

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR)
RESPONSIBLE TRANSPLANTATION,)
)
Plaintiff,)
)
v.)
)
UNITED STATES FOOD AND DRUG)
ADMINISTRATION,)
)
Defendant,)
)
CIRCE BIOMEDICAL, INC., et al.,)
)
Defendant-Intervenors..)

Civ. No. 00-2849 (RMU/AK)

**PLAINTIFF’S REPLY MEMORANDUM IN SUPPORT OF
PLAINTIFF’S MOTION FOR SUMMARY JUDGMENT**

In response to the Food and Drug Administration’s (“FDA’s”) opposition to plaintiff’s motion for summary judgment in this case under the Freedom of Information Act (“FOIA”), plaintiff Campaign for Responsible Transplantation (“CRT”) relies on its opposition to the FDA’s motion for summary judgment. See Plaintiff’s Opposition to Defendants’ Cross-Motion for Summary Judgment (“Pl. Opp.”) CRT makes the following additional points.

1. The FDA continues to insist that plaintiff is not entitled to an order from this Court directing the agency to release all responsive records that concern the other 18 INDs that are similar in kind to the “IND G” records that were released to plaintiff, until after the Court issues some other “rulings” in this case. FDA Opposition (“FDA Opp.”) at 3, 4. However, as CRT has explained, Pl. Opp. at 2-3, the Court will have no occasion to “rule” that the FDA must

release all such similar information, other than in the context requested by plaintiff.

Although this Court allowed the FDA to use the records pertaining to IND G as a “representative” sample of all these other records, the FDA cannot have it both ways. It cannot rely on the “representative” nature of those records to withhold information from plaintiff, yet deny the representative nature of the records that have been released in refusing to now disclose similar records to plaintiff. Yet, that appears to be precisely what the agency has in mind. Thus, it protests that it should not be required to begin locating and releasing all records that are similar in kind to the IND G records that have already been disclosed, because it will necessarily have to “confer with the third-parties who have submitted the INDs and who may have interests in protecting trade secrets and confidential commercial information,” before any such records may be released. FDA Opp. at 4. However, that was the point of allowing the FDA to use the IND G records as “representative” of the thousands of other responsive records that pertain to the other 18 INDs at issue here – to avoid such a lengthy and time-consuming process. Therefore, now that the agency has released hundreds of pages of FDA-generated records pertaining to IND G – largely in response to this Court’s previous ruling, CRT v. FDA, 180 F. Supp.2d 29 (D.D.C. 2001) – it 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.

While the FDA takes issue with CRT’s position that the agency should be required to release all such similar records “immediately,” FDA Opp. a 5, of course plaintiff means as soon as possible after the Court rules on the cross-motions for summary judgment. Thus, to be clear:

in response to plaintiff's motion for summary judgment, CRT requests a ruling that the FDA must immediately disclose to CRT all of the FDA-generated records that pertain to the other 18 INDs, that are similar in kind to the IND G records that the agency has already released.

2. CRT explained that the agency has failed to meet its burden of proof under Exemption 5 that the withheld information is "pre-decisional" because the FDA has not identified the specific role each such document or portion has played in an actual decision or policy-making undertaking by the agency, irrespective of whether the agency can cite to any final decisions. See Pl. SJ Mem. at 21-22; Pl. Opp. at 10. However, relying on Ashley v. Dep't of Labor, 589 F. Supp. 901, 908-09 (D.D.C. 1983), the FDA insists that the agency need not make any such demonstration, but instead may merely assert that the document was generated in the course of some unspecified "continuing process of agency decision-making." FDA Opp. at 16 (emphasis added).

The agency is incorrect. On the contrary, in Ashley, Judge Flannery explained that, to meet its burden of proof under Exemption 5, an agency "carr[ies] a heavy burden of demonstrating that such documents play a role in the deliberative process, and that to meet that burden the agency must provide a detailed description of how each document contributes to that process." 589 F. Supp. at 907 (italics in original; underlining added), citing, Vaughn v. Rosen, 523 F.2d 1136, 1143-44 (D.C. Cir. 1975). Indeed, in upholding the application of Exemption 5 in that case, Judge Flannery further explained that:

[m]ost importantly, with respect to each document, [the agency] has spelled out in detail the precise context within which it was generated and what role in the deliberative process it plays. The documents were all generated pursuant to an established self-evaluation and improvements program designed to enhance [the agency's] enforcement efforts. They were all written by agency personnel who had no decisionmaking authority, and were addressed to agency superiors to help them

formulate general or specific policies. The types of decisions each document was intended to support were described in detail in [the agency's] affidavits.

589 F. Supp. at 908 (emphasis added).

Here, in sharp contrast, as plaintiff has explained, Pl. Opp. at 10-11, the agency insists that it may withhold documents merely by asserting that they relate to either the IND review process or the “develop[ment] [of] FDA policy on xenotransplantation issues.” Def. SJ Mem. at 14. However, as CRT further demonstrated, Pl. Opp. at 11-12, the agency has yet to specify which document relates to which process, or to describe in any concrete way what “polic[ies] on xenotransplantation” the documents pertain to, or even if the particular documents that remain at issue contain advice and recommendations from subordinates to superiors. Rather, the agency appears to be taking the position that any document it generates concerning this relatively new biotechnology is necessarily deliberative in nature, since the agency has not yet decided what to do about xenotransplantation. See, e.g., Second Declaration of Dr. Joyce Frey-Vasconcells, ¶12 (“Because xenotransplantation is a new procedure these documents also reflect the development of FDA policies about xenotransplantation in general, not just FDA decisions about a particular xenotransplantation IND”) (emphasis added).

To allow the agency to withhold documents on this basis would create a gaping hole in the FOIA, since all records generated by an agency are arguably related in some way to the “development of policy” on issues over which the agency exercises jurisdiction. Id.; Def. SJ Mem. at 14. However, the FOIA and the case law interpreting it do not allow such a result. Rather, because the Exemptions, including Exemption 5, are to be narrowly construed, Department of the Air Force v. Rose, 425 U.S. 352, 361 (1976), the FDA must prove much more here – i.e., it must “pinpoint an agency decision or policy to which the document contributed.”

Senate of the Com. of Puerto Rico v. DOJ, 823 F.2d 574, 585 (D.C. Cir. 1987), *quoting Paisley v. CIA*, 712 F.2d 686, 698 (D.C. Cir. 1983).

3. With respect to information that the agency has withheld under Exemption 4, CRT has consistently argued that the agency cannot meet its burden of proof that the disclosure of such information is likely to cause the submitters “substantial” competitive injury, National Parks & Conservation Ass’n v. Morton, 498 F.2d 765, 770 (D.C. Cir. 1974), if the sponsors themselves have already disclosed any such information to the public. See Pl. SJ Mem. at 17-18; Pl. Opp. at 5-6. In response, the agency makes the remarkable assertion that “[i]t is well-established that ‘the party favoring disclosure has the burden of demonstrating that the information sought is identical to information already publicly available.’” FDA Opp. at 13 (emphasis in original), citing Center for Auto Safety v. Nat’l Highway Traffic Safety Admin., 244 F.3d 144, 151 (D.C. Cir. 2001).

However, such a proposition is by no means “well-established,” and common sense dictates that a plaintiff who does now know the precise contents of the requested records cannot possibly demonstrate that “identical” information has already been released by the submitter of the information. In Center for Auto Safety, the Court merely explained that, of course, if a plaintiff could somehow demonstrate that the identical information was already in the public domain, this would make it difficult for an agency to meet its burden of proof under any of the Exemptions. 244 F.3d at 151 (“if identical information is truly public, then enforcement of an exemption cannot fulfill its purposes”), quoting Niagara Mohawk Power Corp. v. United States Department of Energy, 169 F.3d 16, 19 (D.C. Cir. 1999). However, the Court further explained that whether “identical information” has been disclosed is an entirely distinct inquiry from

whether the agency can meet its burden of proof that the information at issue is not “of a kind” that the submitter customarily discloses – for purposes of determining whether the information is truly “confidential” within the meaning of Exemption 4 (where, unlike in this case, the submission of the information was voluntary versus mandatory). Center for Auto Safety, 244 F.3d at 151. Indeed, the Court further explained that, in that case, the district court had incorrectly required the plaintiff to demonstrate both that the information was of a kind that is customarily disclosed and that “the identical information has been disclosed.” Id. at 152. Rather, the Court explained, if the plaintiff could demonstrate that the information was of a kind that was not customarily withheld from the public by the submitter, then the agency would not be able to meet its burden of proof that the information is “confidential” within the meaning of Exemption 4. Id.

Similarly, in this case, where (because the submissions were mandatory) the test of “confidentiality” is whether disclosure is likely to cause the submitter “substantial” competitive harm, National Parks; Critical Mass Energy Project v. NRC, 975 F.2d 871, 873 (D.C.Cir. 1992) (*en banc*), it is plaintiff’s contention that the government cannot meet its burden of proof where the submitter itself has already released similar information to the public – e.g., in an effort to convince investors and the public at large that its biotechnology is both safe and effective. See Pl. SJ Mem. at 17-18. Accordingly, to the extent that any of the information at issue in this case has already been disclosed by the submitters – for example, in the numerous public disclosures that CRT long ago submitted to the FDA, see id. – such information simply may not be withheld under Exemption 4. Therefore, because the agency bears the burden to demonstrate that release of the information is likely to cause “substantial” competitive injury, National Parks, it must

provide some evidence that it has reviewed plaintiff's exhibits and determined that information it seeks to withhold has not already been publicly disclosed by the IND sponsors.

CONCLUSION

For the foregoing reasons, as well as those set forth in plaintiff's memorandum in support of its motion for summary judgment and its memorandum in opposition to the government's cross-motion for summary judgment, plaintiff should be granted summary judgment in this case.

Respectfully submitted,

/s/ Filed electronically

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