

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

BRIEF OF APPELLANT

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STATEMENT IN SUPPORT OF ORAL ARGUMENT

Plaintiff-Appellant, CareToLive, respectfully requests that the Court grant them oral argument in this case. Appellant affirms to the Court that their appeal is meritorious and worthy of oral argument.

**STATEMENT OF SUBJECT MATTER AND APPELLATE
JURISDICTION**

This Court has jurisdiction of a final judgment of the Southern District of Ohio, Eastern Division.

This appeal is from a Final Judgment Entry, disposing of all claims with respect to all parties on June 23, 2009 (dct. #.40).

Notice of Appeal was timely filed with this Sixth Circuit Court on August 14, 2009.

STATEMENT OF APPLICABLE STANDARD OF REVIEW

The Appellate court reviews *de novo* a District Court decision to dismiss a Complaint upon Summary Judgment.

STATEMENT OF ERRORS

- I. IT WAS ERROR FOR THE DISTRICT COURT TO DENY THE PLAINTIFF'S MOTION UNDER RULE 56(f) AND TO DENY THE APPELLANT'S DISCOVERY REQUESTS.

- II. IT WAS ERROR FOR THE DISTRICT COURT TO FIND THAT SUMMARY JUDGMENT SHOULD BE GRANTED TO APPELLEE CONSIDERING APPELLEE DID NOT SUSTAIN THEIR BURDEN TO SUSTAIN THAT REQUESTED RELIEF.
 - A. IT WAS ERROR FOR THE DISTRICT COURT TO GRANT SUMMARY JUDGMENT IN FAVOR OF APPELLEE WITHOUT ALLOWING ANY DISCOVERY AND/OR ALLOWING APPELLANT TO FILE A COMPLETE RESPONSE TO THE APPELLEE MOTION FOR SUMMARY JUDGMENT.

SUMMARY OF CASE

On August 15, 2007 CareToLive (CTL) requested documents from the Food and Drug Administration (FDA) relative to proceedings regarding the licensing of Provenge, an immunotherapy made by Dendreon Corporation, meant for treatment of late stage prostate cancer. The FDA acknowledged receipt of the request as of September 11, 2007. For purposes of this appeal, Appellant is willing to agree that the effective date of the filing for purposes of calculating the due date was September 11, 2007.

The documents were requested by Appellant under the Freedom of Information Act (FOIA) 5 U.S.C.A. § 552. Believing that the Center for Drug Evaluation and Research (CDER) division of the FDA might have responsive documents the FDA FOIA Director sent the request to that division. When the documents were not forthcoming from CDER in accordance with the provisions of the Freedom of Information Act, Appellant filed a motion to enforce the provisions of that act, in the then pending case of CareToLive vs. Andrew von Eshenbach, Case No. 07-729, in the Southern District of Ohio. The motion filed in that case, to enforce the FOIA, was dismissed without prejudice to filing a separate FOIA Complaint if the CDER division of the FDA continued to fail to properly respond. The CDER division of the FDA did continue their refusal to timely provide the

requested documents. A separate FOIA Complaint was then filed by Plaintiff-Appellant on January 5, 2008 in Case No. 08-005. On February 18, 2008 Defendant-Appellee filed a motion to stay proceedings. The court granted the Defendant-Appellee's motion to stay the case (Doc. #. 23) until December 1st 2008 but instructed Defendant that they could have additional time up to May 18th 2009 if they so requested, on the condition that they provided more specifics regarding the reasons for and the amount of time they needed to respond to the FOIA request on or before December 1st (Doc. # 28). On December 1st Defendant-Appellee did request an additional 11 months from the District Court but were instead provided only the additional time until the May 18th date, as previously indicated by the District Court. This extension was granted by the Court even though no further specificity was provided by Defendant-Appellee as was previously ordered by the District Court. The December 1st request for more time, made by Appellee, was again based on the previously asserted "complex" nature of the information request and that motion was granted by the District Court, apparently, in part, on the basis that it was a "complex" search as asserted by Defendant-Appellee. To the contrary the FOIA request was exceedingly simple and very narrowly defined and the classification of it as "complex" was in bad faith.

On May 19th 2009 some 20 months after the original FOIA request, the Defendant-Appellee finally responded to the CareToLive FOIA request by filing an incomplete and evasive response. Both the response and the search were conducted in bad faith. The FDA failed to use due diligence to obtain a proper response for Plaintiff-Appellant during the 20 months they were given to conduct the so called “complex” search and production. In addition, the FDA failed to use due diligence to maintain important public records even though such action was previously ordered by the District Court.

Prior to this long awaited response by the CDER division of the FDA; Concerned about the possible destruction of documents by CDER employee Richard Pazdur, the Appellant filed a motion to preserve evidence in Southern District of Ohio, Eastern Division, Case No. 07-729, on August 1, 2007 (Doc. # 3 of 07-729). That motion was denied by the District Court (Doc. # 20) but the Court did include in its written order denying Plaintiff-Appellant’s motion that no documents involved in the litigation be destroyed and did orally instruct counsel for Defendant-Appellee including counsel for FDA employee Richard Pazdur, to instruct their clients not to destroy any documents. The Court stated in the written part of the order:

(5) The Court DENIES Plaintiff’s Motion for Order to Preserve Evidence. (Doc. # 3.) *Defendants have represented that they are well aware of their*

obligations to preserve relevant evidence and that they took steps to ensure preservation of evidence at the outset of this litigation. Despite Plaintiff's vague assertion in its motion of "specific cause to fear" the destruction of documents, Plaintiff did not present any facts at the conference supporting the need for the requested order. (Emphasis added.)

As would become a trend over the course of two cases and several years of litigation, the District Court asserted that Plaintiff lacked specific evidence yet the Court denied repeated reasonable requests made to that District Court to conduct some simple limited discovery to obtain that evidence, both before and after Appellee filed their motion for summary judgment in this case. The evidence, as the District Court knows, is and has always been within the hands of Appellee. More importantly, the District Court did set forth in that order that Defendants (which included Richard Pazdur) assured the Court that they took steps to preserve evidence at the outset of the litigation. That litigation was filed July 30, 2007, in the midst of swirling controversy over actions of the FDA and specifically Richard Pazdur, relative to the Provenge matter.

As it turns out, the Plaintiff-Appellant's fears were indeed very well founded. The FOIA response finally sent to Appellant CareToLive by the CDER division of the FDA, just prior to the expiration of the *extended* stay of Court proceedings (May 2009), indicated that the documents requested *could not be provided because they had previously been destroyed by CDER employee Richard*

Pazdur. The destruction of documents was done in bad faith. Further, the assertion that those documents cannot still be easily recovered is yet another example of the bad faith of Appellee.

The reason that the FDA obtained the extended stay from the District Court was based on the spurious argument that the request was “complex”. Prior to the CDER response, Appellant had argued to the District Court that the request was very simple and straightforward as it requested just a few on site documents, and thus was clearly not “complex” (Doc. # 18). The time frame for the requested correspondence was even narrowly made for a one month period of communications regarding a very specific topic. Appellant also requested the Court allow some very simple discovery so as to demonstrate that the “complex search” argument was a merely a ruse or delaying tactic by Defendant-Appellee (Doc. # 20), long before the evidence, as seen on the face of FDA’s final response, showed that the search was in fact not at all complex. If Defendant FDA did in fact take steps to preserve evidence, as set forth to the District Court by Appellee (per the Court decision in response to the Plaintiff’s Motion to Preserve Evidence), then they would have known about the destroyed documents nearly 2 years before they shared that information with Appellant and/or the Court. This fact would also have been discovered if a simple request for admissions and/or interrogatories would

have been allowed, as requested. However, the Court denied all of Appellant's request to conduct limited discovery (Doc. #24). The limited discovery, if it would have been allowed, at a minimum, would have shown much earlier that the documents had already been destroyed and deleted, IF in fact they were actually destroyed prior to the assertion by the FDA that a the search and production would be "complex". The Appellant made a second request for limited discovery on December 1, 2008 (Doc. # 26); and again upon the filing of the motion for summary judgment by Defendant-Appellee, which was also denied by the District Court. For its deceptive bad faith actions in this matter the FDA was rewarded, because it avoided disclosing the alleged destruction, at a time when Congress and the world was closely looking into the matter and the media was focused on the controversy surrounding the FDA actions in the Provenge matter.

Following that partial, evasive, and incomplete response to Appellants FOIA request by the FDA, which they filed on May 18, 2009, the Defendant-Appellee filed a motion for summary judgment indicating that since the documents had been destroyed they no longer had the documents to produce and therefore summary judgment should be granted in their favor. Plaintiff-Appellant as part of the 56(f) motion again requested to do some discovery on the issue in order to determine the date of destruction and/or if the documents were retrievable from the computers at

the FDA, via the back-up system or on the internet server and/or on the harddrive. The Plaintiff-Appellant's request for this limited discovery also included a request that the Court order a more specific and complete supplemental affidavit be provided by the Defendant-Appellee but this too was denied. The Plaintiff-Appellant at its own expense also offered to provide the District Court with an affidavit from an IT expert that explained why those documents remain retrievable even after the computer operator believes they have been destroyed. Plaintiff-Appellant filed only a partial response to the Motion for Summary Judgment along with a motion under Federal Rule of Civil Procedure 56(f). The District Court denied the motion filed under Rule 56(f) and simultaneously granted the Defendant-Appellee's Motion for Summary Judgment. Appellant was given no further opportunity to respond completely to Appellee's Motion for Summary Judgment. The Plaintiff-Appellant's Rule 56(f) motion was denied by the District Court at the same time the Court granted the Appellee Motion for Summary Judgment.

Plaintiff-Appellant had requested that the District Court allow them to further respond to the Motion for Summary Judgment by providing an affidavit from their forensic computer expert and/or after allowing them to conduct some very limited discovery to determine the true availability of the documents the FDA

claimed were once possessed but later deleted and destroyed. Both requests were denied by the District Court. The granting of the Defendant-Appellee Motion for Summary Judgment by the District Court terminated the case and resulted in this Appeal.

- I. **IT WAS ERROR FOR THE DISTRICT COURT TO DENY THE PLAINTIFF’S MOTION UNDER RULE 56(f).**

- II. **IT WAS ERROR FOR THE DISTRICT COURT TO FIND THAT SUMMARY JUDGMENT SHOULD BE GRANTED TO APPELLEE CONSIDERING APPELLEE DID NOT SUSTAIN THEIR BURDEN FOR THAT REQUESTED RELIEF.**
 - A. **IT WAS ERROR FOR THE DISTRICT COURT TO GRANT SUMMARY JUDGMENT IN FAVOR OF APPELLEE WITHOUT ALLOWING ANY DISCOVERY OR ALLOWING APPELLANT TO FILE A COMPLETE RESPONSE TO THE APPELLEE MOTION FOR SUMMARY JUDGMENT.**

FACTS AND ARGUMENT

On February 18, 2008 Defendant-Appellee, CDER division of the FDA advised the lower Court that responding to the Plaintiff’s FOIA request was “complex” and that there was no urgent or compelling public reason that justified giving the FOIA priority over other important FOIA requests to the agency. See “Defendant’s Motion to Stay”, Doc. # 10, p. 3.

DIDP assigned it to the “Complex Track” because DIDP determined that Plaintiff’s request sought documents not readily available and would require DIDP to search for and possibly redact documents. Sager

Decl. ¶ 29.

Plaintiff-Appellant properly argued that the labeling of this matter as “complex” by the FDA was a legal and tactical maneuver that was a complete and utter fiction. This Provenge decision was very controversial, was being widely covered by the media and even resulted in a call for an investigation into conflicts of interest among FDA special employees by three members of Congress; so it was important to Defendant-Appellee not to have to make any disclosures, such as the fact the person at the center of the controversy, Richard Pazdur (also known as the “cancer czar”), had destroyed documents involved in the very controversial matter. Plaintiff previously and properly argued to the District Court that this was *not* a complex matter and suggested that the documents could even still be easily located on the computer of CDER employee Richard Pazdur, at the main office of the FDA in Rockville, Maryland. The response essentially seeks correspondence between the FDA and two oncologists recruited by Richard Pazdur for the Provenge AC, between the specific dates of 3/29/07 and 4/30/07. Specifically the entire request consisted merely of the following:

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 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.

The final response, provided 20 months later from the FDA, indicates clearly that neither FOIA personnel nor anyone else within the agency, and specifically, within the agency’s information technology (IT) office, ever conducted a reasonable search for the documents.

On March 25, 2008, long before the final response by the FDA, Plaintiff had requested leave of the District Court to conduct limited discovery by allowing submission of 20 requests for admission to FDA employee Richard Pazdur (which request was later renewed in the Appellant’s motion under Rule 56(f). That request was made long before the later disclosure by the FDA that Richard Pazdur claimed to have destroyed the documents. The District Court originally denied that discovery request *without prejudice to making the request again at the end of the period of stay*, Doc. # 24. Upon the end of the first period of stay, on December 1, 2008, Plaintiff-Appellant did just that; made a second motion for leave to conduct discovery by submitting 20 interrogatories to Defendant FDA. That motion was also denied by the District Court.

The District Court could have at a minimum simply ordered, after two years of litigation and as requested by Appellant, that the FDA at the least have its own IT employee conduct a search for the documents that were admittedly on the computer of Richard Pazdur at some point in April and May 2007 and provide a supplemental affidavit relative to that search to the Court. It was not as if the Appellee could claim surprise regarding the destruction, considering that the fear of such destruction by Richard Pazdur was announced to the Court by motion in another related case and was also even set forth in the Plaintiff's Complaint in this case. The following was set forth in the Appellant's Original FOIA Complaint filed on January 2, 2008 paragraphs 17 and 18.

17. That there are documents responsive to the request possessed by CDER and the Commissioners office is undeniable unless the documents have been destroyed in which case FDA (FOIA), IT employees can recover them.

18. Since there is a fear that some e-mails and hard copies of documents may have disappeared (communications sent to OOD head Richard Pazdur) and may need to be retrieved by an IT person, the order to produce must include a review by IT of the computer hard drive and/or server (IP) of OOD head Richard Pazdur.

Rarely has a Plaintiff so clearly set forth relief that depended on a then unknown but anticipated destruction of documents and even identified the destroyer, which destruction was never admitted until done so in pleadings in this

case by the Appellee, on May 18, 2009. Even that disclosure was made only on Court order on the last day of an extended period of stay obtained by Appellee. Those actions were taken in bad faith.

The FDA responded to the Appellants' FOIA request on the last day of the 15 month period granted to them by the District Court to respond. That response was one page in length and had attached to it a four page letter to then Commissioner Andrew von Eschenbach, which had already been received by Plaintiff directly from the Commissioner in January 2008 (after the media questioned the commissioner's original claim not to possess any responsive documents). At the time the CDER response was provided to Appellant and the Court the FDA contemporaneously filed an affidavit prepared by employee Richard Pazdur declaring that *he did in fact have correspondence relative to the CareToLive FOIA request but that it had all been deleted from his computer and otherwise destroyed by him*. Richard Pazdur claimed not to know the specific date of deletion of the documents on his computer or the date of the shredding of his hard copies.

The first page of the final FOIA response from the CDER Division of the FDA stated that "the following charges may be included in a monthly invoice":
Search \$0

Review \$0

Reproduction \$0.40

Total 0.40.

The “complexity” of the search, the request, the review, and the response is indicative of the amount of resources actually expended by the FDA to conduct this so called “complex” review, which took more than 20 months to compile. In disregard of the importance of this matter to late stage prostate cancer patients who were waiting for this treatment, and who were without other viable treatment options, the Defendant FDA took nearly 20 months to tell the District Court that the documents had been destroyed and deleted possibly/allegedly before the FOIA request was first made, and conveniently just before the Court order not to undertake such destruction. That the alleged destruction may have occurred during pending litigation by CareToLive against the FDA and Richard Pazdur and/or after the District Court order regarding destruction of documents, while suspected to be true, is unknown, but could/can be easily discovered. Even if the attempted destruction occurred earlier as somewhat suggested by the Appellee, the destruction of that correspondence at any time under the circumstances existing was bad faith on the part of FDA employee Richard Pazdur and calls for further inquiry. It is not as if these were dusty 10 year old documents, these were documents involved in a

pending controversial matter at the FDA and were sent and/or received between March 29, 2007 and April 30, of 2007. The Appellee has consistently argued that the Provenge matter is still an “ongoing process” so the destruction of documents regarding an ongoing process demands further inquiry.

While the destruction should have been already known to Appellee long before the first stay was granted, the Appellee still had the audacity, prior to the expiration of the original stay, to seek an additional eleven months of response time in order to expose to the Court that the documents were destroyed and deleted. The unlikely alternative is that nobody but Richard Pazdur knew of the destruction and therefore when he knew he told nobody until the FDA FOIA director happened to walk in his office (or call him) in another part of the building and ask him if he had any responsive documents to which he said “not anymore” wherein they asked him to supply an affidavit to that effect. This would have been almost 2 years after Richard Pazdur knew the controversial documents were being sought. If the alternative reality existed then it was also likely that the destruction by Richard Pazdur was clandestine and for the purpose of hiding the truth of the matter to the public. Either way the FDA did not perform the “complex” search that it promised the Court and Appellant that it was conducting. The search time incurred by the FDA CDER division FOIA office was so slight that it did not even

register on the radar as a significant reportable/billable search time. That was the entire “complexity” of the search and response.

Employee Pazdur was a Defendant in the original litigation filed in July of 2007 and through media statements he made, was well aware of the sensitivity of the documents sought and was subject to the District Court order in that case. That the FDA designated the FOIA request “complex” was at best a mistake, and at worst intentionally misleading. Appellee should not have been able to later claim destruction and deletion and further refuse to supply the date of deletion when they have the capacity to easily discover the date of alleged deletion from the FDA computer (the footprint). The District Court should have allowed discovery on this matter not only because federal employees have a duty to preserve documents but more importantly the destruction may have been an intentional violation of a Court order or undertaken during pending litigation, by an important high level Federal Government employee. Whether the documents are completely destroyed and currently unretrievable and without a remaining “footprint” is unknown based on the limited and almost complete lack of search and/or search information provided by the FDA. That information is easily discoverable and/or easily produced upon Court order.

The Appellee wanted to have it both ways. On the one hand, they claim that Plaintiff's request was "complex", but on the other hand, to answer it, all they did was essentially ask employee Richard Pazdur (who was listed as a "cc" on some of the correspondence, which are in part, the object of the search) if he had any responsive documents; to which he obviously declared that "no, he did not have them any longer". And that, apparently, began, and ended, the Agency's "complex" search for the documents. When asked by the FDA FOIA office to produce an affidavit regarding the status of the sought-after documents, Richard Pazdur simply wrote that while he had the requested communications in his possession at one time, *both* in hardcopy and softcopy (on his computer), he had shredded and deleted them, respectively. That affidavit by Richard Pazdur that indicates previous possession on a particular FDA computer makes this case unique among FOIA cases. That admission came not readily but only after the FDA Commissioner was called to task by the media for failing to "possess" letters addressed and cc'd to him which he then located. That admission by Richard Pazdur came not readily, but only after avoiding responding for 20 months.

Richard Pazdur allegedly took this action despite the fact that he was named a Defendant in a lawsuit filed by CareToLive in July of 2007. He alleges he took this action of destruction even though at the time of destruction there would have

been a pending decision scheduled to be made by the Center for Biologics Evaluation and Research (CBER) on May 15, 2007, regarding the direct subject matter of the communications. Despite his contentions, Richard Pazdur was intricately involved in the Provenge Biologics License Application (BLA) process and actively lobbied CBER regarding their decision both within the FDA and within the media. It is Richard Pazdur's tenuous position that he was not a *supervisor* of CBER, and so, because the documents were unimportant to him as a non-supervisor, he did not keep any of them. This statement is incredulous considering the importance of the matter and the immediate uproar the May 2007 decision caused in the media and among patient advocates, not to mention severely tries to understate his power and influence within the agency (at other times Richard Pazdur has indicated that he "is" the FDA and was referenced during the Provenge AC hearing as "someone in this room" by Dr. Maha Hussain to add emphasis to her coached declarations at the Provenge AC). Richard Pazdur has never voiced any objection to being called the "cancer czar" and actively seeks media attention. Further, in his response to the FOIA request, by purposeful omission, he does not discuss whether there were communications about, and/or with (as in accompanying), those letters. There was certainly accompanying communications because all the other e-mailed employees at the FDA including

the FDA Commissioner did in fact have accompanying communications so they were unlikely sent in a vacuum. Richard Pazdur did not deny that there were such communications and/or whether they were also destroyed rather he just purposefully avoided addressing it in the manner of his response to the District Court. The evasiveness of the response does not indicate whether he construed the request to also ask for the “means of communication” which was defined by CBER to include the e-mails accompanying or discussing those letters (so whether they were also allegedly deleted is unknown). He purposefully avoided the discussion of the e-mail introduction to what has been termed by many as “The Cancer Letters”. Richard Pazdur was invited to be a part of the process of the evaluation of Provenge by CBER, as admitted by CBER in that divisions response to the CareToLive Citizen Petition and in other motion/pleadings, and further, he did undeniably play a very important role in the review of the drug. Specifically, two oncologists who served as special government employees on the Provenge Advisory Committee (AC) meeting on March 29, 2007, were in fact consultants to Richard Pazdur and to his CDER division (within the FDA a more politically powerful division than CBER). They were placed on the Advisory Committee as part of the panel of experts at his request. Further, Richard Pazdur was present at the AC hearing and was observed exchanging notes (coaching) his invited panelist

(Dr. Maha Hussain), who did participate both in the deliberations and in the decision-making process (i.e., vote) on Provenge. Thus, the statement of Richard Pazdur that the documents were not of interest to him does not ring sincere. This is especially so when the FDA defense of the decision, post decision, which was widely criticized by physicians, scientists, and advocates, immediately after the decision was made on May 8, 2007, was largely led by Richard Pazdur in the media. It was the next day after the May 8th decision that Dr. Mark Thornton labeled the decision day as “Black Wednesday” in a now infamous op-ed he wrote in the Wall Street Journal. Mr. Pazdur would have this Court believe that when he received an important letter from a world-renowned oncologist, that not only was a consultant to him previously, but also, that he himself thought an appropriate expert for the panel....an oncologist with whom he had many years of experience working with and who was involved in numerous clinical trials involving drugs for prostate cancer, that he none the less felt the letter was “unimportant”. The communications were so meaningless to Richard Pazdur that he shredded the hard copies and deleted the electronic copies of all communications with his very own consultants/experts, that he thought worthy or recruiting himself, despite the resulting outrage when portions of those letters appeared in a media publication run by an associate of Richard Pazdur. The fact is, the letters, portions of which

were leaked to the publication called The Cancer Letter, a non-peer-reviewed newsletter published in Washington, DC, either before or shortly after they were delivered to Richard Pazdur at the FDA, created an overnight firestorm and Richard Pazdur was well aware of that firestorm and he was immediately believed to be at the center of it (The Cancer Letter was the same newsletter that first published the infamous Imclone/Erbitux information that resulted in Sam Waksil and Martha Stewart being prosecuted and imprisoned and to which the same Richard Pazdur admitted at a Congressional hearing being responsible for leaking). It is an understatement to say these documents and the means of their communication were immediately controversial. The communications from and to Richard Pazdur involved the lobbying of the FDA decision makers and the court of public opinion by two conflicted special government employees, who had both disclosed and undisclosed conflicts of interests and who were selected to participate in the process by Richard Pazdur himself and whom parroted his pronouncements. This action of special government employees (AC panelists) further lobbying the FDA and the media after the AC hearing had ended is contrary to law, was previously unheard of and was not a regular and insignificant event as seemingly asserted by Defendant-Appellee. (CTL can find absolutely no precedent for such an action.)

Richard Pazdur *knew* these documents and the communications surrounding them were and would be important and would be scrutinized from the moment he received them. They were from fellow oncologists that he knew very well. He had specifically selected them himself for the Provenge AC on the basis that he knew they were likely to be critical of Provenge as this new immunological treatment would represent a “new standard of care” for victims of prostate cancer...one that would turn patients away from the current oncologist administered chemotherapeutic treatment of the day (Taxotere) and make it more difficult for the large pharmaceutical houses to run trials over which he and his CDER division held sway. That the approval of Provenge was in the hands of CBER, not CDER, presented a threat to Richard Pazdur’s dominance within the FDA regarding the oversight and approval of cancer drugs and made the matter very personal to him. Richard Pazdur has not shied away from the proclamation that he is the “cancer czar”. He was intent on derailing Provenge as part of a power play within the FDA, once his division CDER had been denied complete control over the drug’s approval, which he sought. There is every reason, therefore, for Richard Pazdur to obfuscate and delay the search for, and the release of, the sought after documents. This is exactly the reason the Freedom of Information Act was passed. To shine the

light and otherwise make more transparent, government actions of this sort by individuals within the government.

Despite the fact that the FDA told this Court that the search of this matter was complex, the total amount of search time was essentially zero, per the FDA invoice for search time. In Defendant's Memorandum in Opposition they state that they provided "detailed declarations describing the agency's thorough searches for documents responsive". The Appellant does not see any such "detailed declarations" describing in detail *the search, anywhere in the record*.

CareToLive did in fact later receive the promised invoice from the FDA (Exhibit B to Plaintiff's Reply to Defendant's Memorandum in Opposition to Plaintiff's Motion under Rule 56(f), to Doc. # 39). That invoice sent by the FDA by regular U.S mail did request that CareToLive mail them 40 cents to pay for the search. Under FOIA the person or organization making the request pays the cost for the search time, review and reproduction. CareToLive promptly obtained a stamp for 43 cents and sent a check to the FDA for the 40 cents. Specifically, the invoice to CareToLive states that the total cost for reproduction, search time, review time, microfiche and other, totaled 40 cents. It was bad faith that the FDA classified a simple request as "complex" then responds so simply and easily 15 months later (having obtained that additional time only because they designated it

“complex”), by providing a single document, said document having previously been provided to Plaintiff from the FDA Commissioner. If the intent of the FDA FOIA office was always to simply ask the embattled Richard Pazdur for the documents verbally, would not a simple phone call to him have sufficed, and would that be anticipated to be a complex phone call? The bounds of the delays and deception delivered unto both Appellant and the District Court on the part of the Appellee knew no limit and add to the doubt that the destruction occurred as indicated.

All of this is even more surprising when one considers that an internal investigation into the Provenge fiasco should have been and likely was initiated more than two years ago. If an investigation was conducted within the FDA then the fact that the documents were destroyed should have been known to FDA Counsel during that previous investigation. In fact, according to the Energy and Commerce Committee of the U.S. House of Representatives, headed up by representatives Dingell and Pallone, the FDA told inquiring members of Congress that they did in fact conduct an internal investigation. The FDA by either not conducting or not otherwise making known publicly that it investigated any of the allegations, made not just by CareToLive but by many others, have caused the FDA to continue to lose credibility with the public over the last several years. That

scrutiny is even more heightened now, in light of the success of Dendreon's Provenge "IMPACT" clinical trial showing definitively that Provenge is a safe and effective treatment for late stage prostate cancer sufferers without viable treatment options, needlessly delayed by the FDA for more than 2 ½ years now. Provenge approval is expected in the coming days/months and will soon become the first immunotherapy to treat cancer ever approved (simply put, immunotherapy trains the body's own immune system to recognize the bad cancer cells and attack them).

While there were ongoing demonstrations in Washington, Chicago, Rockville, and later across the Country regarding the treatment of Provenge and while there were Congressman inquiring of top FDA officials about their handling of the Provenge matter, and under the eyes of the media and while the FDA was suffering through a PR nightmare, Richard Pazdur was determining the importance of communications among himself and the two oncologists that Appellant alleges assisted him to delay Provenge for now 2-1/2 years, he was making the decision they were unimportant and he should destroy them? Nobody in the FDA ever investigated the event until the FOIA office talked to Richard Pazdur in May 2009 by virtue of the CTL FOIA request? This would be contrary to assertions made to various House and Senate representatives and contrary to that which was asserted

in the FDA response to the CareToLive Citizen Petition filed with the agency on July 28, 2007.

While the FDA's memorandum sets forth that the Agency took steps to search, Plaintiff fails to see evidence of any reasonable *search* (Doc. # 29).

The FDA's Nancy Sager says:

18. *Dr. Pazdur did not have any responsive documents.* Dr. Woodcock's staff conducted a search of her files, and they were able to locate only one responsive document, a letter dated April 4, 2007 from Dr. Howard Scher to Dr. Andrew von Eschenbach. Emphasis added.

That is all it says about Richard Pazdur's response? It does not say that any of Richard Pazdur's *staff* conducted a search of Richard Pazdur's files or his computer for correspondence and the means of communication of said correspondence. There was no search of hard drives, back up systems, Internet servers, or any other probing inquiry or actual real search. The FDA clearly knew and should have conducted such an inquiry long before this FOIA Complaint was filed in January 2008. Yet their response was to classify it as "complex" in an effort to cover up the destruction for as long as possible or at least until the media coverage and Congressional interest subsided.

Each of the letters previously turned over by Commissioner von Eschenbach and CBER head Dr. Jesse Goodman that were sent to the FDA by Dr. Scher and Dr. Hussain were sent with other correspondence attached to them or with a

personal message or note introducing the letter. These letters were not sent to the chief antagonist of Provenge, Richard Pazdur, by Dr. Scher and Dr. Hussain without some kind of e-mail introduction and comments and/or an acknowledgment of receipt by Richard Pazdur. This clearly qualified this as a FOIA request that should have been processed as fast track. That it was not, was the first demonstration of bad faith within CDER. Though Richard Pazdur may actually believe that he deleted the e-mails from his government-owned computer, the fact is, all he did was erase their file names from his computer's directory. The sought-after e-mails may still be on his hard drive. (This is tantamount to taking a name plate of a company off the list of the first floor of a building; the space above may or may not still be occupied by the company named on the name plate.)

Regardless, whether or not the e-mails are found on Richard Pazdur's government-owned computer, the fact is, all Government agencies are required to retain electronic (and other forms of documents) for specified periods of time. It would be a relatively simple matter for an information technology (IT) technician or forensic computer expert to search the FDA's e-mail server as well as its Storage Area Network (SAN) e-mail servers using keyword searches. Such searches would rapidly produce the sought after e-mail documents and their attachments.

As stated by the FDA's Frederick Sadler:

On October 10, 2007 DFOI forwarded Plaintiffs request to the DIDP in CDER. DFOI did so, because after consultation with CBER it appeared likely that CDER was also likely to have the requested correspondence.

Richard Pazdur did not deny having the sought after communications, but then he also knew long ago that he was either directly addressed or cc'd on them. He also had a chance to observe the negative treatment of the Commissioner in the media when he was at first not forthcoming with one of the letters.

The FDA's Nancy Sager said this way back on Feb 13, 2008:

Any requests that are not considered simple are placed in the Complex Track.

For requests in the Complex Track, DIDP may need to search, or contact individuals and *direct them to search, numerous agency files*. 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.

However, if DIDP anticipates that a FOIA request in the Complex Track will require *extensive searches for numerous documents in different locations, then multiple individuals in DIDP are assigned to the request. Complex requests that require this level of staffing often involve voluminous records and frequently necessitate extensive time for searching and redaction in order to prepare the records for release. Furthermore, such requests often require substantive input from supervisory staff to determine both the scope of the search and the ultimate releasability of the records.*

27. There are three primary types of organizational and work process changes that have helped DIDP reduced its backlog: (i) *using new information technology systems to increase efficiency;*

In 2001, CDER implemented a new filing system for NDA documents known as the Division Files System ("DFS"), and DIDP integrated this filing system into its document retrieval function. The use of this system was expanded in September 2006 to include abbreviated new drug application ("ANDA") documents. DFS eliminates the paper document search for certain documents and instead *allows electronic searches*. This capability has reduced the time required to search for documents needed to process FOIA requests.

DIDP determined that this request did not meet the criteria for the Simple Track (because it requested documents that were not readily available and would require a search and possible redaction) and therefore assigned it to the Complex Track.

The documents if not destroyed would have been readily available right there at the main FDA building and it appears the FDA thought the same since they never conducted any broader search. It is also clear that the FDA clearly has the ability to do a more extensive search of the computer and the FDA's servers as well as the system back up, the latter being required so that the FDA does not lose important documents. They lack not the ability but merely the desire. The decision of the FDA to look no further than a simple verbal request to Richard Pazdur, in light of the admissions that he once had correspondence and deleted it along with the means of communication of the correspondence, requires that the FDA *at the least actually conduct the complex search that it promised*.

The FDA cannot now say that, "oops", it did not mean that a complex search was needed, and now a simple search is all they will deliver. The Defendant-FDA

cannot and should not be allowed to refuse to have an in house or out of house IT person attempt to recover the communications or to at least determine the date of destruction. This Court cannot allow the FDA to skirt the intent and purpose behind the Freedom of Information Act by designating something complex that they knew is not, in order to get an additional 15 months to respond and then 15 months later say “well, gee, that complex search really was very simple as we are not really even going to conduct a “search” and now gee those documents are now destroyed. So sorry! The Plaintiff could not completely respond to the Defendant-Appellee motion without evidence that is exclusively in the hands of the Defendant and simply discoverable.

Defendant-Appellee FDA complained that such a search as requested by Plaintiff would be too costly. Plaintiff-Appellant does not understand this contention because *it is the Requester and not the FDA that must pay the cost of a requested search. It does not cost the Defendant anything!* All costs of FOIA searches are to be billed to the requester. In this case all costs were in fact billed to Plaintiff-Appellant. Appellant in this case specifically promised to pay all costs associated with such a search. They are supposed to bill for the time spent conducting the search, which in this case they did (40 cents). That the FDA would

trot out “cost” as an illegitimate excuse as to why they did not perform a proper search, lays bare the bad faith that was being perpetrated by them in this case.

Other than the expense, which is a non-starter, the FDA fails to explain the basis for their actions in not conducting a more thorough search of the agencies e-mail computer records (e-mail servers and SAN servers), central back up system, or just Richard Pazdur’s hard drive on the computer, that admittedly previously contained the desired correspondence, and probably still does contain the desired correspondence. Judicial review is frustrated when the Appellee will not disclose why it cannot take additional action to retrieve the correspondence. This Sixth Circuit Court has the right to have this information and to demand further review and explanation from the Appellee.

The District Court seemed to place much too much significance on the fact that discovery is not generally allowed in FOIA cases. This case was improperly pigeon-holed. The District Court failed to recognize the very distinct and unique factual scenario occurring in this very unique case. In this case you have a high profile, widely media covered and controversial matter wherein there was almost immediate pending litigation involving the document destroyer, but yet the high level government employee has been allowed, without even a modicum of allowable inquiry, to assert that he thoughtlessly disposed of the requested

documents smack in the middle of the maelstrom. Further his destruction probably was not fully successful in that the documents likely are still retrievable with minimal effort. While Courts do not *generally* allow discovery in such matters, discovery is proper when any of the following might apply: (1) *when agency action is not adequately explained in the record before the court*; (2) when looking to determine whether the agency considered all relevant factors; (3) *when a record is incomplete*; (4) when a case is so complex that a court needs more evidence to enable it to understand the issues; (5) when evidence arising after the agency action shows whether the decision was correct or not; (6) in certain NEPA cases; (7) in preliminary injunction cases; and (8) *when an agency acts in bad faith*. See, e.g., [*Davis Mountains Trans-Pecos Heritage Assn v. U.S. Air Force*, 249 F. Supp. 2d 763, 776 \(N.D. Tex. 2003\)](#) (Cummings, J.); [*Amfac*, 143 F. Supp. 2d at 11](#).

In some circumstances, the only way a non-agency party can demonstrate to a court the need for extra-record judicial review is to first obtain discovery from the agency." [*Amfac*, 143 F. Supp. 2d at 12](#). In other words, an adequate record can sometimes only be determined "by looking outside the [record] to see what the agency may have ignored." [*Davis*, 249 F. Supp. 2d at 776](#) (citing [*County of Suffolk v. Sec'y of the Interior*, 562 F.2d 1368,1384 \(2d Cir. 1977\)](#)). *Although on notice that the documents might be in unwilling hands, the FDA did nothing to*

verify the veracity or the accuracy of what was claimed to them by a person expected to be exposed by the information, to protect the documents even after Court proclamation to do so, or even investigate apparent chicanery.

This is clearly a case where the FDA has been guilty of having "swept stubborn problems or serious criticism . . . under the rug," so discovery may be permissible. Given the unique and/or unusual circumstances of this case the FDA's CDER division "search" was clearly inadequate.

The Appellant did in fact provide good reason that discovery or an order from the Court that the proper search be completed immediately, or supplemental affidavit be provided, should be ordered or allowed. A proper search or small amount of discovery will uncover the e-mails and/or may at least indicate the date of destruction. Simple questions posed to Richard Pazdur also would indicate why he might have thought it appropriate to destroy letters sent to him by expert oncologists (who are consultants to him), that were selected to participate in the Provenge AC by him, that had taken the time to write highly scientific papers regarding a treatment that was being evaluated by the FDA at the time he received them. So Richard Pazdur states he destroyed documents that the Appellee admits were part of the record of a still ongoing Biologics License Application, which irregularities in the application process were being heatedly disputed by cancer

patient advocates, scientists and physicians and was receiving nationwide media attention. Despite this the District Court quickly denies even limited discovery on the issue and quickly accepts all the precarious propositions asserted by Defendant-Appellee. Richard Pazdur would have received the letters in April 2007, while the FDA was considering approval of Provenge just following the March 30, 2007 AC panel hearing, and prior to the May 15, 2007 PDUFA date, also known as the decision due date. Even limited discovery would have allowed Plaintiff-Appellant to compile more information on the existence of the documents, the precise, location of the documents and/or the date of alleged destruction and whether there was bad faith or delay involved in labeling the request “complex” to avoid earlier disclosure of the documents or destruction thereof. Simple discovery would have allowed Plaintiff-Appellant access so as to present further evidence of bad faith on the part of Defendant-Appellee to the Court or incorrectness as to the current existence of the documents sought. Rarely is there present the extraordinary situation presented in this matter, that at a minimum reasonably compels further inquiry of the FDA.

In the District Court, as part of the Plaintiffs Rule 56(f) motion, the Plaintiff told that Court that if the rule 56(f) was granted or a short extension of time was allowed to file the remainder of Plaintiffs response to the Defendant’s Motion for

Summary Judgment that even without allowing discovery that Plaintiff would submit an affidavit and CV from an IT expert who would present further evidence to that Court that the e-mails are still retrievable from government agencies computers, their e-mail, or their backup (SAN) e-mail servers.

The Freedom of Information Act states:

FOIA 5 USCS § 552

(3) (A) Except with respect to the records made available under paragraphs (1) and (2) of this subsection, and except as provided in subparagraph (E), each agency, upon any request for records which (i) reasonably describes such records and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person.

(B) In making any record available to a person under this paragraph, an agency shall provide the record in any form or format requested by the person if the record is readily reproducible by the Agency in that form or format. *Each agency shall make reasonable efforts to maintain its records in forms or formats that are reproducible for purposes of this section.*

(C) In responding under this paragraph to a request for records, an *agency shall make reasonable efforts to search for the records in electronic form or format*, except when such efforts would significantly interfere with the operation of the agency's automated information system.

(D) For purposes of this paragraph, *the term "search" means to review, manually or by automated means, agency records for the purpose of locating those records which are responsive to a request.*

The Freedom of Information Act itself says that (B) the agency should make reasonable efforts to maintain its records (C) shall make reasonable efforts to

search for the records in electronic form or format, and (D) that search means to review manually or by *automated means*.

Evidence of bad faith stems from the FDA's failure to put forth any argument in the District Court that suggest it took any efforts to maintain documents as mandated by the FOIA. Neither did they put forth evidence that a reasonable search was made, electronic, automated or otherwise, as demanded under FOIA and as made even more necessary considering the circumstances surrounding this very unique case.

The FDA, and the Federal Government in general under the Obama administration, has recently given much lip service to becoming more transparent, but this is a prime example where a government agency allows individual employees not to release documents that they do not want released decreasing rather than increasing promised transparency. The Government speaks of becoming more transparent but increasingly their actions are to be less transparent.

In foot notes/annotations to 5 USCS § 552

Congress finds that—

"(1) the Freedom of Information Act was signed into law on July 4, 1966, because the American people believe that--

"(A) our constitutional democracy, our system of self-government, and our commitment to popular sovereignty depends upon the consent of the

governed;

"(B) such consent is not meaningful unless it is informed consent; and

"(C) as Justice Black noted in his concurring opinion in [Barr v. Matteo \(360 U.S. 564 \(1959\)\)](#), 'The effective functioning of a free government like ours depends largely on the force of an informed public opinion. This calls for the widest possible understanding of the quality of government service rendered by all elective or appointed public officials or employees.';

"(2) the American people firmly believe that our system of government must itself be governed by a presumption of openness;

"(3) the Freedom of Information Act establishes a 'strong presumption in favor of disclosure' as noted by the United States Supreme Court in [United States Department of State v. Ray \(502 U.S. 164 \(1991\)\)](#), a presumption that applies to all agencies governed by that Act;

"(4) 'disclosure, not secrecy, is the dominant objective of the Act,' as noted by the United States Supreme Court in [Department of Air Force v. Rose \(425 U.S. 352 \(1976\)\)](#);

Freedom of Information Act ([5 USCS § 552](#)) is broadly conceived, *seeks to permit access to official information long shielded unnecessarily from public view, attempts to create judicially enforceable public right to secure such information from possibly unwilling official hands*, and attempts to provide workable formula which balances and protects all interests. [EPA v Mink \(1973\) 410 US 73, 93 S Ct 827, 35 L Ed 2d 119, 4 Env't Rep Cas 1913, 1 Media L R 2448, 3 ELR 20057](#) (superseded by statute on other grounds as stated in [Phillippi v CIA \(1976, App DC\) 178 US App DC 243, 546 F2d 1009, 2 Media L R 1208](#)) and (superseded by statute on other grounds as stated in [Brandon v Eckard \(1977, App DC\) 187 US App DC 28, 569 F2d 683, 3 Media L R 1731](#)) and (superseded by statute on other grounds as stated in [CNA Fin. Corp. v Donovan \(1987, App DC\) 265 US App DC 248, 830 F2d 1132, 44 BNA FEP Cas 1648, 34 CCF P 75389, 44 CCH EPD P 37424](#)) and (superseded by statute on other grounds

as stated in [Halpern v FBI \(1999, CA2 NY\) 181 F3d 279, 187 ALR5th 495](#).
Emphasis added

FDA employee Richard Pazdur would be an *unwilling official hand* and the purposes of the FOIA are undermined by *allowing him to completely control the response* and limit any meaningful inquiry.

The policy of the Freedom of Information Act requires that disclosure requirements be construed broadly. [Bristol-Myers Co. v Federal Trade Com. \(1970, App DC\) 138 US App DC 22, 424 F2d 935, 1970 CCH Trade Cases P 73120, cert den \(1970\) 400 US 824, 91 S Ct 46, 27 L Ed 2d 52](#). The primary purpose of the Freedom of Information Act, which provides generally for disclosure of agency records and information, is to open administrative processes to scrutiny of press and general public. [Renegotiation Bd. v Bannerkraft Clothing Co. \(1974\) 415 US 1, 39 L Ed 2d 123, 94 S Ct 1028](#). Purpose of Freedom of Information Act is to pierce veil of administrative secrecy and open agency action to light of public scrutiny. [Wis. Project On Nuclear Arms Control v United States DOC \(2003, App DC\) 354 US App DC 373, 317 F3d 275](#), reh, en banc, den (2003, App DC) [2003 US App LEXIS 11339](#).

Basic purpose of Freedom of Information Act is to insure informed citizenry, which is vital to functioning of democratic society, and is needed to

check against corruption and to hold governors accountable to governed.

[Westchester General Hospital, Inc. v Department of Health, Education & Welfare \(1979, MD Fla\) 464 F Supp 236.](#) Interests must be balanced, yet place emphasis on fullest responsible disclosure. [Dep't of the Air Force v Rose \(1976\) 425 US 352, 48 L Ed 2d 11, 96 S Ct 1592, 1 Media L R 2509.](#)

Disclosure of material in government files has now become the rule, not the exception; Freedom of Information Act, was intended to increase public access to such records through imposition of liberal disclosure requirements limited only by specific, narrowly constructed exemptions and does not authorize withholding of any information except as specifically stated. [Stokes v Brennan \(1973, CA5 Ga\) 476 F2d 699, 22 ALR Fed 317.](#)

Congress did not intend to confer on District Courts general power to deny relief on equitable grounds apart from exemptions in [5 USCS § 552](#) itself. [Soucie v David \(1971, App DC\) 145 US App DC 144, 448 F2d 1067, 2 Env't Rep Cas 1626, 1 Media L R 2435, 1 ELR 20147.](#) Federal courts have no equitable jurisdiction to approve withholding of information not specifically exempt from disclosure under [5 USCS § 552\(b\).](#) [Getman v NLRB \(1971, App DC\) 146 US App DC 209, 450 F2d 670, 78 BNA LRRM 2101, 66 CCH LC P 12010, 16 ALR Fed 499.](#) Freedom of Information Act authorizes suits both to compel disclosure and to *scrutinize*

governmental Agency's decision to disclose. [Burroughs Corp. v Schlesinger \(1975, ED Va\) 403 F Supp 633, 22 CCF P 80027.](#)

That the Federal Public Records Law or Information Act, through which plaintiff seeks to obtain information denied him by agencies of the United States, was intended to require disclosure of government records to any person on proper application is clear, and in considering the issues raised under a motion for summary judgment should be liberally construed to carry out the express purpose of the act, which is discussed by Judge Croake in [Consumers Union of United States, Inc. v. Veterans Administration, D.C., 301 F. Supp. 796, at 799.](#)

Under [Federal Rules of Civil Procedure 56\(d\)](#), the Court is authorized to ascertain what material facts exist without substantial controversy and what material facts are actually and in good faith controverted. An order may then be made specifying facts that appear without substantial controversy and directing such further proceedings in the action as are just.

Because the term "records" is not defined in the Act, the Court is initially put to the task of deciding which of the items requested by plaintiff may be so classified within the contemplation of the statute. It is unfortunate that attention was not given to this point when the law was enacted since the positive provisions of the Act are all but smothered by some nine broad and generalized statements providing for many exemptions.

Efforts have been made to classify the material which may be considered as a record under the Act, e.g., the General Services Administration adopted the following definition in [41 C.F.R. 105-60.104\(a\)](#):

"(a) Records. The term 'records' means all books, papers, maps, photographs, or other documentary materials, *regardless of physical form or characteristics*, made or received by GSA in pursuance of Federal law or in connection with the transaction of public business and preserved or appropriate for preservation as evidence of the organization, functions, policies, decisions, procedures, operations, or other activities of GSA or because of the informational value of data contained therein."

.....
In Jones on Evidence, 5th Ed., Vol. 3, p. 1043, § 535, is found this helpful statement:

"For all practical purposes the term 'document' may be considered as synonymous with 'writing.' A document has been defined as 'any substance having any matter expressed or described upon it by marks capable of being read.' A writing or document, in addition to handwritten or printed or typewritten instruments, which first come to mind, should include inscribed chattels, photographic or other mechanical reproductions and sound recordings -- even though in the case of sound recordings the inscribed marks may not be visible to the eye and may be read only with the use of mechanical devices."

This Court must assume that since no better definition of the term, "record," is provided by legislative enactment, executive order or controlling judicial determination, reliance may be placed on a dictionary of respected ancestry for a reasonably accurate meaning of the word. In Webster's New International Dictionary, this definition appears:

"That which is written or transcribed to perpetuate knowledge of acts or events; also, that on which such record is made, as a monument; a memorial."

Fact that Agency may no longer be in physical possession of a record is not determinative; if Agency notes what records 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.](#)

No reasonable search was conducted by the Defendant-Appellee. Appellee provided the District Court with no details regarding the method of search they conducted and thus did not meet the burdens placed upon a party requesting summary judgment when properly considered in a light most favorable to Appellant.

That the documents are in a centrally located backup storage location, or part of internal or external server records, does not exempt them from being turned over. The FDA did not provide sufficient detail for the Court to evaluate if they do or do not have the documents. If Defendant-Appellee will not conduct a proper search the Court should allow the Plaintiff-Appellant's own forensic computer expert to retrieve the documents. At a minimum there is a clear factual dispute as to whether the documents currently exist and are retrievable. The FDA does not say they are not available, just that such a search would be expensive (although Plaintiff pays). When discovery requests are granted, the scope is "usually limited to the adequacy of the Agency's search and similar matters." *Voniche*, 412 F. Supp. 2d at 71. See *Schrecker v. United States Dep't of Justice*, 217 F. Supp. 2d 29, 35 (D.D.C. 2002) . An exception to limiting the scope of discovery is made if the plaintiff has made a sufficient showing that the Agency acted in bad faith. It is a simple matter to determine the extent of the search that could have been done and

if in fact it was done. To date, by the FDA response, it appears that a proper search was never done.

Summary Judgment was granted to Defendant–Appellee in this matter yet Appellee did not sufficiently satisfy the burden for summary judgment since there are numerous relative factual disputes that must be resolved. When considering a motion for summary judgment, the Court views the evidence in the light most favorable to the nonmoving party, *Gillis v. Louisiana*, 294 F.3d 755, 758 (5th Cir. 2002), and draws all reasonable inferences in favor of that party. *Hunt v. Rapides Healthcare System, L.L.C.*, 277 F.3d 757, 764 (2001). Factual controversies are to be resolved in favor of the nonmoving party, "but only when there is an actual controversy, that is, when both parties have submitted evidence of contradictory facts." *Little v. Liquid Air Corp.*, 37 F.3d 1069, 1075 (5th Cir. 1994). The Court will not, "in the absence of any proof assume that the nonmoving party could or would prove the necessary facts." *See id.* (emphasis in original) (citing *Lujan v. Nat'l Wildlife Fed'n*, 497 U.S. 871, 888, 110 S. Ct. 3177, 111 L. Ed. 2d 695 (1990)).

The material and genuine issues in dispute include:

1. Whether there was a full and complete destruction of the documents sought.

2. Whether the documents are still available and in the possession of the FDA.
3. Whether there is a footprint of the documents remaining.
4. Whether the correspondence that accompanied the letters was also destroyed by Richard Pazdur.
5. When the alleged destruction took place.
6. Whether there was bad faith on the part of the FDA.
7. Whether the FDA conducted a reasonable search.
8. Whether the FDA violated a Court order.
9. Whether the District Court considered the relief specifically asked for in Plaintiff's Complaint.

It is significant that in a related case, the Plaintiff asked that the FDA be ordered to preserve evidence back in August 2007. It is significant that the FDA gives no specific details describing how it conducted the search. It is significant that the FDA classified the requested search as complex and then did no real search. It is significant that the affidavit by Richard Pazdur is evasive and lacks specificity and it is significant that we know there are responsive documents that at least were on an FDA computer at one time. The best evidence the Plaintiff has of the existence of the communications between CDER employee Richard Pazdur and

the sabotaging oncologists he invited to the FDA panel is the affidavit of Richard Pazdur himself who therein essentially admits that he had the requested correspondence on his computer in the midst of a controversy but tried to delete them. That admission standing alone places this case outside the heartland of FOIA cases and at a minimum demands that Plaintiff-Appellee should have been granted the right to conduct limited discovery on the issue so as to fully respond to the Motion for Summary Judgment. It was error for the District Court, considering the unique circumstances of this case to deny all discovery attempts.

Civil Rule of Procedure 56(e)(1) states: The court may permit an affidavit to be supplemented or opposed by depositions, answers to interrogatories, or additional affidavits. Rule 56(f) states:

- (f) When Affidavits Are Unavailable. If a party opposing the motion shows by affidavit that, for specified reasons, it cannot present facts essential to justify its opposition, the court may:
- (1) deny the motion;
 - (2) order a continuance to enable affidavits to be obtained, depositions to be taken, or other discovery to be undertaken; or
 - (3) issue any other just order.

It is an injustice for the Court to deny the Rule 56(f) motion of Plaintiff to conduct any discovery what so ever, though requests were made, considering that the evidence to be produced is solely within the control of the FDA and cannot be obtained by Appellant without some limited discovery. Even without discovery the

District Court could have, as justice demanded, denied the motion for Summary Judgment until or unless the FDA provided more specificity about the search that was conducted and the alleged destruction of the documents sought. The Court should also have granted the requested relief of Plaintiff-Appellant to order the FDA to provide a supplemental affidavit from an FDA IT employee, considering the evidence that the documents did in fact exist and that he/she performed a reasonable search for the documents based on the information from Richard Pazdur that the communications existed on the FDA computers at some time during at least April 2007.

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. *See, e.g., 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); *Public Citizen Health Research Group v. FDA*, 997 F. Supp. 56, 72-73 (D.D.C. 1998), *aff'd in part, rev'd in part*, 337 U.S. App. D.C. 343, 185 F.3d 898 (D.C. Cir. 1999). Usually after the agency has moved for summary judgment, limited discovery can be allowed when the plaintiff can show evidence of agency bad faith or that an exemption should not apply. *Judicial Watch, Inc. v. Department of Justice ("Judicial Watch II")*, 185 F. Supp. 2d 54, 65

(D.D.C. 2002); *see also Carney v. Department of Justice*, 19 F.3d 807, 812 (2nd Cir. 1994); *Heily v. Department of Commerce*, 69 Fed. Appx. 171, 174 (4th Cir. 2003) (when permitted discovery "generally is limited to the scope of agency's search and its indexing and classification procedures"). 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. At a minimum it was error for the District Court not to order a more specific non conclusory supplement to the affidavits explaining the FDA's actions. This is not the typical FOIA case where the parties are arguing over exemptions that would allow the documents to be withheld. The good or bad faith of the FDA in this case is a material issue and some limited discovery should be allowed.

FOIA requires, that unless an exemption applies, "each agency, upon any request for records which (i) reasonably describes such records, and (ii) is made in accordance with published rules stating the time, place, fees (if any), and procedures to be followed, shall make the records promptly available to any person." 5 U.S.C. § 552(a)(3)(A). A FOIA request must be for a "record." O'Reilly, *Federal Information Disclosure*, § 4:18 (2000 ed. & 2007 suppl.). FOIA itself does not define the term "record." However, courts have looked to another statute, 44

[U.S.C. § 3301](#), for the definition and have defined "record" as "materials that have come into the agency's possession in the legitimate conduct of its official duties." O'Reilly, Federal Information Disclosure, § 4:14 (2007 Suppl.). An agency has a duty to construe a FOIA request liberally. [Truitt v. Dep't of State, 283 U.S. App. D.C. 86, 897 F.2d 540, 544-45 \(D.C. Cir. 1990\)](#) (citing Senate Report accompanying relevant provision of FOIA). 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\(a\)\(3\)\(C\)](#); *see also* [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 \(9th Cir. 1985\)](#). While there is no requirement that an agency search every record system, [Truitt, 897 F.2d at 542](#), or that a search be perfect, [Meeropol v. Meese, 252 U.S. App. D.C. 381, 790 F.2d 942, 955-56 \(D.C. Cir. 1986\)](#), the search must be conducted in good faith using methods that are likely to produce the information requested if it exists. *See* [Campbell v. United States Department of Justice, 334 U.S. App. D.C. 20, 164 F.3d 20, 27 \(D.C. Cir. 1998\)](#).

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) (quoting *Weisberg v. United States Department of Justice*, 240 U.S. App. D.C. 339, 745 F.2d 1476, 1485 (D.C. Cir. 1984))).

CONCLUSION

Civil Rule 56 requires the moving party inform the court of the basis of the motion and to identify "those portions of 'the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any,' which it believes demonstrate the absence of a genuine issue of material fact." *Celotex Corp. v. Catrett*, 477 U.S. 317, 323, 106 S.Ct. 2548, 2553, 91 L.Ed.2d 265 (1986).

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).

There are genuine issues of material fact and upon de novo review of this Court, all inferences being construed in favor of Appellant, on the issues of bad faith, reasonableness of search, and current existence of the records, must be resolved before a final decision can be made based on the relief requested in Plaintiff's Complaint.

REQUEST FOR RELIEF

This Court should reverse and remand the decision of the District Court to deny the Plaintiff's Rule 56(f) motion and the Summary Judgment decision in favor of Defendant-Appellee. This Court should also consider other legal or equitable relief such as ordering that certain discovery be allowed by Appellant or by ordering further acts by the Appellee.

s/Kerry M. Donahue

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 17th day of November 2009.

s/Kerry M. Donahue

Kerry M. Donahue

