (including the organization's website, as determined by documented visits to that site provided by CTLs Internet Service provider (ISP)) by the FDA, in part because of the two different lawsuits

by CTL against the FDA. The website, and both lawsuits, at various times discussed the relevance of correspondence of Dr. Richard Pazdur in April 2007, including discussion to the effect that such correspondence would be evidence that could be used to shine light on the denial of a fair and due process to the Provenge BLA.

One of the reasons CareToLive initially made the request as narrow as possible was to avoid the “complex” status that CDER placed on what was intended to be a simple request in the first place. The CDER response—that the destroyed documents are the same as those already provided—is evidence of the bad faith the agency has used in continuing to classify the request as “complex”. Specifically, if the documents sought were only those already provided by the FOIA office of another Center, (that can’t be known without seeing them) the FOIA request should have been designated “fast track” rather than “complex” (or at least, the designation should have been corrected when it became an issue in the District Court).

That there was a different interpretation placed on the FOIA request by both CBER and the Commissioner’s office is indicative that the DIDP office initially interpreted the FOIA request more broadly then did Dr. Richard Pazdur, when he conducted his own unsupervised “search for responsive documents”. The CBER

and Commissioner Office search resulted in the 10 e-mails (2 attached to Exhibit A of R. 29, Defendants Motion for Summary Judgment, and 8 attached to Exhibit B). The e-mails that were produced as part of CDER'S search were zero. CDER even had considerably more information on the scope of the documents sought by the time they replied 1-1/2 years later. Yet they now "play dumb" and pretend not to understand the request in the same way as did CBER and as did the Commissioner's Office.

This "playing dumb" act should not be accepted by this Court. For the Appellee to prevail in this appeal, this Court would have to believe that the FDA's CDER, and more importantly, CDER's Richard Pazdur, did not fully understand the request. Further, the Court would have to determine that the more narrow interpretation of the request, by CDER's Pazdur, was more proper than was the interpretation previously applied by CBER. Where, the requester submits additional information to supplement the initial request, the agency is obliged to incorporate that information in crafting the scope of its search. *See Campbell*, 164 F.3d at 28 ("[C]ourt[s] evaluate the reasonableness of an agency's search based on what the agency knew at its conclusion rather than what the agency speculated at its inception.").

Defendant-Appellee's persistent and inexplicable refusal to properly search at least the office computer of Dr. Richard Pazdur, much less the e-mail server(s) and archives, does not demonstrate a "good faith effort to conduct a reasonable search for the requested records, using methods which can be reasonably expected to produce the information requested." *See* *Oglesby*, 920 F.2d at 68. To the contrary, it actually reflects a distressingly willful disregard of its obligations under FOIA and nothing less than a deliberate attempt to subvert and thwart the intent of the law. See, Negley v. FBI, 658 F. Supp. 2d 50:

> The Defendant's position is further undermined when the Court considers the scope of the request. Plaintiff made clear that he was not requesting records about himself which were maintained only in "main" files. He also provided specific file numbers in his appeals of Defendant's initial decisions and in his amended FOIA request, so as to allow the FBI to construe his FOIA request liberally and broaden its search beyond the main files in the UNI. *Cf.* *Nation Magazine*, 71 F.3d at 890.
>
> Nonetheless, Defendant repeatedly conducted searches of only the one record system, UNI, and *challenged Plaintiff's efforts at every turn*. Initially, it only searched "main" files for the information, in furtherance of its policy of narrowing FOIA searches to this universe…. The FBI e*ventually expanded its search* to include cross-references…In several declarations, Hardy informed Plaintiff that the FBI conducted these searches in the CRS file system….In later deposition testimony, Hardy "clarified" his former testimony and said that *Defendant searched only one component* of CRS, the UNI file system. ….As already noted, the UNI database is searchable only by indexed terms, which are identified at least in part by discretionary decisions left to *case agents who may have limited knowledge*.

> *Regardless of any policy or conventional operating procedures, it is clear that Plaintiff's requests required Defendant to perform more rigorous searches for responsive documents. Cf.* *Wiesner v. Fed. Bureau of Investigation*, 577 F. Supp. 2d 450, 457 (D.D.C. 2008) (taking issue with FBI's "naked reliance on its own procedures" to satisfy its FOIA obligations).

Appellee's focus since the filing of Appellant's First Complaint in the Southern District of Ohio has been on complaining about the lack of evidence that is available to Appellant. Appellee either ignores or simply takes pleasure in the fact that most of the evidence in the case is in the hands of the FDA (in as much as it has not been destroyed in order to protect the agency). Without obtaining the information from that agency, the Appellant is unable (1) to produce what the FDA refuses to give them, particularly without any reasonable assistance/investigation from the District Court or (2) to merely test the truthfulness or accuracy of the conclusions of Appellee, even in light of inconsistencies, improprieties, and malfeasance on the part of FDA's CDER. Appellee misses the point that it was, in fact, the refusal of the lower Court to allow even a modicum of discovery and/or truth testing, combined with the thus-far successful 2-year stonewalling of FDA's CDER, which is the sole contributor to the state of the evidence.

In so much as it is not already abundantly clear, Appellant absolutely and unequivocally denies the fact that all the documents destroyed by Richard Pazdur are duplicates, as contended by Appellee. This was an apparent misperception by

the District Court, which Plaintiff-Appellant would have thought had been clear after 3 years of litigation in two cases. That was a completely erroneous conclusion not based upon a proper review of the record by both Appellee and the District Court. It displays a misunderstanding, in part due to the fiction that Dr. Richard Pazdur has created through his evasive affidavit. First, we do not know specifically what documents were and were not allegedly destroyed. Second, we do not know the exact content of those allegedly destroyed documents. We know only that letters *similar* to the ones received by CBER and the Commissioner also were received by Dr. Richard Pazdur at CDER and were on his computer. However, the *letters sent to Dr. Richard Pazdur were not necessarily the same as those sent to other Centers or the Commissioner*. In fact, the record suggests slight changes to one of the letters sent to CBER, and a unique personal touch added on the one to the Commissioner (as set forth in Appellant's motion to take judicial notice, or also attached in this case to R. 29, Defendant's Motion for summary judgment, Exhibit A, B). Those CBER e-mails indicated that a revision to one letter was being sent to Jesse Goodman at CBER by hard copy after an admitted error in its contents by Dr. Howard Scher and some revisions that occurred with the help of National Cancer Institute (NCI) employee Dr. Alison Martin, whose former boss at CDER was Dr. Richard Pazdur. The alleged author of the letter, Dr. Howard Scher, even instructs

CBER's Jesse Goodman, that the hardcopy will contain changes. There apparently was a concerted effort on the part of several FDA and NCI employees shortly after the March 29, 2007, Provenge Advisory Committee meeting to develop what now is known as the "Scher" letter ... an effort that no doubt resulted in a trail of e-mails of vital interest to the public.

The Scher/Hussain/Fleming leaked letters were published in the Washington D.C. publication, *The Cancer Letter,* almost immediately after they were received by the FDA. The published versions were different from the ones obtained from CBER and the Commissioner (each of which was different from the other). Appellant reluctantly, but perhaps necessarily, gives up future strategy: the *exact content* of the letters received by Dr. Richard Pazdur may shed light on the identity of the person within the FDA that leaked those letters to the media. In addition these were not the only letters requested in the FOIA request.

Dr. Richard Pazdur is purposefully evasive when it comes to declaring whether there ever existed e-mail accompaniments to those letters, or it they were also destroyed, or if there were other letters, or whether he just decided to place his own unique interpretation on the documents requested under the FOIA so that he could justify excluding or even referencing any of those documents or other correspondence. Plaintiff-Appellant is admittedly even more interested in those e-

mails that would have necessarily accompanied and surrounded the letters e-mailed from Drs. Scher and Hussain to/from Dr. Richard Pazdur. We do not know, because it is not clear from the Pazdur declaration, if those e-mails regarding Provenge for that specific time period, between the specific individuals, have, or have not, been destroyed, much less whether they are retrievable with a very simple computer/server search by a knowledgeable computer person. Richard Pazdur made the choice not to conduct a search for those.

The Government must establish the adequacy of its searches by showing "that the agency made a good faith effort to search for the requested documents, using methods 'reasonably calculated' to produce documents responsive to the FOIA request." *Garcia v. U.S. Dep't of Justice*, 181 F. Supp. 2d 356, 366 (S.D.N.Y. 2002) (quoting *Weisberg v. Dep't of Justice*, 745 F.2d 1476, 1485, 240 U.S. App. D.C. 339 (D.C. Cir. 1984)).

The CDER affidavits are conclusory and do not contain sufficient detail of the type of search conducted or the documents searched for. Plaintiff-Appellant has no problem with the search and response from C<u>B</u>ER or from the Commissioner (the commissioner later supplemented his response after the first response was questioned by the media). The issue herein is the C<u>D</u>ER response. The only relevant non-boilerplate paragraphs are contained in R. 29 “Exhibit C” and

"Exhibit D". The only relevant portions of Exhibit C are paragraphs 18, 19 and 20 at page 5. These three paragraphs combined with the Pazdur declaration set forth the entire detail related to the CDER "search". The entire search that took so little time that it did not even make the lowest billable increment the FDA has. Specifically, a review of CBER's response, for example, shows the search time devoted to the search by that Center was 2.75 hours versus the search time spent by CDER, which was *zero*. The search time by the Commissioner's office was approximately 11 hours. Compare that to the CDER search time, which took almost 1-1/2 years longer to obtain, which search time was zero. All of which goes to the lack of good faith of CDER when searching for and responding to Plaintiff-Appellant's FOIA request. The CBER responsive documents are demonstrative of the different effort and different sincerity given to the request by that division, as opposed to the narrow incomplete response by CDER.

Appellee complains it is much too burdensome to have one of their numerous IT staff members spend time to search for the sought-after documents. The proclamation of the FDA must be looked at with suspect considering that they obtained a *20-month stay of the matter in the District Court on the basis that the search was purported to be a "complex" one.*

In ruling on a summary judgment motion, the Court is supposed to accept as true the non-moving party's evidence and draw all inferences in favor of the non-moving party. *Anderson*, 477 U.S. 242, 106 S.Ct. 2505, 91 L.Ed.2d 202 (1986). Appellee has made reference to the fact that there was not a "worldwide" controversy surrounding Dendreon's Provenge at the time Richard Pazdur was allegedly destroying documents. Plaintiff-Appellant in its complete SJ response, which the District Court never allowed to be filed, and/or at an eventual hearing of the matter on the merits, could have provided extensive proof that there was "worldwide controversy" in May 2007. In Fact, CTL substantially did so in the related case (CareToLive vs. von Eschenbach, 07-729). To the extent it is truly contested, CTL can again present hundreds of news articles that appeared in the papers and other media outlets in numerous countries regarding the controversy swirling around Provenge in May 2007. Many web sites contained discussion from participants purportedly from as far away as Germany, Australia and Japan. In addition, CareToLive was prepared to introduce video footage of coverage of the matter from ABC, NBC, CBS, and many major news organizations, and Internet sites in May 2007 (the time of the alleged document destruction). Protesters marched in Chicago and Washington DC, all covered by the media. Debate was raging across the Internet concerning the actions of the FDA with regard to

Provenge. Concerned citizens and their congressional representatives immediately inquired of the FDA's handling of the matter. Appellant is dismayed by the fact that the Appellee would call into question the fact that there was worldwide controversy surrounding Provenge in May 2007, while Richard Pazdur was busy shredding documents related to his role in its delayed approval. Appellant asserts that this is a disputed fact that should have been presented at a final hearing of the matter or, at a minimum, that limited discovery or supplemental response should have been required.

It was error for the Court to deny the Rule 56(f) motion, be unresponsive to the repeated discovery requests, and at the same time, grant summary judgment to Defendant before allowing Plaintiff to file the complete memorandum contra to that motion. It was a due process violation for the Court to decide both motions without any intervening notice to Plaintiff-Appellant, under the circumstances presented. Appellee points out that Appellant, attached an unsigned affidavit to the 56(f) motion/partial SJ response. In fact, CareToLive specifically pointed out that fact to the District Court and requested that if the Court denied the 56(f) motion, that Plaintiff-Appellant be allowed to file a signed affidavit discussing the existence and easy recoverability of the documents, following such a ruling. Instead of allowing the affidavit to be signed and granting CareToLive the right to

file a fully responsive memorandum, including the signed affidavit, the Court denied the 56(f) motion to conduct some limited discovery and provide additional affidavits and instead, granted summary judgment. The Court could not have reached this decision properly if it did not assume the correctness of averments from CareToLive, such as that there was "worldwide" attention and controversy surrounding the FDA decision at the same time that Dr. Pazdur was destroying documents.

It has become common practice for opponents to brand the opposition as "conspiracy theorists". Standard practice in debating is to attack your opponent personally when one's logical arguments are specious. Such is the case here. It not only is improper for the agency to make such sweeping statements in this matter, but clearly points to the weakness of their position. The evidence, as always, must speak for itself. And it will ... if the Government only will produce it, as the law intended.

Even when an Agency may no longer be in physical possession of a record that is not determinative; if Agency notes what records a given request is directed towards, knows where those records are located and is able to produce them, 5 USCS § 552 requires that it do so. Tax Reform Research Group v IRS (1976, DC Dist Col) 419 F Supp 415, 76-2 USTC P 9558, 38 AFTR 2d 5601.

Discovery is permitted when there is a genuine issue as to the adequacy of the agency's search, its identification and retrieval procedures, or its good/bad faith. *Weisberg v. Department of Justice*, 200 U.S. App. D.C. 312, 627 F.2d 365, 371 (D.C. Cir. 1980); *Shurberg Broadcasting of Hartford, Inc. v. FCC*, 617 F. Supp. 825, 832 (D.D.C. 1985); Sometimes, even if an agency's affidavits regarding its search are deficient, courts often, rather than grant discovery, will instead direct the agency to supplement its affidavits. *See Judicial Watch II*, 185 F. Supp. 2d at 65. The agency is under a duty to conduct a "reasonable" search for responsive records using methods that can be reasonably expected to produce the information requested to the extent they exist. 5 U.S.C. § 552(a)(3)(C); *SafeCard Servs., Inc. v. SEC*, 288 U.S. App. D.C. 324, 926 F.2d 1197, 1201 (D.C. Cir. 1991); *Zemansky v. United States EPA*, 767 F.2d 569, 571 (9th Cir. 1985). Before it can obtain summary judgment in a FOIA case, an agency must show beyond a material doubt, and viewing the facts in the light most favorable to the requester, that it "has conducted a search reasonably calculated to uncover all relevant documents." *Steinberg v. United States Department of Justice*, 306 U.S. App. D.C. 240, 23 F.3d 548, 551 (D.C. Cir. 1994). Thus, it is common ground that an agency responding to a FOIA request must make a good faith effort to conduct a search for requested records, using methods that are reasonably calculated to produce all relevant

documents. *See, e.g.*, *Truitt v. Department of State*, 283 U.S. App. D.C. 86, 897 F.2d 540, 542 (D.C. Cir. 1990); *Amnesty Int'l USA v. CIA*, No. 07 Civ. 5435 (LAP), 2008 U.S. Dist. LEXIS 47882, 2008 WL 2519908, at * 9 (S.D.N.Y. June 19, 2008); *Garcia v. United States DOJ*, 181 F. Supp. 2d 356, 368 (S.D.N.Y. 2002). The burden of demonstrating that a FOIA search was adequate rests with the agency. *See Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 812 (2d Cir. 1994). To satisfy that burden, the agency may submit a non-conclusory declaration that explains in reasonable detail the *scope and method* of the agency's search**,** as well as any justifications for non-disclosure. *Id.; see Grand Central P'ship*, 166 F.3d at 488-89; *Safecard Servs., Inc. v. SEC*, 288 U.S. App. D.C. 324, 926 F.2d 1197, 1200 (D. C. Cir. 1991).

A satisfactory agency declaration should provide reasonably detailed information about the type and manner of search performed, the structure of the agency's records system, the files likely to have relevant records, and the files searched, all of which would enable a FOIA requester to challenge the adequacy of the search and the court to rule on such a challenge. *See El Badrawi v. Dep't of Homeland Security*, 583 F. Supp. 2d 285, 2008 U.S. Dist. LEXIS 76038, 2008 WL 4480363, at *7 (D. Conn. Sept. 30, 2008); *Tarullo v. United States DOD*, 170 F. Supp. 2d 271, 274-75 (D. Conn. 2001). "A district court in a FOIA case may grant

summary judgment in favor of an agency on the basis of agency affidavits if they contain *reasonable specificity* of detail rather than merely conclusory statements, and if they are not called into question by contradictory evidence in the record or by evidence of agency bad faith." *Grand Central P'ship*, 166 F.3d at 478.

CONCLUSION

In sum, CDER'S affidavits describing their searches were not relatively detailed and nonconclusory, or submitted in good faith. The affidavits did not describe the structure of the agencies' paper and electronic (including e-mail) file systems, show that any further search was unlikely to disclose additional relevant information, or justify the searches of only certain databases/repositories. The lack of disclosure stymied plaintiff's ability to advocate his position and did not meet the standard adopted by most Circuits. Plaintiff-Appellant was entitled to limited discovery. A genuine issue of material fact existed as to the propriety of CDER's search and response. The declarations did not meet the requisite level of detail to warrant summary judgment on the invocation of 5 U.S.C.S. § 552(b). Reliance is only appropriate, when agency affidavits are ". . . relatively detailed and nonconclusory, and submitted in good faith." Grand Cent. P'ship., Inc. v. Cuomo, 166 F.3d 473, 488-9 (2d Cir. 1999) (citing SafeCard Servs., Inc. v. SEC, 288 U.S.

App. D.C. 324, 926 F.2d 1197, 1200 (D.C. Cir. 1991)). The question before the court is whether or not these affidavits are "relatively detailed and nonconclusory, and submitted in good faith." Id. Because "[a]ffidavits submitted by an agency are accorded a presumption of good faith," Carney, 19 F.3d at 812, this court's initial inquiry necessarily focuses on whether the defendants' affidavits meet the "relatively detailed and nonconclusory" standard. "A reasonably detailed affidavit, setting forth the search terms and the type of search performed, and averring that all files likely to contain responsive materials (if such records exist) were searched, is necessary to afford a FOIA requester an opportunity to challenge the adequacy of the search and to allow the district court to determine if the search was adequate in order to grant summary judgment." Tarullo v. United States DOD, 170 F. Supp. 2d 271 (D. Conn. 2001). Affidavits should "'identify the searched files and describe at least generally the structure of the agency's file system' which renders any further search unlikely to disclose additional relevant information." Katzman v. CIA, 903 F. Supp. 434, 438 (E.D.N.Y. 1995) (quoting Church of Scientology v. IRS, 253 U.S. App. D.C. 78, 792 F.2d 146, 151 (D.C. Cir. 1986), aff'd, 484 U.S. 9, 108 S. Ct. 271, 98 L. Ed. 2d 228 (1987)).The lack of such disclosure stymied CTL's ability to advocate their position and does not meet the "relatively detailed and nonconclusory" standard. FDA'S CDER division has not met its burden of

proving that it conducted a reasonable search of all available repositories as a matter of law. Defendant-Appellee's Motion for Summary Judgment should have been denied.

When agency affidavits fail to meet standards, a "district court will have a number of options for eliciting further detail from the Government. It may require supplemental affidavits or may permit appellant further discovery." Halpern, 181 F.3d at 295. Further, courts have consistently held that "a court should not, of course, cut off discovery before a proper record has been developed; for example, where the agency's response raises serious doubts as to the completeness of the agency's search, where the agency's response is patently incomplete, or where the agency's response is for some other reason unsatisfactory." Exxon Corp. v. FTC, 466 F. Supp. 1088, 1094 (D.D.C. 1978). See Halpern, 181 F.3d at 295 (noting that when an affidavit fails to meet standards, a district court "may permit [plaintiff] further discovery"). Baker & Hostetler LLP v. United States DOC, 374 U.S. App. D.C. 172, 473 F.3d 312, 317 (D.C. Cir. 2006) (quoting SafeCard Servs., Inc. v. SEC, 288 U.S. App. D.C. 324, 926 F.2d 1197 (D.C. Cir. 1991); Weisberg v. United States Dep't of Justice, 200 U.S. App. D.C. 312, 627 F.2d 365, 371 (D.C. Cir. 1980) (holding "[c]ourts have ample authority to protect agencies from oppressive discovery for example, by limiting the scope of permissible

questioning," but cautioning that "the court becomes unduly restrictive when it bans further investigation while the adequacy of the search remains in doubt").

In this case, there were material factual issues, all seemingly improperly resolved on summary judgment in favor of Defendant-Appellee. There were, of course, no depositions, answers to interrogatories, or requests for admissions because the Court specifically denied each and every such request made by Plaintiff-Appellant to obtain said evidence. Alternatively to discovery, Appellant invited the Court to make its own very simple supplemental request regarding specific facts to the Agency.

Improperly and unfortunately, transparency is the exception, not the rule, at the FDA. The “Pazdur” declaration is completely conclusory and lacks sufficient detail regarding his search.

s/Kerry M. Donahue
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Kerry M. Donahue

CERTIFICATE OF SERVICE

It is hereby certified that a copy of the Appellant's brief was filed by e-filing and thus is understood to be served on Appellee's Counsel John Stark, U.S. Attorney's Office, 303 Marconi Boulevard, Suite 200, Columbus, OH 43215 this 3rd day of March 2010.

s/Kerry M. Donahue
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Kerry M. Donahue

CERTIFICATE OF COMPLIANCE

Pursuant to Sixth Cir. R. 32(a)(7)(c), the undersigned certifies this brief complies with the type-volume limitations of Sixth Cir. R. 32(a)(7)(B).

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