UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN HEALTH RESEARCH GROUP, Plaintiff, v. NATIONAL INSTITUTES OF HEALTH, Defendant, and JOHNSON & JOHNSON, Intervenor-Defendant.	Civil Action No. 00-1847 (CKK)

FILED

MAR 12 2002

NANCY MAYER WHITTINGTON, CLERK
U.S. DISTRICT COURT

MEMORANDUM OPINION
(March 11, 2002)

This case comes before the court on motions for summary judgment made by Defendant, National Institutes of Health ("NIH") and Intervenor-Defendant Johnson & Johnson ("J&J"), and a cross-motion for summary judgment made by Plaintiff, Public Citizen Health Research Group ("HRG"). Plaintiff brought suit in this Court to compel Defendant to release two pieces of information: 1) NIH revenues from royalties based on NIH inventions for both intramural and Cooperative Research and Development Agreement ("CRADA") research, and 2) records concerning the percentage of sales that NIH received as royalties, both for the period of 1996-1998. Defendant asserts that the requested information falls within exemptions 3 and 4 of the Freedom of Information Act 5 U.S.C. § 552 (1994 and Supp. IV 1998) ("FOIA"). Upon review of Plaintiff's, Defendant's, and Intervenor-Defendant's motions, this Court finds that the

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information in question satisfies the requirements of exemptions 3 and 4. Accordingly, the Court shall grant Defendant's and Intervenor-Defendant's Motions for Summary Judgment, deny Plaintiff's Motion for Summary Judgment, and dismiss the case from the docket of the Court with prejudice.

I. BACKGROUND

The mission of Defendant is to promote biomedical research in the interest of public health. Def.'s Mot., Decl. of Maria Freire, "Freire Decl." ¶ 4. Most NIH inventions are developed internally by NIH scientists, while other inventions are made by NIH employees working under the terms of a CRADA, authorized by the Federal Technology Transfer Act, ("FTTA"),15 U.S.C. § 3710a, which promotes collaboration between federal laboratories and non-federal parties. *Id.* ¶¶ 7, 15. These CRADA agreements serve as an instrument for federal laboratories to receive research funds from an outside party and also allows the federal laboratories to agree to license the invention arising out of the CRADA to the outside party at the outset of the collaboration without going through the standard licensing regulations required by the Bayh-Dole Act, 35 U.S.C. § 200. *Id.* Many of these "Intramural" and "CRADA" inventions are "early stage technologies" that otherwise would not be further developed but for the protections of the United States patent and licensing system. *See id.* ¶ 9.[1]

Defendant's Office of Technology Transfer ("OTT") decides whether to patent an intramural invention. *Id.* at ¶ 8. If the OTT decides to patent the invention, it markets the intramural invention to commercial partners such as Intervenor-Defendant, Johnson & Johnson,

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[1] Licenses for CRADA inventions are generally similar as the licenses for non-CRADA NIH inventions, Freire Decl. ¶ 17, as a result the Court's discussion of royalty arrangements do not distinguish between the two.

and negotiates a licensing agreement. *Id.* at ¶ 11. Licensing decisions are not simply based on who will pay the highest royalties, but who can best develop and commercialize the technology. Freire Decl. ¶ 10. The licenses require the payment of royalties to the NIH as consideration for the right to use the patented technology. *Id.* ¶ 11. The royalties are negotiated on a case by case basis and are dependent upon the nature of the technology being used. *Id.*

On September 22, 1999, Plaintiff submitted five separate FOIA requests to Defendant seeking information related to NIH licenses.[2] Cornell Decl. ¶ 3. On September 29, 1999, Plaintiff amended one of the five requests, specifically asking for information from the period 1986 to 1998, regarding "NIH revenues," including "a. [a]greements where a collaborator pays NIH in support of research, b. [r]oyalties based on intramural research, and c. [r]oyalties based on inventions arising out of CRADAs." Def.'s Statement of Material Facts as to Which There is No Genuine Issue ("Def.'s Stmt.") ¶ 2 (undisputed) (quoting Def.'s Mot., Decl. of Susan R. Cornell, "Cornell Decl." ¶ 5). In a letter dated April 11, 2000, Defendant informed Plaintiff that records responsive to items "b" & "c" of its September 29, 1999, request had been located and sent to the NIH FOIA office for review, while information responsive to item "a" needed to be requested from the individual NIH Institutes and Centers. *Id.* ¶ 3 (undisputed) (quoting Cornell Decl. ¶ 3.)

As is usual in the typical FOIA case, some of Plaintiff's initial requests were voluntarily withdrawn and others were satisfied by the agency. *See generally* Cornell Decl. During the course of this process, Plaintiff filed another FOIA request on June 22, 2000, seeking "records

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[2] Plaintiff, part of Public Citizen, a nonprofit public interest organization founded in 1971, advocates for, among other things, safe and effective medical devices and drugs. Pl.'s Mot./Opp'n, Decl. of Peter Lurie ("Lurie Decl.") ¶ 2.

concerning the percentage of sales that NIH received as royalties from a) intramural research and b) inventions arising out of CRADAs for the same time period." *Id.* ¶ 4 (undisputed) (quoting Cornell Decl. ¶ 9). Additionally, Plaintiff asked for "information related to these royalty records in six categories: 1) year, 2) collaborator/company, 3) NIH tracking number, 4) NIH institute involved, 5) nature of invention, and 6) whether Standard or Materials CRADA." *Id.* Soon thereafter, Plaintiff filed the present action on July 31, 2000, pursuant to 5 U.S.C. § 552(a)(4)(B) to compel Defendant to release information responsive to its September 29, 1999, and June 22, 2000, requests. Pl.'s Statement of Materia Facts as to Which There is No Genuine Dispute ("Pl.'s Stmt. ¶ 3) (undisputed); *see also* Compl. In response to Plaintiff's Complaint, Defendant notified all of its licensees, from the period of 1986 to 1998, by letter dated September 26, 2000, of Plaintiff's requests and asked them whether they had any objection with the release of the information. Def.'s Stmt. ¶ 5 (undisputed).[3] Four hundred and ninety-one letters were mailed and of those who responded, the overwhelming majority opposed release of the information. Pl.'s Stmt. ¶ 5 (noting of the one hundred sixty-four replies, except for eleven all objected to release of the information); Freire Decl. ¶20.[4]

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[3] Executive Order 12,600 requires that agencies notify parties who are affected by a FOIA request and solicit letters in response. Exec. Order No. 12,600, 52 Fed. Reg. 23781 (June 23, 1987).

[4] The letter provided that failure to respond would indicate that the licensee had no objection to disclosure. Def.'s Mot., Ex. 3, ("Sept. 22, 2000 Letter"). However, the letter also stated that "if we are required to disclose any of your information, you will be notified again." *Id.* The letter also only gave the licensees two weeks to respond. After the deadline, eleven responses were received, nine of which were against disclosure. Def.'s Opp'n/Reply, Supplemental Declaration of Marie Freire, ("Supp. Decl. Freire") ¶ 13. Of the remaining three hundred sixteen non-respondents, twenty letters were mailed to licensees who held licenses outside the period requested by Plaintiff or had their letters returned by the mail service. *Id.* ¶ 14. Of the remaining two hundred ninety-six non-respondents, one-hundred thirteen have license agreements that have expired.

After having conferred by telephone on October 25, 2000, counsel for both parties agreed that only two categories of information are at issue in this case: 1) the request for "NIH revenues from royalties based on NIH inventions, from both intramural and CRADA research," and 2) the request for "records concerning the percentage of sales that NIH received as royalties, both for the period of 1986-1998." Def.'s Stmt. ¶ 6 (undisputed). On October 26, 2000, after having narrowed the scope of the request for purposes of this case, Defendant formally denied Plaintiff's September 29, 1999, and June 22, 2000, requests under FOIA exemptions 4 and 5.

Plaintiff seeks the withheld information "to evaluate whether the government is receiving a reasonable rate of return on the taxpayers' investment in the valuable research done by the NIH. This evaluation is of particular relevance because of the current debate over the pricing of medical products." Lurie Decl. ¶ 9. Defendant argues that the release of this information would substantially impair the competitive position of the licensees and would impair the effectiveness of the licensing program. Def.'s Mot. at 11. In its initial filing, Defendant claimed that the information was properly withheld under FOIA exemptions 3, 4, and 5. Intervenor-Defendant claims that the information was properly withheld only under exemption 4. The Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1331. The material facts required to resolve these motions are not disputed and for the reasons stated *infra*, the Court shall grant Defendant's and Intervenor-Defendant's motions for summary judgment, and deny Plaintiff's motion for summary judgment.

II. LEGAL STANDARD

Federal Rule of Civil Procedure 56(c) requires a court to grant judgment "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that the moving party is entitled to judgment as a matter of law." Fed. R.

Civ. P. 56(c); *Tao v. Freeh*, 27 F.23d 635, 638 (D.C. Cir. 1994). Although the court should draw all inferences from the supporting records submitted by the nonmoving party, the mere existence of a factual dispute, by itself, is not sufficient to bar summary judgment. *Anderson v. Liberty Lobby, Inc.*, 477. U.S. 242, 248 (1986). The adverse party's pleadings must evince the existence of a genuine issue of material fact. *Id.* at 247-248.

To be material, the factual assertion must be capable of affecting the substantive outcome of the litigation; to be genuine, the issue must be supported by sufficient admissible evidence such that a reasonable trier-of-fact could find for the nonmoving party. *Id.*; *Langingham v. United States Navy*, 813 F.2d 1236, 1242-1243 (D.C. Cir. 1987). Mere allegations or denials in the adverse party's pleadings are insufficient to defeat an otherwise proper motion for summary judgment. Rather, the nonmoving party bears the affirmative duty to present, by affidavits or other means, specific facts showing that there is a genuine issue for trial. *Id.* at 1248-1249. The adverse party must do more than simply "Show that there is some metaphysical doubt as to material facts." *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 (1986).

Under the Freedom of Information Act, an agency is required to disclose the information requested unless the record is exempt under one of the Act's exemptions. *Department of Justice v. Tax Analysts*, 492 U.S. 136, 150-151 (1989). The agency asserting the exemption has the burden of proving that it applies. *Critical Mass Energy Project v. NRC*, 975 F.2d 871, 879 (D.C. Cir. 1992) (*en banc*) ("*Critical Mass III*"). This Court reviews the agency's determination that the exemption applies *de novo*. 5 U.S.C. 552(a)(4)(B). Nonetheless, the party requesting the records under the FOIA has the burden of demonstrating the absence of disputed facts. *Public Citizen Health Research Group v. FDA*, 185 F.3d 898, 904-905 (D.C. Cir. 1999).

III. DISCUSSION

A. ***Exemption 5***

Defendant originally had argued that FOIA's fifth exemption shielded the information that it had withheld from Plaintiff. However, in light of the recent Supreme Court case, *Department of the Interior and Bureau of Indian Affairs v. Klamath Water Users Protective Association*, 121 S.Ct. 1060 (2001), Defendant withdrew its reliance on this exemption. Def.'s Resp. to Pl.'s Submission of Supplemental Authority at 1. Consequently, this court need not address whether exemption 5 applies and the Court can proceed to analyze the other two remaining exemptions.

B. ***Exemption 3***

Defendant also seeks protection from disclosure of the requested information under FOIA's third exemption, Section 552(b)(3), that allows agencies to deny requests for the release of information that is:

> specifically exempted from disclosure by statute (other than 552(b) of this title), provided that such statute (A) requires that the matters be withheld from the public in such a manner as to leave no discretion on the issue, or (B) establishes particular criteria for withholding or refers to particular types of matters to be withheld.

5 U.S.C. 552(b)(3). Defendant correctly asserts, and Plaintiff does not dispute, that the Federal Transfer and Technology Act, 15 U.S.C. § 3710a(c)(7)(A), is a qualifying statute under exemption 3. *DeLorme Pub. Co., Inc. v. National Oceanic and Atmospheric Admin. of U.S. Dep't of Commerce*, 917 F. Supp. 867, 872 (D. Me. 1996). Under the FTTA:

> No trade secrets or commercial or financial information that is privileged or confidential, under the meaning of section 552(b)(4) of Title 5, which is obtained in the conduct of research or as a result of activities under this chapter from a non-Federal party participating in a cooperative research and development agreement shall be disclosed.

15 U.S.C. § 3710a(c)(7)(A). As Plaintiff notes in its motion, the FTTA's prohibition on disclosure is "co-extensive with exemption 4." Pl.'s Mot./Opp'n at 7 n.3 ("Because the FTTA's prohibition on disclosure is expressly coextensive with exemption 4, the NIH's exemption 3 and 4 claims stand or fall together."). In other words, for purposes of this case, FOIA exemption 3 is coterminous with FOIA exemption 4. Accordingly, the requirements of exemption 3 are met if the requirements of exemption 4 are likewise satisfied. The Court, therefore, is left to consider whether the information is properly withheld under exemption 4.

C. ***Exemption 4***

Thus, the sole issue left for adjudication is whether the agency may prevent the release of the information by citing exemption 4 of FOIA, 5 U.S.C. § 552(b)(4). Under the fourth exemption, "trade secrets and commercial or financial information obtained from a person and privileged or confidential" are exempt from disclosure. 5 U.S.C. § 552(b)(4). Here, neither party contends that the requested information is a trade secret and thus the Court must look to the second kind of information protected under exemption 4.

The second type of information protected by FOIA's fourth exemption is information that is 1) commercial or financial, 2) obtained from a person outside the government, and 3) privileged or confidential. *Gulf and Western Indus. v. United States,* 615 F.2d 527, 529 (D.C. Cir. 1979). First, it is undisputed that the information that Plaintiff wishes to obtain is commercial or financial information. The terms "commercial" and "financial" should be given their ordinary meaning, and records are "commercial" if the submitting party has a commercial interest in them. *Public Citizen Health Research Group v. FDA,* 704 F.2d 1280, 1290 (D.C. Cir. 1983). Plaintiff concedes that the information, in this case, is commercial in nature. Pl.'s

Mot./Opp'n at 7 (HRG does not dispute the records it seeks, containing royalty rates and revenues, are "commercial.").

Second, the information must be obtained from a person. Originally, Plaintiff conceded that the information, at issue in this case, came from a person. Pl.'s Mot./Opp'n at 7 ("HRG does not dispute that the records it seeks, containing royalty rates and revenues . . . were "'obtained from a person.'"). In its reply brief, Plaintiff now disputes this point, arguing that the requested information is not obtained from a person for the purposes of exemption 4. Pl.'s Reply at 4 ("In its initial memorandum, HRG did not contest that the records at issue here were 'obtained from a person.' However, HRG now believes that it erred in not doing so.").

The Court highly disfavors parties creating new arguments at the reply stage that were not fully briefed during the litigation. *Senior Unsecured Creditors' Comm. of First RepublicBank Corp. v. FDIC*, 749 F. Supp. 758, 772 (N.D. Tex. 1990) (noting that Defendant "raised its third argument for the first time in its reply brief and the court will not consider it in deciding the motion to dismiss."); *see also Carbino v. West*, 168 F.3d 32, 34 (Fed. Cir. 1999) ("There are cogent reasons for not permitting an appellant to raise issues or arguments in a reply brief.") (citing appellate cases for this proposition). By placing a new argument in the Reply, Plaintiff does not permit Defendant or Intervenor-Defendant to competently respond to such an argument. *Wright v. United States*, 139 F.3d 551, 553 (7th Cir. 1998) ("The reason for this rule of waiver is that a reply brief containing new theories deprives the respondent of an opportunity to brief those new issues.").

Even if the Court permitted Plaintiff to make this argument, it would fail. There is no doubt that a corporation may be considered a "person" for the purposes of exemption 4. 5 U.S.C. 551(2). *See, e.g., Allnet Communication Services, Inc. v. FCC*, 800 F. Supp. 984, 988 (D.D.C.

1992) ("'[P]erson' refers to a wide range of entities including corporations, associations and public or private organizations other than agencies."). However, relying on *Federal Open Market Committee of the Federal Reserve System v. Merrill*, Plaintiff argues that the requested information is not obtained from a person for the purposes of exemption 4, because exemption 4 only applies to information obtained from entities outside the government. Pl. Reply at 4 (citing *Federal Market Committee of the Federal Reserve System v. Merrill*, 443 U.S. 340, 360 (1979)). Plaintiff contends that the requested information was not obtained from outside the government since the royalty rate is negotiated between the licensee and the government. Pl.'s Reply at 4.

The Court finds that the royalty information in this case was, indeed, obtained from a person. Plaintiff erroneously cites *Comstock Int'l, Inc. v. Export-Import Bank*, 464 F. Supp. 804, 807 (D.D.C. 1979) for the proposition that information cannot be considered to have been submitted to the government when the information was generated in negotiations. However, the portion of the opinion in *Comstock*, cited by Plaintiff, actually does not address this issue. In *Comstock*, the court noted that the government's interest in obtaining similar information in the future could not be affected because "information contained in the loan agreement is not submitted to the government but rather generated by it through Eximbank's participation in the negotiation process." *Id.* *Comstock* still, however, upheld the withholding of information under exemption 4 based on the fact that the effectiveness of a government program would be impaired; even when the information was obtained through the product of negotiation. *Id.* at 808.

Even though the final royalty rate is arrived at through negotiation, Freire Decl. ¶ 12, this does not alter the fact that the licensee is the ultimate source of this information. Documents that contain "summaries or reformulations of information supplied by a source outside of the

government" are protected under exemption 4. *Judicial Watch, Inc. v. Export-Import Bank*, 108 F. Supp. 2d 19, 28 (D.D.C. 2000) (citing *Gulf and W. Indus.*, 615 F.2d at 529-30. In this case, the royalty rate is the rate embodied in an agreement that the licensee agrees to pay to Defendant. It is the rate provided by the licensees to the NIH in the royalty arrangements. If the licensee wishes to become involved with a certain technology, it must submit proposed royalty information. If it fails to submit any information it cannot license the technology. While the final royalty rates may reflect negotiation between the agency and the licensee, the licensee still must provide the information in the first instance. Therefore, the Court finds that the agency obtained this information from a person within the meaning of exemption 4.

Thus, as Plaintiff noted in its original motion, "the only issue for resolution by this Court is whether the material is 'confidential' within the meaning of exemption 4.[5] Pl.'s Mot. at 7. Ordinarily, to determine whether information is confidential, this Court must first determine whether the requested information was submitted voluntarily or whether its submission was required. *McDonnell Douglas Corp. v. NASA*, 180 F.3d 303, 304 (D.C. Cir. 1999). If the information was submitted voluntarily, then the information is "confidential for the purpose of Exemption 4 if it is of a kind that would customarily not be released to the public by the person from whom it was obtained." *Critical Mass III*, 975 F.2d at 879. If the government requires the submission of information, then the information is "confidential" if it 1) impairs the government's ability to obtain necessary information in the future, or 2) causes substantial harm to the competitive position of the person from whom the information was obtained. *McDonnell*

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[5] Defendant also argues that the information was privileged. However, because the Court finds the withheld information to be confidential, it need not reach the question of whether the information is also privileged.

Douglas, 180 F.3d at 305 (citing *National Parks & Conservation Ass'n v. Morton*, 498 F.2d 765 (D.C. Cir. 1974) (*National Parks I*)). In this case, the parties have proceeded under the assumption that the information in question was, in fact, required to be submitted and the Court agrees. *Cf. McDonnell Douglas Corp. v. NASA*, 895 F. Supp. 316, 318 (D.D.C. 1995) ("Price is an essential and required piece of information for the contract, no matter how it was achieved."). As a result, the Court needs to analyze the information requested by Plaintiff under the two prong test originally articulated in *National Parks I*.

In conducting this inquiry, our circuit has reaffirmed the central role a rough balancing must play between the private and public interests when considering a withholding under exemption 4. *Public Citizen Health Research Group v. FDA*, 185 F.3d 898, 904 (D.C. Cir. 1999) ("We reject Public Citizen's proposal because a consequentialist approach to the public interest in disclosure is inconsistent with the balance of private and public interests the Congress struck in Exemption 4."). When conducting this balancing, the Court is permitted to look beyond the two factors set forth in *National Parks I* (serious competitive harm and impairment of government information gathering), however, these other consideration "can be introduced into the balance only as factors weighing against disclosure in a manner similar to the two interests identified in *National Parks I*." *Washington Post Co. v. HHS*, 865 F.2d 320, 326 (D.C. Cir. 1989). The Court is therefore charged with balancing the public interest in disclosure against the private interest in withholding the information.

Before even addressing this balancing, however, the Court needs to consider Plaintiff's argument regarding the sufficiency of Defendant's evidentiary support. The Court determines that the agency has provided specific, credible evidence to meet its burden of withholding the royalty information. Unlike Plaintiff's affiant, who provides no support for his conclusions,

Defendant has provided extensive support for its conclusions regarding the likelihood of substantial competitive harm and the impairment of the effectiveness of its licensing program. Defendant's main affiant, Dr. Freire, conclusively establishes from her personal knowledge, as head of the OTT, the competitive harm that licensees would face if the royalty information was made public. Freire Decl. ¶¶ 29 (at 11)[6]-31. Plaintiff contends that Dr. Freire's declaration is inadequate under Rule 56(e) of the federal rules of Civil Procedure because "it is not based on personal knowledge of the licensee's practices, does not demonstrate that Dr. Freire is competent to testify about the licensee's practices (as either a fact witness or an expert witness), and does not set forth facts with regard to those practices that would be admissible in evidence." Pl.'s Mot./Opp'n at 13.

In response to Plaintiff's contention regarding Dr. Freire's competency, the Court notes that this line of argument is completely unavailing. Dr. Freire is extraordinarily well-credentialed, particularly in the field of technology transfer, and can conclusively and authoritatively provide a thoughtful opinion on the withheld information. Def.'s Opp'n/Reply, Supp. Decl. Freire ¶¶ 3-7. Additionally, Dr. Freire's statements in her affidavit are based on her own understanding of how disclosure of the royalty information would affect Defendant and its licensees. Many of her representations are supported by citation to the letters received by the NIH from its licenses, but these are in addition to her own "personal knowledge" of the representations made by the various pharmaceutical companies.

Defendant has also included an additional eleven affidavits that support Dr. Freire's conclusions. The Court has reviewed these affidavits and they provide detailed and exhaustive

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[6] This affidavit contained two paragraphs labeled 28 and 29. This is the reason for the Court including the corresponding page number.

support for withholding the information. *See e.g.*, Def.'s Opp'n/Reply (various exhibits). On the other hand, Plaintiff's affiant, Dr. Schondelmeyer, provides no independent support for his conclusions. No reasonable fact-finder could find for Plaintiff on the basis of the meager evidence presented to rebut Defendant's witnesses.

Returning to the "rough balancing" the Court must make between private and public interests, two primary factors counsel against release of the information. First, the licensees would be placed at a substantial competitive disadvantage if the information was released. Second, disclosure of the royalty information would impair the efficient and effective performance of Defendant's licensing program. After reviewing the evidence, the Court concludes that the information should be withheld.

Substantial Competitive Harm

The Court concludes that Defendant has shown that release of the information at issue in this case would likely cause substantial competitive harm to the licensees. A party need not demonstrate actual competitive harm in order to show that releasing the information would likely cause substantial competitive harm. *Gulf and W. Indus.*, 615 F.2d at 530. Rather, a party need only demonstrate the existence of actual competition and the likelihood of substantial competitive injury. *Id*; *see also CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1152 (D.C. Cir. 1987). Further, while the parties cannot rest on a "conclusory and generalized allegation of substantial competitive harm," the court need not engage in a sophisticated economic analysis to determine whether there is a likelihood of substantial competitive injury. *Public Citizen v. FDA*, 704 F.2d at 1291.

In this case, there is evidence that the licensees face actual competition. In making this determination, this Court has been reminded by the United States Court of Appeals for the

District of Columbia Circuit that "[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*." *Id.* at 1291 n.30 (quoting Connelly, *Secrets and Smokescreens: A Legal and Economic Analysis of Government Disclosures of Business Data*, 1981 Wis. L. Rev. 207, 230). The evidence reveals that the licensees are engaged in actual competition such that if the proprietary information was released it could be used by the licensees' competitors to their advantage. The pharmaceutical industry is a highly competitive market where companies routinely attempt to discover a possible advantage over their competitors. Freire Decl. ¶ 27; Def.'s Opp'n/Reply, Ex. 9, Decl. of Mark Edwards ¶¶ 9-10. Thus, in this case the Court determines that the licensees face actual competition.

Based on the evidence in the record, the Court also concludes that there is a likelihood that the licensees would face substantial competitive harm. Plaintiff makes a number of arguments in an attempt to rebut this point. First, Plaintiff argues that the royalty rate information would not help a licensee's competitors calculate a licensee's cost structure for a particular technology. Second, Plaintiff contends that because companies voluntarily reveal royalty rates in other contexts, Defendant should be required to release the information at issue in this case. Third, Plaintiff observes that disclosure would not reveal information related to a licensee's strategic plan. Fourth, Plaintiff argues that the letters sent from the licensees to Defendant actually demonstrate that a majority of licensees do not object to disclosing the royalty information. Plaintiff contends that this fact should lend support to its contention that no substantial competitive harm would come from releasing the information. Lastly, Plaintiff seeks to analogize the royalty rate to the price of a contract and argues that the contract prices between the government and a private party is not confidential. The Court shall consider each of these

arguments in turn.

Plaintiff first argues that the royalty rate is such a small percentage of the total cost of a drug, that calculating a product's cost would not be possible from the release of such a low figure. Pl.'s Mot./Opp'n at 17 (citing Decl. of Stephen W. Schondelmeyer ("Schondelmeyer Decl.") ¶¶ 13-14). This argument fails because it does not comport with the nature of the pharmaceutical industry's cost structure and lacks compelling sophistication necessary to provide a competent analysis of the actual cost structure facing the licensees. Most firms in the pharmaceutical industry have a similar sunk costs, thus release of this information, even if it provided only a small percentage of the product's costs, could easily lead to a competitor being able to make a rough calculation of a firm's profit margin on a particular drug. Intervenor-Defendant specifically notes that this is the case:

> With the exception of royalty rates, the other fixed costs and competitive market conditions involving a product can generally be predicted with significant accuracy by companies in the pharmaceutical industry. [R]oyalty rates are also one of the truly unknown factors in th[e] cost structure. . . . [I]f this information is disclosed, J&J's cost structures and profit margins for products that are the subject of its NIH licensing agreements would be known with much greater precision, and other companies would be able to undermine J&J's efforts to market such products.

Intervenor-Def.'s Opp'n/Reply, Supplemental Declaration of Geoffrey Dellenbaugh ("Supp. Decl. Dellenbaugh") ¶¶ 7-8; *see also* Pl.'s Reply, Ex. 11, Decl. of Milton H. Grannatt ¶ 8 ("Based upon established formulae and factors applied to the biotechnology industries, with detailed royalty information in hand, it would be relatively easy for our competitors to calculate the costs and profit margins for our pharmaceutical products."); Ex. 1, Decl. of Bertram A. Spilker ("Spilker Decl.") ¶ 10 ("[i]t is typically impossible to determine [from other sources of information] the amount of royalty income received from, or paid for, a specific drug."); Ex. 2,

Decl. of Robert T. Hrubiec ¶ 15 ("The amount of royalties paid for a license significantly affects the price of a pharmaceutical product since the royalty amount is considered part of the fixed cost of the product. Disclosure of such information unfairly provides valuable information to competitors."); Ex. 3, Decl. of Stephen Juelsgaard ¶ 6 ("A competitor's knowledge that Genentech has a substantial royalty obligation and as a consequence has diminished pricing flexibility and a lower profit margin may well lead that competitor to develop and commercialize a product where it otherwise would not have done so in the absence of such knowledge.").

Additionally, these affidavits are not only from licensees who have a stake in the outcome of the litigation. Defendant has provided an affidavit from the head of the Technology Office at MIT who likewise concludes that the royalty information is highly confidential and proprietary. *Id.*, Ex. 7, Decl. of Lita Nelsen ¶ 11 ("Competitors of the licensee company could be expected to derive strategy information . . . and cost/margin information, among other pieces of information.").[7] Thus, Plaintiff's unsubstantiated statements about the cost structure have no

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[7] The Court has also reviewed the letters submitted by Defendant and finds that most also precisely state the competitive harm that would transpire if the information were released. Def.'s Mot., Ex. 12, Letter from American Home Products at 7 ("[P]roviding competitors the royalty rate (which is typically expressed as a percentage of sales) of a particular license would help the competitor calculate the marginal costs of any product of an AHP Entity that incorporates the technology."); Ex. 9, Letter from Cook Inc. at 1 ("Royalties paid by Cook to NIH reflect Cook's costs of goods, margins and prices. If royalty amounts paid by Cook are disclosed, Cook's costs of goods, margins and prices with respect to products upon which Cook pays royalties are necessarily disclosed as well."); Ex. 18, Letter from Schering-Plough at 3 ("Such 'inside' information would allow competitors to price competing products more effectively to capture market share"); Ex. 21, Letter from Millennium at 3 ("disclosure of sensitive marketing and pricing information would cause competitive injury because it would allow competitors and customers to estimate a company's profit margin and production costs, thereby giving competitors an insight into a company's competitive strengths and weaknesses . . .competitors could make projections of the Company's current and future cost and prices based on current pricing information."); Ex. 22, Letter from NeoPharm ("[O]ur Company is a small research and development company . . . our substantially larger competitors in the pharmaceutical industry would receive an unfair advantage by being able to use their knowledge of our Royalty Payments

basis in actual fact. More to the point, aside from the statement of its affiant, *who provides no independent support for his conclusions*, Plaintiff has not provided the necessary proof to convince a reasonable fact finder that the royalty information is not a significant factor in a licensee's cost structure.

Moreover, courts in this circuit have held that information that competitors could use to derive a firm's profit margin constitutes serious competitive harm. *See Trans-Pacific Policing Agreement v. United States Customs Serv.*, 177 F.3d 1022, 1026 (D.C. Cir. 1999) ("As the District Court held, a person could then use the HTS numbers to unlock some of the ambiguities and inaccuracies on the . . . and thereby gain a picture of an importer's intentions, profit margin, and other plans. . . . We have no doubt that, based on the record before the District Court, Customs met its burden under Exemption 4.") (internal quotation marks omitted); *Mitsubishi Elec. Corp. v. United States Dep't of Justice*, No. 76-0813, 1977 WL 1382, at * 5 (D.D.C. Apr. 1, 1977) ("Licensing agreements contain royalty rates, the disclosure of which would facilitate estimates of profit margins and divulge sensitive provisions for safeguarding secrecy and effecting quality control.") (adopting government affidavit).

Plaintiff next contends that because companies occasionally voluntarily reveal royalty rates, in different contexts, the utility of the information to a competitor is likely to be *de minimis*. None of the exhibits provided by Plaintiff show any of Defendant's licensees voluntarily revealing their royalty arrangement with the NIH. In fact, of the eight articles submitted by Plaintiff as a result of an Internet database search, none are germane to the

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to (1) predict the prices at which will be able to market our products."). Due to hearsay concerns, the Court does not rely on these letters in reaching its decision. However it merely notes them to show the support Defendant had in reaching its conclusion.

information at issue in this case. Pl.'s Mot./Opp'n, Schondelmeyer Decl., Ex. C. For example, two of the articles are not even about royalty rates in the context of a license. *Id.* at C-6 (royalty rate to be paid to acquiring company); C-7 (royalty rate to be paid to investors in a firm's notes). Two of the articles relate to a settlement of patent litigation between the University of Minnesota and a pharmaceutical company, whereby the University of Minnesota received the royalty payments that they had previously negotiated with the firm. *Id.* at C-1, C-2. Other articles relate to private royalty arrangements between companies. *Id.* at C-4, C-5, C-8. Only one of the articles even relates to a licensing arrangement with the government; and the pharmaceutical firm mentioned in that article does not have any licenses with Defendant. *Id.* at C-3; Def.'s Opp'n at 19.

The evidence submitted by Plaintiff to support its argument that royalty agreements are publicly disclosed is thus, wholly unsubstantiated. The Court determines that royalty information is usually kept confidential. *See* Supp. Decl. Dellenbaugh ¶ 4 (noting that Intervenor-Defendant almost never releases royalty rate and payment information contained in its licensing agreements); *see also* Spilker Decl. ¶ 13 ("Dr. Schondelmeyer's broad, conclusory assertion . . . that it is not unusual for companies to release this detailed royalty information on their own, or with partners from whom they have licensed a product . . . lacks evidentiary support. In my experience, it is untrue. The rule, rather than the exception, is that pharmaceutical companies go to great lengths to maintain the confidential and proprietary nature of such information.") (internal quotation marks omitted).

Plaintiff next criticizes Defendant's argument that disclosure would reveal sufficient information as to a licensee's strategic planning. Pl.'s Mot./Opp'n at 19-20. Without belaboring this point, the Court notes that if a competitor realized information about how much a licensee

was paying for a royalty, it would immediately know the value the firm placed on that particular technology. This knowledge, in turn, would certainly help competitors know which technologies and which areas of the market the licensee found particularly fruitful. Furthermore, Plaintiff's contention that there are other sources of strategic information does not lend any credence to the notion that the specific royalty information in this lawsuit should be released. Simply because a competitor has other means of ascertaining the strategy of a licensee does not mean that the royalty information at issue in this suit should not be disclosed.

Plaintiff next attempts to challenge the credibility of Defendant's position by noting that Defendant received only one hundred and sixty-four replies to its request of the licensees for their position on releasing this information. Since the letter sent to the licensees stated that failure to reply meant that the agency would assume that there was no objection to disclosure of this information, Plaintiff argues that the great percentage of licensees do not object to disclosure. However, the agency explains that actually only one hundred and eighty-three collaborators with active licenses failed to respond. Supp. Decl. Freire ¶ 14. Additionally, given that the letter provided only a two-week time period to respond and that the letter specifically stated that the agency would notify the parties if it was required to disclose the information, the Court concludes that evidence that the agency did not receive a response from a licensee does not lend credence to a conclusion that a majority of licensees favored release of the royalty information. The evidence of those who did respond was overwhelmingly against disclosure which tips the scales heavily toward a conclusion that release of the information would likely cause substantial competitive injury and impede the effective functioning of the licensing department.

Notably, even if the Court determined that release of the information was appropriate for

licensees that did not object to disclosure, the Court finds that the inability of Defendant to complete its statutory mission, as described *infra*, counsels against targeted disclosure. In other words, even if the non-response to the Defendant's letter was enough to prompt the Court to order the royalty information released, it would not do so because of the Court's overriding concern that the Government's efficient and effective management of the licensing program would be impaired if the royalty information was disclosed.

Lastly, Plaintiff makes a broad assertion that "the price of a contract between the government and private party is not confidential." Pl. Mot./Opp'n at 8. Basically Plaintiff contends that the royalty rates and royalty amounts do not qualify for withholding under exemption 4 because they are analogous to the total price of a contract between the government and a private party, which in certain cases has been required to be disclosed. However, most of the cases Plaintiff cites are those in the "reverse FOIA" context, where the agency seeks to disclose the information and a private entity, suing under the Administrative Procedure Act, seeks to block that disclosure. As noted by the court in *Gulf Western*, reverse FOIA cases are "diametrically different" from the traditional FOIA case. *Gulf W. Indus.*, 615 F.2d at 531. As the Court in *Gulf Western* noted, the test is whether the withheld information would likely cause substantial competitive harm. *Id.* As amply demonstrated above, the competitive harm to the licensees has been clearly demonstrated.

In fact, in many of the cases Plaintiff cites, the courts held that contract prices were not confidential for the purposes of the *National Parks* test because the alleged harm was speculative. *Martin Marietta Corp. v. Dalton*, 974 F. Supp. 37, 40 (D.D.C. 1997) (permitted release of line item and unit pricing because Defendant failed to demonstrate with specificity precisely how it will suffer harm); *Brownstein Zeidman & Schomer v. Department of Air Force*,

781 F. Supp. 31, 33 (D.D.C. 1991) (permitting release of unit prices because the alleged harm was merely speculative). Plaintiff misconstrues the recent Court of Appeals decision of *McDonnell Douglas Corp.*, by simply citing it for the proposition that "it is undisputed that the total price of the contract may be made public." *McDonnell Douglas*, 180 F.3d at 306 (holding that line item pricing information in contract between NASA and McDonnell Douglas was confidential commercial or financial information under the *National Parks* test). Rather, in that case, the Court of Appeals implicitly acknowledged that contract price information that otherwise would not be confidential could, in fact, be considered confidential for the purposes of the Trade Secrets Act and FOIA if it could be demonstrated that the submitting party would be substantially harmed by its release. *Id.*

As a result, this Court concludes that the release of negotiated royalty terms of contracts for both CRADA and intramural research would cause substantial competitive harm to submitting companies, and are therefore exempt from disclosure under exemption 4 of the Freedom of Information Act. Simply put, the Court finds that there is actual competition present and that there is the substantial likelihood of competitive harm if the withheld information was to be released. From the overwhelming evidence submitted by Defendant and Intervenor-Defendant, the Court finds as a matter of law that release of the information would not pose a substantial competitive harm to the licensees. While the Court is extremely cognizant of the mandate underlying the Freedom of Information Act for public disclosure, in conducting the balancing of private and public interests, the Court determines that the private interests favoring withholding the information dominate the balancing. The licensees would likely suffer substantial competitive harm if this information was released.

In addition, because the requirements for exemption 4 and exemption 3 are co-extensive,

this court holds that the information is also exempt from release under exemption 3 of the Freedom of Information Act. While the Court conceivably could stop the analysis at this point and grant Defendant and Intervenor-Defendant's motions, it nevertheless analyzes the remaining basis cited by Defendant for withholding the information in the interest of thoroughness.

Disclosure Would Impair Defendant's Ability to Effectively Implement the Licensing Program

Defendant does not argue that the government's ability to receive this information in the future would likely be impaired (first prong of *National Parks I* test). Def.'s Opp'n/Reply at 7 n.5 ("NIH does not claim, as a basis to withhold, that the government's ability to obtain information from submitters in the future would be impaired; rather, it is that its program effectiveness is likely to be impaired."). Rather, Defendant argues that the licensing program's effectiveness would be diminished if the information was released. Essentially, Defendant contends that its ability to fulfill its statutory mandate under the Bayh-Dole Act would be seriously deterred by the release of the royalty information to Plaintiff.

At the outset, Plaintiff argues that it is improper to even consider whether the effectiveness of a government program would be diminished if the information was released. Plaintiff contends that the "NIH, in effect, seeks to create a tenth exemption, applicable whenever an agency wants to avoid disclosure of otherwise non-exempt information." Pl.'s Reply at 14. Plaintiff criticizes Defendant's citation to *Judicial Watch*, 108 F. Supp. 2d at 30 ("impairment of an agency's ability to carry out its statutory purpose is sufficient to cause to justify a finding of confidentiality within the context of Exemption 4") and *Comstock International, Inc. v. Export-Import Bank*, 464 F. Supp. 804, 808 (D.D.C. 1979) ("*National Parks I* . . . however, expressly left open the possibility that other governmental interests, such as the interest in program effectiveness, are embodied by [exemption 4]") because it argues that the Court of Appeals for

the District of Columbia Circuit has not recognized such an exemption. *Id.* at 13. However, Plaintiff has completely misconstrued circuit precedent.

As stated by the Court of Appeals for the District of Columbia Circuit in *Washington Post v. HHS*, 865 F.2d at 327, a case directly relied on by Plaintiff, "[W]e think a fair reading of our cases makes it clear that other interests can be introduced into the balance only as factors weighing against disclosure, in a manner similar to the two interests identified in *National Parks I*." Following that decision, the Court of Appeals held in *Critical Mass III*:

> It should be evident from this review that the two interests identified in the National Parks test are not exclusive. Although we overrule our decision in *Critical Mass I*, we note that the panel there adopted the First Circuit's conclusion that the exemption also protects a governmental interest in administrative efficiency and effectiveness. *See Critical Mass* [*Energy Project v. Nuclear Regulatory Comm'n*, 830 F.2d 278, 286 (D.C. Cir. 1987)] (citing *9 to 5 Org. for Women Office Workers* [*v. Bd. of Governors of the Fed. Reserve Sys.*, 721 F.2d 1, 11 (1st Cir. 1983); *see also id.* at 12 (Breyer, J., dissenting) (agreeing with the court's expansion of the National Parks test while disagreeing with the application of the expanded standard to the case before the court).]. And today, of course, we recognize a private interest in preserving the confidentiality of information that is provided the Government on a voluntary basis. We offer no opinion as to whether any other governmental or private interest might also fall within the exemption's protection.

Id. Plaintiff merely cites the last sentence from this paragraph to support its view that our circuit has not ruled on the issue of whether the effectiveness of a government program can be considered as a factor in making a determination of whether the private interest in withholding the information is impaired. This is plainly contradicted by the text of the case. As noted in *Critical Mass I*, and as reaffirmed in *Critical Mass III*, impairment of the effectiveness of a government program is a proper factor for consideration in conducting an analysis under FOIA exemption 4.

In this case, under the Bayh-Dole Act, Congress has directed federal agencies to use the patent system to promote inventions arising from federally supported research. 35 U.S.C. § 200 (2001) ("It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities."). Thus, under the Bayh-Dole Act, the function of commercializing invention is left up to the private sector. Additionally, under the FTTA, Defendant is encouraged to work with private organizations to assign rights to a collaboration without going through the licensing regulation required by the Bayh-Dole Act. Freire Decl. ¶ 15.

The Court finds that if the royalty information were disclosed, the effectiveness of Defendant's licensing program would be impaired. Plaintiff first argues, without any support, that as there is no competitive harm in releasing this information, licensees will not stop working with the agency in order to collaborate on certain technologies. Additionally, Plaintiff contends that because Defendant offers a "treasure trove" of new technologies, there will always be potential licensees ready to partner with the agency. Schondelmeyer Decl. ¶ 8. Plaintiff's arguments are wholly unsubstantiated and without merit.[8]

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[8] The Court notes that Plaintiff also seeks to rebut Defendant's and Intervenor-Defendant's arguments under this prong of the analysis by again claiming that a majority of licensees did not object to the disclosure of the royalty information. Pl.'s Reply at 16. From this fact, Plaintiff argues that the licensing program would not be impaired because a significant number of licensees actually have no objection to the royalty rate being disclosed and therefore, presumably, would not be dissuaded from licensing with the agency. However, as the Court noted *supra*, the fact that a number of licensees did not respond to Defendant's request for their views is not necessarily probative of their position. Moreover, the overwhelming number of comments the agency received were against disclosure. Even if a majority of licensees were indifferent to disclosure, that does not necessarily translate into a finding that the NIH would not

Plaintiff first argues that there is no substantial competitive harm in releasing this information, and therefore companies will not be deterred from licensing technology from Defendant. Pl.'s Mot./Opp'n at 24-25. However, the Court has already concluded that licensees could face substantial competitive harm if the information were to be released. The Court, therefore, agrees with Defendant's observation that if the government were compelled to disclose the information in dispute in this case, "it would seriously impair OTT in carrying out its public health responsibilities, since NIH would cease to be an attractive or viable licensor of patented technology." Freire Decl. ¶ 24; *see also* Def.'s Opp'n/Reply at 8 ("licensees will not negotiate with NIH without an expectation that the financial terms of the licenses will remain confidential.").[9] Such a result obviously would hinder the agency in fulfilling its statutory mandate.

Affidavits submitted by industry participants unanimously support this view. *See e.g.*, Def.'s Opp'n/Reply, Ex. 2, Decl. of Robert T. Hrubiec ¶ 14 ("Public disclosure of royalty and other financial information in such agreements would have a chilling effect on Cephalon's future decisions to enter into agreements with the NIH because of the negative impact such disclosure would have on Cephalon's competitive position."); Ex. 3, Decl. of Stephen Juelsgaard ¶ 9 ("Because of these concerns, Genentech would be more reluctant to deal with an entity, including

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be seriously harmed if the information was made public. Scores of licensees have already stated they would be much less willing to work with the NIH if royalty information was disclosed. This, in and of itself, is sufficient for the Court to find that Defendant's effective management of the license program would be impaired if the royalty information was released. While Plaintiff criticizes these statements of licensees that they would be less willing to work with the NIH in the future, Plaintiff offers not *one* piece of rebuttal evidence to demonstrate that this is not the case.

[9] The Court notes that Defendant takes confidentiality of this information very seriously because every licensing agreement contains a confidentiality clause. Freire Decl. ¶ 18.

the NIH, that has a policy of, or is otherwise obligated to, disclose the royalty rates it has in its licensing agreements with Genentech."); Ex. 6, Decl. of James M. Hussey ¶ 14 ("While we value our collaboration with the NIH, it is not, in all circumstances, 'the only game in town.'"). Additionally, Intervenor-Defendant notes that such disclosure would "chill" all future dealings between J&J and the NIH. Dellenbaugh Decl. ¶ 8. Intervenor-Defendant contends that having the royalty and revenue information disclosed would essentially "defeat the commercial goals of J&J and its affiliates." *Id.* Thus, the Court determines that the licensees would not wish to partner with Defendant and therefore the agency would have significant difficulty fulfilling its statutory mandate.

Second, Plaintiff argues that because the "NIH offers a treasure trove of new technologies to pharmaceutical and medical device companies . . . [a]s long as these discoveries hold commercial value, there will be interest on the part of private firms to license these inventions and to develop them for commercial purposes." Schondelmeyer Decl. ¶¶ 8, 10; *see also* Pl.'s Mot./Opp'n at 25. However, this assertion is an oversimplification of the extent to which the licensing process is competitive. It is true that over the past fifteen years, certain technologies have been extremely competitive. Freire Decl. ¶ 28 at 10. However, for most technologies the market operates with only one interested participant. The vast majority of NIH inventions require active marketing by the OTT and it is often the case that the OTT has but one firm interested in licensing a specific technology. Supp. Decl. Freire ¶ 8 . In fact in Fiscal Year 2000, forty-five applications for exclusive licenses were received. *Id.* Of these forty-five applications, only two technologies had two applications each. Thus, forty-one of the applications had no competition. *Id.* Furthermore, in applications for nonexclusive licenses, Defendant received two hundred fifty-three applications; only thirty-one of which had more than one application. *Id.*

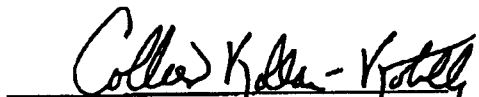
Currently, OTT has approximately two-thousand technologies available for licensing, thirty percent of which have been available for more than five years. *Id.* ¶ 9. Thus, it is beyond dispute, that, for the majority of NIH technologies there is only one (and sometimes zero) firms interested in obtaining a license. *Id.*

Given these statistics, the Court cannot conclude that there is a "treasure trove" of new technologies that will always be able to draw potential licensees. As a result, the Court concludes that there will be a diminution in the number of firms willing to engage in partnership with Defendant to license new technologies.

The Court concludes that in balancing the public interest in disclosure against the private interest in withholding information, the private interest prevails. In this case, the agency has substantially demonstrated that the effectiveness of the licensing program would be critically impaired if the royalty information was released. Plaintiff's attempt to rebut the facts presented by Defendant is wholly unsubstantiated. Based on the record considered in evaluating the private interest in this case, the Court concludes as a matter of law that the strong public interest in disclosure under the Freedom of Information Act outweighs the private interest in withholding the information.

IV. CONCLUSION

Based on the foregoing analysis, the Court concludes that the NIH appropriately withheld, pursuant to exemptions 3 and 4 of the Freedom of Information Act, the information relating to "NIH revenues from : 1)agreements where a collaborator pays NIH in support of research, 2) royalties based on intramural research, and 3) royalties based on inventions arising out of CRADA's" and "records concerning the percentage of sales that NIH received as royalties from a) intramural research, and b) inventions arising out of CRADA's for the period of 1996-1998." Releasing the royalty information would likely cause competitive harm to the licensees and would also likely impair the effectiveness of Defendant's licensing program. Accordingly, this Court grants Defendant's Motion for Summary Judgment, Intervenor-Defendant's Motion for Summary Judgment and denies Plaintiff's cross-motion for summary judgment.



COLLEEN KOLLAR-KOTELLY
United States District Judge

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

PUBLIC CITIZEN HEALTH RESEARCH GROUP, Plaintiff, v. NATIONAL INSTITUTES OF HEALTH, Defendant, and JOHNSON & JOHNSON, Intervenor-Defendant.	Civil Action No. 00-1847 (CKK)

FILED ✓

MAR 1 2 2002

NANCY MAYER WHITTINGTON, CLERK
U.S. DISTRICT COURT

ORDER
(March 11, 2002)

For the reasons stated in the accompanying Memorandum Opinion, it is, this 11 of March, 2002, hereby

ORDERED that Defendant National Institute of Health's Motion for Summary Judgment [#12] is GRANTED; it is further

ORDERED that Intervenor–Defendant Johnson & Johnson's Motion for Summary Judgement [#21] is GRANTED; it is further.

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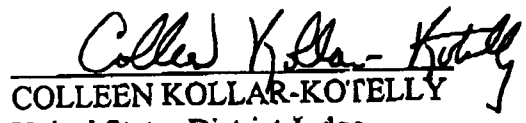
ORDERED that Plaintiff Public Health Research Group's Motion for Summary Judgement [# 22] is DENIED; and it is further

ORDERED that this case be dismissed from the docket of the Court with prejudice.

SO ORDERED.



COLLEEN KOLLAR-KOTELLY
United States District Judge