

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS
EAST ST. LOUIS DIVISION**

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(DROSPIRENONE))	DRH-PMF
MARKETING, SALES)	
PRACTICES AND)	
PRODUCTS	
LIABILITY	
LITIGATION	

This Document Relates to:

ALL CASES

CASE MANAGEMENT ORDER NUMBER 46

**Regarding Bayer's Motion to Compel Discovery
From Plaintiffs' Designated Expert Dr. Lidegaard**

INTRODUCTION

This matter is before the Court on Bayer HealthCare Pharmaceuticals, Inc.'s (Bayer) motion for an order compelling discovery of plaintiff's designated expert Dr. Lidegaard, pursuant to Federal Rules of Civil Procedure 37(a) and 26(b)(4)(A) (Doc 2058).

BACKGROUND

On August 1, 2011, plaintiffs disclosed Dr. Lidegaard as a retained expert whose opinions may be presented at trial and produced his expert report (Doc. 2058 p. 2). Thereafter, Bayer served requests for production of Dr. Lidegaard's

documents pursuant to CMO 38 and also appended a broader document request as a rider to its notice of Dr. Lidegaard's deposition. *Id.*

On August 29, 2011, the Court heard argument and ruled on the scope of the Lidegaard document production. In that hearing, the Court concluded that documents considered by Dr. Lidegaard in rendering the opinions in his expert report must be disclosed to Bayer ten days in advance of Dr. Lidegaard's deposition. The Court also concluded that an unpublished manuscript written by Dr. Lidegaard (as well as that manuscript's peer review comments and underlying data) was not to be produced at this time. Dr. Lidegaard's manuscript has since been published in a medical journal, the BMJ (formerly British Medical Journal) (Doc. 2058 pp. 3-4).

Shortly after the August 29th hearing, Dr. Lidegaard's deposition was rescheduled from a date in mid-September to a date in mid-October. *Id.* at p. 2. In addition, plaintiffs agreed to produce certain documents ten days in advance of Dr. Lidegaard's deposition. *Id.* On September 2, 2011, plaintiffs produced Dr. Lidegaard's rebuttal report. *Id.* But on October 3, 2011, plaintiffs cancelled Dr. Lidegaard's October deposition and withdrew Dr. Lidegaard as a testifying expert. *Id.*

BAYER'S MOTION AND PLAINTIFFS' RESPONSE

Bayer seeks production of Dr. Lidegaard's documents, including documents that relate to compensation for Dr. Lidegaard's work as an expert for plaintiffs and the facts or data that Dr. Lidegaard considered in forming his opinions. *Id.*

at p. 4. In addition to the documents that relate to compensation for Dr. Lidegaard, Bayer seeks production of documents relating to (1) the BMJ study; (2) draft manuscripts, peer review notes, and interim reports relating to the “Danish study 1995-2005” and the Danish reanalysis; and (3) any and all documents that plaintiffs agreed to provide 10 days in advance of the deposition (Doc. 2058 p. 4). Bayer contends, that pursuant to Seventh Circuit law, because plaintiffs have produced Dr. Lidegaard’s expert report, Bayer is entitled to the requested discovery (despite plaintiff’s withdrawal of Dr. Lidegaard as a testifying expert). *Id.* at pp. 1, 3-4.

Plaintiffs responded to Bayer’s motion on November 11, 2011 (Doc. 2082). After reviewing plaintiffs’ response, it appears that, with one exception, the disputed issues have been resolved by agreement. Plaintiffs have agreed to provide the following documents:

- (a) any and all documents that relate to compensation for Dr. Lidegaard’s work as an expert for Plaintiffs;
- (b) the study designs, statistical analysis, and study protocols considered in performing his study published in the British Medical Journal (“BMJ”) in 2009, to the extent available;
- (c) the study designs, statistical analysis, and study protocols considered in performing his study published in the BMJ in 2011, to the extent available and not already in Defendants possession; and
- (d) draft manuscripts and interim reports relating to the “Danish study 1995-2000” and the “Danish reanalysis,” to the extent available and not already in the Defendants possession.”

*Id.*¹

Plaintiffs' agreement resolves everything but Bayer's request for peer review comments of published papers. *Id.* at pp. 4-7. Plaintiffs contend, given the strong public policy in favor of preserving confidentiality in the peer review process, the Court should find that the probative value to Bayer of Dr. Lidegaard's peer review notes is outweighed by the burden imposed on the scientific and academic communities. *Id.* at pp. 1, 4-7.

LEGAL STANDARD

Federal Rule of Civil Procedure 26 provides that the “[p]arties may obtain discovery regarding any nonprivileged matter that is relevant to any party's claim or defense.” Fed. R. Civ. P. 26(b)(1). Discoverable information is not limited to evidence admissible at trial. Instead, such information is relevant “if the discovery appears reasonably calculated to lead to the discovery of admissible evidence.” *Id.* However, while the scope of permissible discovery is broad, it is not unlimited. A court can limit discovery if the court believes it is unreasonably cumulative, if the party seeking discovery has already had ample opportunity to

¹ With regard to these requests, plaintiffs note they will only provide material “considered by” (as opposed to “related to” or “relied on”) Dr. Lidegaard in forming the opinions in his report. The Court agrees that, pursuant to Federal Rule of Civil Procedure 26(a)(2)(B), the appropriate standard is “considered by.” In this regard, the Court notes that the phrase “related to” is broader in scope than the phrase “considered by,” which requires that Dr. Lidegaard reflected on the material in question. The Court also notes that the phrase “considered by” invokes a broader spectrum than then the phrase “relied on,” which requires dependence.

do so, or if the burden of the proposed discovery outweighs its likely benefit. Fed. R. Civ. P. 26(b)(2).

In the context of motions to compel, the Seventh Circuit instructs that a “district court may grant or deny the motion in whole or in part, and similar to ruling on a request for a protective order under Rule 26(c), the district court may fashion a ruling appropriate for the circumstances of the case.” *Gile v. United Air Lines, Inc.*, 95 F.3d 492, 496 (7th Cir. 1996). As with all discovery matters, district courts have broad discretion in determining motions to compel. See *Peals v. Terre Haute Police Dep’t*, 535 F.2d 621, 629 (7th Cir. 2008).

ANALYSIS

The peer review process is vital to academic quality. In the scientific community, peer review material identifies strengths and weaknesses in a researcher’s material. This helps to ensure integrity and reliability in scientific activity and reporting.

The pillars of a successful peer review process are confidentiality and anonymity; anything less discourages candid discussion and weakens the process. Accordingly, peer review material has traditionally been protected from public disclosure. Although the Seventh Circuit has not addressed the peer review matters at issue in the current litigation, it has recognized that research data may be entitled to protection in the course of civil discovery. See *Dow Chemical Co. v. Allen*, 672 F.2d 1262 (7th Cir. 1982).

In *Dow Chemical*, the Seventh Circuit affirmed a district court decision to quash a subpoena issued to university researchers seeking research material, including research notes, reports, working papers, and raw data relating to ongoing studies.² Among other things, the Appellate Court noted disclosure of the requested material could interfere with the researchers' academic freedom and that such an intrusion could set a precedent "capable of chilling" scientific research on a larger scale. *Id.* at 1276-77.

In the instant case, Bayer's request for peer review materials imposes a significant burden on the scientific and academic communities. The researchers that generated the peer review material Bayer is seeking expected their comments and analyses to remain confidential. Requiring disclosure would violate these expectations. If researchers believe their peer review comments will be subject to disclosure in litigation they will be less likely to engage in the peer review process. Further, public disclosure will discourage a candid peer review process. This is particularly troubling where, as here, medical research is in issue. Scientific research in the medical community affects public health and safety. Therefore,

² To be clear, there are a number of factors that distinguish *Dow Chemical* from the present case. *Dow Chemical* involved an adjudicative subpoena issued by an administrative law judge. The research material sought related to ongoing studies and had not yet been subject to peer review. Thus, a majority of the issues considered by the Appellate Court are not relevant here (such as the court's concerns regarding *premature* publicity relating to the unpublished studies). Nonetheless, the Seventh Circuit's discussion regarding the importance of academic freedom and the burden discovery may impose on researchers is informative.

damage to the peer review process can also undermine efforts to improve public health and safety.

Considering these factors, the Court concludes that to disclose the requested peer review comments would be a burden far greater on the academic and scientific community than the probative value to be gained by the defendant so as to render disclosure inappropriate. Accordingly, Bayer's request for peer review material is **DENIED**.

CONCLUSION

Bayer's motion to compel is **DENIED** in part and **GRANTED** in part by agreement of the plaintiffs. The plaintiffs will provide Bayer with the study designs, statistical analysis, study protocols, draft manuscripts, and interim reports for the requested publish studies. However, the request for peer review material is **DENIED**.

So Ordered

 Digitally signed by
David R. Herndon
Date: 2011.11.15
12:08:34 -06'00'



Chief Judge
United States District Court

Date: November 15, 2011