[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 06-11774

D.C. Docket No. 04-00552 CV-FTM-29-SPC

ROBERT SHARKEY,
MRS. ROBERT SHARKEY, on behalf of
Ryan Reid Sharkey, a minor,

Plaintiffs-Appellants,

versus

FOOD & DRUG ADMINISTRATION,
MERCK & CO., INC.,

Defendants-Appellees.

Appeal from the United States District Court
for the Middle District of Florida

(October 5, 2007)

Before ANDERSON and COX, Circuit Judges, and KING,[*] District Judge.

PER CURIAM:

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[*] The Honorable James Lawrence King, United States District Judge for the Southern District of Florida, sitting by designation.

We must determine in this appeal whether the district court properly granted summary judgment on the ground that records requested under the Freedom of Information Act, 5 U.S.C. § 552 (2000) ("FOIA"), are protected from disclosure under Exemption 4 of the FOIA. We are convinced that the Defendants have carried their burden of proving the applicability of Exception 4 and affirm summary judgment in their favor.

I. FACTUAL AND PROCEDURAL BACKGROUND

Plaintiffs, Dr. and Mrs. Sharkey, filed a FOIA request with the Food and Drug Administration ("FDA") seeking "records reflecting the net number of doses in each lot of Recombivax HB and Engerix-B hepatitis B vaccine[s] distributed in the United States." (R.1-39, Attach. 1, Ex. A.) The request defined "net number of doses" as "the number of doses distributed less the number of doses returned to the manufacturer." (R.1-39, Attach. 1, Ex. A.) The Sharkeys, whose son had experienced an adverse reaction to a hepatitis B vaccine, alleged they needed these records to determine whether an adverse reaction was in fact the cause of his medical problems. (R.1-1 ¶¶ 5-6.)

The FDA identified nineteen responsive documents filed by Merck & Co., Inc. ("Merck") and GlaxoSmithKline, Inc. ("Glaxo") pursuant to federal regulations mandating periodic reporting of vaccine distributions. 21 C.F.R. § 600.81 (2007).

The FDA refused to disclose all nineteen of the documents, citing Exemption 4 of the FOIA, which exempts from disclosure records containing trade secrets and confidential commercial information. 5 U.S.C. § 552(b)(4).

The Sharkeys filed an administrative appeal with the United States Department of Health and Human Services ("DHHS"). While this appeal was pending, the Sharkeys filed a lawsuit in federal district court seeking an order compelling the FDA to disclose the records. The DHHS then notified the Sharkeys that its response to the their lawsuit would address issues raised in their appeal and it would therefore take no further administrative action on it. (R.1-39, Attach. 1, Ex. H.)

The FDA filed an answer, as did Merck, who intervened as a defendant.[1] The FDA and Merck then filed motions for summary judgment supported by a *Vaughn* index[2] and sworn declarations detailing the competitive harm that Merck and Glaxo would suffer if the FDA released the requested records.

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[1] Merck is one of two companies licensed in the United States to manufacture hepatitis B vaccine; Glaxo is the other. Glaxo is not a party in this lawsuit, although it submitted affidavits in support of the FDA's decision to withhold the requested records. The FDA relied on the potential harm to both Merck and Glaxo in refusing to disclose the requested records; therefore, we will also consider the potential harm to Glaxo.

[2] A *Vaughn* index, somewhat like a privilege log, allows courts to consider whether an exemption bars disclosure of withheld documents, without necessitating release of the documents. *See Vaughn v. Rosen*, 484 F.2d 820 (D.C. Cir. 1973).

The Sharkeys opposed the FDA's and Merck's motions for summary judgment and filed a cross-motion for summary judgment or, in the alternative, for leave to conduct discovery pursuant to Fed. R. Civ. P. 56(f) (permitting limited discovery where the party opposing a motion for summary judgment cannot by affidavit present facts essential to justify its opposition). The Sharkeys supported their motions and opposition to the Defendants' motions with the affidavits of Donald Marks, M.D., Ph.D, and their attorney. Dr. Marks opined that release of the requested information would not cause Merck and Glaxo any competitive harm (Marks Aff., R.1-45, Ex. B ¶ 13) and the Sharkeys' attorney stated that he expected discovery would produce facts supporting their position that no competitive harm will result from disclosure (Maglio Aff., R.1-45, Ex. D ¶ 6).

The district court adopted the amended report and recommendation of the magistrate judge to whom the case had been referred and granted the Defendants' motions for summary judgment. (R.2-64.) The magistrate judge found that the declarations submitted by the Defendants were sufficient to demonstrate that "there is actual competition in the hepatitis B vaccine market[;] . . . that the release of the net number of doses per lot would in fact cause competitive harm" to Merck and Glaxo; and that the evidence presented by the Sharkeys did not raise a genuine issue of material fact regarding competitive harm. (R.2-60 at 10-12.) The district court

denied the Sharkeys' motion for discovery, based on the magistrate judge's finding that the Sharkeys' attorney's affidavit was conclusory and "that the factual basis provided by the Defendants [was] sufficient to make an informed decision on the Motion without further discovery." (R.2-60 at 13.) The Sharkeys appeal.

II. CONTENTIONS OF THE PARTIES

The Sharkeys argue that the Defendants have not carried their burden of proving that the withheld information falls within a FOIA exemption. More specifically, the Sharkeys maintain that the declarations submitted by the Defendants fail to explain how release of the requested information would cause substantial competitive harm to Merck or Glaxo, and the Sharkeys also maintain that even if the declarations adequately explain how release of the information would cause substantial competitive harm, the Defendants were not entitled to summary judgment because the Sharkeys' affidavits create a genuine issue of material fact regarding the likelihood of substantial competitive harm. Accordingly, they argue, the district court should have permitted limited discovery before ruling on whether Exemption 4 barred release of the records.

The Defendants respond that summary judgment in their favor was proper because their declarations contain factual evidence detailing the competitive harm likely to result from release of the withheld records. By contrast, the Defendants

argue, the Sharkeys' affidavits are conclusory as they merely deny the assertions made in the Defendants' declarations without offering contradictory evidence sufficient to create a genuine issue of material fact. Finally, the Defendants argue the Sharkeys did not put forth sufficient evidence to justify their discovery request under Rule 56(f).

III. STANDARDS OF REVIEW

The parties dispute what standard of review we apply in reviewing summary judgment in a FOIA claim. The Sharkeys argue that we should apply de novo review, as we typically do on appeals from summary judgment. *Times Publ'g Co. v. U.S. Dep't of Commerce*, 236 F.3d 1286, 1288 n.1 (11th Cir. 2001). Defendants, on the other hand, argue that assessing the applicability of Exemption 4 involves factual determinations, and therefore, we should review only for clear error. *Miscavige v. IRS*, 2 F.3d 366, 367 (11th Cir. 1993). Because we determine that summary judgment should be affirmed under either standard, we need not resolve this dispute. *See Marecek v. BellSouth Servs., Inc.*, 49 F.3d 702, 707 (11th Cir. 1995) (declining to decide which standard of review applies where the parties dispute the applicable standard and the district court's opinion can be affirmed under either).

We review denial of a discovery motion under Rule 56(f) for abuse of discretion. *Jackson v. Cintas Corp.*, 425 F.3d 1313, 1316 (11th Cir. 2005).

IV. DISCUSSION

A. FOIA and Exemption 4

The FOIA generally requires federal agencies to disclose records in their possession upon request. 5 U.S.C. § 552(a)(3)(A). The FOIA "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)). Recognizing, however, that entities submitting records to the government will at times reserve a strong interest in ensuring the confidentiality of the information submitted, Congress included in the FOIA exemptions by which the responding agency may withhold records. It is clear that the FOIA's disclosure provisions are construed broadly and its exemptions narrowly, with the burden "squarely on the government" to prove an exemption applies. *Ely v. FBI*, 781 F.2d 1487, 1489 (11th Cir. 1986).

In withholding the requested information in this case, the FDA cited Exemption 4, which permits the government to withhold "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). The Defendants do not contend that the requested information

constitutes trade secrets.[3] Instead, they contend the requested information contains the net number of doses of the hepatitis B vaccine in each lot of hepatitis B vaccine distributed in the United States. This information, they contend, is confidential commercial information. Thus, the issue on appeal is whether the Defendants have carried their burden of proving the requested information is "confidential" within the meaning of Exemption 4.

Vaccine manufacturers are required by FDA regulations to submit information regarding the quantity of vaccines they distribute. 21 C.F.R. § 600.81. Information in a mandatory submission is considered confidential within the meaning of Exemption 4 if its disclosure would either "impair the Government's ability to obtain necessary information in the future; or . . . cause substantial harm to the competitive position of the person from whom the information was obtained." *Nat'l Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 770 (D.C. Cir. 1974) (footnote omitted). The Defendants do not argue that disclosure will impair the Government's ability to obtain future information from Merck and Glaxo; rather, they argue that Merck and Glaxo will suffer substantial competitive harm from disclosure. In order to prove substantial competitive harm, the Defendants must demonstrate (1) that there is a

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[3] It is undisputed that Merck and Glaxo are "person[s]" under the FOIA. *See* 5 U.S.C. § 551(2) (defining "person" to include corporations).

competitive market for the hepatitis B vaccine and (2) that substantial competitive injury will result from disclosure. *See Miami Herald Publ'g Co. v. U.S. Small Bus. Admin.*, 670 F.2d 610, 613-14 (5th Cir. Unit B 1982).[4]

The district court found, and we agree, that the declarations submitted by the Defendants in support of their motions for summary judgment establish that Merck and Glaxo are engaged in actual competition for sales of hepatitis B vaccine. The evidence submitted by the Sharkeys does not raise a material issue of fact to the contrary. Consequently, we must only determine whether the Defendants' submissions establish without dispute that Merck and Glaxo would suffer substantial competitive injury if the FDA disclosed the requested records.

In order to succeed, the Defendants "need not 'show actual competitive harm.'" *Pub. Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291 (D.C. Cir. 1983) (quoting *Gulf & W. Indus., Inc. v. United States*, 615 F.2d 527, 530 (D.C. Cir. 1979)). "No actual adverse effect on competition need be shown . . . . The court need only exercise its judgment in light of the nature of the material sought and the competitive circumstances in which the [submitter] does business . . . ." *Miami Herald*, 670 F.2d at 614 (quoting *Nat'l Parks & Conservation Ass'n v. Kleppe*, 547 F.2d 673, 683 (D.C.

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[4] Cases decided by Unit B of the former Fifth Circuit are binding precedent in this circuit. *Stein v. Reynolds Sec., Inc.*, 667 F.2d 33, 34 (11th Cir. 1982).

Cir. 1976)) (internal quotation marks omitted). The Defendants must prove that disclosure of the requested records will reveal otherwise non-public information and that release of that information will result in competitive injury.

The Defendants maintain that release of the requested records will make public two categories of otherwise non-public information. First, the Defendants argue that release of the net number of doses distributed per lot would reveal the manufacturers' domestic market shares and sales volume. Second, the Defendants argue that release of the net number of doses distributed per lot would reveal each manufacturers' production capacity.

The district court relied on numerous declarations offered by the Defendants in holding that substantial competitive harm would result from disclosure. After reviewing the declarations, we conclude that disclosure of the net number of doses distributed per lot will, at a minimum, reveal the manufacturers' market shares and sales volume for the hepatitis B vaccine. Given this conclusion, we need not decide whether release of the records will reveal production capacity.

The Defendants' declarations assert that the requested information would allow competitors to "make determinations" regarding and "provide insight into" the manufacturers' respective market shares and sales volume. (Thomas Decl., R.1-39, Attach. 2 ¶ 5; Ryan Decl., R.1-39, Attach. 1 ¶ 27.) This is somewhat intuitive.

Because Merck and Glaxo are the only two domestic sellers of the hepatitis B vaccine, disclosure of the net number of doses per lot per manufacturer would clearly allow a competitor to better estimate Merck's and Glaxo's market share. And, contrary to the Sharkeys' suggestion, this information was not made publicly available in a report produced by the Centers for Disease Control and Prevention. (R.1-39, Attach. 1, Ex. J.) [5] As the FDA's declaration explains, this report provides only the total net number of doses distributed for hepatitis B vaccines in the United States during the period from 1991-2001. (Ryan Decl., R.1-39, Attach. 1 ¶ 26 n.4.) This report does not provide distribution data by manufacturer (which would be publicized under Plaintiffs' request), nor does it include the net number of does per lot by specific manufacturer (which would also be publicized under Plaintiffs' request). (Ryan Decl., R.1-39, Attach. 1 ¶ 26 n.4.) Even if the report revealed the information the Sharkeys claim it does, it does not account for the number of doses distributed between 2001 and March 10, 2003 (the date of the Sharkeys' first request), numbers which would certainly be made public for the first time if the records were disclosed. Therefore, we find that the Defendants have demonstrated

[5] The report is CDC, Surveillance for Safety After Immunization: Vaccine Adverse Event Reporting System (VAERS)–United States, 1991-2001, 52 Morbidity & Mortality Wkly. Rep., No. SS-01 (Jan. 24, 2003).

that disclosure of the withheld information will reveal their market shares and sales volume of the hepatitis B vaccine in the United States.

Our inquiry does not end here, however. Having determined that disclosure of the net number of doses per lot of each manufacturers' hepatitis B vaccine will reveal market share and sales volume, we now must decide whether the district court correctly found that Merck's and Glaxo's competitors' knowledge of this information would likely result in substantial competitive harm to the manufacturers. While some of the Defendants' declarations are conclusory in explaining how release of the records will result in competitive harm, others contain explanations beyond "conclusory and generalized allegations" of competitive injury that are sufficient to support a finding of substantial competitive harm. *See Pub. Citizen*, 704 F.2d at 1291.

The Defendants argue that knowledge of their market share will allow a competitor to better estimate even more confidential information, such as production capacity and manufacturing specifics. (Ryan Decl., R.1-39, Attach. 1 ¶¶ 27-28; Twyman Decl., R.2-52, Ex. B ¶ 7.) The Defendants contend that with this information, a competitor can estimate Merck's and Glaxo's ability to fill large orders for bid and price its bid to exploit this knowledge. (Twyman Decl., R.2-52, Ex. B ¶ 7.) For example, if the World Health Organization submitted bids for a large order

of vaccine, international competitors, with knowledge of the above information, could price their bids in order to take advantage of Merck's and Glaxo's inability to fill the order. Additionally, competitors with knowledge of sales volume will know the optimum volume of doses per lot of vaccine distributed by Merck and Glaxo, information that the Defendants maintain is kept highly confidential. (Ryan Decl., R.1-39, Attach. 1 ¶ 28.) Consequently, release of the withheld records would result in a very real, competitive harm that we believe is protected by Exemption 4. *Cf. Lion Raisins Inc. v. U.S. Dep't of Agric.*, 354 F.3d 1072, 1081 (9th Cir. 2004) (affirming "substantial competitive harm" finding where disclosure would allow competitor to infer production volume, thus allowing it to underbid produce distributor).

Our conclusion that market share and sales volume qualifies as confidential information is supported by Merck's declaration detailing the drastic measures it takes to ensure this information remains confidential. (*See* Turner Decl., R.1-39, Attach. 3 ¶ 4.) Both the efforts to keep this information confidential and the highly sensitive information that may be gleaned from it leads us to conclude that public knowledge of Merck's and Glaxo's domestic market shares and sales volume of the hepatitis B vaccine will likely result in substantial competitive harm.

Even so, the Defendants are not entitled to summary judgment if the Sharkeys' affidavits create a genuine issue of material fact. But, we agree with the district court that they do not. The only evidence presented by the Sharkeys that disclosure of the withheld records will not cause competitive harm is the affidavit of Dr. Marks, who states that no harm will result because Merck and Glaxo already know each other's respective market share. (Marks Aff., R.1-45, Ex. B ¶ 14.) While this may be true, Dr. Marks fails to account for the competitive harm that may result if an international competitor or third-party considering entry into the hepatitis B vaccine market[6] learns the market shares of Merck and Glaxo. Nor does Dr. Marks convince us that knowledge of Merck's or Glaxo's sales volume will not be advantageous to an international competitor or third-party entrant.

The Defendants have offered evidence showing that disclosure of the net number of doses per lot per manufacturer of hepatitis B vaccine will likely result in substantial competitive harm. Because the Sharkeys have failed to create a genuine issue of material fact otherwise, the district court correctly granted summary judgment in favor of the Defendants.

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[6] While Merck and Glaxo are currently the only hepatitis B manufacturers licensed to distribute in the United States, the field may one day become more occupied. *See, e.g.*, Press Release, Dynavax, Dynavax Initiates Pivotal Phase 3 Trial for Hepatitis B Vaccine (June 23, 2005). (R.2-53, Attach. 3.)

B. Rule 56(f) Motion

Even if the Sharkeys failed to create a genuine issue of material fact on the issue of competitive harm resulting from disclosure, the district court had within its discretion the power to postpone ruling on the summary judgment motions and permit limited discovery. Fed. R. Civ. P. 56(f).

In support of their motion for discovery, the Sharkeys submitted the affidavit of their attorney, Altom Maglio. He believed that through discovery, the Sharkeys would be able to find facts showing that the hepatitis B vaccine market is not competitive and that Merck and Glaxo will not suffer competitive harm from release of the withheld information. (Maglio Aff., R.1-45, Ex. D ¶ 6.) He also explains the efforts already undertaken to counter the factual allegations in the Defendants' declarations, including talking to vaccine experts. (Maglio Aff., R.1-45, Ex. D ¶ 5.)

The district court denied the motion for discovery. On this record, we cannot say the district court abused its discretion. "A Rule 56(f) motion must be supported by an affidavit which sets forth with particularity the facts the moving party expects to discover and how those facts would create a genuine issue of material fact precluding summary judgment." *Harbert Int'l, Inc. v. James*, 157 F.3d 1271, 1280 (11th Cir. 1998). Mr. Maglio's affidavit fails this standard. Instead, his affidavit merely criticizes all of the Defendants' declarations as conclusory and fails to state

with particularity the facts he believes discovery will reveal sufficient to create a genuine issue of material fact.

V. CONCLUSION

For the above reasons, the Defendants' motions for summary judgment were properly granted and we find no abuse of discretion in the denial of the motion for discovery.

AFFIRMED.