

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE)
 TRANSPLANTATION,)
)
 Plaintiff,)
)
 v.)
)
 UNITED STATES FOOD AND DRUG)
 ADMINISTRATION,)
)
 Defendant.)
 _____)

Civil Action No. 00-2849 (RMU)

**DEFENDANT'S OPPOSITION TO PLAINTIFF'S MOTION
FOR AN AWARD OF ATTORNEY FEES AND COSTS**

Defendant, the United States Food and Drug Administration (“FDA”), respectfully submits this Opposition to Plaintiff's Motion for an Award of Attorney Fees and Costs and Memorandum in Support ("Motion"). This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552, *et seq.*, arising from plaintiff's FOIA request of March 9, 2000, for records concerning xenotransplantation clinical trials.¹ This Court upheld the FDA’s revised sample Vaughn index and the FDA completed production of all responsive documents pursuant to that index. In the instant Motion, Plaintiff now requests that the Court award attorney fees and costs associated with this case, arguing mainly that the Court’s order to revise the index caused the FDA to release documents. Because this argument is, for all intents and purposes, the same “catalyst theory” that was rejected by the Supreme Court in Buckhannon Bd. and Care Home,

¹ Xenotransplantation is defined as "any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (A) live cells, tissues, or organs from a nonhuman animal source or (B) human body fluids, cells, tissues or organs that have had *ex vivo* contact with live nonhuman animal cells, tissues, or organs." PHS Guideline on Infectious Disease Issues in Xenotransplantation (Jan. 19, 2001).

Inc. v. West Virginia Dep't of Health and Human Resources, 532 U.S. 598 (2001), and for the other reasons explained below, the Court should deny plaintiff's Motion.

Facts and Procedural Background

Plaintiff's original FOIA request sought all records regarding: (1) applications to conduct clinical trials in humans that involve xenotransplantation; and (2) past and present clinical trials involving xenotransplantation. See Campaign for Responsible Transplantation v. FDA, 180 F. Supp. 2d 29, 31 (D.D.C. 2001) ("CRT I"). Plaintiff subsequently narrowed its FOIA request to include only records pertaining to xenotransplantation clinical trials in general and FDA generated records in the thirty-five investigational new drug applications ("INDs") involving xenotransplantation. Because of the potential volume of records responsive to the FOIA request, even as narrowed, FDA moved the Court for leave to file a sample Vaughn² index for a representative IND rather than a comprehensive Vaughn index for all thirty-five INDs. Over plaintiff's objection, the Court granted FDA's motion. Id. at 35. Plaintiff then selected an IND ("IND G") sponsored by GenVec, Inc., as the representative IND. See Dkt. 119 ("CRT III") at 3.

The parties filed cross-motions for summary judgment with respect to contested issues concerning privileges asserted by FDA and the adequacy of FDA's Vaughn indices for IND G. On September 3, 2002, the Court granted, in part, and denied, in part, the cross-motions for summary judgment. See Campaign for Responsible Transplantation v. FDA, 219 F. Supp. 2d 106 (D.D.C. 2002) ("CRT II") (awarding FDA summary judgment on issue of adequacy of search but requiring FDA to file a more detailed sample Vaughn index). After this ruling, plaintiff agreed to further narrow its FOIA request to include only documents generated by FDA and

² See Vaughn v. Rosen, 484 F.2d 820 (D.C. Cir. 1973).

concerning clinical trials involving pigs and non-human primates, leaving 19 INDs at issue. See Dkt. 119 at 3.

On December 20, 2002, FDA submitted a revised Vaughn index pursuant to the Court's order. See Dkt. 88. The parties then filed revised cross-motions for summary judgment. Plaintiff requested in its motion that the Court order the immediate disclosure of the records associated with the remaining eighteen INDs. See Dkt. 112-1 at 3. In response to plaintiff's request for immediate release, FDA did not contest the issue of whether it would release the responsive documents, rather, FDA merely pointed out that it would be a massive project to produce the documents and that it would take some time:

FDA estimates that there are 126,000 pages of documents that will need to be reviewed in processing the remaining eighteen responsive INDs. Once those documents are collected, it will be an extremely time-consuming process for FDA to review and process all of them. Moreover, prior to release, it is likely that FDA will need to confer with the third-parties who have submitted the INDs and who may have interests in protecting trade secrets and confidential commercial information. Requiring FDA to release these documents immediately – even if it were otherwise possible – would prejudice these third-parties, who would be deprived of an opportunity to protect their legitimate FOIA Exemption 4 interests. This conferring with third-parties is likely to benefit Plaintiff as well – some of the documents pertaining to IND-G that FDA provided to Plaintiff would have been exempt from disclosure under Exemption 4, but for the consent to release by the entity that had submitted the information to FDA.

Dkt. 115 at 3.

On September 24, 2004, the Court granted FDA's motion for summary judgment and denied plaintiff's motion for summary judgment. See Dkt. 118 at 1. The Court found that FDA had properly invoked Exemptions 4 and 5 of the FOIA and upheld the basis for all of FDA's withholding of documents. See CRT III, Dkt. 119 at 2.

The Court's order directed FDA to produce only those documents that were "similar in

kind to the IND G records that the FDA has already released." See Dkt. 118 at 1. This order directly flowed from the reasoning underlying the preparation of a representative Vaughn index; after the court and all parties agreed to the universe of material to be released, FDA would search the remaining 18 INDs for such releasable material--according to the sample Vaughn index--and produce it to plaintiff. See Dkt.115 at 3. Importantly, FDA never contested the actual release of these records or portions of records. The Court acknowledged, in its opinion, that the parties were in agreement on the timing and scope of the documents to be produced:

Despite some initial disagreement between the parties as to when the FDA had to release the other IND documents, it appears that *the parties both understood that the disclosure was to occur after the court's ruling on the cross-motions for summary judgment*. That time has arrived. Because IND G was supposed to be representative of all of the INDs, the FDA must now disclose all FDA generated records that pertain to the other 18 INDs that are similar in kind to the IND G records that the FDA has already released.

CRT III, Dkt. 119 at 22 (internal citations omitted) (emphasis added). The Court did not identify a deadline for production and did not require any process different from that described in FDA's opposition to plaintiff's motion for summary judgment. See Dkt. 124-2 at ¶ 12.

On April 1, 2005, plaintiff moved the Court to order FDA to expedite processing of the remaining uncontested, releasable documents. See Dkt. 123. On May 3, 2005, the Court denied plaintiff's motion. See Dkt. 128.

Legal Standard

Under FOIA, a plaintiff may be awarded attorney fees only if: 1) the plaintiff is *eligible* for such an award; and 2) the plaintiff is also *entitled* to the award. 5 U.S.C. § 552(a)(4)(E); see also Tax Analysts v. U.S. Dep't of Justice, 965 F.2d 1092, 1093 (D.C. Cir. 1992). A plaintiff who "substantially prevails" under FOIA is *eligible* for such an award. Oil, Chemical and

Atomic Workers Intel Union, AFL-CIO v. U.S. Dep't of Energy, 288 F.3d 452, 454 (D.C. Cir. 2002). However, eligibility for fees is not dispositive. If a plaintiff is eligible, a court should then consider a number of factors in determining whether plaintiff is *entitled* to fees, including: the benefit to the public, if any, derived from the case; the commercial benefit to the plaintiff and the nature of its interest in the records sought; and whether the Government's withholding of the records sought had a reasonable basis in law. Tax Analysts, 965 F.2d at 1093. Furthermore, an award of fees is a matter left to the sound discretion of the Court. Id. at 1094; see also Chamberlain v. Kurtz, 589 F.2d 827, 842 (5th Cir. 1979), cert. denied, 444 U.S. 842 (1979) ("there is no presumption in favor of awarding attorneys' fees in an FOIA case."). Plaintiff is neither eligible nor entitled to an award of attorney fees, and its motion should be denied.

Argument

I. Plaintiff is Not *Eligible* for an Award of Attorney Fees.

The law is clear that in order for a plaintiff to become eligible for an award of attorney fees under FOIA, it must have been awarded either a judgment on the merits or a court-ordered consent decree. Oil, Chemical and Atomic Workers, 288 F.3d 452, 456-57 (D.C. Cir. 2002). In Buckhannon Bd. and Care Home, Inc. v. West Virginia Dep't of Health and Human Resources, 532 U.S. 598, 600 (2001), the Supreme Court considered whether the term "prevailing party" in federal fee-shifting statutes "includes a party that has failed to secure a judgment on the merits or a court-ordered consent decree, but has nonetheless achieved the desired result because the lawsuit brought about a voluntary change in the defendant's conduct." The Buckhannon Court rejected this type of "catalyst theory" as a basis for an award of attorney fees, stating:

A defendant's voluntary change in conduct, although perhaps accomplishing what the

plaintiff sought to achieve by the lawsuit, lacks the necessary judicial *imprimatur* on the change. Our precedents thus counsel against holding that the term prevailing party authorizes an award of attorney's fees *without* a corresponding alteration in the legal relationship of the parties.

Id. at 605 (emphasis in original).

The D.C. Circuit applied Buckhannon to FOIA cases in Oil, Chemical and Atomic Workers, holding that the "substantially prevail" language in the FOIA attorney fees statute was the functional equivalent of the "prevailing party" language in other statutes. The court held that in order for the plaintiff in a FOIA action to become eligible for an award of attorney fees, it must have been awarded either a judgment on the merits or a court-ordered consent decree. Oil, Chemical and Atomic Workers, 288 F.3d at 456-57 (citing Buckhannon, 532 U.S. at 603). The court further explained that "[t]he discussion in Buckhannon also makes clear that there must be some sort of 'judicial relief' in favor of the party seeking an award of fees." Id. at 458. This required a "court ordered chang[e] in the legal relationship between [the plaintiff] and the defendant." Id. (citing Buckhannon, 532 U.S. at 604) (alterations in original). Additionally, if the defendant voluntarily changed its conduct the court was not to analyze the reasons for such a change in determining whether a plaintiff was to recover fees. Id. at 459 ("Buckhannon clearly instructs that we are not to analyze 'the defendant's subjective motivations in changing its conduct.'").

In this case, plaintiff argues in its motion that it received a favorable judgment on the merits that altered the legal relationship of the parties in both: 1) the Court's September 3, 2002, Order requiring a more detailed Vaughn index, and 2) the Court's September 24, 2004, Order requiring production of the releasable documents remaining in the other INDs, pursuant to the

sample Vaughn index. However, neither order resulted in the release of any contested, withheld documents sought by plaintiff. Rather, as discussed below, those orders set out an organized structure for producing the documents. Therefore, neither order was a judgment on the merits altering the legal relationship of the parties, and plaintiff did not "substantially prevail" under FOIA.

First, the Court's September 3, 2002 order requiring FDA to submit a new sample Vaughn index was an interim order concerning a procedural ruling, not a judgment on the merits that altered the legal relationship of the parties. See Oil, Chemical and Atomic Workers, 288 F.3d at 458-59. Rejecting a Vaughn index is a far cry from ordering production of any particular document, especially when the "remedy" ordered is for the agency to file another Vaughn index. (It bears noting that ordering an agency to produce a Vaughn index does not change any legal obligations of the agency, since producing such an index is necessarily required anyway.)

The September 2, 2002 order did not require FDA to release any documents sought by plaintiff. The purpose of this order was instead merely to give the Court a more adequate basis to consider whether contested documents were lawfully withheld. Indeed, the Court expressly explained:

Rather than rule on the basis of inadequate Vaughn indices, the court orders FDA to submit new representative Vaughn indices with proper detailed document descriptions and reasons for withholding that illuminate the contents of the documents and the reasons for nondisclosure.

CRT II, 219 F. Supp. 2d at 116 (emphasis added). The Court explicitly explained that it was not ruling on the merits but was instead requiring further information so as to rule later on the merits. The order for a new representative Vaughn index thus addressed not the ends but the means of

the litigation, which is not the type of judicial decree that warrants a fee award. See Thomas v. Nat'l Sci. Found., 330 F.3d 486, 493-94 (D.C. Cir. 2003) (in a case brought under a fee-shifting provision similar to the FOIA, fees were not warranted, even though the court entered partial summary judgment for plaintiff, because the order was a mere legal declaration lacking concrete judicial relief sought by plaintiff). At best, plaintiff's argument is simply another version of the catalyst theory squarely rejected by the Supreme Court in Buckhannon. Therefore, the September 2, 2002, order cannot be the basis for a ruling that plaintiff "substantially prevailed" under FOIA.

In the second order on September 24, 2004, which plaintiff contends also demonstrates that it "substantially prevailed," the Court granted summary judgment to FDA and denied summary judgment to plaintiff. See Dkt. 118. The Court upheld *all* of FDA's justifications for exempting documents, or portions of documents, from disclosure. It is patently unreasonable for plaintiff to claim that it substantially prevailed in an order so clearly decided in favor of FDA.

Nevertheless, plaintiff argues that the part of the Court's order that required FDA to produce documents not exempt from release from the remaining 18 INDs was a judgment in its favor. See Dkt. 132-1 at 12. Plaintiff conveniently ignores that the FDA never contested the release of these non-exempt documents. In Oil, Chemical and Atomic Workers, the D.C. Circuit held that a stipulation and order dismissing the case did not constitute a judgment on the merits because the court had no contested issues before it; thus, a court-ordered change in the legal relationship between the parties was impossible. Oil, Chemical and Atomic Workers, 288 F.3d at 458. The D.C. Circuit explained that the stipulation and order in Oil, Chemical and Atomic Workers did not alter the legal relationship of the parties, because "[i]ts only effect was to

dismiss the [plaintiff's] lawsuit with a court order when no court order was needed." Id.

Similarly here, the only effect of this Court's September 24, 2004, Order was to signal the start of the FDA's agreed-upon processing of the non-exempt documents pertaining to the other 18 INDs. FDA explained that it would produce these non-exempt documents after the Court ruled on the cross-motions for summary judgment. See Dkt. 115 at 3 ("[a]fter the Court has ruled on Plaintiff's objections to FDA's withholdings pertaining to IND-G, the government (assuming it does not appeal any adverse decision) will begin processing the remaining INDs, in a manner consistent with those rulings"). It was appropriate for FDA to wait until after the Court's ruling to begin processing the non-exempt documents because, given the volume of documents at issue, FDA needed to know the universe of documents subject to release.

The Court *and* plaintiff concurred with FDA's approach, although plaintiff now claims otherwise in its motion. Plaintiff now erroneously claims that no understanding existed between parties that processing of the non-exempt records pertaining to the other 18 INDs would take place after the Court ruled on the cross-motions for summary judgment. In plaintiff's words, this is a "self-serving statement" by FDA and "simply is not correct." See Dkt. 132-1 at 19 n.5. However, in CRT III, the Court acknowledged that, "the parties both understood that the disclosure [of the non-exempt documents pertaining to the other 18 INDs] was to occur after the court's ruling on the cross-motions for summary judgment." CRT III, Dkt. 119 at 22. Plaintiff stated to the Court that "[w]hile the FDA takes issue with CRT's position that the agency should be required to release all [non-exempt] records 'immediately,' *of course* plaintiff means as soon as possible after the Court rules on the cross-motions for summary judgment." See Dkt. 116 at 2 (emphasis added). This exchange makes clear that the order dealt with how – rather than if – the

documents would be released. There is no basis to view the release of the non-exempt documents as a contested issue before the Court. Thus, the Court's September 24, 2004 Order to disclose the non-exempt documents pertaining to the other 18 INDs was not a judgment on the merits that altered the legal relationship of the parties. Plaintiff did not "substantially prevail" under FOIA.

Despite the obvious weaknesses in plaintiff's case that it is eligible for fees, in an attempt to bolster its argument, it cites three FOIA cases in which a particular plaintiff was deemed eligible. See Dkt. 132-1 at 12, 13 (citing Edmonds v. FBI, 417 F.3d 1319 (D.C. Cir. 2005); Judicial Watch v. U.S. Dep't of Commerce, 384 F. Supp. 2d 163 (D.D.C. 2005), appeal docketed, No. 05-5366 (D.C. Cir. Oct. 4, 2005); and Piper v. U.S. Dep't of Justice, 339 F. Supp. 2d 13 (D.D.C. 2004)). These cases are easily distinguishable. In two of them, the courts, upon the plaintiffs' motions, ruled that the defendants had unlawfully withheld *contested* documents. See Judicial Watch, 384 F. Supp. 2d at 168 ("In the early stages of litigation, the Court ordered [defendant] to release numerous unlawfully withheld documents"); see also Piper, 339 F. Supp. 2d at 20 (ordering release of documents unlawfully withheld under various FOIA exemptions). The orders to release these contested documents were critical in deeming the plaintiff eligible for fees. As explained above, this Court never ordered the release of *any* contested documents sought by the plaintiff. *Every* withholding by FDA was held to be lawful by this Court.

In the third case, Edmonds v. FBI, a court order requiring the expedited processing of a FOIA request supplied the requisite "judicially sanctioned change in the legal relationship of the parties" required for fee eligibility. Edmonds, 417 F.3d at 1322-23. Unlike this case, the court in Edmonds granted plaintiff partial summary judgment compelling defendant to expedite

processing of documents by a specified date. *Id.* at 1324. The facts of this case differ significantly because this Court never ordered FDA to expedite processing of plaintiff's FOIA requests. Nor did this court ever order FDA to turn over the non-exempt documents pertaining to the other 18 INDs by a specific date. Indeed, when plaintiff filed a motion to expedite processing of documents, the Court denied it. *See* Dkt. 128. Plaintiff's reliance on these cases is misplaced and its contention that it "substantially prevailed" is simply untenable.

II. Plaintiff is Not *Entitled* to an Award of Attorney Fees.

Even if the Court were to find plaintiff eligible for an award of attorney fees, it would also have to find that plaintiff was entitled to such an award, in order for plaintiff to prevail on its motion for fees. In deciding whether plaintiff is entitled to an award of attorney fees, a court considers: 1) the public benefit derived from the case; 2) the commercial benefit to the plaintiff; 3) the nature of the plaintiff's interest in the records; and 4) whether the Government's withholding of the records had a reasonable basis in law. *Tax Analysts*, 965 F.2d at 1093. The weight given to each of these criteria is in the Court's discretion. *Id.* at 1094. The entitlement criteria presuppose a victory by the plaintiff in obtaining contested documents. Because that is simply not the case here, the entitlement analysis is inherently problematic. Defendant, nevertheless, analyzes each prong below. An analysis of the criteria here makes clear that plaintiff is not entitled to attorney fees, even if the court were to find plaintiff eligible for such fees.

Under the first prong, this lawsuit has not provided public benefit. FDA has spent countless hours and resources that are much-needed elsewhere defending this lawsuit, and it has not resulted in plaintiff being awarded a single *contested* document. Moreover, plaintiff's use of

the *uncontested* documents does not substantially serve the public interest. In examining this factor, the Court must "evaluate the specific documents at issue in the case at hand," to determine whether "the complainant's victory is likely to add to the fund of information that citizens may use in making vital political choices." Cotton v. Heyman, 63 F.3d 1115, 1120 (D.C. Cir. 1995). Here, as discussed in the eligibility section, supra, there was no victory by plaintiff that might add to the fund of public information. Indeed, FDA did not contest – and plaintiff did not compel – the production of documents that would otherwise be deemed to be non-public or non-releasable. Further, plaintiff plans to use the documents only to further its own mission of "seeking a total ban on xenotransplantation[,]" see <http://www.crt-online.org/>, without balancing possible benefits to the public health of this new medical treatment. Certainly this Court should avoid endorsing plaintiff's position that a "total ban" is necessarily in the public interest.

With respect to the second and third prongs, the documents sought by plaintiff have significant commercial and personal value. Courts have held that "[a]lthough listed as separate factors, the commercial benefit to plaintiff from FOIA disclosure and the nature of plaintiff's interest in disclosure are closely related and often considered together." Piper, 339 F. Supp. 2d at 21 (citing Cotton, 63 F.3d at 1120). Plaintiff is an international coalition and its membership includes physicians, scientists, veterinarians, and lawyers. See Dkt. 132-1 at 3. Without question, members of this coalition could have commercial and personal interests in a ban on xenotransplantation. See Dkt. 132-1 at 2 (in which plaintiff admits that it "believes that there are more . . . cost-effective ways to resolve the alleged shortage of human organs for transplantation. . ." than xenotransplantation). Additionally, the documents sought by plaintiff contained valuable trade secret and confidential commercial information. Had FDA not been victorious in

preventing plaintiff from obtaining information exempt from public disclosure, plaintiff's dissemination of it certainly could have had a significant commercial impact. This effectively undermines any claim to the second and third factors favoring plaintiff.

The fourth prong of the entitlement test weighs so heavily in FDA's favor all by itself that plaintiff cannot possibly be entitled to fees. The D.C. Circuit has held that "although the test of entitlement [to attorney fees under FOIA] involves a balance of several factors, . . . there can be no doubt that a party is not entitled to fees if the Government's legal basis for withholding requested records is correct," Chesapeake Bay Foundation v. USDA, 11 F.3d 211, 216 (D.C. Cir. 1993); see also Piper, 339 F. Supp. 2d at 22 (citing Cotton, 63 F.3d at 1117) ("[u]nder [the fourth prong], where the agency's interpretation of its legal right to withhold information is correct as a matter of law, fees should not be awarded"). Even if an agency erroneously interprets the law, its withholdings will be considered reasonable if the interpretation has a colorable basis in law. See Cotton, 63 F.3d at 1117. In this case, the Court held that *every* withholding by FDA was lawful; thus, plainly plaintiff cannot meet the fourth prong and therefore is not entitled to attorney fees. See Dkt. 119.

Plaintiff's argument that it is entitled to fees for the uncontested, non-exempt documents is misplaced. Because the resolution of the parties' cross-motions for summary judgment would define the parameters for the document production, as a practical matter, FDA could not have started preparing the non-exempt documents until after the Court's September 24, 2004 ruling on the cross-motions.³ This Court *and* plaintiff agreed with this approach. See CRT III, Dkt. 119 at

³ Plaintiff cites Miller v. U.S. Dep't of State, 779 F.2d 1378, 1390 (8th Cir. 1985), for the proposition that "'practical explanations' . . . do not supply the necessary 'reasonable legal bases' for withholding requested records." See Dkt. 132-1 at 19. Miller, though, is distinguishable for

22; see also Dkt. 116 at 2.

Plaintiff also ignores FDA's obligations under Exemption 4 of FOIA, the Trade Secrets Act ("TSA"), 18 U.S.C. § 1906, the FDCA, 21 U.S.C. § 331(j), and the regulations implementing those statutes made the production of these documents very difficult and time-consuming. See Dkt. 124-2. FDA cannot, as plaintiff seems to assume, merely release documents in their entirety without taking into account and protecting trade secret and confidential commercial information. The law makes clear that FDA must diligently protect this information.⁴ Before disclosure, FDA had to first redact confidential commercial and trade secret information from the documents and, in some cases, consult with sponsors who submitted this information to FDA in

several reasons. First, FDA did not *withhold* any non-exempt documents, but diligently undertook the time-consuming job of reviewing, redacting, and releasing over 126,000 pages of documents. In contrast, the production of a mere 360 documents by the defendant in Miller was bogged down for almost two years not only by processing backlogs, but also by confusion and administrative error. See Miller, 779 F.2d at 1378. The documents at issue in Miller were also not replete with trade secret and confidential commercial information, as were documents here. Lastly, Miller was decided before Buckhannon when the "catalyst theory" was still good law. The plaintiff in Miller was found eligible for fees merely because the lawsuit had a causative effect on the release of the information, even though the plaintiff received no favorable judgment. Id. at 1389. After Buckhannon, the plaintiff in Miller most likely have not been found to be eligible for attorney fees and would have never reached the entitlement prong of the test. See Buckhannon, 532 U.S. at 605.

⁴ Exemption 4 of FOIA protects "trade secrets and commercial or financial information obtained from a person that is privileged or confidential." 5 U.S.C. § 552(b)(4). The exemption covers two categories of information in agency records: (1) trade secrets; and (2) information that is (a) commercial or financial, (b) obtained from a person, and (c) privileged or confidential. Nat'l Parks & Conservation Ass'n v. Morton, 498 F.2d 765, 766 (D.C. Cir. 1974). The Trade Secrets Act ("TSA"), 18 U.S.C. § 1906, also prohibits the release of trade secret and commercial or financial information obtained from a person that is privileged or confidential, unless otherwise authorized by law. Additionally, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301, et seq., explicitly prohibits the release by FDA, except in limited circumstances, of information acquired by the agency "concerning any method or process which as a trade secret is entitled to protection." 21 U.S.C. § 331(j).

xenotransplantation INDs. In short, FDA's processing and release of the uncontested, non-exempt documents was surely not obdurate or recalcitrant. See Piper, 339 F. Supp. 2d at 22 (citing Cuneo v. Rumsfeld, 553 F.2d 1360, 1366 (D.C. Cir. 1977) (internal citation omitted) ("This factor seeks to discourage obdurate behavior on the part of the government and weed out those cases where the government was recalcitrant in its opposition to plaintiff's FOIA request.")). Therefore, it is clear that plaintiff cannot meet any – let alone all – of the four prongs of the entitlement test.

CONCLUSION

For the reasons stated above, plaintiff is neither eligible nor entitled to attorney fees and this Court should deny Plaintiff's Motion for Attorney Fees.

February 23, 2006

Respectfully submitted,

/s/
KENNETH L. WAINSTEIN, D.C. Bar # 451058
United States Attorney

/s/
R. CRAIG LAWRENCE, D.C. Bar # 171538
Assistant United States Attorney

/s/
ALAN BURCH, D.C. Bar # 470655
Assistant United States Attorney
555 4th St., N.W.
Washington, D.C. 20530
(202) 514-7204
alan.burch@usdoj.gov

OF COUNSEL:

PAULA STANDARD
Acting General Counsel
Department of Health and Human Services

SHELDON T. BRADSHAW
Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel for Litigation

JAMES R. JOHNSON
Trial Attorney
Office of General Counsel
5600 Fishers Lane (GCF-1), Room 6-89
Rockville, MD 20857, (301) 827-5212