NO. 06-11774-II

IN THE UNITED STATES COURT OF APPEALS
FOR THE ELEVENTH CIRCUIT

DR. AND MRS. ROBERT SHARKEY, on behalf of
RYAN REED SHARKEY, a minor,
Plaintiffs/Appellants,

v.

FOOD AND DRUG ADMINISTRATION,
Defendant/Appellee,

and

MERCK & CO., INC.,
Defendant-Intervenor/Appellee.

ON APPEAL FROM THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF FLORIDA

BRIEF FOR APPELLANTS

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April 26, 2006

CERTIFICATE OF INTERESTED PERSONS AND CORPORATE DISCLOSURE STATEMENT

Pursuant to Eleventh Circuit Rule 26.1-1, the undersigned counsel certifies that the following persons or entities have an interest in the outcome of this appeal:

Marie A. Borland

Hon. Sheri Polster Chappell

Hon. Virginia M. Hernandez Covington

Food and Drug Administration

GlaxoSmithKline Biologicals, SA

Charles T. Harden, III

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SmithKline Beecham Corporation d/b/a GlaxoSmithKline

Brian Wolfman

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Michael T. Kirkpatrick

STATEMENT REGARDING ORAL ARGUMENT

Plaintiffs/Appellants request oral argument. This appeal raises important questions regarding the government's obligation to produce records pursuant to the Freedom of Information Act and the ability of the public to monitor vaccine safety. Plaintiffs/Appellants believe that oral argument will help resolve the issues presented.

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STATEMENT OF JURISDICTION

This appeal is from an order granting summary judgment in a Freedom of Information Act case. *See* 5 U.S.C. § 552. On March 1, 2006, the district court entered an opinion and order granting defendants' motions for summary judgment and denying plaintiffs' motion for summary judgment or, in the alternative, for discovery. The district court clerk entered a judgment consistent with that order on March 2, 2006. Plaintiffs filed an Amended Notice of Appeal on March 7, 2006. This Court has jurisdiction under 28 U.S.C. § 1291.

STATEMENT OF THE ISSUES

I. Whether the defendants carried their burden of showing that the records requested by plaintiffs constitute confidential commercial information subject to withholding under Exemption 4 of the Freedom of Information Act, 5 U.S.C. § 552(b)(4).

II. Whether the district court erred in granting summary judgment for defendants and denying plaintiffs the opportunity to take discovery even though plaintiffs submitted evidence disputing material facts.

STATEMENT OF THE CASE

Plaintiffs brought this action under the Freedom of Information Act (FOIA), 5 U.S.C. § 552, to compel the Food and Drug Administration (FDA) to produce

records showing the net number of doses by lot of hepatitis B vaccine distributed in the United States. The FDA, joined by Defendant-Intervenor Merck & Co., Inc. (Merck), asserted that the requested records contain confidential commercial information subject to withholding under FOIA Exemption 4, 5 U.S.C. § 552(b)(4), and the district court so held. As shown below, the district court erred in holding that Exemption 4 applies, and the requested records should be released.

A. Proceedings and Disposition Below

On March 10, 2003, plaintiffs submitted a FOIA request to FDA seeking "records reflecting the net number of doses in each lot of Recombivax HB and Engerix-B hepatitis B vaccine distributed in the United States." Doc. No. 39-2, Ex. A.[1] The request defined the "net number of doses" as "the number of doses distributed less the number of doses returned to the manufacturer." *Id.* The request did not seek records that would reveal the total number of doses produced in each lot, but only the number of doses distributed and not returned.

The FDA located 19 documents responsive to plaintiffs' FOIA request but withheld them in full on the ground that "[a]ll of the responsive documents contain

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[1] "Doc. No." refers to the document number in the district court record. "RE" refers to the Record Excerpts filed with this brief. *See* 11th Cir. R. 30-1. The RE numbers correspond to the document numbers in the district court record.

confidential commercial information that is exempt from disclosure under Exemption 4 of the FOIA." Doc. No. 39-2 at ¶ 17. Plaintiffs filed an administrative appeal of FDA's denial, explaining that "[t]he yearly [net] number of doses of Recombivax HB and Engerix-B hepatitis B vaccine distributed in the United States has been previously disclosed by your agency. All this request is asking for is an additional breakdown of the [net] number of doses by lot for both vaccines." Doc. No. 39-2, Ex. G. The government failed to timely respond to plaintiffs' administrative appeal. *See* RE 10 at ¶ 17. On November 10, 2004, plaintiffs filed this action. RE 1. FDA filed an answer, and Merck intervened and filed an answer. RE 10 & 19.

On May 18, 2005, the district court held a pretrial conference. Doc. No. 35. The court set deadlines for FDA and Merck to file dispositive motions and a deadline for plaintiffs to respond to defendants' dispositive motions, file a cross-dispositive motion, and/or seek discovery. Doc. No. 37.

FDA and Merck filed motions for summary judgment. Doc. Nos. 38 & 40. Plaintiffs responded and filed a cross-motion for summary judgment. Doc. No. 44. Plaintiffs moved in the alternative, pursuant to Federal Rule of Civil Procedure 56(f), for leave to conduct discovery and an extension of time to respond in greater detail to defendants' factual allegations. *Id.* Plaintiffs argued that (1) summary

judgment should be entered for plaintiffs because FDA had refused to release documents responsive to plaintiffs' FOIA request and defendants failed to demonstrate that the documents are subject to Exemption 4; and (2) to the extent that defendants' assertions, if true, could establish that Exemption 4 applied, plaintiffs submitted contrary evidence sufficient to preclude summary judgment and warrant discovery. Doc. No. 45.

Pursuant to 28 U.S.C. § 636(b)(1)(B), the district court referred the motions to a magistrate judge to issue a report and recommendation (R&R). Doc. No. 57. On January 23, 2006, the magistrate judge filed an amended report recommending that the district court grant defendants' motions and deny plaintiffs' motion. RE 60. On January 31, 2006, plaintiffs filed objections to the R&R. Doc. No. 61. By order of March 1, 2006, the district court adopted the R&R in full. RE 64. Judgment was entered on March 2, 2006 (RE 65), and on March 7, 2006, plaintiffs filed their amended notice of appeal. Doc. No. 67.

B. Facts

Two brands of hepatitis B vaccine are approved for use in the United States. Doc. No. 39-4 at ¶ 6. Merck sells hepatitis B vaccine under the brand name "Recombivax HB." Glaxo sells hepatitis B vaccine under the brand name

"Engerix-B."[2] The two brands of hepatitis B vaccine are interchangeable.[3] A course of immunization initiated with one brand can be completed with the other. *See* Engerix-B Prescribing Information at 5.

The total net doses of hepatitis B vaccine distributed in the United States, broken out by year, was published in the January 24, 2003, issue of the Center for Disease Control and Prevention's (CDC) Morbidity and Mortality Weekly Report. Doc. No. 39-2, Ex. J at 11, Table 1. In 2001, for example, 28,698,635 doses of hepatitis B vaccine were distributed and not returned. *Id*. Because each manufacturer already knows the net number of doses it distributed for use in the United States, each manufacturer can easily calculate the other manufacturer's sales volume and market share. Doc. No. 45, Ex. B at ¶ 14.

Vaccines are produced and distributed in quantities known as "lots," which vary substantially in size. *See* Doc. No. 39-2, Ex. J at 7. Each lot is assigned an

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[2]Engerix-B is manufactured by GlaxoSmithKline Biologicals, SA, a Belgian company, and distributed in the United States by SmithKline Beecham Corporation d/b/a GlaxoSmithKline, a Pennsylvania corporation. Doc. No. 39-3 at ¶¶ 2-3; Doc. No. 53-2 at ¶¶ 2-3. This brief will refer to the manufacturer and distributor of Engerix-B as "Glaxo."

[3]*Compare* Engerix-B Prescribing Information (available at: http://us.gsk.com/products/ assets/us_engerixb.pdf) *with* Recombivax HB Prescribing Information (available at: http://www.merck.com/product/usa/ pi_circulars/r/recombivax_hb/recombivax_pi.pdf).

identification number to aid in tracking its distribution and use. Vaccine manufacturers are required to submit lot-specific product distribution information to FDA. 21 C.F.R. § 600.81. FDA maintains this information in its Lot Distribution Database (LDD), which includes, for each vaccine product: "the product lot identification number; the doses per unit per lot; the number of doses distributed per lot; the number of doses returned per lot to the manufacturer; and the net number of doses per lot, which is a lot-specific calculation of the total number of doses distributed minus the total number of doses returned." Doc. No. 39-3 at ¶ 20.

Because some adverse reactions to vaccines may not be detected during prelicensure clinical studies, "postmarketing monitoring of adverse events after vaccinations is essential." Doc. No. 39-2, Ex. J at 1. FDA monitors adverse reactions to vaccines through the Vaccine Adverse Events Reporting System (VAERS), a vaccine safety surveillance program it administers with the CDC. VAERS accepts reports of "suspected adverse events after administration of any vaccine licensed in the United States." *Id.* VAERS data, including the name of the vaccine manufacturer and the lot number of vaccine dose associated with the adverse reaction, is publicly available. *See* http://vaers.hhs.gov/.

The rate of adverse event reports for each vaccine type can be calculated by dividing the total net number of doses distributed by the number of adverse event reports. For example, during 1991-2001, 276,503,724 net doses of the hepatitis B vaccine were distributed in the United States, and 32,559 adverse events were reported. Doc. No. 39-2, Ex. J at Tables 1 & 3. Thus, the hepatitis B vaccine has an adverse event reporting rate of 11.8 reports per 100,000 net doses distributed. *Id.*

However, although one of the objectives of VAERS is to "identify vaccine lots with increased numbers or types of reported adverse events," *id*. at 1, independent researchers cannot use VAERS data to determine whether some lots have a higher rate of reported adverse events than other lots, because, although VAERS makes publicly available the number of adverse event reports for a particular lot, it does not make publicly available the net number of doses distributed in each lot. A person can use VAERS data to determine, for example, that there have been three adverse reaction reports associated with a particular vaccine lot. But unless the person knows whether three doses, or three thousand doses, or three million doses, were distributed in that lot, the person will not know whether the lot has an adverse event reporting rate of 100%, or .1%, or .0001%. Without knowing the net number of doses distributed by lot, the person will not

know what denominator to use to calculate the adverse reaction reporting rate. *See id*. at 3. Indeed, FDA reportedly uses the VAERS data and the net lot distribution figures to calculate the rate of reported adverse events associated with each vaccine lot. *Id.* at 7 ("FDA medical officers evaluate reporting rates of adverse events by lot, as needed, looking for unexpected patterns.").

On March 10, 2003, plaintiffs submitted their FOIA request to FDA, seeking the net number of doses in each lot of hepatitis B vaccine distributed in the United States to assist their son's physicians in determining whether an adverse reaction to the hepatitis B vaccine was the cause of his severe injuries. RE 1 at ¶ 4. Release of the requested information would also facilitate independent research on vaccine safety—a matter of significant public concern. Doc. No. 39-2, Ex. J at 7. The National Network for Immunization Information, a coalition including the Infectious Diseases Society of America, the American Academy of Pediatrics, and the American Academy of Family Physicians, has taken the position that release of the requested information "will have an important benefit and is unlikely to put any vaccine manufacturer at a competitive disadvantage in the marketplace." Doc. No. 45, Ex. A at 2.

Plaintiffs' FOIA request does not seek the total number of doses manufactured in each lot, but only the number of doses from each lot that were

distributed in the United States and not returned (the net number of doses). Thus, the requested information will reveal that a particular lot contained *at least* the net number of doses, but it will reveal nothing about the total number of doses that were produced, or that could have been produced, as part of the lot.

With its motion for summary judgment, FDA provided a *Vaughn* Index that identifies and describes the 19 documents responsive to Plaintiffs' request. Doc. No. 39-2, Ex. I; *see Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir 1973) (describing agency obligation to explain basis for withholding records purportedly exempt from disclosure under FOIA). The *Vaughn* Index indicates that each of the 19 documents has been withheld in full on the ground that it contains "confidential commercial information" subject to withholding under FOIA Exemption 4, 5 U.S.C. § 552(b)(4). As support for this assertion, FDA relies on the manufacturers' claims that release of the requested records could provide each manufacturer with insight into the other's market share and production capacity. *See* Doc. No. 39-2 at ¶¶ 27-28; Doc. No. 39-3 at ¶ 5; Doc. No. 39-4 at ¶¶ 5-6. As explained in detail below, the manufacturers' claims are not sufficient to establish that release of the specific information requested would likely cause substantial competitive harm; thus, defendants' Exemption 4 claim must fail. Moreover, even if those claims would be sufficient if uncontested, the district court erred in

entering summary judgment for defendants and denying plaintiffs the opportunity to take discovery, because plaintiffs submitted evidence disputing defendants' claims.

C. Standard of Review

Where the district court decides a FOIA case at summary judgment, this Court reviews the decision *de novo*. *Office of the Capital Collateral Counsel, N. Region of Florida ex rel. Mordenti v. Dep't of Justice*, 331 F.3d 799, 802 (11th Cir. 2003); *Times Pub. Co. v. U.S. Dep't of Commerce*, 236 F.3d 1286, 1288 n.1 (11th Cir. 2001). It reviews denials of discovery sought under Rule 56(f) for abuse of discretion. *See Burks v. American Cast Iron Pipe Co.*, 212 F.3d 1333, 1336 (11th Cir. 2000).

SUMMARY OF THE ARGUMENT

It is undisputed that plaintiffs made a valid FOIA request, the FDA has responsive documents, and the responsive documents have not been produced. Thus, plaintiffs are entitled to summary judgment unless defendants can show that the requested documents are "confidential commercial information" subject to withholding under FOIA Exemption 4. To do so, defendants must prove that release of the requested documents would cause substantial competitive harm to the two companies that were required to submit the information to FDA.

Defendants have failed to meet their burden to show that FOIA Exemption 4 applies because they have not, and cannot, explain *how* release of the specific information requested could cause competitive harm to either Merck or Glaxo. Defendants claim that release of the records would cause competitive injury by revealing each manufacturer's market share and production capacity. But market share information cannot cause competitive harm because it is already available to the two manufacturers, and lot-specific information about the net number of doses distributed does not reveal the gross number of doses produced in the lot, much less anything about the maximum number of doses that either manufacturer could produce. Thus, defendants have failed to show that the requested records are covered by Exemption 4, and the district court should have ordered FDA to produce the records.

Moreover, defendants would not be entitled to summary judgment even if their assertions logically supported their claim that competitive harm would result from disclosure of the requested data, because plaintiffs provided evidence to dispute the facts on which defendants rely. Thus, even if the district court concluded that defendants' assertions, if uncontroverted, would provide an adequate basis for their Exemption 4 claim, the district court should have allowed

discovery as requested by plaintiffs, then resolved the material fact disputes before determining whether Exemption 4 applies.

ARGUMENT

I. Defendants Have the Burden to Show That the Requested Information Is Exempt from Disclosure.

FOIA is a "broad disclosure statute which evidences a 'strong public policy in favor of public access to information in the possession of federal agencies.'" *Cochran v. United States*, 770 F.2d 949, 954 (11th Cir. 1985) (quoting *Brown v. FBI*, 658 F.2d 71, 73 (2d Cir. 1981)). FOIA provides an expansive right of access to federal agency records, requiring agencies to release records unless those records are subject to one of the statute's narrow exemptions. *Ely v. FBI,* 781 F.2d 1487, 1489 (11th Cir. 1986). These limited exemptions "do not obscure the basic policy that disclosure, not secrecy, is the dominant objective of the Act." *Dep't of the Air Force v. Rose,* 425 U.S. 352, 361, 96 S. Ct. 1592, 1599 (1976). Accordingly, although FOIA's disclosure provisions are read broadly, its exemptions are read narrowly, and records are presumed subject to disclosure "absent a clear showing to the contrary." *Ely*, 781 F.2d at 1489. In determining whether records are exempt from disclosure, the burden is on the government

agency seeking to prevent disclosure. *Times Pub.*, 236 F.3d at 1289; *Ely,* 781 F.2d at 1489-90.

The court should not defer to the agency's reasoning for withholding the information and must decide *de novo* whether an exemption applies. *See* 5 U.S.C. § 552(a)(4)(B); *see also Mead Data Cent., Inc. v. U.S. Dep't of the Air Force*, 566 F.2d 242, 251 (D.C. Cir. 1977) ("[T]he agency's opinions carry no more weight than those of any other litigant in an adversarial contest before a court."). Nor should the court defer to agency regulations on the scope of FOIA's exemptions. *See Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1287 (D.C. Cir. 1983).

FOIA Exemption 4 allows the government to withhold "commercial or financial information obtained from a person [that is] privileged or confidential." 5 U.S.C. § 552(b)(4).[4] When, as here, the government has obtained information from someone who is legally required to submit the information, the information is

[4]Although Exemption 4 also applies to "trade secrets," this term is construed narrowly as "a secret, commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort." *Public Citizen*, 704 F.2d at 1288. The government has correctly conceded that the documents responsive to plaintiffs' request do not contain "trade secrets" within the meaning of Exemption 4. Doc. No. 39-1 at 12 n.1.

considered confidential within the meaning of Exemption 4 only if its disclosure would "cause substantial harm to the competitive position of the person from whom the information was obtained." *Nat'l Parks & Conservation Ass'n v. Morton (Nat'l Parks I)*, 498 F.2d 765, 770 (D.C. Cir. 1974).[5] "In order to show a likelihood of substantial competitive harm, the agency must show (i) that the entity that will suffer harm is in actual competition, and (ii) that substantial competitive injury will result from disclosure." *Miami Herald Pub. Co. v. U.S. Small Bus. Admin.*, 670 F.2d 610, 613-14 (5th Cir. Unit B 1982) (citing *Gulf & W. Indus., Inc., v. United States*, 615 F.2d 527, 530 (D.C. Cir. 1979); *Nat'l Parks & Conservation Ass'n v. Kleppe (Nat'l Parks II)*, 547 F.2d 673, 679 (D.C. Cir. 1976)). The government must prove the elements of "substantial competitive harm" through concrete evidence, because "conclusory and generalized allegations of substantial competitive harm . . . are unacceptable and cannot support an agency's decision to withhold requested documents." *Public Citizen*, 704 F.2d at 1291; *see also Niagara Mohawk Power Corp. v. U.S. Dep't of Energy*, 169 F.3d 16, 18 (D.C. Cir. 1999) (noting that "the agency has the burden of showing that

[5]In *Critical Mass Energy Project v. Nuclear Regulatory Comm'n*, 975 F.2d 871, 879 (D.C. Cir. 1992) (en banc), the D.C. Circuit subsequently clarified that for *voluntary* submissions the government need not demonstrate substantial competitive harm to claim Exemption 4 and simultaneously affirmed the *National Parks* standard for *mandatory* submissions.

requested information comes within a FOIA exemption" and that "we have more than once held that such conclusory and generalized assertions are not enough" to meet the burden); *Miami Herald*, 670 F.2d at 614 n.9 (describing conclusory evidence as inadequate to carry government's Exemption 4 burden).

II. The Records Should Be Released Because Defendants Have Failed to Establish That Disclosure of the Requested Information Would Cause Substantial Competitive Harm.

Defendants' claim that Merck and Glaxo could suffer competitive harm from release of the requested information is based on two flawed assertions. First, defendants claim that release of the net number of doses distributed per lot would cause competitive harm by revealing market share and sales volume information. In fact, no such harm could result because the two manufacturers already know or can easily calculate each other's market share and sales volume. Second, defendants claim that release of the requested information would cause competitive harm by revealing information related to each manufacturer's production capacity. In fact, no such harm could result because the specific information requested—the net number of doses distributed broken out by lot—cannot reveal the total number of doses manufactured in the lot, nor can it reveal the manufacturer's production capabilities. Because defendants cannot

show how release of the requested information could cause competitive harm, defendants' Exemption 4 claim must be rejected.

A. Release of the net number of doses distributed per lot cannot provide either manufacturer any previously-unavailable information about the other's market share or sales volume.

In an attempt to show that "substantial competitive injury will result from disclosure" of the requested information, *Miami Herald*, 670 F.2d at 614, defendants assert that the requested information would reveal each manufacturer's domestic sales volume and market share, and that revelation of such information could cause them competitive harm. Doc. No. 39-2 at ¶¶ 27-28; Doc. No. 39-3 at ¶ 5. Although the former claim may be true, the latter claim—which is necessary to trigger Exemption 4—is specious. Merck and Glaxo are the only manufacturers licensed to distribute hepatitis B vaccine in the United States, and each manufacturer already knows the net number of doses it distributed. Because the total net number of doses of hepatitis B vaccine distributed in the United States has been published, s*ee, e.g.,* Doc. No. 39-2, Ex. J at Table 1 (reporting the total net number of does distributed each year from 1991 through 2001), each manufacturer already knows, or can easily calculate, the other's sales volume and market share. Doc. No. 45, Ex. B at ¶ 14. Competitive harm cannot result from disclosure of information that the purported competitors already have or can easily

obtain. *See Worthington Compressors, Inc. v. Costle*, 662 F.2d 45, 51 (D.C. Cir. 1981) ("If the information is freely or cheaply available from other sources, such as reverse engineering, it can hardly be called confidential and agency disclosure is unlikely to cause competitive harm to the submitter.").

To the extent defendants suggest that disclosure of each company's share of the total doses distributed in the United States could harm either company with respect to competition for sales in foreign markets or in future competition with a new entrant in the United States market, defendants once again have failed to offer any explanation of *how* the requested information could cause such harm. *See Public Citizen*, 704 F.2d at 1291 ("[C]onclusory and generalized allegations of substantial competitive harm . . . are unacceptable and cannot support an agency's decision to withhold requested documents."). Plaintiffs specifically only asked for information regarding net doses per lot distributed *within the United States*; it is difficult to see how release of this information would cause them competitive harm abroad. Moreover, a showing of substantial competitive harm cannot be based on claims that a submitter may face future or potential competition. Rather, "the test explicitly requires proof that the submitters face *actual* competition." *Niagara Mohawk*, 169 F.3d at 19 (citing *Nat'l Parks II*, 547 F.2d at 679).

B. Release of the specific information requested would not reveal each manufacturer's production capacity.

Defendants allege that release of the requested records could cause competitive injury by revealing each manufacturer's production capacity and manufacturing capabilities. Doc. No. 39-2 at ¶ 27; Doc. No. 39-3 at ¶ 5; Doc. No. 39-4 at ¶ 5; Doc. No. 52, Ex. A at ¶ 7; Doc. No. 53-3 at ¶ 4. This claim rests on two flawed assumptions: 1) that plaintiffs seek the total number of doses produced in each lot; and 2) that the total number of doses in each lot equals the manufacturer's maximum production capacity.

Defendants misapprehend the scope of plaintiffs' FOIA request. Plaintiffs do not seek the total number of doses manufactured in each lot. Rather, plaintiffs seek "the net number of doses in each lot of Recombivax HB and Engerix-B hepatitis B vaccine distributed in the United States." Doc. No. 39-2, Ex. A. The total net number of doses is already known. Plaintiffs simply request records that break out the total net number of doses by lot.

The net number of doses (doses distributed less doses returned) broken out by lot does not reveal the total lot size because there is no reason to believe that every dose made in a lot is distributed and none is returned. On the contrary, doses within a particular lot may be distributed but returned unused, held as

inventory, or distributed outside the United States. *See, e.g.,* Doc. No. 52, Ex. A at ¶ 7 (acknowledging that "not all doses produced are immediately sold; some go into inventory"). Because these variables will remain unknown even if the net number of doses by lot is revealed, release of the responsive documents will not allow anyone to determine the number of doses actually manufactured in any given lot.

Moreover, the requested information cannot reveal anything about either manufacturer's production *capacity*. The requested information will reveal that each lot contained *at least* the net number of doses, but, as noted above, it will not reveal how many additional doses were produced as part of that lot, nor how many additional doses *could* have been produced (which is, after all, what reveals the manufacturer's production *capacity*). Doc. No. 45, Ex. B at ¶ 20 ("Lots vary in size for a multitude of reasons and there is no reason to believe that the largest lot would represent a manufacturer's maximum capacity.").

Defendants assert that estimating vaccine manufacturing capacity is a complex equation consisting of many variables, and that revelation of the requested information, even if it would not, in itself, cause injury, might make it more likely that the equation will be solved and result in competitive harm. Doc. No. 53-3 at ¶¶ 6-7. Defendants' theory cannot sustain their burden. Release of

data does not cause substantial competitive harm when it is "made up of too many fluctuating variables for competitors to gain any advantage from the disclosure." *GC Micro Corp. v. Defense Logistics Agency*, 33 F.3d 1109, 1115 (9th Cir. 1994); *see also Ctr. for Pub. Integrity v. Dep't of Energy*, 191 F. Supp. 2d 187, 194-95 (D.D.C. 2002) (rejecting argument that "if the total amount of a bidder's offer is known, then the bidder's competitors can reconstruct each factor in the bidder's calculations in order to discern its valuation methodology" because "this is tantamount to attempting to solve for x in the equation x + y + z = $3.65 billion without knowing the other variables").

Similarly, one of defendants' declarants suggests, without explanation, that "knowledge regarding the number of doses in any given lot" of vaccine might provide a competitor with insight into the manufacturer's "process parameters," such as incubation times. Doc. No. 39-4 at ¶ 5. Even if this assertion was adequately explained—which it is not—the revelation of a single variable in a complex process will not cause competitive harm. *GC Micro Corp.*, 33 F.3d at 1114-15; *Ctr. for Pub. Integrity*, 191 F. Supp. 2d at 194-95.

III. Even If Defendants' Declarations, If Uncontested, Would Be Sufficient to Meet Defendants' Burden, the District Court Erred in Granting Summary Judgment For Defendants and Denying Plaintiffs Discovery, Because Material Facts Are in Dispute.

As explained above, defendants failed to establish that Exemption 4 applies because the allegations of competitive harm are not logically connected to release of the specific information requested. Because defendants failed to meet their burden, the district court should have entered summary judgment for plaintiffs. But even assuming that defendants' declarations did provide an adequate basis to establish that Exemption 4 applies, the district court erred in granting summary judgment for defendants because material facts are in dispute.

Summary judgment is only appropriate when, on the evidence before the court, "there is no genuine issue as to any material fact and [] the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). The court must draw all reasonable inferences in the non-movant's favor and cannot weigh conflicting evidence to resolve disputes. *See Stephens v. Dep't of Health and Human Servs.*, 901 F.2d 1571, 1573 (11th Cir. 1990). "FOIA cases are not immune to summary judgment requirements." *Alyeska Pipeline Serv. Co. v. U.S. EPA*, 856 F.2d 309, 313 (D.C. Cir. 1988). Thus, "if material facts are genuinely in issue or, though undisputed, are susceptible to divergent inferences bearing upon

an issue critical to disposition of the case, summary judgment is not available." *Id.* at 314.

The district court accepted and adopted the amended report and recommendation (R&R) issued by the magistrate judge. RE 64 (adopting RE 60). The magistrate judge concluded that release of the requested information would cause competitive harm based on defendants' assertions that

1) Release of the withheld information could provide insight into the two manufacturers' respective production capacities and might allow competitors to deduce the incubation times used by Merck during the manufacturing process;
2) Release of the withheld information could provide insight into the two manufacturers' respective marketing capabilities, giving insight into market share and sales volume for specific time periods;
3) Such insights could cause competitive harm because the disclosure would result in a significant competitive disadvantage for Merck and Glaxo; and
4) Knowing the number of doses per lot would allow a competitor to better estimate Merck's profit margins, manufacturing capabilities, and production specifics.

RE 60 at 9-10 (citing Doc. Nos. 39-2 at ¶¶ 27-28; 39-3 at ¶ 5; 39-4 at ¶¶ 5-6; and 52, Ex. B at ¶ 7). Each of these conclusions is disputed in an affidavit submitted by Donald H. Marks, M.D., Ph.D., an expert in the research, development, production, and regulation of recombinant vaccines, who concluded that "disclosure of the requested information would not cause Merck and Glaxo any competitive harm." Doc. No. 45, Ex. B at ¶ 13.

With respect to the issue of production capacity and manufacturing capability, Dr. Marks explained that

> [t]he claim that disclosure of the net number of doses in each lot of hepatitis B vaccine would disclose the manufacturer's maximum capacity is incorrect. Lots vary in size for a multitude of reasons and there is no reason to believe that the largest lot would represent a manufacturer's maximum capacity. Furthermore, knowledge by Glaxo or Merck of the other's maximum capacity in the past for the production of the hepatitis B vaccine would cause neither any competitive harm.

Id. at ¶ 20. Dr. Marks further explained that "[t]here are simply too many variables . . . , such as the specific types and sizes of equipment utilized in the production of each lot," to determine maximum volume from the net number of doses in each lot of vaccine. *Id.* at ¶ 19.

With respect to whether release of the requested information would allow either manufacturer to deduce the incubation times used during the other's

manufacturing process or otherwise estimate production specifics, Dr. Marks explained that it would not:

> Disclosure of the net number of doses per lot of hepatitis B vaccine would not give the two manufacturers of hepatitis B vaccine in the United States any information about each other's production processes or capabilities. Knowledge of how many doses the other manufacturer has made in a given lot does not give insight into the processes the manufacturer uses to make those doses. Furthermore, the vaccine development and production industry, particularly for older vaccines such as the recombinant hepatitis B vaccine, is comprised of a relatively small group of people. Due to lateral hires from other manufacturers, the exchange of information at scientific and industry meetings and in scientific and industry publications, patent filings, and licensing agreements, there is very little that each manufacturer of the hepatitis B vaccine in the United States does not know about the production processes and capabilities of the other. For example, the incubation times used by Merck and Glaxo in manufacturing the hepatitis B vaccine are generally known in the vaccine industry.

Id. at ¶¶ 17-18. Significantly, Glaxo's declarant does not dispute that the incubation times for the two brands of hepatitis B vaccine are generally known within the vaccine industry. Doc. No. 53-3 at 2 n.1.

Dr. Marks also explained that the requested information would not reveal any previously unknown information about market share or sales volume:

> Disclosure of the net number of doses per lot of hepatitis B vaccine would not give the two manufacturers of hepatitis B vaccine in the United States any new information about each other's market share. The manufacturers already know the aggregate number of doses sold in the United States, and they already know how many doses they

> sold. Because there are only two manufacturers of the hepatitis B vaccine, Merck and Glaxo, each manufacturer can determine the number of doses sold by the other manufacturer, and thereby its market share, by subtracting the number of doses each sold from the aggregate number of doses of the vaccine sold in the United States.

Id. at ¶ 14.

Finally, Dr. Marks explained that the net number of doses per lot is unrelated to marketing strategy or product distribution plans. Thus, release of the requested data cannot provide either manufacturer with a competitive advantage or disadvantage in those areas of their business. *Id.* at ¶¶ 15-16.

The magistrate judge erred by rejecting plaintiffs' evidence on the basis that "Dr. Marks' comments are too speculative and not based on a sufficient factual basis to override Exemption Four." RE 60 at 11. First, Dr. Marks' affidavit contains *more* detail, explanation, and factual support than the declarations on which the magistrate judge relied. *Compare* Doc. No. 45, Ex. A at ¶¶ 13-20, *with* Doc. Nos. 39-2 at ¶¶ 27-28; 39-3 at ¶ 5; 39-4 at ¶¶ 5-6; and 52, Ex. B at ¶ 7. Thus, if defendants' declarations contain sufficient explanation and factual detail to establish that the requested information is subject to Exemption 4—and plaintiffs contend that they do not—then Dr. Marks's affidavit is more than sufficient to demonstrate that material facts are in dispute.

Second, contrary to the Magistrate Judge's view, it is not plaintiffs' burden "to override Exemption Four." Rather, it is defendants' burden to prove the applicability of Exemption 4 with undisputed facts. *Ely*, 781 F.2d at 1489-90 ("The burden is squarely on the government to prove that the information in question is covered by one of the exemptions.").

As explained in Section II above, summary judgment should have been entered for plaintiffs because defendants' submissions are insufficient to prove that the requested information is covered by Exemption 4. Nevertheless, plaintiffs moved in the alternative for discovery pursuant to Federal Rule of Civil Procedure 56(f) to better develop the record with respect to the contested issues. Even if the district court concluded that defendants' allegations, if uncontested, would have been sufficient to carry their burden, because material facts *were* contested, it should have allowed discovery as requested by plaintiffs, then resolved any remaining dispute of material fact before resolving the Exemption 4 claim.

Where an agency's affidavits contain sufficient evidence to meet the agency's burden, discovery is justified if plaintiffs can "provide some tangible evidence that an exemption claimed by the agency should not apply or summary judgment is otherwise inappropriate." *Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 812 (2d Cir. 1994). Plaintiffs have more than done so. Both the affidavit of

Dr. Marks and the application of common sense refute defendants' claims that release of the requested information could reveal anything new about each manufacturer's production processes, marketing strategies, product distribution plans, or maximum manufacturing capacity. Plaintiffs have been hindered, however, in their ability to provide further detail to rebut defendants' claims, because defendants have not explained their theory as to *how* release of the *particular information requested* could cause Merck and Glaxo to suffer substantial competitive harm. Doc. No. 45, Ex. D at ¶ 4. Plaintiffs sought leave to take discovery from FDA and the manufacturers to seek such explanation. *Id.* Such discovery would have allowed plaintiffs to depose defendants' declarants to more clearly expose the lack of factual support for defendants' claims, and to provide more detail about why release of the requested records would not reveal confidential information about the manufacturers' marketing strategies or production specifics. Thus, to the extent the Court is not prepared to rule now that plaintiffs should have been granted summary judgment—as plaintiffs believe it should—discovery should be allowed. *See Leigh v. Warner Bros., Inc.*, 212 F.3d 1210, 1219 (11th Cir. 2000) ("Federal Rule of Civil Procedure 56(f) allows courts to defer ruling on summary judgment motions until the non-moving party has been able to conduct all necessary discovery."); *Florida Power & Light Co. v.*

Allis Chalmers Corp., 893 F.2d 1313, 1316 (11th Cir. 1990) ("Before entering summary judgment, the district court must ensure that the parties have an adequate opportunity for discovery."). In light of the apparent fact disputes and plaintiffs' Rule 56(f) proffer, the district court erred in denying plaintiffs any opportunity for discovery.

CONCLUSION

For the foregoing reasons, the Court should reverse the decision of the district court and order FDA to disclose the requested information. In the alternative, the Court should remand the case and instruct the district court to allow plaintiffs to take discovery under Rule 56(f).

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing Brief for Appellants complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B). The brief is composed in a 14-point proportional typeface, Times New Roman. As calculated by my word processing software (WordPerfect), the Brief contains 6,131 words, excluding the parts exempted by Fed. R. App. P. 32(a)(7)(B)(iii).

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CERTIFICATE OF SERVICE

I hereby certify that on April 26, 2006, I filed the foregoing Brief for Appellants by mailing it to the Clerk of the U.S. Court of Appeals for the Eleventh Circuit by First-Class Mail. Also on that date, I served a copy of this brief by mailing it to:

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