656 F.Supp.2d 68
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United States District Court,
District of Columbia.
IN DEFENSE OF ANIMALS, Plaintiff,
v.
UNITED STATES DEPARTMENT OF AGRICULTURE, et. al., Defendants.
Civil Action No. 02-557 (RWR).

Sept. 18, 2009.

Background: Freedom of Information Act (FOIA) requester, an animal protection organization, sought to compel Department of Agriculture (USDA) to release records concerning its investigation of research facility operator's alleged violations of Animal Welfare Act (AWA). Operator's parent intervened, and opposed disclosure primarily under FOIA's exemption for confidential commercial information obtained from a person. The District Court, Oberdorfer, J., 501 F.Supp.2d 1, denied parties' cross-motions for summary judgment.

Holdings: Following bench trial, the District Court, Richard W. Roberts, J., held that:
(1) evidence that operator would suffer harm due to customers' perceptions was insufficient to support application of FOIA confidentiality exemption, and
(2) generalizations about competitors' identifying operating procedures, or pharmaceutical compounds being tested, also did not support application of exemption.

Judgment for requester.

West Headnotes

[1] Records 326 54

326 Records
326II Public Access
326II(B) General Statutory Disclosure Requirements
326k53 Matters Subject to Disclosure; Exemptions
326k54 k. In general. Most Cited Cases
Freedom of Information Act (FOIA) exemptions are narrowly construed. 5 U.S.C.A. § 552(b).

[2] Records 326 65

326 Records
326II Public Access
326II(B) General Statutory Disclosure Requirements
326k61 Proceedings for Disclosure
326k65 k. Evidence and burden of proof. Most Cited Cases
Burden is on government agency to sustain its action in withholding requested documents under exemption of Freedom of Information Act (FOIA). 5 U.S.C.A. § 552(b).

[3] Records 326 59

326 Records
326II Public Access
326II(B) General Statutory Disclosure Requirements
326k53 Matters Subject to Disclosure; Exemptions
326k59 k. Trade secrets and commercial or financial information. Most Cited Cases
Commercial information is “confidential,” under Freedom of Information Act's (FOIA) exemption for confidential commercial information obtained from a person, if disclosure would either: (1) impair government's ability to obtain necessary information in the future, or (2) cause substantial harm to competitive position of person from whom it was obtained. 5 U.S.C.A. § 552(b)(4).

[4] Records 326 59

326 Records
326II Public Access
326II(B) General Statutory Disclosure Requirements

326k53 Matters Subject to Disclosure; Exemptions
326k59 k. Trade secrets and commercial or financial information. Most Cited Cases
Type of competitive injury covered under Freedom of Information Act's (FOIA) exemption for confidential commercial information obtained from a person is limited to that which may flow from competitors' use of released information; competitive injury justifying exemption does not mean simply injury to competitive position flowing from customer or employee disgruntlement, or from embarrassing publicity attending public revelations. 5 U.S.C.A. § 552(b)(4).

[5] Records 326 59

326 Records
326II Public Access
326II(B) General Statutory Disclosure Requirements
326k53 Matters Subject to Disclosure; Exemptions
326k59 k. Trade secrets and commercial or financial information. Most Cited Cases
In order to satisfy "substantial harm to competitive position" prong of Freedom of Information Act's (FOIA) exemption for confidential commercial information obtained from a person, agency need not prove actual competitive harm, but rather must show: (1) actual competition, and (2) likelihood of substantial competitive injury. 5 U.S.C.A. § 552(b)(4).

[6] Records 326 65

326 Records
326II Public Access
326II(B) General Statutory Disclosure Requirements
326k61 Proceedings for Disclosure
326k65 k. Evidence and burden of proof. Most Cited Cases
In addition to establishing that information is properly withheld under claimed Freedom of Information Act (FOIA) exemption, agency seeking to withhold information bears burden of establishing that all reasonably segregable non-exempt portions of records are disclosed. 5 U.S.C.A. § 552(b).

[7] Records 326 59

326 Records
326II Public Access
326II(B) General Statutory Disclosure Requirements
326k53 Matters Subject to Disclosure; Exemptions
326k59 k. Trade secrets and commercial or financial information. Most Cited Cases
Evidence that operator of research facility that had been investigated by Department of Agriculture (USDA) pursuant to Animal Welfare Act (AWA) would suffer harm by release of investigation records, because operator's customers or potential customers would perceive disclosure as breach of operator's confidentiality agreements, was insufficient to satisfy "likelihood of substantial competitive injury" criterion of Freedom of Information Act's (FOIA) exemption for confidential commercial information; evidence did not show injury flowing from competitors' use of released information. 5 U.S.C.A. § 552(b)(4); Animal Welfare Act, 7 U.S.C.A. § 2131 et seq.

[8] Records 326 59

326 Records
326II Public Access
326II(B) General Statutory Disclosure Requirements
326k53 Matters Subject to Disclosure; Exemptions
326k59 k. Trade secrets and commercial or financial information. Most Cited Cases
Conclusory, generalized contentions that release of records of Department of Agriculture's (USDA) investigation of research facility pursuant to Animal Welfare Act (AWA) could enable facility operator's competitors to identify its standard operating procedures (SOPs) or pharmaceutical compounds being tested was insufficient to satisfy "likelihood of

substantial competitive injury" criterion of Freedom of Information Act's (FOIA) exemption for confidential commercial information; specificity was required as to likelihood of competitors' use for competitive advantage, or explanation of how unique SOPs were implicated. 5 U.S.C.A. § 552(b)(4); Animal Welfare Act, 7 U.S.C.A. § 2131 et seq.

***70** Eric Robert Glitzenstein, Katherine A. Meyer, Meyer Glitzenstein & Crystal, Washington, DC, for Plaintiff.

Anne Davis Work, U.S. Department of Justice Office of Information and Privacy, Washington, DC, for Defendants.

MEMORANDUM OPINION

RICHARD W. ROBERTS, District Judge.

Plaintiff In Defense of Animals ("IDA") brought this action against the United States Department of Agriculture ("USDA") seeking to compel the disclosure of records relating to the USDA's investigation of Huntingdon Life Sciences, Inc. ("HLS") under the Freedom of Information Act ("FOIA"), 5 U.S.C. § 552. Life Sciences Research, Inc. ("LSR"), the parent company of HLS, later intervened as a defendant in this action. At trial, the defendants carried the burden to prove that information contained in the 1017 pages of agency records remaining in issue had been properly withheld under FOIA Exemption 4 exempting release of records that would cause substantial competitive harm to HLS. Because the defendants have not carried their burden to demonstrate that the records at issue were properly withheld under Exemption 4, with all reasonably segregable material disclosed, judgment will be entered for the plaintiff.

BACKGROUND FINDINGS OF FACT

IDA, an animal protection organization, brought this FOIA action against the USDA seeking the disclosure of records concerning the USDA's investigation of HLS, a contract research organization ("CRO") with a registered research facility located in New Jersey that is regulated by the USDA under the Animal Welfare Act ("AWA"). IDA submitted a FOIA request to the USDA requesting "all records relating to the agency's investigation of HLS." (Stip. Facts ¶ 17.) In response, the USDA released thirty-one pages to IDA, including a report of violation, the administrative complaint against HLS and the consent decision and order. (*Id.* ¶ 18.) IDA brought this action to compel the USDA to provide IDA with additional records responsive to their FOIA request. (*Id.* ¶ 19.) The USDA informed IDA that it had identified 2778 pages of responsive records, of which it released 228 pages in full; released 146 pages in part, with personal information withheld under FOIA Exemption 6; withheld 19 pages in full and one page in part under FOIA Exemption 5, and sent 2384 pages to HLS to obtain HLS' views as to whether such records were exempt from disclosure under FOIA Exemption 4. (*Id.* ¶ 21.)

During the course of litigation, the parties reduced the number of documents at ***71** issue and narrowed the scope of issues for trial. The USDA released additional documents to IDA. IDA "agreed to forgo test protocols and protocol amendments; animal tracking and assessment records; the identification of any compound or product; and the identity of any customer of HLS; and dosing charts." [FN1] (*Id.* ¶ 25.) The parties filed cross-motions for summary judgment which were denied without prejudice because the defendants failed to provide an adequate *Vaughn* index [FN2] or other evidence upon which the court could assess whether the information withheld was properly exempted. The defendants were ordered to prepare "a comprehensive *Vaughn* index describing the documents withheld (and to the extent necessary, portions thereof), the reasons for nondisclosure, and the reasons for nonsegregability." (Mem. Op. & Order at 2, 34 (Sept. 28, 2004).) The defendants provided a *Vaughn* index to IDA and the parties renewed their cross-motions for summary judgment.

FN1. In addition, IDA also agreed before trial not to seek information withheld under Exemptions 5, 6, and 7(C). (Stip. Facts ¶ 38(f).)

FN2. A *Vaughn* index, which derives its name from *Vaughn v. Rosen*, 484 F.2d 820 (D.C.Cir.1973), describes with specificity the documents withheld or redacted and the proffered justification for the nondisclosure. *Id.* at 826-27. It "usually consists of a detailed affidavit, the purpose of which is to 'permit the court system effectively and efficiently to evaluate the factual nature of disputed information.' " *John Doe Agency v. John Doe Corp.*, 493 U.S. 146, 149 n. 2, 110 S.Ct. 471, 107 L.Ed.2d 462 (1989) (quoting *Vaughn*, 484 F.2d at 826). At the least, the agency must provide an examining court with sufficient detail to permit *de novo* review of the agency's explanations. *See Judicial Watch, Inc. v. U.S. Postal Serv.*, 297 F.Supp.2d 252, 257 (D.D.C.2004).

After in camera review of a sampling of these documents at issue, Judge Oberdorfer denied the parties' renewed cross-motions for summary judgment, concluding that there was a disputed material fact as to whether disclosure of documents withheld under FOIA Exemption 4 would cause substantial competitive harm to HLS. *In Def. of Animals v. USDA*, 501 F.Supp.2d 1, 8 (D.D.C.2007). He advised the parties that "[a] trial on the merits would be greatly facilitated by expert testimony on the ability of competitors to reverse engineer proprietary information from the disputed documents, as well as the likelihood of effective advantage to a competitor from the redacted data." *Id.*

FOIA Exemption 4 prevents disclosure of "trade secrets and commercial or financial information obtained from a person and privileged or confidential [.]" 5 U.S.C. § 552(b)(4). Remaining at issue in this case are 1017 pages of agency records created before or during 1998 that relate to seven animal studies conducted at HLS. (Stip. Facts ¶¶ 39-40.) The USDA has withheld 503 pages in full and 514 pages in part under Exemption 4. (*Id.* ¶ 36.) The 1017 pages are grouped into the following eleven categories: (1) Institutional Animal Care and Use Committee ("IACUC") records (56 pages withheld in part); (2) HLS memoranda (33 pages withheld in full and 7 pages withheld in part); (3) USDA investigatory memoranda (27 pages withheld in part); (4) necropsy and postmortem examination reports (23 pages withheld in full); (5) viability records (58 pages withheld in full and 397 pages withheld in part); (6) veterinary treatment requests and logs (94 pages withheld in full and 20 pages withheld in part); (7) observation sheets (28 pages withheld in full); (8) miscellaneous records pertaining to animal cages (7 pages withheld in part); (9) final test reports and related records (124 pages withheld in full); (10) clinical observation reports (121 pages withheld in full); and (11) ***72** interim test reports (22 pages withheld in full). (*Id.*)

The parties conducted a two-day trial. LSR called as witnesses Michael Caulfield, the General Manager of HLS, and Dr. Robert Szot, an expert in the fields of toxicology, early-stage drug development, and the relationship between the pharmaceutical industry and CROs.

LEGAL FRAMEWORK

[1][2] FOIA requires each federal agency to make available for public perusal government records unless the requested documents fall under one of nine categories of exemptions. 5 U.S.C. §§ 552(a)-(b). FOIA exemptions "must be narrowly construed" and "the burden is on the agency to sustain its action." *John Doe Agency v. John Doe Corp.*, 493 U.S. 146, 152, 110 S.Ct. 471, 107 L.Ed.2d 462 (1989) (internal quotation marks omitted); 5 U.S.C. § 552(a)(4)(B).

A. *Exemption 4*

FOIA Exemption 4 prevents disclosure of "trade

secrets and commercial or financial information obtained from a person and privileged or confidential [.]" 5 U.S.C. § 552(b)(4). The parties have previously agreed that trade secret protection does not apply in this case and that the information withheld under Exemption 4 is "commercial" and "obtained from a person." *In Def. of Animals,* 501 F.Supp.2d at 6. The remaining question, then, is whether the withheld commercial information is "confidential." FN3

FN3. The defendants do not contend such information is "privileged." (*See* USDA's Mem. in Support of Its Renewed Mot. for Summ. J. at 4.)

[3] In the District of Columbia Circuit, commercial information is "confidential" under Exemption 4 if "disclosure would either '(1) ... impair the Government's ability to obtain necessary information in the future; or (2) ... cause substantial harm to the competitive position of the person from whom it was obtained.' " *Pub. Citizen Health Research Group v. FDA,* 704 F.2d 1280, 1290-91 (D.C.Cir.1983) (alteration in original) (quoting *Nat'l Parks & Conservation Ass'n v. Morton,* 498 F.2d 765, 770 (D.C.Cir.1974) (footnote omitted)). Where the government obtains information involuntarily, disclosure does not impair the government's ability to obtain similar information in the future. *See Nat'l Parks,* 498 F.2d at 770. In this case, the defendants, conceding that the documents at issue were obtained involuntarily, allege that the records are properly withheld under the second prong of the *National Parks* test because disclosure of the information withheld would cause substantial harm to HLS's competitive position. FN4

FN4. On the eve of trial, after more than four years of litigation and two rounds of summary judgment where it conceded that the USDA obtained the documents at issue involuntarily, LSR attempted to argue for the first time that the documents at issue were disclosed voluntarily to the USDA and are properly withheld under the first part of the *National Parks* test on the basis that disclosure "would impair the Government's ability to obtain necessary information in the future." LSR was judicially estopped from raising this untimely argument that was clearly inconsistent with the position it maintained for years. *See In Def. of Animals v. USDA,* 589 F.Supp.2d 41, 43 (D.D.C.2008).

[4] The type of competitive injury covered under Exemption 4 is limited to "that which may flow from *competitors*' use of the released information [.]" *Ctr. to Prevent Handgun Violence v. U.S. Dep't of the Treasury,* 981 F.Supp. 20, 23 (D.D.C.1997) (emphasis in original) (rejecting the Bureau of Alcohol, Tobacco, and Firearms' argument that releasing reports would ***73** subject licensed gun dealers to "unwarranted criticism and harassment" as irrelevant to the competitive harm analysis); *see Worthington Compressors, Inc. v. Costle,* 662 F.2d 45, 51-52 (D.C.Cir.1981) (inquiring "whether release of the requested information, given its commercial value to competitors and the cost of acquiring it through other means," will create a "windfall for competitors" that puts the disclosing entity at a commercial disadvantage). As the court of appeals has explained:

> "[t]he important point for competitive harm in the FOIA context ... is that it be limited to harm flowing from the affirmative use of proprietary information *by competitors.* Competitive harm should not be taken to mean simply any injury to competitive position, as might flow from customer or employee disgruntlement or from the embarrassing publicity attendant upon public revelations concerning, for example, illegal or unethical payments to government officials or violations of civil rights, environmental or safety laws."

Pub. Citizen Health Research Group, 704 F.2d at 1291 n. 30 (quoting Mark Q. Connelly, *Secrets and Smokescreens: A Legal and Economic Analysis of Government Disclosures of Business Data,* 1981 Wis. L.Rev. 207, 235-36 (emphasis and alteration

in original)).

[5] To satisfy Exemption 4, an agency need not prove "actual competitive harm" but must show (1) actual competition and (2) the "likelihood of substantial competitive injury." *Id.* at 1291 (internal citation omitted). While "the court need not conduct a sophisticated economic analysis of the likely effects of disclosure, [c]onclusory and generalized allegations of substantial competitive harm ... cannot support an agency's decision to withhold requested documents." *Id.* (internal citation omitted); *see Founding Church of Scientology of Wash., D.C., Inc. v. Nat'l Sec. Agency*, 610 F.2d 824, 830 (D.C.Cir.1979) (finding an agency's "conclusory and generalized allegations of exemptions" insufficient to support summary judgment for the agency (internal quotation marks omitted)). "The defendant must show exactly who [is likely to be] injured by the release of [the] information and explain the concrete injury." *Delta Ltd. v. U.S. Customs & Border Protection Bureau*, 393 F.Supp.2d 15, 19 (D.D.C.2005).

B. *Segregability*

[6] In addition to establishing that information is properly withheld under the claimed FOIA exemption, an agency seeking to withhold information bears the burden of establishing that all reasonably segregrable non-exempt portions of records are disclosed. *Keys v. Dep't of Homeland Sec.*, 510 F.Supp.2d 121, 130 (D.D.C.2007) ("The burden is on the agency to adequately demonstrate that all reasonably segregable, non-exempt material was disclosed.") Because "[t]he focus of the FOIA is information, not documents ... non-exempt portions of a document must be disclosed unless they are inextricably intertwined with exempt portions." *Mead Data Central, Inc. v. U.S. Dep't of the Air Force*, 566 F.2d 242, 260 (D.C.Cir.1977); *see* 5 U.S.C. § 552(b) (stating that an agency must disclose "[a]ny reasonably segregable portion of a record ... after deletion of the portions which are exempt."). "[A]n agency cannot justify withholding an entire document simply by showing that it contains some exempt material." *Mead Data Central*, 566 F.2d at 260. Instead, an agency must provide "a detailed justification" that "describe[s] what proportion of the information in a document is non-exempt and how that material is dispersed throughout the document."***74** FN5 *Id.* at 261.

FN5. A court may also consider "the information content of the non-exempt material which a FOIA plaintiff seeks to have segregated and disclosed" and "may decline to order an agency to commit significant time and resources to the separation of disjointed words, phrases, or even sentences which taken separately or together have minimal or no information content." *Id.* at 261 n. 55.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

I. SUBSTANTIAL COMPETITIVE HARM

A. *Findings of fact*

The defendants presented the testimony of two witnesses, Caulfield and Szot, to explain why the records at issue are being properly withheld under Exemption 4.

1. Caulfield testimony

Caulfield, HLS's General Manager, testified that he had general familiarity with all the categories of documents being withheld in full or withheld in part. He testified that he had been involved in HLS's determinations and communications with the USDA as to what records should be withheld from disclosure. (Trial Tr. Day 1 ("Day 1 Tr."), 87:18-24, Dec. 16, 2008.) On cross-examination, however, Caulfield clarified that while "he was very familiar with the categories of documents[,]" he had "not looked at [all of] the documents them-

selves for some significant period of time." (Day 1 Tr. 90:10-13.) He stated that he reviewed only "certain documents" in preparation for trial. (Day 1 Tr. 90:16-19.) As background, Caulfield testified that the majority of HLS's business consists of "pre-clinical safety assessment" or "toxicology" work for customers in the pharmaceutical and biotech sectors. He explained that such research "largely rel[ies] on animal tests to determine whether a drug is safe to proceed into clinical trials" using human subjects. (Day 1 Tr. 23:2-6, 16-20, 22.)

For the specific categories of documents at issue, Caulfield described the withheld one hundred and twenty-one pages of clinical observation reports as containing data documenting "detailed physical observation[s]" of animals "that are on active tests" that are collected to determine the effect of the dose level of the drug given to the animal. (Day 1 Tr. 48:5-7, 18-24.) Regarding the pages of veterinary treatment requests and logs withheld in full and in part, Caulfield explained that they contain "documentation of a specific effect that was seen in an animal, whether it be drug related or [otherwise], a recommended treatment, and in some cases, follow-up observations and additional treatments." (Day 1 Tr. 46:22-47:1.) Caulfield testified that the raw data found in these types of documents are used by HLS's toxicologists to create reports for clients for future submission to the FDA. (Day 1 Tr. 49:16-24.) In addition, Caulfield testified that the necropsy and postmortem examination reports withheld in full contain data about an animal at the time of death, and such reports "enable [HLS] to ascertain [the] gross microscopic effects that a drug may have actually had on an animal ... [which] in many cases [are] not evident through the detailed weekly physical exams." (Day 1 Tr. 50:7-21.) Similarly, Caulfield testified that the documents categorized as "viability records," which contain twice-a-day observations of the effects of drugs on animals in a study, are also "considered raw data." (Day 1 Tr. 52:4-15.) He stated that HLS considers all of the raw data contained in these documents to be confidential according to ***75** company policy. (Day 1 Tr. 51:12-14; 53:2-4.)

Regarding the twenty-two pages of interim test reports withheld in full, Caulfield testified that the reports are HLS's product that it produces to customers and that such reports "contain the full range of assessments, evaluations and analysis on the toxic profile of a given compound." (Day 1 Tr. 55:21-25.) He continued to explain that the reports

> contain individual data for respective animals, group effects, statistical evaluations and a section called Materials and Methods, which generally specifies the methods that [HLS] employed, the equipment that [they] used, the statistical regimens [they] undertook, the software that generated and reported the data that's contained within that report and any other specifics of the study that the client might deem relevant.

(Day 1 Tr. 55:25-56:7.) Caulfield testified that the one hundred twenty-four pages of final test reports and related records withheld in full are similar to interim test reports insofar as what information they contain and are also produced to HLS clients. (Day 1 Tr. 57:3-8.) He further testified that the twenty-eight pages of observation sheets at issue contain "observations of animals in [a] study over a specified interval of time," including body weight and food consumption data, to demonstrate the effect of a particular drug. (Day 1 Tr. 58:24-59:4.)

In addition, for the twenty-seven pages of internal USDA Investigatory Memoranda withheld in part, Caulfield testified that the portions withheld were "essentially a USDA discussion of a variety of toxic effects that were either derived from [HLS's] study records or [that the USDA] had seen during their on-site visitations to [HLS's] laboratory in 1997." (Day 1 Tr. 54:21-24.) For the documents categorized as internal HLS memoranda, Caulfield stated that the pages and portions withheld from these documents "contain discussions either with internal HLS scientists or in some instances with [HLS] customers on the effects of the test com-

pound that were seen in [HLS's] studies[.]" (Day 1 Tr. 57:25-58:4.) In addition, Caulfield recalled that the redacted portions of the fifty-six pages of IACUC records were "minutes discussing, or program reviews discussing particular protocols[.]" (Day 1 Tr. 59:17-20.) Finally, Caulfield testified that information withheld from the seven pages categorized as miscellaneous records pertaining to animal cages relate to a proprietary design created by HLS for primate caging. (Day 1 Tr. 53:20-24.) He recalled that the information redacted was "design schematics and drawings of the like." (Day 1 Tr. 53:24-25.)

Caulfield testified that he represented HLS in its discussions with the USDA as to what information should be redacted from the pages at issue in this case. (Day 1 Tr. 87:18-24.) He stated that during his conversations with the USDA about releasing the records at issue, "his primary concern at the time was that [they] not release records that were reflective of the effects of drugs or any of the particulars ... that were under the auspices of the confidentiality agreement." (Day 1 Tr. 88:2-7.) Caulfield testified that he believed that all of the records at issue, except for the miscellaneous records pertaining to animal cages and some IACUC records, would contain information about HLS's standard operating procedures ("SOPs").[FN6] He explained that SOPs "drive ***76** how [data] are collected," and are required by the Federal Good Laboratory Practice Regulations "to ensure the quality and integrity of the data." (Day 1 Tr. 74:4-10.) He stated that HLS "do[es] not share them with any of [their competitors or any other third parties," except for regulators and sometimes clients. (Day 1 Tr. 75:10-11.) Caulfield further testified that it was his opinion based on his previous experience writing or approving HLS's standard operating procedures and fielding regulatory inspections by the FDA assessing HLS' procedures that the withheld records are "susceptible to a reverse engineering" of HLS's SOPs.[FN7] (Day 1 Tr. 77:5-22.)

FN6. Caulfield made no attempt to specify which of the withheld IACUC records at issue did or did not contain information about HLS's SOPs.

FN7. Caulfield, designated only as a lay witness, could not and did not offer any expert opinion testimony as to how the information in the records at issue could be reverse engineered by competitors in relevant industries to recreate HLS's SOPs.

2. Szot testimony

Szot testifying as an expert in toxicology, early-stage drug development, and "the relationship between [the pharmaceutical industry] and the retaining of CROs for studies," (Trial Tr. Day 2 ("Day 2 Tr."), 20:9-24, Dec. 17, 2008), stated that the purpose for which he was retained and of his testimony was to discuss his views on confidentiality. (*See* Day 2 Tr. 95:18-22.) Szot testified that his concerns about confidentiality included whether HLS's customers would perceive disclosure of information as a breach of confidentiality, and "the concept that release of certain types of data can be reverse engineered to find out additional information[,]" but clarified that reverse engineering was not the "central purpose" of his testimony. (Day 2 Tr. 95:12-22, 98:8-18.) He testified that in preparation for his testimony, he had a single visit to HLS that lasted approximately three to four hours at which he had an opportunity to view the documents at issue in their unredacted form before preparing his expert report. (Day 2 Tr. 23:1-5, 21-23.) Szot stated that his purpose during his visit "was not to look at each document and determine the significance of every one," but rather "to determine what type of data was in question and could that data be harmful to HLS or to anyone else." (Day 2 Tr. 24:8-14.) He testified that he used the descriptions of the documents contained in the *Vaughn* index to create a random sample of documents that included approximately four to five documents from the different categories of documents for a total of ap-

proximately thirty documents, and examined these documents in their unredacted form to form his opinions. (*See* Day 2 Tr. 24:14-25:4; 67:2-8; 72:7-12.) Szot recalled "review[ing] examples of viability records, necropsy and postmortem records, clinical observation raw data, veterinary treatment requests and IACUC meetings." (Day 2 Tr. 28:9-12.) He also recalled seeing some "documents pertaining to purchasing of animal cages [and] miscellaneous records." (Day 2 Tr. 28:12-14.) Szot could not recall reviewing interim or final test reports but did remember some Huntingdon memoranda. (Day 2 Tr. 28:14-21.) He also reviewed some of HLS's confidential agreements with its customers. (*See* Day 2 Tr. 29:2-8.) Upon cross-examination, Szot denied reviewing any USDA investigatory records. (Day 2 Tr. 93:20.)

Szot opined that nonclinical toxicology studies, such as those done by HLS, play a "critical role" in drug development because such studies are a necessary precursor to any studies using human subjects. (Day 2 Tr. 29:16-25.) He testified that toxicology studies vary by length and complexity, and may take up to three years, but such studies are "critical for approval from the FDA to initiate studies in humans." (Day 2 Tr. ***77** 31:15-32:13.) With respect to HLS's competitive market, Szot testified that both large and small pharmaceutical companies might use a CRO for their toxicology studies. (Day 2 Tr. 33:16-34:3.) He testified that competition among the CROs that provide toxicology services is "fierce." Szot estimated that there are at least 20 CROs in the United States and noted that in the past five years, similar entities have emerged in countries like Brazil, China, India, Russia that are active in the marketplace. (Day 2 Tr. 52:1-10.) He also opined that there is fierce competition among the pharmaceutical companies to be the first to get a product to market because "the first one out there is usually the most successful in terms of financial gain." (Day 2 Tr. 53:5-7.) He posited that the first company to market a drug can "get the physicians to be aware of their product," and once physicians begin using a product, "its hard to wean [them] away to another product." (Day 2 Tr. 53:7-12.)

Szot explained that a company choosing a CRO typically considers, among other things, the CRO's previous experience in conducting the study to be commissioned; the experience and qualifications of the CRO's senior scientist; the qualifications of the CRO's technical staff, including how they are trained and whether they are certified; whether the CRO has been appropriately certified; the CRO's facilities; and the CRO's quality assurance unit, the independent group of scientists that monitors the CRO's studies to ensure they are conducted according to good laboratory practices. (Day 2 Tr. 34:9-36:6.) Szot also testified that a potential customer looks for a CRO that can ensure the confidentiality of a client's study. (Day 2 Tr. 36:14-37:11.) He explained that confidentiality is important to a customer because "the information a client would give to a CRO is proprietary" and might include, for example, the kind of compound being developed and its chemical name, or information about the client's research goals and plans for the future. (Day 2 Tr. 37:16-25.)

Moreover, Szot testified that based on his review of the records he selected, he concluded that release "would be of harm to [HLS] because, for one reason, clients would assume that if this data were made public, that their confidentiality agreement with the CRO had been breached[,]" and it would be unlikely that "potential study sponsors would conduct studies at a CRO that could not maintain the confidentiality of its study data." (Day 2 Tr. 43:4-12; 61:12-18.) He stated that if he were working for a pharmaceutical company and he discovered that data was released from HLS, he "would never go to HLS again for conducting another study, regardless of the reason why it was released." (Day 2 Tr. 62:8-12.)

In addition, Szot testified that he believed the records at issue contain confidential information because they "would show observations that were related to reactions to the drugs being tested." (Day 2 Tr. 41:21-23.) Specifically, he opined that veterin-

ary treatment requests "would suggest how often toxicity was observed that was rather significant [and] require attention of a veterinarian." (Day 2 Tr. 42:5-7.) Similarly, viability records would be "a reflection of toxicity." (Day 2 Tr. 42:12.) He testified that necropsy and postmortem examination reports would show "what was happening in the tissues of the animals that had been given drugs" and observation sheets would "reflect what was seen by the technician in looking at the animals ... and could be reflective of what [a] drug potentially does to animals." (Day 2 Tr. 42:8-11, 16-23.) Szot explained that certain classes of drugs produce "characteristic effects on toxicity [that] are readily recognizable." (Day 2 Tr. 44:4-25.) He testified that because certain compounds***78** have "specific types of toxicity" that are recognizable as a sign of that compound, if data on toxicity were released, it would be possible for persons using other information such as a company's financial documents or patent-related documents, to determine what compound or group of compounds are being tested. (Day 2 Tr. 44:23-45:15.) He further testified a competitor engaged in its own toxicology study producing similar results might use the information it could gather about what compounds were being tested to determine whether to continue its own efforts or alter its strategy. (Day 2 Tr. 45:16-46:25.) Szot suggested that "astute scientist[s]," such as senior toxicologists or directors of toxicology in the pharmaceutical industry are "always looking for information that would help them identify what is going on with compounds that they're testing." (Day 2 Tr. 60:2-11.) Thus, he concluded that "[i]t is ... possible that with knowledge of approximate study dates and raw data characteristics, competitors of HLS study sponsors may gain information that could adversely affect fair competition between the companies." (Day 2 Tr. 61:19-22.)

Szot also explained that on the other hand, there are other compounds that do not produce signature toxicology results. (Day 2 Tr. 47:24-48:1.) He identified an unusual heartbeat, a necrotic skin flap, and increased or decreased blood pressure as examples of nonunique symptoms that could be caused by different kinds of substances. (Day 2 Tr. 123:16-124:8.) Similarly, Szot conceded that data revealing that an animal had an "anaphylactic response" standing alone wouldn't reveal information about a particular compound being tested. (Day 2 Tr. 125:3-7.) Importantly, Szot conceded on cross-examination that he did not know what drugs were being tested by HLS during the time frame covered by the records at issue. (Day 2 Tr. 125:8-10.)

Regarding the usefulness of data over time, Szot explained that companies generally develop and study a "series of compounds" with "many different types of molecular entities very similar to the original" that they begin with and such development may last a number of years. (Day 2 Tr. 46:10-16.) Szot also testified that on average, it takes eight to ten years from the pre-clinical testing stage for a drug to reach the market, although it could be longer. (Day 2 Tr. 121:12-17.) He opined that because of the length of toxicology studies and the considerable time it takes for a drug to reach the market, even information about a study done ten or fifteen years ago may still provide an advantage to competitors still developing compounds in the same series. (*See* Day 2 Tr. 46:17-25; 48:7-12.)

3. Findings

The defendants have established at least three reasons why they believe the withheld records should not be disclosed to IDA. One reason both witnesses identified as to why the records at issue should not be disclosed is that HLS's customers would perceive disclosure of the records at issue as a breach of HLS's agreements with its customers to keep their toxicology studies confidential. In addition, Caulfield's testimony established that another possible reason the withheld records should not be disclosed is that the records may contain information about HLS's SOPs, and HLS has an interest in preventing disclosure of information about its SOPs to its competitors because competitors could arguably use such information to their advantage when man-

aging their own SOPs. However, Caulfield's explanation of SOPs reveals that the Federal Good Laboratory Practice Regulations are "very specific and particular in terms of ***79** what [any company's] SOPs need to contain in order to ensure the quality and integrity of the data" it collects. (Day 1 Tr. 74:4-9.) Thus, while certain portions of a company's SOPs, if revealed, might be capable of providing an advantage to a competitor, certain portions of a company's SOPs necessarily will be reflective only of procedures required by the applicable regulations. Caulfield's testimony offers no explanation as to whether the records at issue would reveal SOPs unique to HLS that might provide a competitive advantage or would reveal SOPs that were merely reflective of procedures required under the federal regulations.

A third reason offered by the defendants in support of nondisclosure is that some of the data contained in the withheld records, with the exception of the miscellaneous records relating to animal cages, might reveal the compounds being studied by HLS at the time the records were created. Szot's undisputed testimony established that some toxicology data can, in certain circumstances, identify the particular compound or series of compounds being tested, and a competitor engaged in similar toxicology research might be able to use such information to decide whether to continue, abandon, or modify its own research efforts. (*See* Day 2 Tr. 44:23-46:25.) On the other hand, Szot's undisputed testimony also established that certain symptoms and observations are common for numerous compounds or attributable to other causes beyond a reaction to a particular compound, and are not unique to a single or limited number of compounds. As a result, some research data or recorded observations might not help a competitor seeking a competitive advantage. (See Day 2 Tr. 123:4-125:1.) Szot did not opine whether the particular data withheld in this case are data that could be used to identify certain compounds or if they are benign data that would not inform a competitor about the specific compound studied. Furthermore, Caulfield testified that it was his understanding that "all observations have been deleted from [the] documents [at issue], other than those relating to animals escaping their cages or getting injured in connection with their cages[,]" and acknowledged that it was outside his area of expertise to determine which observations might be unique to drugs being tested and which observations were not unique to any single drug or limited group of compounds. (*See* Day 1 Tr. 177:2-178:10.) Accordingly, neither Caulfield nor Szot established that the particular data withheld in this case are data from which competitors could identify specific drugs being tested, rather than data recording nonunique symptoms.

Moreover, when identifying the possible harms that may flow from the release of the records at issue, neither Caulfield nor Szot correlated the potential harms he identified to specific withheld records. Although both Caulfield and Szot testified that customers' perceptions of HLS's ability to keep its research confidential was an important factor in their assessments of whether the records at issue should not be disclosed, neither identified which records, if released, would be harmful to HLS's competitive position solely because the information released could be used by HLS's or its customers' competitors to gain advantage in the toxicology, pharmaceutical or CRO industries.

B. *Conclusions of law*

The defendants bore the burden at trial of establishing that HLS or its clients face actual competition and that there is a likelihood that HLS or its clients would suffer a substantial competitive injury if the information withheld is released because the information could be used by their competitors for commercial gain. *See* ***80***Pub. Citizen Health Research Group,* 704 F.2d at 1291. The defendants have carried their burden of demonstrating that there is actual competition in the contract research business among CROs that provide toxicology research to secure study sponsors, and there is actual competition in the pharmaceutical industry to be the

first to get a particular type of drug to market. The undisputed testimony of both Caulfield and Szot attested to the presence of multiple CROs competing against HLS to provide research services to pharmaceutical clients, and pressure among pharmaceutical clients to be the first to market a new drug.

[7] On the other hand, the defendants have not carried their burden with respect to whether the disclosure of the withheld information in the 1017 pages at issue in this case has a likelihood of causing substantial competitive injury to HLS or its clients. As the court of appeals has instructed, the competitive harm that matters is a competitor's affirmative use of proprietary information that could reap a commercial windfall for the competitor, rather than the harm caused by a customer or other third party's negative reaction to disclosure. *See id.*; *Worthington Compressors, Inc.*, 662 F.2d at 51-52. Thus, the defendants' evidence that HLS would suffer harm by release of the records at issue because their customers or potential customers would perceive disclosure as a breach of HLS's confidentiality agreements with HLS's customers does not satisfy their burden under Exemption 4 in this case.

[8] With respect to the defendants' evidence that competitors could use the withheld records to identify HLS's SOPs or the compounds being tested, the defendants' evidence provides no more than the "[c]onclusory and generalized allegations" that the court of appeals has rejected as insufficient to sustain a claimed exemption from disclosure. *Pub. Citizen Health Research Group*, 704 F.2d at 1291. While Caulfield's and Szot's testimony established that there are at least two potential ways competitors might be able to use information likely to be found in the records at issue, neither related competitors' potential uses of information to the specific records at issue with sufficient detail to establish by a preponderance of the evidence that competitors of HLS or its clients are likely to use the particular records at issue to cause substantial harm to HLS or its clients. Szot, having reviewed only approximately 30 of the 1017 pages at issue, made only general statements as to the kind of information he found in the samples he reviewed, concluded that the kind of data he reviewed might be able to be used by competitors, but also conceded that some data would reveal benign results from which competitors could not draw specific conclusions. Szot's generalized opinions, unaccompanied by any assessment of the likelihood that the particular information withheld from each of the 1017 pages at issue are data that competitors would be able to use for commercial advantage, rather than benign data, are an insufficient basis upon which to conclude that there is a likelihood of substantial competitive injury in this case. Similarly, Caulfield's testimony that a competitor might be able to recreate HLS's SOPs was merely a generalized assertion lacking any explanations that suggest that the withheld records implicated unique SOPs, rather than procedures required by regulation. Caulfield, testifying as a lay witness, was not qualified to and did not opine on the likelihood that competitors in the toxicology, pharmaceutical, or CRO industries could use the information contained in the withheld records.

***81** In addition, Caulfield's and Szot's testimony reveals that they reviewed the records at issue with the belief that the documents at issue should be withheld from release to prevent negative customer reaction. There is no evidence suggesting that either witness analyzed the documents to ascertain whether the records withheld could be withheld for the sole purpose of preventing competitors' use of the information for commercial advantage. As a result, neither Caulfield nor Szot established a likelihood that disclosure would cause a competitive harm. Thus, while the defendants have carried their burden of showing that HLS and its clients experienced actual competition, they have not shown that there is a likelihood that release of the particular information withheld in this case would cause HLS or its clients to suffer a substantial competitive injury.

II. SEGREGABILITY OF NONEXEMPT INFORMATION

Judge Oberdorfer found in 2007 that the *Vaughn* index is devoid of any segregability analysis. *See In Defense of Animals*, 501 F.Supp.2d at 3. At trial, the defendants introduced no other evidence on the issue of segregability. Neither Caulfield's nor Szot's testimony spoke to the specifics of individual documents.

Caulfield's testimony established that at the time he was involved in deciding which records were to be withheld in this case, his redaction decisions were made not solely to prevent the release of information that competitors could use to their commercial advantage. He admitted that preventing the release of information that HLS's customers viewed as confidential was a consideration in his discussions with the USDA as to which records should be withheld. Caulfield offered no testimony suggesting he ever reviewed the documents at issue again for the purpose of examining whether the information withheld could actually be used by HLS's or its clients' competitors to gain a commercial advantage over HLS or its clients.[FN8]

> FN8. Nor did the defendants establish that Caulfield would be qualified to give such an opinion.

He further testified that at present, "he was very familiar with the categories of documents[,]" but he had "not looked at the documents themselves for some significant period of time." (Day 1 Tr. 90:10-13.) He said that he looked at "certain documents" in preparation for trial, but it had been "some number of years" since he had reviewed all of the documents. (Day 1 Tr. 90:16-19.) He further testified that he "had little or no involvement in the *Vaughn* index and [had] not studied it," and could not testify as to whether the *Vaughn* index prepared accurately reflects HLS and the USDA's "joint understanding" of what materials could be released to IDA. (Day 1 Tr. 88:21-25.) Caulfield offered no testimony that he ever examined the records at issue for the purpose of determining whether only that information which could be used by competitors for commercial advantage had been redacted and that all other information reasonably segregated from information that could be used by competitors had been appropriately released. Accordingly, Caulfield's testimony does not provide any evidence on the issue of segregability.

Similarly, Szot did not offer any testimony on the issue of segregability. Szot expressly conceded that he could not "say that there is no information in [the USDA reports] that has been withheld from the plaintiffs that does not contain standard ***82** operating procedures, protocols, or raw data[.]" (Day 2 Tr. 95:5-11.) He testified that he looked at unredacted versions of the documents at issue (Day 2 Tr. 25:19-21), and he admitted on cross-examination that he did not look at the documents "with a knowledge of exactly what would be deleted from them" and did not know at the time he was reviewing his sample of documents that approximately five hundred pages of documents were withheld from disclosure in their entirety. (Day 2 Tr. 72:13-18; 73:3-14; 73:25-74:4.) Because Szot, by his own admission, did not view the records at issue for the purpose of assessing whether the withheld portions were limited to information that could be used by HLS's competitors for commercial advantage, his testimony provides defendants no support on the question of segregability.

B. *Conclusions of law*

None of the testimony or other evidence admitted at trial provides any analysis as to whether all information that could not be used by HLS's or its clients' competitors for commercial advantage has been reasonably segregated from any of the 1017 pages. The defendants have failed to carry their burden of establishing that all reasonably segregable nonexempt information has been disclosed with respect to any of the 1017 pages at issue. Because the defendants have entirely failed to carry their burden on segregability, there is no basis upon which to conclude that any of the records at issue have been properly withheld under Exemption 4. Thus, judgment will be entered for the plaintiff and the USDA

will be ordered to release the records that have been withheld in full or in part.

CONCLUSION

The defendants failed to carry their burden of proving that there is a likelihood that the information withheld from the 1017 pages at issue, if released, could be used by competitors for their commercial advantage and that all reasonably segregable nonexempts portions of the records at issue have been disclosed. Because the defendants have failed to justify the withholding of the records at issue under Exemption 4, judgment will be entered for IDA and the USDA will be ordered to disclose all 1017 pages remaining at issue in this case. Since IDA has voluntarily agreed to forego certain information that may be contained in the withheld records, the USDA will be permitted to redact the information that IDA has voluntarily agreed to forego. A final judgment accompanies this Memorandum Opinion directing how disclosure shall occur.

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