

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATE OF AMERICA <i>ex rel.</i> ,	:	
STEPHEN A. KRAHLING and JOAN A.	:	
WLOCHOWSKI,	:	CIVIL ACTION
Plaintiffs,	:	NO. 10-4374
	:	
v.	:	
	:	
MERCK & CO., INC.,	:	
Defendant.	:	

ORDER

AND NOW, this 16th day of September, 2015, upon consideration of the full record, including the Order of the Honorable Lynne A. Sitarski, United States Magistrate Judge, dated July 31, 2015, (Dkt No. 83), Relators’ Objections to Judge Sitarski’s July 31, 2015 Order, (Dkt No. 84), and Defendants’ Response, (Dkt No. 86), it is hereby ORDERED that:

1. Said Objections are OVERRULED;
2. Judge Sitarski’s July 31, 2015 Order is AFFIRMED;
3. Relators’ Motion is DENIED.ⁱ

BY THE COURT:

/s/ C. Darnell Jones, II

C. Darnell Jones, II J.

ⁱ Relators filed objections to Judge Sitarski’s Order denying Relators’ motion to compel Merck to answer Interrogatory 1 of Relators’ First Set of Interrogatories. (Dkt No. 84 [hereinafter Objs.].) Interrogatory 1 (First Set) asked that Merck “State as a percentage, the current Efficacy of the mumps component of Merck’s MMRII vaccine, and the basis for your answer, including any Tests on which it is based.” (Merck’s Resp. to First Set of Interrogatories [hereinafter Merck’s Int. Resp.] at 5.) The “Definitions” section of the First Set of Interrogatories defined “efficacy” to mean how “the term is used in the current package insert” for the vaccine. (Objs. at 5.) The current package insert describes “efficacy” in the following manner: “Efficacy of measles, mumps, and rubella vaccines was established in a series of double-blind controlled field trials which demonstrate a high degree of protective efficacy afforded by the individual vaccine components.” (Dkt No. 86, Ex. 1, M-M-R® II Package Insert.) In Merck’s answer, Merck objected to the term “current efficacy.” (Merck’s Int. Resp.) Merck explained that the “Interrogatories define ‘efficacy’ in the context of specific double-blind controlled trials, which is how the term is often used.” (Merck’s Int. Resp.) Merck wrote that “there are no ‘current efficacy’ clinical

trials involving Merck's mumps vaccine and [] it is not now possible to conduct such double-blind controlled studies." (Merck's Int. Resp.)

In her opinion, Judge Sitarski defined "efficacy" as: "[e]fficacy of measles, mumps, and rubella vaccines [] established in a series of double-blind controlled field trials which demonstrate a high degree of protective efficacy afforded by the individual vaccine components." (Dkt No. 83 [hereinafter Order] at 3 n. 3.) Judge Sitarski found that the question's use of the term "current efficacy" was "vague and confusing, and therefore Merck's explanation for answering the interrogatory with the 'efficacy' of Merck's mumps vaccine, not the 'current efficacy' is justified." (Order at 4 n. 3 (internal citations omitted.))

A District Court may reverse a Magistrate Judge's order for a non-dispositive matter under 28 U.S.C. § 636(b)(1)(A) only if it is clearly erroneous or contrary to law. Fed. R. Civ. P. 72(b). A ruling is clearly erroneous if the reviewing court has "the definite and firm conviction that a mistake has been committed." *Haines v. Liggett Group, Inc.*, 975 F.2d 81, 92 (3d Cir. 1992). "Clear error thus requires something more than simple disagreement." *F.T.C. v. NHS Systems, Inc.*, 2011 WL 5979573, at *3 (E.D. Pa. 2011). Under the clearly erroneous standard, the District Court shall not reverse the Magistrate Judge's determination even where the Court might have decided the matter differently. *Cardona v. Gen. Motors. Corp.*, 942 F.Supp. 968, 971 (D.N.J. 1996).

The proper standard of review for standard discovery orders is the "clearly erroneous or contrary to law" standard. *Haines v. Liggett Grp. Inc.*, 975 F.2d 81, 92 (3d Cir. 1992) (citing 28 U.S.C. § 636(b)(1)(A); Fed. R. Civ. P. Rule 72(a)); *see also Cipollone v. Liggett Group, Inc.*, 785 F.2d 1108, 1113 (3d Cir.1986); *John F. Harkins Co. v. Waldinger Corp.*, 796 F.2d 657, 662 (3d Cir. 1986). A discovery order is "not dispositive of a claim or defense of a party" as contemplated by Fed. R. Civ. P. 72(a); *In re Gabapentin Patent Litig.*, 312 F. Supp. 2d 653, 662 (D.N.J. 2004).

In this matter, Relators are challenging Judge Sitarski's ruling as to Merck's objection, and the sufficiency of Merck's answer, to Interrogatory 1 (First Set). Relators argue that Judge Sitarski erred as a matter of law by (1) using the incorrect definition of "efficacy" in her analysis and (2) failing to consider that Merck had, allegedly, previously vouched for the "current efficacy" of the vaccine, and, as such, was capable of providing an answer. First, the Court finds that Judge Sitarski used the appropriate definition of "efficacy" in her analysis. The Interrogatories stated that the term "efficacy" was meant as it was used on the current package insert. Judge Sitarski cited directly to the current package insert. Any grammatical exclusions made by Judge Sitarski did not change the meaning of the citation.

Second, Relators point to instances where Merck stated that the vaccine has "tremendous efficacy," (Objs. at 3), and that the vaccine's "high degree of protective efficacy" "remains undisputedly true." (Objs. at 3.) As a preliminary matter, the Court notes that Judge Sitarski did in fact consider such arguments. (Order at 4 n. 3.) Nonetheless, the Court considers such arguments herein. Relators argue that if Merck's position is that the "efficacy" stated on the label remains "undisputedly true," then the "efficacy" on the label should reflect the "current efficacy" of the vaccine today. This is where colloquial use of language, while sounding logical, confuses the issue. The word "efficacy" carries a scientifically specific meaning. Thus, the parties are having two different conversations. Relators are stating that if the "efficacy" in the packaging is still "true," then Merck should be able to state the "current efficacy." Merck is stating that the "efficacy" stated in the label remains "true," but that it does not reflect "current" trials, and thus, does not reflect "current efficacy." As Judge Sitarski astutely explained, "Relators define 'current efficacy' as 'what the efficacy is today,' or 'the efficacy...six months ago'....Merck stated that...it could not give the 'current efficacy' of its vaccine because '[y]ou would actually need a current trial to get current efficacy dat[a].'" (Order at 4 n. 3.) In short, Relators argue that Merck did not answer the question; Merck argues that the question cannot be answered.

The Court agrees with Judge Sitarski. The question's stated definition of "current efficacy" is nonsensical at worst and confusing at best. Interrogatories do not allow a vague question to lead to an imprecise, misleading answer. The Court finds that Judge Sitarski did not commit clear error.