IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant, and CIRCE BIOMEDICAL, INC., DIACRIN, INC., DIACRIN/GENZYME LLC, and NEXTRAN, INC., Defendant-Intervenors.	C.A. No. 00-2849 (RMU)

DEFENDANT-INTERVENORS' MOTION FOR LEAVE TO FILE REPLY MEMORANDUM IN SUPPORT OF THE FDA'S CROSS-MOTION FOR SUMMARY JUDGMENT AND STATEMENT OF POINTS AND AUTHORITIES

Defendant-Intervenors, Circe Biomedical, Inc., Diacrin, Inc., Diacrin/Genzyme LLC, and Nextran, Inc., (collectively "Defendant-Intervenors") request leave to file the attached Reply Memorandum in support of the cross-motion for summary judgment filed by Defendant Food and Drug Administration ("FDA") on March 29, 2002.

BACKGROUND

On December 4, 2001 this Court issued an Initial Scheduling and Procedures Order directing Plaintiff, Campaign for Responsible Transplantation, to file its motion for summary judgment by January 15, 2002. The order further directed all parties to submit oppositions or cross-motions by March 15, 2002. FDA obtained a two week extension of this deadline and filed its cross-motion for summary judgment on March 29, 2002. Plaintiff subsequently was granted an enlargement of time to file its opposition to FDA's cross-motion, as well as Plaintiff's reply to Defendant-Intervenors' memorandum opposing Plaintiff's motion for summary judgment. This Court's order of April 25, 2002, granting Plaintiff's enlargement of time, directed FDA to file any reply to Plaintiff's opposition by June 10, 2002. The order did not specifically address whether Defendant-Intervenors may file a reply brief.

Statement of Points and Authorities

Defendant-Intervenors' Reply Memorandum is necessary to address allegations raised by Plaintiff that are specific to Defendant-Intervenors. Plaintiff asserts, for the first time, that Defendant-Intervenors "failed to do the work necessary to assist the government in meeting its burden of proof" in regard to documents withheld under 5 U.S.C. § 552(b)(4). Plaintiff's Reply to Defendant Intervenors' Memorandum in Opposition to Plaintiff's Motion for Summary Judgment ("Plaintiff's Reply") at 8. Plaintiff also apparently maintains, while ignoring Defendant-Intervenors' declarations, that FDA-generated documents containing confidential trade secret and proprietary information from Defendant-Intervenors' investigational new drug applications ("INDs")

should be released to CRT, and the public, without prior review by IND sponsors who have not yet seen the documents. See Letter from Amy R. Atwood to Counsel for Defendant and Defendant-Intervenors (Feb. 22, 2002), Pl. Ex. YY. Finally, Plaintiff argues that this Court should admit Plaintiff's Statement of Undisputed Facts because FDA did not dispute these facts. However, Plaintiff's ignores, and by its argument to admit Plaintiff's Statement asks this Court to ignore, the Defendant-Intervenors' Opposition to Plaintiff's Statements of Undisputed Facts. See Plaintiff's Reply Memorandum in Support of Plaintiff's Motion for Summary Judgment and in Opposition to the Government's Cross-Motion for Summary Judgment ("Plaintiff's Opp.") at 10-11 at 11, n.6. Defendant-Intervenors are in the best position to address these issues, thus the attached Reply Memorandum will be of assistance to this Court. See Lee County v. U.S., 1994 U.S. Dist. LEXIS 5655, *6 n.3 (D.D.C. 1994)(unpublished).

The filing of Defendant-Intervenors' Reply Memorandum is within the deadlines set by this Court in its April 25, 2002 order. Thus, there will be no delay in this proceeding by allowing Defendant-Intervenors' Reply Memorandum.

Pursuant to LCvR 7.1(m), Mary Kate Whalen of Hyman, Phelps & McNamara, P.C., counsel for Defendant-Intervenor Nextran, Inc., spoke by telephone on June 7 and 10, 2002 with Amy Atwood of Meyer & Glitzenstein, counsel for Plaintiff. Ms. Atwood represented that the Plaintiff would take no position on the instant motion. Jalena Specht of Covington & Burling, counsel for Circe Biomedical, Inc., communicated with Assistant United States Attorney Brian J. Sonfield, counsel for the

government, on June 10, 2002. Mr. Sonfield stated that the government had no objection to the filing of Defendant-Intervenors' Reply Memorandum.

CONCLUSION

For the foregoing reasons Defendant-Intervenors' Motion for Leave to File Reply Memorandum should be granted. A copy of the Proposed Order is attached hereto.

Respectfully submitted,

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Dated: June 10, 2002

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant, and CIRCE BIOMEDICAL, INC., DIACRIN, INC., DIACRIN/GENZYME LLC, and NEXTRAN, INC. , Defendant-Intervenors.	)	C.A. No. 00-2849 (RMU)

PROPOSED ORDER

Upon consideration of Defendant-Intervenors' Motion for Leave to File Reply Memorandum, and noting no opposition thereto, it is this _____ day of ____, 2002

ORDERED, that Defendant-Intervenors' Motion for Leave to File Reply Memorandum is GRANTED.

So ORDERED.

_____
Richard M. Urbina
United States District Court Judge

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UNITED STATES DISTRICT COURT
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CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendant, and CIRCE BIOMEDICAL, INC., DIACRIN, INC., DIACRIN/GENZYME LLC, and NEXTRAN, INC., Defendant-Intervenors.	C.A. No. 00-2849 (RMU)

DEFENDANT-INTERVENORS' REPLY MEMORANDUM IN SUPPORT OF FDA'S CROSS-MOTION FOR SUMMARY JUDGMENT

INTRODUCTION

Defendant-Intervenors submit this Reply Memorandum in support of the cross-motion for summary judgment by Defendant Food and Drug Administration ("FDA"). Defendant-Intervenors, Circe Biomedical, Inc., Diacrin, Inc., Diacrin/Genzyme LLC, and Nextran, Inc., have provided extensive confidential commercial and trade secret information to FDA in connection with their investigational new drug applications ("INDs"). They have knowledge of their IND information, FDA's processes, and their extensive communications with FDA about their INDs. Based on this extensive knowledge, Defendant-Intervenors have filed declarations

showing that many of the FDA-generated documents sought by CRT contain confidential commercial and trade secret information and are therefore exempt from disclosure under 5 U.S.C. §552(b)(4) ("Exemption 4"). See Affidavit of E. Michael Egan at ¶¶ 17-33; Declaration of John S. Logan, Ph.D., Nextran, Inc. at ¶¶ 6-14; Declaration of Elizabeth Chen, Circe Biomedical, Inc. at ¶¶ 5-11.[1] Plaintiff Campaign for Responsible Transplantation ("CRT") barely mentioned these declarations in its Reply Memorandum In Support Of Plaintiff's Motion For Summary Judgment And In Opposition To The Government's Cross-Motion For Summary Judgment ("Plaintiff's Opp.").

The only issue before the Court at this summary judgment stage is whether FDA's sample Vaughn Index adequately describes the agency documents in IND G that have been withheld by FDA. Contrary to Plaintiff's assertions, there is no basis at this time to order the public disclosure of the documents listed in the sample Vaughn Index, much less those in other INDs that FDA has not reviewed or indexed. If the Court were to determine that the sample Vaughn Index is inadequate, then FDA should be directed to prepare a more detailed Index. If any of the documents in IND G that FDA has found to be exempt are to be released outside FDA, then the Sponsor of IND G should be given the opportunity to review those documents, as Defendant-Intervenors have proposed. See Defendant-Intervenors' Opp. at 23. This will enable the Sponsor to provide a more detailed description of the documents and to identify any portions of those documents that are no longer confidential because previously disclosed to the public. It would be an unprecedented breach of Exemption 4 to order the disclosure of contested

[1] These declarations were attached as Exhibits A, B, and C respectively to Defendant-Intervenors' Memorandum of Points And Authorities In Opposition To Plaintiffs' Motion For Summary Judgment ("Defendant-Intervenors' Opp."). For convenience the declarations are referred to herein as "Exhibit A," "Exhibit B," and "Exhibit C," respectively.

documents to the Plaintiff – and hence to the public – without giving the Sponsors an opportunity to review them.

ARGUMENT

I. The Declarations Of Defendant-Intervenors Demonstrate That The FDA-Generated Documents Contain Confidential Commercial And Trade Secret Information Protected Under Exemption 4.

Defendant-Intervenors have not been permitted to review the FDA-generated documents at issue. See Exhibit A at ¶ 8; see also Exhibit B at ¶¶14, 17; Exhibit C at ¶ 10. However, Defendant-Intervenors draw on extensive experience in communicating with FDA about confidential information in their INDs. As their declarations show, there is ample reason to believe that FDA has made a correct assessment in withholding some of its documents because the information they contain is protected under Exemption 4 ("the Exemption 4 Documents"). See Exhibit A at ¶¶ 17-22; Exhibit B at ¶¶ 6, 7, 14-17; Exhibit C at ¶¶ 5, 6, 10.

Ignoring the declarations of Defendant-Intervenors, CRT unfairly asserts that they have "failed to do the work necessary to assist the government in meeting its burden of proof" in respect to the documents withheld under Exemption 4. See Plaintiff's Reply To Defendant-Intervenors' Opp. at 8. Plaintiff's assertion is wrong in two respects.

First, Defendant-Intervenors offered to provide assistance to FDA in responding to Plaintiff's concerns about the Vaughn index for IND G. See Declaration of Jalena G. Specht, Esq. at ¶¶ 3, 8-10 (attached as Exhibit 1). FDA declined the Defendant-Intervenors' offer. Id. at ¶ 11.

Second, FDA regulations and policies prohibit the disclosure of these documents outside the agency. See 21 C.F.R. §§ 312.130, 314.430, 601.50-51. In light of the fact that Defendant-Intervenors have not had the opportunity to review virtually all of the FDA-generated documents, see Exhibit A at ¶ 8; Exhibit B at ¶¶ 14, 17; Exhibit C at ¶ 10, Defendant-Intervenors have done everything they can do at this stage. FDA has stated what kinds of information the Exemption 4 Documents contain. See Fourth Declaration of Lesia M. Banks in Support of Defendant's Cross-Motion for Summary Judgment at ¶¶ 10-12. Defendant-Intervenors have confirmed that information of those types is kept confidential. See Exhibit A at ¶¶ 28-33; Exhibit B at ¶¶ 14, 17, 20; Exhibit C at ¶ 10. Defendant-Intervenors have given specific examples of this confidential and trade secret information. See Exhibit A at ¶¶ 28-33; Exhibit B at ¶¶ 6, 7; Exhibit C at ¶¶ 5, 6. For instance, Diacrin has in its possession one of the documents – a letter from the FDA's CBER to Diacrin – and Diacrin's chief operating officer has explained in detail that this letter contains confidential information. See Exhibit A at ¶ 33 (explaining that the CBER letter contains detailed confidential information about subjects such as interim analysis of an ongoing study, plans for safety monitoring, the analytical plan for a clinical trial, and the schedule for testing and archiving of samples).

CRT makes no response to the declarations of Defendant-Intervenors. CRT criticizes FDA for failing to respond to CRT's showing that the IND Sponsors have publicly disclosed some information about xenotransplantation research. See Plaintiff's Opp. at 10-11. But Defendant-Intervenors expressly did respond to CRT's showing. Defendant-Intervenors acknowledge that they disclose some information about products in development to shareholders or potential investors. Even so, much of the copious and detailed information submitted to FDA

remains confidential, and the Defendant-Intervenors' declarations point to many examples. See Exhibit A at ¶ 24; Exhibit B at ¶ 10; Exhibit C at ¶ 8.

If the Court should consider ordering the release of the Exemption 4 Documents to anyone outside FDA, the Court should provide an opportunity for the Sponsor of IND G to review the documents pertaining to its own IND. See Defendant-Intervenors' Opp. at 23. In this way the Sponsor will be able to assess the exact contents of the Exemption 4 Documents and to explain in detail where they contain trade secret and confidential commercial information. CRT does not articulate any reason to oppose such an option.[2] It would be an unprecedented breach of Exemption 4 to disclose the contested documents to CRT without allowing the Sponsor to review them first. If this were done, as CRT requests, then the Sponsors would be denied a meaningful opportunity to protect their confidential information and trade secrets.

CRT further argues that FDA's sample Vaughn Index fails to distinguish whether the FDA-generated documents contain trade secrets or confidential commercial information. See Plaintiff's Opp. at 10. But this distinction is irrelevant in this context because Exemption 4 protects both categories. Defendant-Intervenors' declarations show that much of the information submitted to FDA bears a direct relationship to the productive process -- the hallmark of trade secret analysis, see Public Citizen Health Research Group v. FDA, 704 F.2d 1280, 1288 (D.C. Cir. 1983) -- such as information about manufacturing and production processes, specifications and techniques, assay development processes and cell transportation methods. Exhibit A at ¶¶ 21, 26, 29, 30, 32; Exhibit B at ¶¶ 6, 8; Exhibit C at ¶ 5, 15. Defendant-Intervenors also

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[2] In a February 22, 2002 letter to Defendant-Intervenors, counsel for CRT asserted that Defendant-Intervenors should not have any further opportunity to address the FDA-generated documents after this round of summary judgment briefing. See Letter from Amy R. Atwood to Counsel for Defendant and Defendant-Intervenors (Feb. 22, 2002), Pl. Ex. YY. Plaintiff does not state any basis for this position,

provided to FDA confidential commercial information -- such as detailed scientific information, preclinical testing protocols, design of clinical studies, trial results, and study conclusions -- the release of which would result in competitive harm. See Exhibit A at ¶¶ 18, 19, 25-33; Exhibit B at ¶¶ 6-11; Exhibit C at ¶¶ 5-10.

II. Plaintiff's Assertions About Potential Health Risks Are Not Material And Are Not Admitted For Purposes Of Summary Judgment.

Plaintiff's Statement Of Undisputed Material Facts ("Plaintiff's Statement") begins with a lengthy diatribe about xenotransplantation. See Plaintiff's Statement at 2-11. Plaintiff's brief contends that its assertions about potential health risks are admitted for purposes of summary judgment. Plaintiff's Opp. at 11, n.6. This assertion is wrong for two simple reasons.

First, public health speculation is irrelevant to this summary judgment dispute. This dispute concerns the adequacy of the FDA's sample Vaughn Index. See Plaintiff's Motion for Summary Judgment at 1. Congress struck a balance, when it enacted Exemption 4, between the interest in disclosure, on the one hand, and the interest in protecting trade secrets and confidential commercial information, on the other hand. Public Citizen Health Research Group v. FDA, 185 F.3d 898, 904 (D.C. Cir. 1999) (Public Citizen II) (citing Critical Mass. Energy Project v. NRC, 975 F. 2d 871, 872 (D.C. Cir. 1992) (en banc)). Plaintiff has no basis for seeking to override this balance by arguing a "consequentialist approach." Id. Where the documents at issue are protected by Exemption 4, Plaintiff is not entitled to the Exemption 4 documents -- no matter what Plaintiff believes about xenotransplantation.

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however. Plaintiff appears to be ignoring the fact that the Sponsors have not yet had an opportunity to review the documents at issue.

Second, Defendant-Intervenors expressly responded that Plaintiff's statements are not material. See Defendant-Intervenors' Joint Response To Plaintiff's Statement of Material Facts at 1. Defendant-Intervenors are parties to this action and filed a timely and appropriate response to Plaintiff's Statement. As a result the statements should not be deemed admitted. See LCVR 7.1(h).

CONCLUSION

For the foregoing reasons (as well as those set forth in Defendant-Intervenors' Opp.), Plaintiff's Motion for Summary Judgment should be denied and FDA's Cross-Motion for Summary Judgment should be granted.

Respectfully submitted,

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Dated: June 10, 2002

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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., Defendant-Intervenor, DIACRIN, INC. AND DIACRIN/GENZYME LLC, Defendant-Intervenor, and NEXTRAN INC., Defendant-Intervenor.	Civil Action No. 00-2849 (RMU)

DECLARATION OF JALENA G. SPECHT

1. My name is Jalena G. Specht, and I am an associate at the law firm of Covington & Burling, 1201 Pennsylvania Avenue NW, Washington, DC, 20004. As such, I have assisted with the firm's representation of Circe Biomedical, Inc. (Circe) as a Defendant-Intervenor in the above-captioned action brought pursuant to the Freedom of Information Act (FOIA). In this action, Plaintiff Campaign for Responsible Transplantation (CRT) seeks disclosure of FDA-generated documents, many of which contain material submitted to FDA by Circe, Diacrin, Inc.,

Diacrin/Genzyme LLC, or Nextran Inc. (collectively, Defendant-Intervenors). The statements in this declaration are based on my personal knowledge.

2. I have read (a) Plaintiff's Reply Memorandum in Support of Plaintiff's Motion for Summary Judgment and in Opposition to the Government's Cross-Motion for Summary Judgment and (b) Plaintiff's Reply to Defendant Intervenors' Memorandum in Opposition to Plaintiff's Motion for Summary Judgment, both submitted to the Court on May 8, 2002. In these submissions, Plaintiff contends that Defendant-Intervenors have hindered the progress of this action by failing "to ascertain from the [A]gency what responsive information of theirs is 'trade secrets' or 'confidential commercial information'..." and failing "to do the work necessary to assist the government in meeting its burden of proof." Pl. Reply to Def.-Int. at 6-8.

3. To the contrary, Defendant-Intervenors have offered to work with FDA throughout the course of this litigation in an effort to resolve the legal dispute in this case while protecting the confidentiality of their trade secrets and confidential commercial information submitted to FDA.

4. Defendant-Intervenors intervened in this action to protect the confidentiality of their trade secrets and confidential commercial information submitted to FDA in connection with investigational new drug applications (INDs) for xenotransplantation products.

5. The documents sought by Plaintiff are FDA-generated records (a) concerning xenotransplantation clinical trials generally and (b) pertaining to specific xenotransplantation INDs. Accordingly, papers created and submitted to FDA by Defendant-Intervenors are not at issue in this case.

6. As ordered by the Court, FDA compiled a Vaughn index of FDA-generated documents relating to xenotransplantation clinical trials generally and relating specifically to IND "G." Def. Notice of Filing (Aug. 31, 2001).

7. Plaintiff challenged the adequacy of FDA's Vaughn index in its motion for summary judgment on January 15, 2002. Pl. Mot. for Summ. J. at 28-29.

8. Based on FDA's Vaughn index, it was apparent that thousands of documents remained at issue – including nearly 700 documents in IND "G" and thousands more from the other INDs that were not indexed. Defendant-Intervenors recognized that responding to Plaintiff's concerns would place a massive burden on the Agency, and therefore sought to offer assistance to FDA to respond to Plaintiff's concerns.

9. Specifically, representatives of the Defendant-Intervenors met with Michael Levy, Esq., from FDA's Office of the Chief Counsel on January 31, 2002. At this meeting, Defendant-Intervenors jointly offered to provide funding for an assistant to help FDA respond to Plaintiff's concerns. Defendant-Intervenors specified that this assistant would not be affiliated with any Defendant-Intervenor and would be prohibited from disclosing any trade secrets or confidential commercial information in the FDA-generated documents.

10. Mr. Levy pointed out that FDA was withholding many of the documents requested by Plaintiff based on the government deliberative process privilege. He explained that for any third party to conduct the type of review we proposed, FDA personnel would first need to redact from each document any material that the Agency wished to protect based on this privilege. Mr. Levy explained that if FDA personnel were to review the documents individually in order to complete this redaction, the assistance offered by Defendant-Intervenors would be unlikely to save the

Agency time or effort. Nonetheless, Mr. Levy agreed to discuss Defendant-Intervenors' proposal with officials at FDA.

11. On February 8, 2002, I spoke with Mr. Levy regarding Defendant-Intervenors' proposal described in ¶ 9. Mr. Levy said that he had discussed the proposal with officials at FDA, and that the Agency declined Defendant-Intervenors' proposal. He explained that funding of an assistant by Defendant-Intervenors, even if the assistant was not affiliated with any Defendant-Intervenor, could be viewed as compromising the Agency's impartiality.

Jalena G. Specht, Esq.

Dated: June 10, 2002

CERTIFICATE OF SERVICE

I, R. Ian Kluge, hereby certify that on this 10th day of June, 2002, I caused copies of the foregoing Defendant-Intervenors' Motion for Leave to File Reply Memorandum in Support of the FDA's Cross-Motion for Summary Judgment and Statement of Points and Authorities and Defendant-Intervenors' Reply Memorandum and in Support of FDA's Cross-Motion For Summary Judgment to be served by first class mail, prepaid, on the following:

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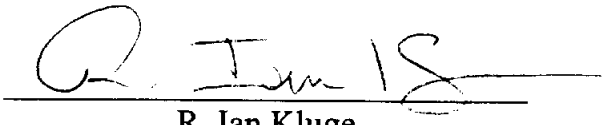

R. Ian Kluge