**UNITED STATES DISTRICT COURT**
**MIDDLE DISTRICT OF FLORIDA**
**FT. MYERS DIVISION**

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

Plaintiffs,

v. Civil Action No. 2:04-CV-552

FOOD AND DRUG ADMINISTRATION,

Defendant,

and

MERCK & CO., INC.,

Defendant-Intervenor.
_____/

**PLAINTIFFS' OBJECTIONS TO MAGISTRATE JUDGE'S**
**REPORT AND RECOMMENDATIONS**

Pursuant to Fed. R. Civ. P. 72(b) and Local Rule 6.02, plaintiffs object to the Magistrate Judge's amended report and recommendation (R&R) (Doc. No. 60) filed January 23, 2006. Pursuant to Fed. R. Civ. P. 72(a), plaintiffs object to the Magistrate Judge's Order (Doc. No. 58) filed January 17, 2006.

The Magistrate Judge erred in recommending that the Court deny plaintiffs' motion for summary judgment (Doc. No. 44) and grant defendants' motions for summary judgment (Doc. Nos. 38 & 40), by:

1) Concluding "that the release of the net number of doses per lot [of hepatitis B vaccine] would in fact cause competitive harm to Merck" (R&R at 12), even though defendants failed to establish *how* release of the *particular information requested* could cause competitive harm to either of the two manufacturers;

2) Recommending that "no *further* discovery be allowed in this action" (R&R at 13) (emphasis added), even though no discovery has yet been allowed, and even though plaintiffs cannot respond in greater detail to defendants' motions because of the conclusory nature of defendants' supporting declarations; and

3) Relying on facts and arguments not timely raised by defendants and denying plaintiffs' motion for leave to file a reply memorandum.

Accordingly, the Court should decline to adopt the R&R, sustain plaintiffs' objections, and grant plaintiffs' motion for summary judgment.

**A. There Is Insufficient Evidence to Support the Magistrate Judge's Conclusion That Release of the *Specific Information Requested* Could Cause Competitive Harm.**

The Magistrate Judge found that "[i]t is clear from the declarations provided by the Defendants that Merck and GlaxoSmithKline regard the net number of doses per lot to be confidential information vital to their respective competitive advantage and that release of the information from one of the manufacturers would cause competitive harm to both manufacturers in the United States and internationally." R&R at 11. As factual support for this conclusion, the Magistrate Judge relies solely on paragraphs 27 and 28 of the Ryan Declaration (Doc. No. 39-2), paragraphs 5 and 6 of the Thomas Declaration (Doc. No. 39-3), paragraphs 3 to 6 of the Turner Declaration (Doc. No. 39-4), and paragraph 7 of the Twyman Declaration (Ex. B to Doc. No. 52). R&R at 9-10.[1]

The Magistrate Judge's conclusion that the manufacturers seek to keep secret the net number of doses per lot is insufficient to establish that the requested information is confidential

[1]The Magistrate Judge noted that "[i]n addition to the affidavits and declarations, the Defendants provided a Vaughan [sic] Index with the described documents and rationale for the claimed exemption." R&R at 9. The FDA did provide a Vaughn Index that describes the documents at issue and identifies FOIA Exemption 4 as the reason they have been withheld. *See* Ex. I to Ryan Decl. However, the Vaughn Index does not provide any "rationale" or explanation for the government's invocation of FOIA Exemption 4.

commercial information under FOIA Exemption 4.[2] *See Nat'l Parks & Conservation Ass'n v. Morton*, 498 F.2d 765, 767 (D.C. Cir. 1974) ("Whether particular information would customarily be disclosed to the public by the person from whom it was obtained is not the only relevant inquiry in determining whether that information is 'confidential' for purposes of section 552(b)(4)."). Rather, defendants must show that disclosure of the information would "cause substantial harm to the competitive position of the person from whom the information was obtained." *Id.* at 770.

To support the conclusion that release of the requested information would cause competitive harm, the Magistrate Judge relies, without any discussion or analysis, 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 (Ryan Decl. ¶ 27, Thomas Decl. ¶ 5, Turner Decl. ¶ 5);

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 (Ryan Decl. ¶¶ 27-28, Thomas Decl. ¶ 5);

3) Such insights could cause competitive harm because the disclosure would result in a significant competitive disadvantage for Merck and GlaxoSmithKline (Thomas Decl. ¶ 5, Turner Decl. ¶ 6); 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. (Twyman Decl. ¶ 7).

[2]Although the issue in this case is the applicability of Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4), on page 5 of the R&R the Magistrate Judge, instead of citing FOIA, quotes a similar provision of the Government in the Sunshine Act, 5 U.S.C. § 552b(c)(4). The Magistrate Judge makes the same error on page 6 of the R&R in the parenthetical explanation of *Inter Ocean Free Zone, Inc. v. U.S. Customs Service*, 982 F. Supp 867 (S.D. Fla. 1997).

R&R at 9-10. These assertions are insufficient "to prove that the information in question is covered by" FOIA Exemption 4, *Ely v. FBI*, 781 F.2d 1487, 1489-90 (11th Cir. 1986), because they offer no explanation of how disclosure of *the requested information* could cause substantial competitive harm. *See Public Citizen Health Research Group v. FDA*, 704 F.2d 1280, 1291 (D.C. Cir. 1983) ("[C]onclusory and generalized allegations of substantial competitive harm . . . are unacceptable and cannot support an agency's decision to withhold requested documents."); *Miami Herald Publ'g Co. v. U.S. Small Bus. Admin.*, 670 F.2d 610, 613-14 & 614 n.9 (5th Cir. Unit B 1982) (describing conclusory evidence as inadequate to carry the government's Exemption 4 burden). A careful review of defendants' declarations reveals that the harms predicted would arise, if at all, only from the release of information beyond the scope of plaintiffs' request, and a common-sense analysis of the undisputed facts demonstrates that release of the requested documents could not cause competitive injury.

Plaintiffs seek the *net* number of doses (number of doses used) by lot of hepatitis B vaccine distributed in the United States, not the *gross* number of doses produced in each lot. It is undisputed that the total *net* number of doses of hepatitis B vaccine used in the United States is already a matter of public record. *See* Doc. No. 39-1 at 16-17 n.3; Doc. No. 39-2 (Ryan Decl.), Ex. J at 11, Table 1. It is also undisputed that there are only two manufacturers of hepatitis B vaccine used in the United States. Turner Decl. ¶ 6. Each manufacturer knows the net number of doses it has distributed and, by subtracting this number from the total, can calculate the net number of doses distributed by the other manufacturer. These facts negate defendants' assertions that disclosure of the information requested would tell each manufacturer something it does not already know about the other's market share and sales volume.

The only new information that either manufacturer could gain from release of the requested documents is a breakdown *by lot* of the doses used. Such a breakdown cannot reveal anything about manufacturing or production capacities and capabilities. It can reveal only that each lot contained *at least* the number of doses used, but it will not reveal how many additional doses were produced as part of that lot (and either returned unused, held as inventory, and/or distributed overseas), or how many additional doses *could* have been produced. The competitive harm alleged by defendants could arise, if at all, only from release of the *gross* number of doses in each lot—information that is beyond the scope of plaintiffs' request. Indeed, the Magistrate Judge relied in part on the assertions made in the Turner and Twyman declarations, but neither declaration even mentions the *net* number of doses per lot, focusing instead on the *gross* number of doses per lot. *See* Turner Decl. ¶¶ 3-6 (discussing "the number of doses per lot," "lot yield," and "batch size and product yield"); Twyman Decl. ¶ 7 ("the number of doses in a lot").[3]

The Magistrate Judge also concluded, without citation or explanation, that: 1) disclosure of the requested information "could effect [sic] Merck's position when competing for bids in an emergency situation not only within the United States but internationally" and 2) "should a lot be damaged with or without Merck's involvement, such information could be devastating to its ability to compete." R&R at 12. Plaintiffs object to these findings because they are speculative, without foundation, and wholly unexplained.

The Magistrate Judge further concluded that the affidavit submitted by Donald H. Marks, MD, Ph.D, (Ex. B to Doc. No. 45), is "too speculative and not based upon a sufficient factual basis" to rebut the declarations submitted by defendants. R&R at 11. Plaintiffs object to this

[3]Without explanation, the R&R adds the word "net" to the sentence drawn from paragraph 7 of the Twyman declaration. R&R at 10.

finding because defendants have the burden of proving that the requested documents are exempt from disclosure, *Ely*, 781 F.2d at 1489, and, because plaintiffs are the non-moving parties, all reasonable inferences drawn from the record must be viewed in the light most favorable to plaintiffs. *Whatley v. CNA Ins. Co.*, 189 F.3d 1310, 1313 (11th Cir. 1999). The Magistrate Judge erred by finding that "Dr. Marks does not provide sufficient factual justification for his opinions but simply makes conclusory statements that the manufacturers should know by association with others or open market information the confidential information they seek to protect." R&R at 10-11. Dr. Marks did not state that the two manufacturers "should" know anything; rather, based on his experience and expertise in the development, production, and regulation of recombinant vaccines, Dr. Marks stated that the manufacturers *do* know much about each other's production processes and capabilities, and he explained in detail that the specific information requested is unrelated to marketing strategies, product distribution plans, or maximum manufacturing capacity. Marks Aff. ¶¶ 13-20.

Because neither the Magistrate Judge nor defendants have offered any explanation of *how* knowledge of the *net* number of doses *by lot* could cause substantial competitive harm to either manufacturer, the record does not support the Magistrate Judge's conclusion that the requested information may be withheld under FOIA Exemption 4.

**B. If Plaintiffs Are Not Granted Summary Judgment, the Court Should Allow Discovery.**

Because defendants have failed to prove that the documents at issue are covered by FOIA Exemption 4, the Court should grant summary judgment to plaintiffs, and no discovery is necessary. Nevertheless, plaintiffs moved in the alternative for discovery pursuant to Fed. R. Civ. P. 56(f), in the event that the Court found that the factual assertions in defendants' declarations, if true, could be adequate to support an Exemption 4 claim. As explained above,

plaintiffs' expert and defendants' declarants disagree as to whether the requested information could reveal anything new about each manufacturer's production processes, marketing strategies, product distribution plans, or maximum manufacturing capacity, and the disagreement arises in large part from defendants' misapprehension of the scope of plaintiffs' request. However, plaintiffs have been hindered in their ability to rebut in detail defendants' claims, because defendants have not explained *how* release of the *particular information requested* could cause Merck and Glaxo to suffer substantial competitive harm. Discovery would allow plaintiffs to seek such an explanation and respond in detail.

The Magistrate Judge recommends that discovery not be allowed because she has already determined that defendants' evidence is sufficient to support summary judgment for defendants. R&R at 13. This reason is not adequate to deny the request for discovery. Plaintiffs requested that the Court defer ruling and allow discovery *only if* the Court were satisfied that defendants' evidence could support summary judgment for defendants, because plaintiffs cannot respond in further detail to defendants' allegations without obtaining an explanation of the basis of the allegations. *See Carney v. U.S. Dep't of Justice*, 19 F.3d 807, 812 (2d Cir. 1994) (holding that even 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"); *see also 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.").

The Magistrate Judge also found that plaintiffs' Rule 56(f) proffer was too conclusory to support the request for discovery. However, plaintiffs' affidavit explains in detail why plaintiffs have been unable thus far to gather evidence to counter defendants' factual allegations, why plaintiffs need to understand the basis of defendants' allegations in order to respond to them in detail, the progress made in gathering relevant information without resort to formal discovery methods, and the type of information likely to be revealed if discovery were allowed. Maglio Aff., (Ex. D to Doc. No. 45), ¶¶ 3-7; *see also Resolution Trust Corp. v. North Bridge Associates, Inc.*, 22 F.3d 1198, 1206 (1st Cir. 1994) ("[A] Rule 56(f) proffer need not be presented in a form suitable for admission as evidence at trial, so long as it rises sufficiently above mere speculation."). Finally, the Magistrate Judge apparently believed that plaintiffs were seeking "additional" or "further" discovery. R&R at 13. In fact, plaintiffs have not had any opportunity to take discovery. During the preliminary pretrial conference, the Magistrate Judge and the parties recognized that the need for discovery could be determined only after defendants had filed their dispositive motions. *See* Doc. No. 37 (setting deadline for plaintiffs to seek discovery after defendants' deadline for filing dispositive motions).

**C. The Magistrate Judge Erred by Relying on Facts and Arguments Not Timely Raised by Defendants and Denying Plaintiffs' Motion for Leave to File a Reply.**

Plaintiffs' memorandum in opposition to defendants' motions for summary judgment and in support of plaintiffs' cross-motion (Doc. No. 45) was based on defendants' failure to carry their burden of proving that the records responsive to plaintiffs' FOIA request were subject to withholding under FOIA Exemption 4, 5 U.S.C. § 552(b)(4). Defendants used their oppositions to plaintiffs' cross-motion (Doc. Nos. 52 & 53) to submit new facts and arguments in support of

their original summary judgment motions. Because the new facts and arguments were not timely raised, they should not be considered.

The Magistrate Judge based her finding "that there is significant competition between Merck and GlaxoSmithKline" entirely on the Dosanjh Declaration (Doc. No. 53-2) filed on August 8, 2005. R&R at 8. This information should have been submitted with defendants' motions for summary judgment filed on June 10 and 20, 2005. Fed. R. Civ. P. 6(d) ("When a motion is supported by affidavit, the affidavit shall be served with the motion."). Because it was submitted out of time, and only after plaintiffs showed that defendants had failed to establish that Merck and Glaxo are in actual competition with regard to hepatitis B vaccine (Doc. No. 45 at 6-8), it should not have been considered.

Similarly, the Magistrate Judge based her finding that disclosure of the requested documents would cause competitive harm, in part, on paragraph 7 of the Twyman Declaration (Ex. B to Doc. No. 52). R&R at 10. Like the Dosanjh Declaration, the Twyman Declaration was submitted out of time and should not have been considered.

At a minimum, the Magistrate Judge should have allowed plaintiffs an opportunity to address defendants' late-filed submissions. Thus, the Magistrate Judge erred when she entered an order denying plaintiffs' motion for leave to file a reply memorandum, on the grounds that the request was moot because plaintiffs could respond to the R&R, and because the Magistrate Judge found that the "current motions and current responses are sufficient for the Court to determine the issue of summary judgment." Doc. No. 58. Plaintiffs object to the Magistrate Judge's denial of their motion to file a reply because it denied plaintiffs any opportunity to address the facts and arguments raised by defendants for the first time in defendants' responses to plaintiffs' opposition and cross-motion. Moreover, the issue is not moot because even though

plaintiffs have explained their objections to the Magistrate Judge's findings, the District Judge will conduct a *de novo* review of the facts and law. 28 U.S.C. § 636(b)(1)(C). Because a District Judge conducting a *de novo* review of objections to a Magistrate Judge's findings and conclusions may consider the entire record, the arguments that plaintiffs sought to raise in their reply should be considered.

**CONCLUSION**

For the foregoing reasons, the Court should decline to adopt the Magistrate Judge's Amended Report and Recommendation (Doc. No. 60), sustain Plaintiffs' objections, deny defendants' motions for summary judgment, grant plaintiffs' motion for summary judgment, and order the FDA to produce the requested records. In the alternative, the Court should grant plaintiffs leave to take discovery and an extension of time to respond more completely to the factual allegations on which defendants base their motions.

Dated: January 31, 2006

Respectfully submitted,

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