

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)

ORDER SETTING DOCUMENT PRODUCTION SCHEDULE

UPON CONSIDERATION of the parties Joint Status Report dated May 24, 2005, and the entire record herein, it is hereby

ORDERED that the Defendant shall comply with the following deadlines in this case:

- By June 6, 2005, Defendant shall have made good faith efforts to negotiate with GenVec regarding the appropriate redactions for one of its two remaining INDs and shall produce the materials where GenVec and Defendant agree to release.
- By June 20, 2005, Defendant shall have made good faith efforts to negotiate with GenVec regarding the appropriate redactions for the other remaining IND and shall produce the materials where GenVec and Defendant agree to release.
- By July 19, 2005, Defendant shall have made good faith efforts to negotiate with ExCorp, Algenix, and Dr. Watanabe regarding the appropriate redactions for their three respective INDs and shall produce the materials where these submitters and Defendant agree to release.

- By August 18, 2005, Defendant shall have made good faith efforts to negotiate with Arbios Systems regarding the appropriate redactions for its IND and shall produce the materials where Arbios Systems and Defendant agree to release.
- By September 30, 2005, in the event that any of these submitters still object to disclosure of information which the agency deems should be released, Defendant shall issue letters, pursuant to 21 C.F.R. § 20.55, to GenVec, Excorp, Algenix, Dr. Watanabe, and/or Arbios Systems, respectively, requiring the submitter to intervene in this action and file a Vaughn index (itemizing redactions sought by submitter but not supported by the agency) within 30 days of the date of Defendant's letter or waive its objections to release, provided that if the submitter fails to do so within those 30 days, within one week following the end of that 30-day period, Defendant shall release to Plaintiff all such information that Defendant determined must be released pursuant to this Court's orders.

So Ordered, this _____ day of _____, 2005.

RICARDO M. URBINA
United States District Judge

IN THE UNITED STATES DISTRICT COURT
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CAMPAIGN FOR RESPONSIBLE TRANSPLANTATION,)
)
Plaintiff,)
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v.) No. 00-2849 (RMU)
)
U.S. FOOD AND DRUG ADMINISTRATION,)
)
Defendant.)
_____)

JOINT STATUS REPORT

Plaintiff, the Campaign for Responsible Transplantation, and Defendant, the U.S. Food and Drug Administration, respectfully file their Joint Status Report, as required by Order of this Court dated May 3, 2005. A proposed Order Setting Schedule for Production is attached.

Counsel for the plaintiff, defendant, and agency met face-to-face last Thursday, May 19, 2005, and worked out a proposed schedule for production of the remaining documents in this case, which involves plaintiff's request for records relating to xenotransplantation. Of the 18 investigational new drug application files ("INDs") at issue, there now remain only six that have not yet been produced. For two of these, both for GenVec, the agency expects to be able to produce them soon.

Two of the four submitters for the other four INDs have indicated that they intend to demand more restrictive withholdings than the agency has determined are appropriate under the governing Vaughn index and the Court's July 23, 2001, and September 24, 2004, orders in this case (hereinafter "the Court's orders"). The agency has reason to believe that the third submitter may take a similar approach. The fourth submitter has not yet responded to the agency's persistent attempts to contact him.

The parties agreed to establish deadlines for the agency to produce the records that the submitters and the agency agree must be released pursuant to this Court's orders. To provide for the contingency that the agency and any of these five submitters cannot agree on the proper scope of disclosure, the parties further propose a later deadline for the agency to issue a letter to the submitter, pursuant to 21 C.F.R. § 20.55, requiring the submitter to intervene in this action to prevent the agency from disclosing the records which the agency deems appropriate for disclosure under the governing Vaughn index and this Court's orders.

Accordingly, the proposed scheduling order would set the following deadlines:

- June 6, 2005, for the agency to have made good faith efforts to negotiate with GenVec regarding the appropriate redactions for one of its two remaining INDs, and to produce the materials that GenVec and the agency agree to release.
- June 20, 2005, for the agency to have made good faith efforts to negotiate with GenVec regarding the appropriate redactions for the other one of its remaining INDs, and to produce the materials that GenVec and the agency agree to release.
- July 19, 2005, for the agency to have made good faith efforts to negotiate with ExCorp, Algenix, and Dr. Watanabe regarding the appropriate redactions for their three respective INDs, and to produce the materials that these submitters and the agency agree to release.
- August 18, 2005, for the agency to have made good faith efforts to negotiate with Arbios Systems regarding the appropriate redactions for its IND, and to produce the materials that Arbios Systems and the agency agree to release.
- September 30, 2005, in the event that any of these submitters still object to disclosure of information which the agency deems should be released, for the agency to issue letters,

pursuant to 21 C.F.R. § 20.55, to GenVec, Excorp, Algenix, Dr. Watanabe, and/or Arbios Systems, respectively, requiring the submitter to intervene in this action and file a Vaughn index (itemizing redactions sought by submitter but not supported by the agency) within 30 days of the date of the agency's letter or waive its objections to release, provided that if the submitter fails to do so within those 30 days, within one week following the end of the 30-day period, the agency will release to plaintiff all such information that the agency determined must be released pursuant to this Court's orders .

May 24, 2005

Respectfully submitted,

/s/
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