

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION**

IN RE: GADOLINIUM-BASED) **Case No. 1:08 GD 50000**
CONTRAST AGENTS PRODUCTS) **MDL No. 1909**
LIABILITY LITIGATION)
) **Judge Dan Aaron Polster**
)
) **ORDER**
)
_____)

THIS DOCUMENT APPLIES TO ALL CASES

In this product liability multi-district litigation (“MDL”), Plaintiffs allege that they have suffered substantial injuries caused by the use, in magnetic resonance imaging procedures performed on them, of gadolinium-based contrast agents (“GBCAs”) that were manufactured, marketed and/or sold by Defendants. At a teleconference conducted on May 13, 2008, liaison counsel reported the status of the parties’ discussions regarding a protective order. They informed the Court that the parties had agreed to all terms but one, detailed below. The Court asked the parties to file briefs on this isolated issue no later than May 20, 2008 (ECF No. 72), and the parties timely filed their briefs (ECF Nos. 73, 75, 76). The arguments are briefly summarized as follows.

Plaintiffs seek inclusion of two provisions in the proposed protective order that would allow them to disclose some of Defendants’ documents designated “Confidential” or “Highly Confidential” (hereafter, “designated documents”), produced during discovery, to

“plaintiffs’ treating physicians, including any personnel providing MRI and/or MRA services,” presumably for deposition purposes. (ECF No. 73 at 3 (citing Ex. A ¶¶ 28(k), 29(j)).) Plaintiffs explain that they expect Defendants to argue, among other things, that (1) they provided adequate warnings to the treating physicians; (2) any claims for inadequate warnings are barred by the learned intermediary doctrine; and/or (3) the treating physicians knew or should have known of the dangers of their product. (Id.) Further, the information contained in some of the Defendants’ designated documents may include draft warning labels, unpublished clinical trial data or other information which, if it had been disclosed to the medical community, might have impacted the decision of the physician to prescribe the MRI or MRA scan using the GBCA. (Id.) Thus, they will be substantially prejudiced in their efforts to litigate their claims and oppose Defendants’ affirmative defenses if the treating physicians cannot be shown these designated documents. (Id.)

The Bayer and GE Defendants do not have any objection to the inclusion of ¶¶ 28(k) and 29(j) in the proposed protective order. (ECF No. 73, at 2 n.3.)

Defendants Mallinckrodt Inc. and Bracco Diagnostics, Inc., however, oppose disclosure of their designated documents, because they claim that the treating physicians will be called on to “review, analyze and provide off-the-cuff opinion testimony on the content of Defendants’ internal documents” which is “beyond the scope, experience and relevance of witnesses in this litigation.” (ECF No. 76, at 2.) They are concerned that Plaintiffs are seeking to elicit expert opinion from fact witnesses (the treating physicians) which is inadmissible, inflammatory and highly prejudicial. (Id. at 3.) In the event the Court allows such disclosure, these Defendants ask that a safe-harbor provision be included in the protective order. (Id. at 6.)

Such provision would require Plaintiffs to give these Defendants 14-day advance notice of Plaintiffs' intent to provide treating physicians with Mallinckrodt's and Bracco's designated documents, identified by bates range, so that they can properly prepare meaningful cross examination of the treating physicians. (Id. at 6, 4.) These Defendants also ask that the Court limit the number of designated documents disclosed to each treating physician to ten to fifteen to avoid marathon-length depositions.

Defendant Novation, LLC incorporates the arguments of Defendants Mallinckrodt Inc. and Bracco Diagnostics. (ECF No. 75, at 1.) Novation asks, moreover, that it be "completely exempted" from any provision in the protective order authorizing Plaintiffs to share Novation's designated documents due to its "unique position" in this MDL. Novation claims that it is a minor player which does not manufacture or distribute gadolinium but is merely a group purchasing agent that "facilitate[s] contracts between healthcare providers and manufacturers and distributors of medical supplies." (Id. at 2.) As such, Novation's designated documents consist largely of business records reflecting its competitive marketing strategies. Novation argues that the disclosure of this information to physicians is irrelevant to the clinical administration of GBCAs. Furthermore, exposing its strategies to physicians involved in the renegotiation of contracts with Novation could compromise its business advantage. (Id.) Alternatively, Novation seeks the same 14-day notice provision requested by Mallinckrodt and Bracco. (Id. at 3.)

For good cause shown, the Court finds that the inclusion of the two disputed provisions (i.e., ¶¶ 28(k) and 29(j)) permitting disclosure of designated documents to Plaintiffs' treating physicians who agree to be bound by the provisions of the order is justified provided

Plaintiffs give Defendants Mallinckrodt Inc., Bracco Diagnostics and Novation, LLC 14-day advance notice of disclosure of those Defendants' designated documents to treating physicians, identifying the documents by bates number. The Court will put no limitation on the number of designated documents that may be disclosed to the treating physicians, and assumes that Plaintiffs will exercise discretion in limiting the number of designated documents they so seek to disclose.

IT IS SO ORDERED.

/s/Dan Aaron Polster May 27, 2008
Dan Aaron Polster
United States District Judge