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**SAME RESULT, DIFFERENT COURT**

**MDL Judge Slams the Door on Expert's General Causation Opinions in Bausch & Lomb's Contact Lens Solution Litigation**

The federal judge presiding over the ReNu<sup>®</sup> with MoistureLoc<sup>®</sup> MDL has granted Bausch & Lomb's motion to exclude the general causation opinions of plaintiffs' sole expert as to non-*Fusarium* infections.

Wednesday's ruling, issued by Judge David Norton of the U.S. District Court for the District of South Carolina, comes on the heels of a similar ruling issued in the parallel New York state consolidated proceeding. On July 15, 2009, Justice Shirley Werner Kornreich excluded the testimony of multiple plaintiffs' experts who opined that ReNu<sup>®</sup> with MoistureLoc<sup>®</sup> was capable of causing non-*Fusarium* infections. These two rulings effectively eliminate almost 1,000 remaining cases, which is 95 percent of the existing litigation.

The MDL plaintiffs offered the opinions of a single, well-credentialed expert, Dr. Elisabeth Cohen. Following extensive briefing, a three-day joint state and federal *Daubert/Frye* hearing was conducted in June to assess the reliability of Cohen's opinions.

At issue was whether Bausch & Lomb's contact lens solution could cause infections other than *Fusarium* keratitis—a rare but serious corneal infection linked to the use of MoistureLoc<sup>®</sup> in a CDC-sponsored epidemiologic study. Plaintiffs argued that MoistureLoc<sup>®</sup> caused other infections such as viral, bacterial and *Acanthamoeba* (grouped together by the court under the heading "non-*Fusarium* infections").

Plaintiffs attempted to bootstrap the data on *Fusarium* infections and extrapolate from *in vitro* studies showing that MoistureLoc<sup>®</sup> could lose efficacy against other organisms when exposed to various extreme conditions. Judge Norton ruled that Cohen's opinions fail to "meet the *Daubert* standard for scientific reliability and, accordingly, must be excluded."

*Daubert's* general acceptance prong figured prominently in the decision. The court noted that "[p]laintiffs have cited no published, peer-reviewed or scientific literature

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### Pharmaceutical & Medical Device

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concluding that MoistureLoc<sup>®</sup> is related to an increased rate of non-Fusarium infections because there is none."The court rejected Cohen's effort to rely on *in vitro* testing as the basis for her opinion, saying "In vitro tests generate hypotheses but lack sufficient reliability, standing alone, to demonstrate causation in humans."

Another important consideration was Cohen's willingness to alter her opinions throughout the course of the litigation, often in response to Bausch & Lomb challenges. "[R]oughly two weeks before the scheduled joint *Frye/Daubert* hearing, and after Bausch & Lomb filed its *Daubert* motion . . . Dr. Cohen executed an affidavit in which she abandoned a number of her prior opinions." Furthermore, "[p]laintiffs' expert's opinions continued to change even during the joint *Frye/Daubert* hearing. During cross examination Dr. Cohen retreated from several of her opinions when confronted with contradictory information." On this issue, the court said "Dr. Cohen's changing opinions, and willingness to abandon or qualify her opinions when faced with further facts, undermines the reliability of her opinions."

Judge Norton's ruling also emphasized Cohen's failure to consider contrary data. Specifically, Cohen failed to consider or explain four published studies cited by Bausch & Lomb's experts that showed no association between MoistureLoc<sup>®</sup> and the development of non-*Fusarium* infections. "This failure to address this contrary data renders plaintiffs' theory inherently unreliable."

The case is *In re Bausch & Lomb, Inc. Contact Lens Solution Products Liability Litigation*, No. 2:06-MN-77777-DCN, (D.S.C. August 26, 2009). Shook, Hardy & Bacon attorneys [Marie Woodbury](#), [Eric Anielak](#), and [Harvey Kaplan](#) represented Bausch & Lomb.

## RULE 11 ALIVE AND WELL IN MASS TORT CONTEXT

On August 26, 2009, in the *Digitek*<sup>®</sup> (digoxin) MDL in the U.S. District Court for the Southern District of West Virginia, Magistrate Judge Mary Stanley issued an order that requires plaintiffs in 39 cases to respond to requests for admission aimed at uncovering whether they had a sufficient evidentiary basis to file suit.

The order sends an important message that plaintiffs' attorneys are accountable up front and rightly notes that "Rule 11 applies to the same extent in mass tort and multidistrict litigation as it does in more conventional disputes."The order is significant because no other court has specifically ruled that Rule 11 applies in the mass-tort context.

The defendants' requests for admission asked plaintiffs to admit that they were not in possession of medical or pharmacy records when they filed their complaints and served their fact sheets.

Magistrate Stanley dismissed plaintiffs' argument that defendants cannot seek sanctions under Rule 11 because plaintiff fact sheets constitute discovery responses and Rule 11 does not apply to discovery responses, saying: "The defendants are

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not attempting to discover whether the plaintiffs committed sanctionable conduct in their Plaintiff Fact Sheets. Instead, they are trying to gather information as to whether there were appropriate Rule 11 prefiling investigations.”

Plaintiffs also contended that the requests were not calculated to lead to the discovery of admissible evidence because the facts and considerations factoring into the decision to file suit do not relate to issues of liability and damages. Magistrate Stanley saw it differently: “If the plaintiffs in thirty nine identified cases in fact failed to comply with Rule 11, serious issues arise as to the merits of those plaintiffs’ claims. The defendants would be able to use the information gathered from the requests to support a defense that the claims lack evidentiary basis.”

Plaintiffs’ argument that the requests sought privileged information fared no better. Magistrate Stanley noted that the plaintiffs failed to produce a privilege log and “failed to proffer any reason why the privileges might apply.”

Magistrate Stanley took apart plaintiffs’ claim that the requests violate the policy against engaging in satellite litigation on Rule 11 issues. She noted that discovery on Rule 11 issues should be conducted only in “extraordinary circumstances”—and then found that such circumstances existed. “First, the defendants have voiced serious concerns about whether certain counsel had sufficient evidentiary support to justify initiating suit. Based upon the allegations in the complaints, a prefiling investigation without first obtaining medical and pharmacy records would be reasonable only in an extremely limited set of circumstances. The records would be essential in determining whether the plaintiffs have a colorable claim.”

Finally, Magistrate Stanley concluded that defendants’ requests were concise, simple and straightforward and, therefore, unlikely to invite protracted satellite litigation. Accordingly, plaintiffs were given 20 days to respond to the requests for admission.

The case is *In re: Digitek® Prod. Liab. Litig.*, MDL No. 1968 (S.D. W. Va., Aug. 26, 2009). Defendants in the *Digitek®* litigation include Actavis Totowa L.L.C. and Mylan Pharmaceuticals, Inc. Shook, Hardy & Bacon attorney [Harvey Kaplan](#) represents Mylan. ■