UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION,	)	
Plaintiff,	)	
v.	)	Civ. No. 00-2849 (RMU/AK)
UNITED STATES FOOD AND DRUG ADMINISTRATION,	)	
Defendant,	)	

PLAINTIFF'S REPLY MEMORANDUM IN SUPPORT OF
PLAINTIFF'S MOTION FOR AN AWARD OF ATTORNEYS' FEES AND COSTS

As plaintiff Campaign for Responsible Transplantation ("CRT") demonstrated in its opening memorandum in support of its motion for fees ("Fees Mem."), it is eligible for fees in this case because, as a direct result of the Court's September 3, 2002 and September 24, 2004 rulings, it obtained access to thousands of documents that defendant Food and Drug Administration ("FDA") had withheld from CRT under the Freedom of Information Act ("FOIA"), first during the administrative process, and then, even after CRT was forced to file a lawsuit. As CRT also demonstrated, it is also entitled to a fee award here, because it meets all of the criteria for such awards.

In response, the government argues that CRT did not obtain any relief as a result of the Court's rulings, and that CRT is also not entitled to any fees under the applicable criteria. Defendant's Opposition to Plaintiff's Motion For An Award Of Attorney Fees and Costs ("FDA Opp."). However, as further demonstrated below, the FDA is wrong on both counts.

A. Plaintiff Is Eligible For An Award Of Fees and Costs

As the Court of Appeals for this Circuit has explained, the significance of the Supreme Court's ruling in Buckhannon Board & Care Home, Inc. v. W. Virginia Dep't of Health & Human Res., 532 U.S. 598, 604 (2001) is that, to be considered a "prevailing party" under a fee shifting statute, such as the FOIA, there must be "some sort of 'judicial relief' in favor of the party seek an award of fees." Oil, Chemical & Atomic Workers Int'l Union v. DOE, 288 F.3d 452, 458 (D.C. Cir. 2002) ("OCAW") (emphasis added).

Here, as explained in its opening memorandum, CRT easily satisfies this test, since it obtained thousands of documents from the FDA as a direct result of this Court's September 3, 2002 order granting CRT summary judgment on the ground that the agency had failed to meet its statutory burden of proof that those documents were in fact exempt from disclosure. See Campaign for Responsible Transportation v. FDA, 219 F. Supp. 106, 116 (D.D.C. 2002) ("CRT II").

Thus, as a direct result of that ruling, and the Court's concomitant order that the agency file a *new* Vaughn index to demonstrate that the documents that it had withheld from CRT for over two years [ck] were in fact exempt from disclosure, the FDA then released a thousand "IND G" documents for which it simply could not provide the requisite Court-ordered justification. See Fees Mem. at 7. Indeed, because the agency was using a "representative Vaughn Index" to justify its withholding of all of the records at issue in this case, the Court's September 23, 2002 ruling is also directly responsible for the agency's subsequent release of thousands of additional records – pertaining to the other 18 INDs – that the agency also originally claimed were exempt from disclosure, but had to disclose once the Court granted summary judgment to CRT on the

inadequacy of the agency's original Vaughn index. See Fees Mem. at 12. Therefore, CRT has clearly met the requirement that it obtain "some" relief as the result of a Court order. OCAW, 288 F.3d at 458.

Tellingly, in its opposition the FDA does not dispute – nor can it – that its release of thousands of documents, which it had previously insisted were exempt from disclosure, was the result of the agency's obligation to comply with this Court's September 3, 2002 Order. Indeed, once the Court ruled that the agency had not met its burden of proof, and that, to do so, it must submit a better Vaughn index, the agency was forced, by operation of law – i.e., its inability to meet its evidentiary burden with respect to thousands of documents – to disclose those records to CRT. See 5 U.S.C. § 552 (b) (agencies must provide to a requester all non-exempt records). This is precisely why holding a agency to the requirements of Vaughn v. Rosen is crucial to vindication of a FOIA plaintiff's statutory rights – i.e., to ensure that the agency does not withhold records that are not in fact exempt from disclosure. See, e.g., Vaughn v. Rosen, 484 F.2d 820, 826 (D.C. Cir. 1973) (explaining that Vaughn index was intended to remedy the Government "contend[ing] that large masses of information are exempt, when in fact part of the information should be disclosed"); id. ("[i]t is vital that some process be formulated that will . . . assure that a party's right to information is not submerged beneath governmental obfuscation and mischaracterization"); see also, e.g., Founding Church of Scientology v. Bell, 603 f.2d 945, 949 (D.C. Cir. 1979) (explaining that although requiring agencies to comply with the requirements of Vaughn places an administrative burden on the agencies, "less exacting standards would not satisfy the FOIA's unambiguous policy in favor of the fullest possible disclosure of government records") (emphasis added).

Thus, this case is very different from OCAW, where the Court denied fees to plaintiffs because "the court had not rendered any judgment about the legality of the government's withholding any information." 288 F.3d at 457. Here, the Court rendered precisely such a judgment when it granted summary judgment for plaintiff on the grounds that the FDA had not met its burden of proof that all of the documents it was withholding from CRT were in fact exempt from disclosure.

Nor are the facts of this case remotely similar to either Buckhannon or Thomas v. National Science Foundation, 330 F.3d 486 (D.C. Cir. 2003), since in both of those cases – decided under different fee shifting statutes – the plaintiffs did not obtain any relief as a result of a court ruling. Rather, in Buckhannon, the fire code provisions that the plaintiff had challenged were repealed by the legislature, see 532 U.S. at 601, and in Thomas, the plaintiff's claim for relief was mooted by Congress before any such relief had been granted by the court. See 330 F.3d at 488. Indeed, in Thomas, the Court emphasized that a party is entitled to fees where it obtains a court judgment that changes the legal relationship between the parties "in a way that afford[s] [plaintiffs] the relief that they sought." Id. at 493 (emphasis added). Here, as a direct result of this Court's grant of summary judgment in CRT II, CRT obtained thousands of documents – precisely the relief that it sought in bringing this case.

CRT's eligibility for fees is also fully supported by Edmonds v. FBI, 417 F.3d 1319, 1322-23 (D.C. Cir. 2005), where the Court of Appeals held that the district court's order requiring the expedited processing of a FOIA request supplied the requisite "judicially sanctioned change in the legal relationship of the parties." Here, as in Edmonds, this Court's grant of summary judgment "vindicated a statutory right," 417 F.3d at 1324 – i.e., the right to obtain all

of the requested records that the agency could not prove are exempt from disclosure. See 5 U.S.C. § 552(b). Indeed, just as the order requiring expedited processing in Edmonds led to the release of hundreds of non-exempt records, see 417 F.3d at 1322, here, the Court's September 3, 2002 ruling led to the release of thousands of non-exempt records, including both the IND G documents and all of the similar documents that concerned the other 18 INDs.

The Court's final September 24, 2004 Order in this case, further demonstrates that CRT prevailed, since the Court ordered "that the FDA shall 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." (Emphasis added). While the FDA insists that this decision was also of no moment, since (a) it did not result in the release of any "contested" documents to CRT, FDA Opp. at 10; and (b) the parties had always agreed that the FDA could continue to withhold these documents until the very end of the case, FDA Opp. at 9, the agency is wrong on both points.

As demonstrated above, many of the thousands of documents that this Court ordered the FDA to disclose had been withheld from CRT in their entirety, first during the administrative phase, and then, after CRT was required to file a lawsuit, when the agency submitted its first "representative" Vaughn index. Indeed, all of the documents concerning the other 18 INDs that were similar in kind to the IND G documents that the agency originally insisted were exempt from disclosure in its original Vaughn index, but later had to release after the Court granted CRT summary judgment, were certainly "contested" by the FDA,– at the time it filed its original – inadequate – Vaughn index.

In addition, even after the FDA released thousands of IND-G documents that it could no longer withhold on the basis of the *new* Vaughn index that was required by the Court, the agency

nevertheless refused to release all of the other IND records that were similar in kind, but instead chose to wait until this Court ordered them to do so. As demonstrated in its opening brief, Fees Mem. at 7-9, CRT consistently took the position that the FDA had to release these non-exempt records as soon as possible.

The one statement by the plaintiff upon which the FDA relies for the notion that CRT somehow acquiesced in the government's 2 ½ year recalcitrance in releasing those thousands of additional non-exempt records, Opp. at 9, is taken completely out of context. Because the FDA still had not released any of the thousands of nonexempt records that were similar in kind to the IND G records that it had been forced to release as a result of CRT II, CRT was simply requesting the Court to order the agency to do so. See Fees Mem at 7-8. In addition, because the FDA had indicated that it would not release any such records without first affording all of the intervenor companies an opportunity to contest such disclosures, plaintiff was requesting that the Court order the "immediate" release of the records – i.e., without allowing another round of submitter objections – since, according to the agency, the whole reason it used a "representative sample" was that the IND G records were "essentially identical" to all of the other IND records at issue in the case. See Plaintiff's Reply Memorandum In Support of Plaintiff's Motion for Summary Judgment at 2 (February 19, 2004) (the FDA "must be required to disclose to CRT all of the similar FDA-generated records that pertain to the other 18 INDs, without allowing third parties to oppose such disclosure. Otherwise, it is not at all clear why the Court allowed the agency to use a representative sample to begin with"); FDA's Memorandum In Opposition To Plaintiff's Motion for Summary Judgment (February 5, 2004) at 4 ("prior to release, it is likely that FDA will need to confer with the third-parties who have submitted INDs and who may have

interests in protecting trade secrets and confidential commercial information").

Therefore, because, as a result of this Court's rulings, CRT received thousands of documents that the FDA had previously withheld from CRT for several years, CRT is eligible for an award of reasonable attorney's fees and costs.

B. Plaintiff Is Also Entitled To A Fee Award Under All Of The Applicable Criteria.

As CRT demonstrated in its opening memorandum, Fees Mem. at 13-19, it is also entitled to a fee award in this case, since it meets all of the criteria that the Court must weigh in deciding this issue. In response, the FDA has failed to demonstrate that any of these criteria counsel against a fee award.

First, as demonstrated above, there is no merit to the FDA's insistence that there is no public benefit from the release of these documents because CRT did not obtain the release of any "contested" document. FDA Opp. at 11. On the contrary, as a direct result of bringing this lawsuit, CRT obtained the release of thousands of documents that the FDA had withheld from CRT for many years concerning this extremely controversial bio-technology.

Second, the FDA's contention that there can be no public benefit here because the Court should not "endors[e]" CRT's position that xenotransplantation should be banned, FDA Opp. at 12, makes no sense. The public benefit accrues from shining the light on a matter of great public interest, which, the agency itself recognized was crucial with respect to this precise issue. See Fees Mem. at 14-15.

Third, CRT submitted the sworn declaration of Ms. Fano to demonstrate that there was no commercial or personal interest in obtaining these documents, and the FDA has failed to

present any evidence disputing those sworn statements. Indeed, CRT's lack of any commercial interest weighs heavily in favor of an award of fees here. See, e.g., United Association of Journeymen and Apprentices, Local 598 v. Dep't of the Army, 841 F.2d 1459, 1461 (9th Cir. 1988) (the absence of a commercial interest in the documents "would weigh in favor of a fee award . . . since the fee award section of the Act was intended to encourage complainants who lack substantial pecuniary incentives to pursue their claims").

The FDA's assertion that members of the CRT coalition "could" have some commercial and personal interests "in a ban on xenotransplantation," FDA Opp. at 12, is completely speculative and disputed by Ms. Fano's uncontested sworn declaration. See Fano Declaration ¶ 5 ("CRT's sole interest in bringing this FOIA case was to find out and disseminate to the public information concerning the FDA's decisions to approve clinical trials involving xenotransplantation and to ensure that the FDA was abiding by all relevant laws and regulations governing such experiments. unsupported by any evidence in the record"). Similarly, FDA's allegation that some of the documents that were not obtained by plaintiff "contained valuable trade secret and confidential commercial information," FDA Opp. at 12, also makes no sense, not only because, as Ms. Fano explains in her declaration, CRT had no commercial interest in bringing this case, but also because the relevant inquiry is CRT's interest in the documents that it successfully obtained.

Finally, there also is no merit to the FDA's argument that its position in this case – with respect to the records that plaintiff was successful in obtaining – was "reasonable." See FDA Opp. at 13-14. As demonstrated above, and in CRT's opening memorandum, the FDA's assertion that "the Court held that *every* withholding by FDA was lawful," FDA Opp. at 13, is

simply incorrect. The Court certainly did not hold that the FDA's decision to withhold thousands of non-exempt records from CRT for many years was lawful.

On the contrary, in CRT II, the Court held that the FDA had not met its burden of proof that any of the documents it was withholding were exempt from disclosure. As a result, the agency was required to submit a new Vaughn index which forced the agency to turn over thousands of documents – both IND G documents and other IND documents – that were not exempt from disclosure, and therefore had been improperly withheld from CRT for over four years. In addition, although in 2002 the agency knew that thousands of other IND records that were similar in kind to the non-exempt IND G records would also have to be disclosed to CRT, the agency nevertheless refused to release any such records until the Court ordered it to so on September 24, 2004, and, even then, the agency did not release a single such document until CRT filed a motion to enforce that Order. See Fees Mem. at 9-10.

CONCLUSION

For the foregoing reasons, as well as those set forth in plaintiff's opening memorandum, plaintiff's request for an award of attorneys' fees and costs should be granted, and the FDA should be ordered to reimburse CRT for its reasonable attorney's fees and costs in this case.

Respectfully submitted,

/s/ Filed electronically

Katherine A. Meyer
(D.C. Bar No. 244301)
Howard Crystal
(D.C. Bar No. 446189)
Meyer Glitzenstein & Crystal
1601 Connecticut Ave., N.W.
Suite 700
Washington, D.C. 20009
(202) 588-5206

Date: March 9, 2006