IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

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

DEFENDANT'S OPPOSITION TO PLAINTIFF'S EXPEDITED MOTION TO ENFORCE THIS COURT'S SEPTEMBER 24, 2004 ORDER

Defendant, the United States Food and Drug Administration ("FDA"), respectfully submits this Opposition to Plaintiff's Expedited Motion to Enforce This Court's September 24, 2004 Order and Memorandum in Support ("Motion"). This is an action under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552 *et seq.*, as amended, arising from plaintiff's FOIA request of March 9, 2000, for records concerning xenotransplantation clinical trials.[1] In its Motion, plaintiff requests that the Court enforce its Order of September 24, 2004, by requiring FDA to release within ten days records associated with the files of the eighteen investigational new drug applications ("INDs") involving xenotransplantation that are still at issue in this case. The Motion also seeks attorney's fees and costs. Alternatively, plaintiff requests that FDA be held in civil contempt. For reasons stated below, the Court should deny plaintiff's Motion.

[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).

I. 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 in general and FDA generated records in files for INDs involving xenotransplantation, of which there were thirty-five in total. Because of the potential volume of records associated with the FOIA request, even as narrowed by plaintiff, FDA moved the Court for leave to file a sample Vaughn Index for a representative IND rather than a comprehensive Vaughn Index for all thirty-five INDs.[2] The Court granted FDA's motion. Id. at 35. Plaintiff selected an IND ("IND-G") sponsored by GenVec, Inc. ("GenVec"), as the representative IND.[3] CRT III at 3.

The parties twice filed cross-motions for summary judgment with respect to privileges asserted by FDA and the adequacy of FDA's Vaughn Indices for IND-G and the records pertaining to xenotransplantation in general. On September 3, 2003, the Court granted, in part, and denied, in part, the first set of cross-motions for summary judgment. See Campaign for

---

[2] As noted, plaintiff has since narrowed its request to nineteen INDs.

[3] As discussed more fully in a declaration submitted by E. Michael Egan of GenVec, Inc. ("GenVec"), two of the sponsors who intervened in this case have since merged and formed a new company, GenVec, which now holds the proprietary interest in six of the INDs. See Egan Decl. ¶ 3. For the sake of simplicity, defendant refers to all of the sponsors associated with these INDs as GenVec, regardless of their identity at an earlier stage of the proceedings. There were also three additional intervenors: Circe Biomedical, Inc. ("Circe"); Nextran, Inc.; and Novartis Pharmaceuticals Corporation ("Novartis"). Novartis has since withdrawn as an intervenor. Thus, there are effectively three remaining intervenors, compared to six originally.

Responsible Transplantation v. FDA, 219 F. Supp. 2d 106 (D.D.C. 2002) ("CRT II"). By Order and Memorandum Opinion dated September 24, 2004 ("CRT III"), the Court addressed the second set of cross-motions for summary judgment by denying plaintiff's and granting defendant's.

As further narrowed by plaintiff before the Court's ruling in September 2004, there were eighteen INDs other than IND-G that were potentially responsive to plaintiff's FOIA request. CRT III at 22. As the Court acknowledged in its Opinion of September 24, 2004, FDA was to process the remaining responsive INDs consistent with the Court's subsequent rulings regarding IND-G. Id.

In addition to ruling on the parties' cross-motions for summary judgment in September 2004, the Court also ruled on plaintiff's request that it order the immediate disclosure of the records associated with the remaining eighteen INDs that were similar to those released for IND-G. Id. at 4. Defendant explained that it was to begin processing the remaining eighteen INDs after the Court's rulings as to IND-G in manner consistent with those rulings, as that decision would set the parameters for the agency to follow. See Def. Opp. Pl. Mot. Summ. J. (Feb. 5, 2004) ("Opp.") at 3. Defendant pointed out that the process for releasing documents in those INDs to plaintiff would be a large project requiring as much as one year to complete:

> 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.

Id. at 4 (emphasis added).

Subsequently, the Court held that FDA was required to produce records relating to the other INDs:

> 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, at 22 (internal citations omitted). The accompanying Order simply directed FDA "to disclose all FDA generated records that pertain to the other eighteen INDs that are similar in kind to the IN[D] G records that the FDA has already released."

The Court did not set a deadline for production, nor did FDA read the Order or Opinion to require a process different from the one described in defendant's opposition to plaintiff's motion for summary judgment. Third Declaration by Beth Brockner Ryan ("3d Brockner Ryan Decl.") at ¶ 12. Defendant made clear the enormous amount of work that processing the records associated with these eighteen remaining INDs would entail and advised both plaintiff and the court that the production of these records could take up to one year. See Opp. at 4.

As the FDA's declarations demonstrate, it is processing the remaining responsive records as expeditiously as it can given its resource constraints, the need to coordinate with sponsor representatives, and numerous other demands on those working on the production.

II. FACTS

In its Motion, plaintiff moves the Court to order FDA to produce all of the records associated with the eighteen remaining INDs within ten days. The Court should deny plaintiff's motion. As established by the declarations filed in support of defendant's opposition, such a deadline would be impossible for FDA to meet.

Plaintiff argues that "defendant is in blatant disregard of the Court's Order" by failing to produce any records within six months of the Order, that there is no need for further review of the records associated with the eighteen remaining INDs, and that intervenor-defendants should not be involved in the review of these records. Mot. at 4-7. In making these arguments, plaintiff glosses over a production schedule, to which it agreed, that did not anticipate any production until March 7, 2005. Moreover, plaintiff fails to take into account the time and resources FDA must expend in processing records for release under FOIA and the numerous other demands placed on the employees processing its request.

Plaintiff also ignores FDA's obligations under Exemption 4 of FOIA, Trade Secrets Act ("TSA"), 18 U.S.C. § 1906, 21 U.S.C. § 331(j), and regulations implementing those statutes. FDA cannot, as plaintiff seems to assume, make public the trade secrets and confidential commercial information (collectively "TS/CCI") held by the agency without the consent of the submitter. This is particularly true in light of the demonstrated interest of the defendant-intervenors in protecting certain information at issue in this litigation. Plaintiff fails to appreciate that the process adopted by FDA for reviewing the records in the remaining INDs will, in fact, ultimately promote both a more expeditious production of those records and the sponsors'

voluntary release of certain privileged information to plaintiff. Finally, plaintiff misapprehends the purpose for processing and creating a Vaughn Index for IND-G.

As described more fully in the attached declarations, FDA has far from ignored the Court's Order with respect to the remaining eighteen INDs. Because the resolution of the parties' cross-motions for summary judgment would define the parameters for the production, FDA did not begin gathering the responsive documents for the remaining eighteen INDs and, as a practical matter, could not have started to prepare these records for release until after the Court's September 24, 2004, ruling on those cross-motions. See Opp. at 3; 3d Brockner Ryan Decl. ¶ 12.

A. Formulating a Plan

After being notified of the Court's Order directing production of the FDA generated records associated with the remaining INDs, FDA immediately began discussions to implement the Order in the most efficient and appropriate manner. See 3d Brockner Ryan Decl. ¶ 14. For reasons articulated more fully below, among the considerations were the regulation permitting FDA to require the sponsors to itemize and index TS/CCI when there is a judicial challenge to FDA's failure to release records on the basis of Exemption 4 of FOIA, see 21 C.F.R. § 20.55, and FDA's regulation prohibiting the public disclosure of records in an IND file if FDA has not approved an application of a biologics license ("BLA") in connection with the product at issue in that IND. See 21 C.F.R. §§ 601. 50(b), 601.51(c) and (d)(1); 3d Brockner Ryan Decl. ¶ 15. FDA also contemplated various options for using FDA's limited resources, as described in more detail

in Ms. Brockner Ryan's Third Declaration, to process the eighteen remaining INDs as quickly as practicable.[4] 3d Brockner Ryan Decl. ¶ 15.

After evaluating its options, FDA concluded that 21 C.F.R. § 20.55 permitted FDA to require the sponsors of the INDs to review the records for TS/CCI and either identify information they believed should be withheld by FDA or waive any privileges under Exemption 4, in which case FDA could promptly release the records. Id. ¶¶ 15, 17. In this case, providing a sponsor with an opportunity to review the records for each IND entailed a four-step process: (1) identify FDA generated records in the files for each IND and segregate those from submissions by the sponsor ("Step One"); (2) copy and review the FDA generated records for information reflecting the Agency's deliberative process that was exempt from disclosure under Exemption 5, 5 U.S.C. 552(b)(5) ("Step Two"); (3) send the records for each IND to its sponsor and provide the sponsor with a reasonable time to review the records for TS/CCI and identify same ("Step Three"); and (4) review any proposed redactions by the sponsor and adopt those consistent with Exemption 4 of FOIA and the Court's September 24, 2004 Order ("Step Four"). 3d Brockner Ryan Decl. ¶ 16.

Although at first glance this system may seem cumbersome, it actually dramatically reduces the time and resources necessary for producing a large volume of records, as compared to the amount of time it would take the agency to produce such records without input from the sponsors. Id. ¶ 17. The system assists the agency in focusing only on material of concern to the sponsor. Not only does the system provide a logistical benefit by having the sponsors shoulder

---

[4] As detailed extensively in Ms. Brockner Ryan's declaration, the office charged with processing the responsive records in this cases, the Access Litigation and Freedom of Information Branch ("ALFOI") in FDA's Center for Biologics Evaluation and Research ("CBER") has a small staff of seven people and has numerous, at times conflicting, demands on its time and resources. See 3d Brockner Ryan Decl. ¶¶ 23-39.

some of the load, it also permits the agency to resolve any disputes with the sponsors before production, rather than spawning additional litigation. Indeed, the fact that five of the sponsors intervened in this case makes clear their intent to protect TS/CCI from disclosure.

As a result of limited resources, if FDA had elected to undertake--by itself--the process of reviewing all of the FDA generated documents for each of the eighteen remaining INDs for TS/CCI, it would have taken FDA far longer to process those records. Id. Redacting TS/CCI from documents associated with the biologics approval process is a time-consuming task that requires researching scientific issues and the availability of information in the public domain. Id. Moreover, if FDA made the decisions itself, the sponsors would not have had an opportunity to waive the privilege under Exemption 4, so plaintiff could well receive less information in the responsive records than it would without the involvement of the sponsors. Id.

B. Implementing the Court's Order

After realigning resources in the office charged with processing the records, FDA began gathering the records associated with each of the eighteen responsive INDs. Id. ¶ 18. FDA had collected the responsive records by the middle of October 2004. Id. For the next six weeks, FDA completed Step One of the process described above for each of the eighteen remaining INDs by segregating FDA generated documents from the documents submitted to FDA by the sponsors. Id.

By December 13, 2004, plaintiff had specifically requested that FDA prioritize release of the records for the INDs submitted by GenVec and Circe. Id. ¶ 19. Because of this request, FDA began to implement Step Two of the process described above for the records for GenVec's INDs

by reviewing them for information reflecting the agency's deliberative process. Id. By January 18, 2005, FDA had completed Step Two for two of GenVec's INDs. Id.

On or about January 18, 2005, the parties agreed to a schedule for production of the FDA generated documents for the eighteen remaining INDs. See Declaration of G. Matthew Warren ("Warren Decl.") ¶ 3. The production schedule anticipated release of the FDA generated records associated with one IND every two weeks, beginning on February 21, 2005. Id. Plaintiff offered to draft a stipulation and consent order that would have formalized this agreement with the Court but never presented one to defendant. Id. FDA devoted the resources necessary to meet, if not exceed, the objective of producing the records associated with a single IND every two weeks beginning February 21, 2005. 3d Brockner Ryan Decl. ¶ 20.

C. Communications with GenVec

Because plaintiff had asked FDA to prioritize the records for GenVec's INDs, FDA concentrated its efforts on processing those records and attempting to get a response from GenVec. On January 18, 2005, the same day that the parties agreed to a production schedule, FDA shipped the records for two of GenVec's INDs to the company's attorney, Jeremy Monthy. Warren Decl. ¶ 4. In an accompanying letter, FDA advised Mr. Monthy of developments in the case and stated that the purpose for sending the documents was:

> to provide [GenVec] with an opportunity to identify information in those records that [GenVec] believe[s] is exempt from disclosure under FOIA Exemption 4, 21 C.F.R. §§ 20.61 and 20.63, or other applicable statutes or regulations. Because FDA is operating under a court order, we would appreciate your prompt response. If by February 3, 2005, I do not receive a written response from you, either identifying information in the documents that you believe to be exempt from disclosure or otherwise objecting, FDA will regard your failure to respond as consent to release the enclosed documents to [plaintiff].

Id. Over the course of the next six weeks, FDA sent records for an additional three INDs to counsel for GenVec with similar letters. Id.

Subsequently, Mr. Monthy contacted FDA to seek an extension to the February 3 deadline. Id. ¶ 5. He represented that a change in corporate structure resulting in the merger of three companies made it difficult for him to find the individual with the authority to review the records for the INDs provided to GenVec. Id.; Egan Decl. ¶ 8. FDA informed Mr. Monthy that FDA needed a response for at least one of the INDs by February 15 if FDA was going to be able to produce some records to plaintiff by February 21, 2005. Warren Decl. ¶ 5. Mr. Monthy contacted FDA on February 15 to say that GenVec would not be able to provide records before February 21. Id. ¶ 6. Undersigned counsel, Alan Burch, notified plaintiff's counsel and obtained from plaintiff's counsel an extension until March 7, 2005, to produce records associated with the first of the eighteen remaining INDs. Id. Government counsel informed plaintiff's counsel that the reason for the delay was GenVec's failure to review the records in a timely manner. Id. FDA later advised GenVec that it would need responses during the week of February 28 to be able to meet the new deadline with plaintiff. Id.

On March 7, 2005, FDA counsel contacted GenVec counsel to see whether it had reviewed any of the responsive documents for the five INDs that FDA had sent. Id. ¶ 7. Mr. Monthy responded that GenVec had scheduled an internal meeting for March 11, 2005, "to resolve the issue of who has standing to lodge objections to the responsive INDs." Id. Mr. Monthy continued, "I have been pressing them for weeks, however, regarding the documents themselves, so I hope to get privilege designations for at least one IND to you soon after that meeting." Id. On March 15, FDA followed up with Mr. Monthy on the status of GenVec's

reviewing process by voice-mail and e-mail. Id. ¶ 8. In the e-mail, FDA reminded GenVec of the deadlines imposed by the January 18 and February 3 letters, and FDA reminded GenVec that it would regard a failure to respond by the deadlines as a consent to the release of the records sent to GenVec with those letters. Id. Mr. Monthy responded the next day with an e-mail in which he apologized for the delay and communicated that his client was "firmly opposed to unauthorized disclosure of the documents but that [they] were working as quickly as possible to review the documents." Id. ¶ 9. Several days later, Mr. Monthy followed up on his e-mail with another status report, in which he stated that he had spoken to his client that afternoon and "learned that the administrative issues ha[d] finally been resolved." Id. He expected "experienced counsel to review at least one IND on Monday or Tuesday at the latest[] and will pass the reservations [sic] as soon as [he] receive[d] them." Id.

D. Recent Developments

On March 22, 2005, plaintiff counsel contacted government counsel to notify defendant that plaintiff would file a motion to compel immediate release of the remaining responsive documents if it did not receive any of them before March 29, 2005. Id. FDA immediately began implementing Step Two of the process described above for each the INDs associated with other sponsors by reviewing those records for information privileged under Exemption 5. 3d Brockner Ryan Decl. ¶ 21. By April 1, FDA had completed Step 2 for each of the remaining eighteen INDs. Id. By that same day, FDA had sent FDA generated documents to sponsors for all but two of those INDs for completion of Step 3 of the process.[5] Warren Decl. ¶ 13. The

[5] FDA was unable to locate the current holders of the two remaining INDs because one sponsor is now a defunct company and the other did not have current contact information in the agency's database.

accompanying letters set deadlines for responding that ranged from April 4, 2005, until April 22, 2005. Id. FDA has since contacted the sponsor whose deadline was April 4, 2005, and obtained written consent to release records for that IND with no redactions for TS/CCI. Id. FDA has begun copying those records and expects to release them to plaintiff with in the next few business days. 3d Brockner Ryan Decl. ¶ 22.

Since plaintiff filed the instant motion, FDA counsel has contacted the sponsor whose deadline was April 4, 2005, and obtained written consent to release records for that IND with no redactions for TS/CCI. Id. FDA has begun copying those records for release to plaintiff with in the next few business days. See id. ¶ 22. FDA has also received a letter from Mr. Monthy in which he indicates that GenVec has completed its review of the records for the first four INDs sent to GenVec. Warren Decl. ¶ 3. Attached to the letter was a chart containing privilege designations for those records. Id. FDA has begun processing the records. Id.

III. PLAINTIFF'S MOTION TO ENFORCE SHOULD BE DENIED.

A. It Is Essential, and Works to Plaintiff's Benefit, for FDA to Consult with the Sponsors of INDs.

1. *Interests Protected by Exemption 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).

Information that relates to a business or trade is considered "commercial or financial." See, e.g., Lepelletier v. FDIC, 977 F. Supp. 456, 459 (D.D.C. 1997) ("identities of business having unclaimed deposits" deemed "financial information"), aff'd in part, rev'd in part & remanded on other grounds, 164 F.3d 37 (D.C. Cir. 1999). Courts have held that the terms "commercial" and "financial" should be given their ordinary meanings. See, e.g., Judicial Watch, Inc. v. Export-Import Bank, 108 F. Supp. 2d 19, 28 (D.D.C. 2000) (citing Public Citizen Health Research v. FDA, 704 F.2d 1280, 1290 (D.C. Cir. 1983); Washington Post Co. v. HHS, 690 F.2d 252, 266 (D.C. Cir. 1982)). If a submitter has a commercial interest in the information, it will be considered "commercial" for purposes of Exemption 4. Public Citizen, 704 F.2d at 1290. Documents generated by the federal government that contain summaries or reformulations of information supplied by a source outside the government are included under Exemption 4. See, e.g., Gulf & W. Indus., Inc. v. United States, 615 F.2d 527, 529-30 (D.C. Cir. 1979) (contractor information contained in agency audit report).

Information is confidential for purposes of Exemption 4 if its disclosure is likely "(1) to impair the Government's ability to obtain necessary information in the future; or (2) to cause substantial harm to the competitive position of the person from whom the information was obtained." Nat'l Parks, 498 F.2d at 770. These two tests apply when the submission of the

information is "compelled" by the government. Critical Mass Energy Project v. NRC, 975 F.2d 871, 878 (D.C. Cir. 1992). In the instant matter, FDA regulations require sponsors to submit information, much of which is confidential, to FDA prior to commencing with a clinical trial of an investigational new drug; thus, rendering their IND submissions "compelled" for purposes of FOIA. See 21 C.F.R. §§ 312.20-312.35. Under the second test outlined in National Parks, which is applicable in this case, Exemption 4 protects information whenever there is evidence of "'actual competition and a likelihood of substantial competitive injury'" to the provider of that information. Judicial Watch, 108 F. Supp. 2d at 29 (quoting CNA Fin. Corp. v. Donovan, 830 F.2d 1132, 1152 (D.C. Cir. 1987)).

2. *Interest of Sponsors in the Disclosure of Information in an IND*

Exemption 4 is intended to safeguard the interests of both the government and those submitting information to the government. Nat'l Parks, 498 F.2d at 767. As this court has recognized in this case, sponsors of INDs have an interest in protecting confidential commercial information and trade secrets submitted in connection with their INDs. In fact, the Court permitted six sponsors to intervene in light of their interest in protecting information in the IND files. See Order dated March 1, 2001; see also Public Citizen Health Research Group v. FDA, 185 F.3d 898, 903-06 (D.C. Cir. 1999) (upholding FDA's application of Exemption 4 to material in an IND file); CRT III at 9 (same). The Court has likewise permitted sponsors to intervene in another FOIA case in which information about clinical trials conducted under an IND was at issue. See Public Citizen Health Research Group v. FDA, 953 F. Supp. 400, 402 (D.D.C. 1996) (discussing both defendant-intervenors and the nature of the information at issue). In both cases, the Court relied extensively on the affidavits of these intervenor-defendants in reaching a

decision about whether FDA had sustained its burden in demonstrating that the withheld information was privileged under Exemption 4. See CRT III at 8-10; Public Citizen, 953 F. Supp. at 403. Although FDA will ultimately exercise its own judgment in determining whether Exemption 4 applies to particular information, see Nat'l Parks, 498 F.2d at 767, involving the sponsors in this process both speeds production and minimizes the likelihood of prompting further ancillary litigation, which could impede actual production.

3. *21 C.F.R. § 20.55*

Because another party's interests are at stake when records appear to contain TS/CCI, FDA's regulations also contemplate the involvement of the submitters of such records whenever there is a judicial challenge to FDA's failure to release those records.[6] Under 21 C.F.R. § 20.55, FDA will "inform the person affected [by the litigation], i.e., the person who submitted the record, and will require that such person intervene to defend the exempt status of the record." 21 C.F.R. § 20.55. Furthermore, FDA's regulations state that, "[i]f the affected person fails to intervene to defend the exempt status of the records and to itemize and index the disputed records, [FDA] will take this failure into consideration in deciding whether that person has waived such exemption so as to require [FDA] to promptly make the records available for public disclosure." Id. Under 21 C.F.R. § 20.55, FDA does not construe a failure to respond as a *per se* waiver of TS/CCI but merely considers it as a factor in evaluating whether to release the information without receiving the sponsor's response. 3d Brockner Ryan Decl. ¶ 18.

[6] Another regulation, 21 C.F.R. § 20.61(e), pertains to consultation with such submitters under certain circumstances arising before the start of litigation.

The purpose of 21 C.F.R. § 20.55 is not only to protect FDA from ancillary litigation regarding the release of TS/CCI but also to conserve agency resources by requiring outside parties to shoulder some of the burden of protecting their interests. Id. The process provides an opportunity for persons who are in a better position to know whether the information has some commercial or financial value to them to identify such information and provide evidence in support of its supposed privileged status. Moreover, because 21 C.F.R. § 20.55 compels affected persons to defend proposed redactions in court, they are far less likely to insist on those redactions unless they are both important to them and clearly within the privilege of Exemption 4, see id., thereby ultimately benefitting the parties and the Court. In fact, some of the material in IND-G was released simply because the sponsor agreed voluntarily disclose such information

4. *Risk of Ancillary Litigation.*

In the present case, the situation FDA confronted was especially difficult. In their motions to intervene, the intervenors argued that everything in FDA's files was exempt from disclosure under 21 C.F.R. §§ 601.50 and 601.51(d) and stated that they had relied on those regulations in submitting information to FDA. See, e.g., Circe's Memo. Supp. Mot. Int., filed January 12, 2001, ("Mot. Int.") at 3. As defendant-intervenors correctly noted, FDA's regulations state that FDA may not even disclose the existence of an IND "before a biologics license application [BLA] has been approved [for the product in the IND] unless it [the IND] has previously been publicly disclosed or acknowledged." 21 C.F.R. § 601.51(b); see also 21 C.F.R. § 601.50(a). No data or information associated with an IND file is available for public disclosure "[i]f the existence of a biological product file has not been publicly disclosed or acknowledged," and even if the existence of a biological product file has been publically disclosed, "no data or

information contained in the file is available for public disclosure before such license is issued." 21 C.F.R. § 601.51(c), (d)(1). FDA has not approved a BLA for any xenotransplantation product to date. See 3d Brockner Ryan Decl. ¶ 10.

The very fact of intervention by these sponsors in the present case demonstrated their interest in protecting the information in the INDs at issue.[7] Faced with the prospect of having to contend with a reverse-FOIA suit based on FDA's own regulations that either sought to enjoin FDA from releasing the information or sought monetary compensation for alleged damage to the sponsors' commercial or financial interests, FDA opted to provide sponsors with an opportunity to review the responsive records for the remaining INDs as a means of avoiding such a risk. The process had the added benefit of potentially speeding production of the responsive records, conserving agency resources, and creating an opportunity for the sponsors to waive any privileges associated with TS/CCI.

B. Plaintiff Was on Notice that Processing the Records Associated with the Remaining INDs Would Take a Significant Amount of Time and that Defendant Would Be Consulting with the Sponsors before Releasing those Records.

In its Motion, plaintiff expresses surprise both that it has taken FDA more than six months to produce any of the records associated with the remaining eighteen INDs and that FDA has involved the sponsors of the INDs in the reviewing process. But, as stated above, defendant

---

[7] The drug industry takes very seriously the release of confidential commercial information and trade secrets submitted to the agency very seriously and is willing to pursue judicial relief if it disagrees with the agency's release of material it believes warrants protection. See Jerome Stevens Pharms., Inc. v. FDA, No. 02-1939 (RMU) (D.D.C. filed Oct. 2, 2002) (involving allegations of improper release of trade secrets). In fact, this Court has entered an order preventing the further dissemination of information privileged under Exemption 4 when FDA inadvertently released it to a plaintiff in a FOIA case. See Public Citizen, 953 F. Supp. at 404-06.

notified both plaintiff and the Court that it could take FDA up to one year to prepare for release the records at issue and that the process for doing so would entail consulting with the sponsors. Opp. at 4.[8]

Furthermore, on October 1, 2002, plaintiff signed a Memorandum of Understanding ("MOU") with defendant and the defendant-intervenors that established a procedure and a timetable for providing the defendant-intervenors, and GenVec in particular, with an opportunity to review documents arguably containing TS/CCI and propose redactions or waive any associated privilege. See 3d Brockner Ryan Decl. ¶ 13. On October 2, 2003, plaintiff filed that MOU with the Court. Although the documents at issue in 2002 were those associated with IND-G and xenotransplantation in general, the MOU put the plaintiff on notice that FDA would be consulting with the sponsors as to records in IND files.[9]

Finally, as discussed above, plaintiff was aware that defendant-intervenors had become involved in the case for the express purpose of protecting the TS/CCI in the documents which are responsive to plaintiff's FOIA request. See, e.g., Mot. Int., *passim*. These same defendant-intervenors repeatedly emphasized that all records associated with an IND were exempt from disclosure under 21 C.F.R. §§ 601.50 and 601.51. Id. at 3.

---

[8] Defendant also described the process it intended to adopt for reviewing these records in its Sur-Reply submitted to the Court and served on the plaintiff on September 9, 2003, although the Court denied as moot defendant' motion to file a sur-reply after striking the parties' cross-motions for summary judgment for unrelated reasons.

[9] It is also worth noting the context of the MOU. There was a need for the parties to be in agreement as to the schedule for the sponsors' review because the Court had directed FDA to file new Vaughn Indices by November 10. The defendant-intervenors agreed to the schedule as part of the MOU, and the MOU was submitted to the Court. As a result, FDA was able to meet the clear deadlines imposed by the MOU.

C. The Procedures Adopted by FDA to Process the Records for the Remaining Eighteen INDs Are Not Inconsistent with the Purpose for Producing a Sample Vaughn Index.

Plaintiff also argues that, under the rationale used for creating the sample Vaughn Index, FDA should be able to produce immediately the records associated with the eighteen remaining INDs. Plaintiff misses the point of the sample Vaughn Index. FDA never argued, nor has the Court ever held, that the purpose of the sample Vaughn Index was to address the individual privileges associated with each of the nineteen INDs. The purpose of the sample Vaughn Index for IND-G was to establish the general nature of the privileges that were likely to be asserted with respect to the remaining eighteen INDs, after consultation with their sponsors. Complying with the Court's Order to "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" still requires reviewing each of documents in the IND files for the particular application of the privileges that were litigated in the cross-motions for summary judgment. See CRT III at 22. Involving the sponsors in the process was simply the most efficient manner of completing those individual reviews. As stated above, FDA expects to evaluate each sponsor's records after receiving the sponsor's input to ensure that the redactions are consistent with the Court's rulings regarding IND-G and the sample Vaughn Index.

D. FDA Is and Has Been Making Good Faith Efforts to Comply with the Informal Production Schedule.

As described in more detail above, defendant worked with plaintiff in developing an informal production schedule that would require FDA to produce the records associated with each IND every two weeks beginning February 21, 2005. Plaintiff could have memorialized that

agreement with the Court but opted not to do so. Nonetheless, FDA made every effort to prioritize its work according to plaintiff's stated preference that FDA focus on GenVec's INDs. When FDA encountered obstacles in obtaining GenVec's cooperation in reviewing the records for TS/CCI, FDA contacted plaintiff to notify it of these difficulties and sought an extension until March 7, which plaintiff granted.

In any event, FDA had informed plaintiff by way of its Opposition to Plaintiff's Motion for Summary Judgement in February 2004 both that it would be consulting with sponsors and that the process could take up to one year. Although FDA has encountered a few hitches, a year has not yet passed. FDA hopes to complete its process for preparing these records for release well before a full year passes. In fact, FDA expects to release some records to plaintiff by as early as next week. See 3d Brockner Ryan. Decl. at ¶ 22. FDA is also about to begin processing records associated with four additional INDs, sponsored by GenVec, and expects to release those records to plaintiff in the near future. See Warren Decl. ¶ 13.

IV. THE GOVERNMENT SHOULD NOT BE HELD IN CONTEMPT.

In the alternative, plaintiff requests that FDA be held in civil contempt for its failure to produce any records associated with the remaining eighteen INDs. "For contempt to issue, two conditions must be present: (1) the existence of a reasonably clear and specific order . . . and (2) violation of that order by the defendant." Landmark Legal Found. v. EPA, 272 F. Supp. 2d 70, 75 (D.D.C. 2003). Neither element is met here.

Plaintiff contends that the Court's Order from September 24, 2004, clearly compelled production of at least some of the remaining responsive records within the past six months. However, that Order did not include a timetable for production; it simply directed FDA to

"disclose all FDA generated records that pertain to the other 18 INDs that are similar in kind to the IN[D] G records that the FDA has already released." As discussed above, consistent with FDA's understanding of the Order, the context of the Order, and the unambiguous statements FDA made regarding the time it would take to produce these documents, as well as relevant statutes and its own regulations, FDA has made every effort to comply with the Order and intends to fulfill its obligations. Plaintiff's own willingness to enter into a production schedule that was set to begin in February suggests that plaintiff also understood that the Court had not imposed a specific deadline in its Order. Given that the Court has neither established a deadline for production of responsive records for the eighteen remaining INDs nor endorsed a formal agreement by the parties, the Court should decline plaintiff's request to hold FDA in contempt for its failure to produce any responsive records in the past six months.

V. ATTORNEY'S FEES AND COSTS

Plaintiff also seeks attorney's fees and costs associated with this motion. By order dated December 6, 2004, the Court granted plaintiff's unopposed motion to permit plaintiff to file any motion under Rule 54 of the Federal Rules of Civil Procedure for attorney's fees and costs associated with bringing this action until thirty days after defendants' compliance with the Court's Order or the Court resolves any disputes associated with that Order. This approach is similar to that taken in most FOIA cases. See Anderson v. HHS, 3 F.3d 1383, 1385 (10th Cir. 1993) ("[T]he fee issue is ancillary to the merits of the controversy."). The Court should not diverge from that approach and should postpone ruling on plaintiff's request for fees until the conclusion of the case.

VI. CONCLUSION

In its Motion, plaintiff requests that the Court enforce its Order of September 24, 2004, by requiring FDA to release within ten days records associated with the files of eighteen investigational new drug applications ("INDs") involving xenotransplantation. The Motion also seeks attorney's fees and costs. Alternatively, plaintiff requests that FDA be held in civil contempt. For reasons stated above, the Court should deny plaintiff's Motion.

April 7, 2005

Respectfully submitted,

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

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

ALAN BURCH, D.C. Bar # 470655
Assistant United States Attorney
555 4th Street, NW
Washington, D.C. 20530
202-514-7204, alan.burch@usdoj.gov

OF COUNSEL:

ALEX M. AZAR, II
General Counsel
Department of Health and Human Services

GERALD F. MASOUDI
Acting Chief Counsel
Food and Drug Division

ERIC M. BLUMBERG
Deputy Chief Counsel for Litigation

G. MATTHEW WARREN
Associate Chief Counsel
Office of General Counsel
5600 Fishers Lane (GCF-1), Room 6-64
Rockville, MD 20857
(301) 827-2724