SUPREME COURT OF THE STATE OF NEW YORK — NEW YORK COUNTY

PRESENT: SHIRLEY WERNER KORNREICH PART 54
Justice

BAUSCH & LOMB CONTACT LENS SOLUTION PRODUCT LIABILITY LITIGATION

INDEX NO. 766000/2007

MOTION DATE 6/2/09

MOTION SEQ. NO. 10

MOTION CAL. NO.

The following papers, numbered 1 to ____ were read on this motion to/for preclude expert opinion on general causation of non-Fusarium infections

PAPERS NUMBERED

Notice of Motion/ Order to Show Cause — Affidavits — Exhibits

Answering Affidavits — Exhibits

Replying Affidavits

Cross-Motion: ☐ Yes ☒ No

Upon the foregoing papers, it is ordered, as a supplement to the prior order filed 6/2/09, that this motion

MOTION IS DECIDED IN ACCORDANCE WITH ACCOMPANYING MEMORANDUM DECISION AND ORDER.

Dated: July 14, 2009

J.S.C.

Check one: ☐ FINAL DISPOSITION ☒ NON-FINAL DISPOSITION

Check if appropriate: DO NOT POST

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: PART 54

BAUSCH & LOMB CONTACT LENS SOLUTION PRODUCT LIABILITY LITIGATION	INDEX NO. 766000/2007
THIS DOCUMENT APPLIES TO ALL CASES	DECISION AND ORDER

KORNREICH, SHIRLEY WERNER, J.:

Defendant in these joined products liability personal injury actions, Bausch & Lomb Incorporated (B & L), moves to exclude the opinions of plaintiffs' experts that the contact lens solution ReNu with MoistureLoc (ReNu ML) was capable of causing non-*Fusarium* infections. B & L also moves to strike from the Court's consideration the belated, May 18, 2009 affidavit of plaintiffs' expert Dr. Elizabeth Cohen, the opinions she expresses in the affidavit and any expert testimony of Dr. Gerald McGwin, Jr. regarding non-*Fusarium* infections. Plaintiffs oppose. A three-day joint *Frye/Daubert* hearing was held, and the parties presented testimony of three expert witnesses and submitted numerous articles, deposition transcripts and other exhibits.

I. *Background*

Beginning in 2004, B & L manufactured and distributed ReNu ML, a multipurpose contact-lens solution that cleans and disinfects contact lenses. It was taken off the market in 2006. This is an action to recover damages for personal injuries allegedly suffered by plaintiffs as a direct and proximate result of B & L's negligent and wrongful conduct in connection with the design, development, manufacture, testing, packaging, advertising, promoting, marketing, distribution, labeling, and/or sale of ReNu ML.

ReNu ML was a unique, patented product that was developed to enhance comfort for contact-lens wearers. Many wearers experience dry eye, a condition that often results in consumers discontinuing their use of contact lenses. To address this problem, B & L incorporated a trio of polymers, plastic molecules that increase the comfort level of contact lenses. ReNu ML contained one disinfectant called Alexidine. Like all contact-lens solutions, ReNu ML was classified as a medical device and was subject to the regulatory authority of the United States Food and Drug Administration (FDA). *See* 21 C.F.R. 886.5928. Premarket testing, using FDA criteria, demonstrated that ReNu ML was effective in killing microorganisms, including *Fusarium*, that can cause eye infections.

The measure of a contact lens solution's disinfectant efficacy (its bactericidal and fungicidal properties) is based on a "kill rate." A kill rate is expressed, according to the International Standard Organization (ISO) test protocols, as a "log reduction." A log reduction is a multiple of 10 reduction in the number of microbes: 1 log reduction means 10 times less microbes, a 2 log reduction means 100 times less and a 3 log reduction means 1000 times less. Accordingly, if there were 1,000,000 bacteria contaminating a contact lens case and after use of a contact lens solution there was a 3 log reduction in the number of those bacteria, there would be 1,000 bacteria remaining.

To demonstrate a sufficiently effective and acceptable kill rate/efficacy to obtain FDA marketing approval, contact lens solutions must pass the ISO "stand alone" test. ISO 14729, Sec. 4. l. at page.2. To pass the "stand alone" test, contact lens solutions must demonstrate a greater than 3 log reduction for bacteria and a greater than 1 log reduction for fungi. *Id.* In its pre-marketing testing, ReNu ML "showed a reduction in the number of bacteria of 4.3-4.8 log units

[i.e., more than 10,000 times reduction (10x 10x 10x 10) and close to 100,000 times reduction [10 x 10 x 10 x 10 x 10], much greater than the 3.0 log units required by the ISO test. ReNu ML demonstrated a 3.2 log reduction in Fusarium concentrations compared to the FDA requirement of a 1.0 log reduction.

The requisite data documenting the safety and efficacy of the product was submitted to the FDA in December 2003, and the FDA cleared ReNu ML for sale and distribution in the United States on May 19, 2004. B & L began distributing ReNu ML in the United States in August 2004. B & L released it for sale in Asia, including Hong Kong, Singapore, and Malaysia shortly thereafter. It marketed the product as "a safe and effective multi-purpose contact lens solution which 'cleans, rinses, disinfects, and stores soft contact lenses' and 'makes daily lens care easy.'" (Compl. P 10.) In February 2006, Hong Kong and Singapore reported outbreaks of Fusarium keratitis among ReNu ML users.

A contact lens rests on the cornea, the clear layer of the eye in front of the iris, pupil and lens. Microbial keratitis is the general term for corneal infections caused by any one of several microbial pathogens, that is, microorganisms that can cause disease. These include bacteria, fungi, viruses, and Acanthamoeba. If the specific microbe causing the infection is known, the diagnosis of microbial keratitis may be further specified to identify the causative microbe. Accordingly, corneal infections caused by Fusarium, a specific type of fungus, are denominated as Fusarium keratitis. Symptoms can include eye pain, eye discomfort, decrease in vision, light hypersensitivity, eye redness, eye burning, itching and a white filmy patch in the cornea. If not properly treated, surgery may be required to remove fungal and/or ulcer lesions; in severe cases, permanent corneal scarring may develop and, sometimes, a corneal transplant is required.

Contact-lens wearers are approximately 80 times more likely than healthy non-wearers to experience a microbial keratitis . The background or baseline rate of microbial keratitis is estimated to be between 4 and 21 per 10,000 in wearers of soft contact lenses. The majority of contact-lens-related keratitis is bacterial in nature. Prior to 2006, the baseline rate for contact-lens related Fusarium keratitis in the United States was not known, but was rare.

The first report of Fusarium keratitis associated with ReNu ML use in the United States was received by B & L on March 2, 2006. B & L conducted an internal investigation and cooperated with ongoing investigations by the U.S. Food & Drug Administration (FDA) and Center for Disease Control (CDC). The CDC fully investigated thirty cases and found that twenty-six of twenty-eight patients with Fusarium keratitis who wore soft contact lenses also used ReNu ML. The FDA and the CDC issued a joint press release on April 10, 2006, reporting the increasing numbers of Fusarium keratitis associated with ReNu ML. On April 13, 2006, B & L suspended domestic shipments of the product, and on May 15, 2006, the company announced a voluntary global withdrawal.

Ultimately, the CDC identified 164 patients with confirmed cases of Fusarium keratitis, 94 of whom reported exclusive use of ReNu ML as their contact-lens solution. After conducting a case-control study, the results of which were published in the Journal of the American Medical Association, the CDC concluded that the U.S. outbreak of Fusarium keratitis was associated with the use of ReNu ML.Case-control studies published in Hong Kong and Singapore likewise concluded that there was an association between the use of ReNu ML and Fusarium keratitis.

Suits against B & L were commenced across the United States. On August 14, 2006, the Judicial Panel on Multi-District Litigation consolidated Federal cases relating to ReNu ML for pretrial proceedings and assigned the Multi-District Litigation (MDL) to Chief Judge David Norton of the District of South Carolina in Charleston. *In re Bausch & Lomb, Inc. Contact Lens Solution Products Liability Litigation*, 444 F. Supp. 2d 1336 (J.P.M.L. 2006). The suits filed in New York State courts were consolidated before this court for joint pre-trial proceedings. A joint hearing under New York State (*Frye*) and Federal (*Daubert*) law was held to decide the admissibility of opinions by plaintiffs' experts on the issue of general causation, that is whether ReNu ML is capable of causing non-*Fusarium* infections.[1]

The plaintiffs originally had seven experts whose mechanism of action hypotheses fell into the following general categories: 1) Chemical Instability: Allegations that ReNu ML was an unstable solution due to its chemical makeup, resulting in the deactivation or unavailability of the solution's disinfectant, Alexidine, to kill microbes; 2) Biofilms: Allegations that ReNu ML's chemical makeup supported the formation of microbial biofilm communities that were more resistant to disinfectants than stand-alone microbes; 3) Polymer Films: Alleged ability of ReNu ML, absent misuse, to form a polymer film in which microbes other than Fusarium could survive; 4) Evaporation: Alleged deactivation of Alexidine after evaporation of the ReNu ML solution; 5) Temperature: Possible effects of heat during the storage and shipment of ReNu ML, which alone or in conjunction with other mechanisms allegedly deactivated Alexidine; and 6)

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[1]The joint *Frye/Daubert* hearing was held in Federal court in New York on June 3-5, 2009. The hearing was held jointly in recognition of the importance of coordinating related Federal and State litigations in order to reduce costs and delays. *See* Manual for Complex Litigation [Fourth] §§ 20, 20.31.

Corneal Toxicity: Allegations that the ReNu ML solution was harmful to human corneas, making contact-lens wearers' eyes more susceptible to infection.

With the exception of preliminary testing on fungal biofilms by one of plaintiffs' experts, plaintiffs' experts did not test their hypotheses. In their May 22, 2009 opposition to B & L's motion challenging plaintiffs' expert opinions, plaintiffs withdrew four of their seven experts, as well as their opinions. Plaintiffs relied on the remaining theories of evaporation, polymer films and biofilms. Plaintiffs also presented, shortly before and at the hearing, newer hypotheses based on: 1) a loss of efficacy theory derived from B&L's post-recall *in vitro* studies showing that under various conditions of non-compliant use, ReNu ML lost efficacy against Fusarium and the bacterium staphylococcus; and 2) a test showing the growth of a variety of microorganisms in the solution inside of opened bottles of ReNu ML obtained from the United States, Hong Kong and Singapore.

II. *The June 3-5, 2009 Hearing*

A. *Plaintiffs' Evidence*

Plaintiffs did not submit any peer-reviewed studies, articles or case reports concluding that there is a causal relationship between ReNu with MoistureLoc (ReNu ML) and non-*fusarium* infections. The New York plaintiffs submitted the opinions of the following expert witnesses: Dr. Elizabeth J. Cohen (an ophthalmologist), Dr. Michael Brown (a microbiologist) and Dr. Gerald McGwin (an epidemiologist). They rely only on these experts and their opinions.[2]

1. *Dr. Elizabeth J. Cohen*

[2]Dr. Cohen is plaintiffs' sole expert in the Federal MDL litigation.

Dr. Cohen is a Harvard Medical School graduate, a board certified ophthalmologist and a world-renowned corneal specialist. For the past 20 years, Dr. Cohen has been a Professor of Ophthalmology at the Jefferson Medical College, Thomas Jefferson University and, for the past 16 years also has served as Co-Director and then Director of the Cornea Service at the Wills Eye Hospital, Philadelphia, Pennsylvania. Additionally, Dr. Cohen has served as an Editor and/or has served on the Editorial Board as a peer-reviewer, for leading ophthalmological professional journals: Cornea, the Archives of Ophthalmology, the American Journal of Ophthalmology, Evidence-Based Eye Care and the Contact Lens Association of Ophthalmologists Journal.

She has written more than 200 peer-reviewed articles and more than 25 book chapters, almost all of which relate to her area of specialty--the cornea. She has authored several articles directly related to the issues involved in this litigation, including a Comment for the Archives of Ophthalmology entitled, *Fungal Keratitis Associated with Contact Lenses*, and articles in peer-reviewed journals such as Cornea and the Archives of Ophthalmology, entitled *Trends in Contact Lens-Associated Corneal Ulcers, An Outbreak of Fusarium Keratitis Associated with Contact Lens Use in the Northeastern United States, Fusarium Keratitis Associated with Soft contact Lens Wear, Methods of Disinfecting Contact Lenses to Avoid Corneal Disorders,* and *Contact Lens Solutions are Part of the Problem* (in press). Dr. Cohen has never published in regard to the general causation theory she posited at the *Frye/Daubert* hearing. Nor, as an administrator at the Cornea Service at Wills, did she report any rise in bacterial or non-Fusarium infections while ReNu ML was on the market.

It is Dr. Cohen's general causation opinion that ReNu ML is capable of being a

substantial contributing factor and was a risk factor in the development of non-Fusarium corneal infections, including bacterial and other fungal and microbial infections, in users of ReNu ML who developed such infections. She testified that the bases for her opinions were a number of B & L studies showing that ReNu ML lost efficacy as a disinfecting solution to kill microorganisms both in the bottle and after the bottle was opened, that it was related to evaporation and film formation that was unique to this product compared to other products tested and that the loss of efficacy involved multiple organisms.

Dr. Cohen's opinions have been provided in three written installments–an original report, a supplemental report and an affidavit provided shortly before the joint *Frye/Daubert* hearing.[3] Plaintiffs withdrew from consideration any opinions of Dr. Cohen that are inconsistent with the opinions she reaches in her affidavit, served two weeks prior to the hearing, after expert depositions were completed. B & L argues that Dr. Cohen's affidavit should be excluded because it is based on *in vitro* testing conducted by B & L that Dr. Cohen either had not reviewed or relied on for her original and supplemental reports or prior to her deposition. *In vitro* tests are laboratory tests done before animal or human testing. The parties agree that *in vitro* testing is an important first step in the process of developing a new product for human use.

Dr. Cohen's Hearing Testimony

Dr. Cohen testified that a large number of contact lens care systems are contaminated. She agreed that there is more contamination in the lens cases than there is infection in the cornea of the eye, and that it is generally accepted that the purpose of disinfecting lens care products is

[3]Dr. Cohen's affidavit is dated May 18, 2009. The *Frye* hearing took place on June 3-5, 2009.

to decrease the microbial load in order to secondarily decrease the risk of infection. In a 1996 article titled *Methods of Disinfecting Contact Lenses to Avoid Corneal Disorders* that she co-authored, Dr. Cohen wrote, "no ideal disinfection system exists for contact lens care, meticulous care of contact lenses with appropriate cleaning and disinfecting can help minimize the risk of infection."

In an earlier article titled *Patterns of Lens Care Practices and Lens Product Contamination From Contact Lens Associated Microbial Keratitis* that she co-authored in 1987, Dr. Cohen wrote, ""Recent reports have suggested several predisposing factors in the pathogenesis of infectious keratitis in contact lens wearers. These factors include contact lens overwear with hypoxic stress, contact lens contamination, inappropriate lens care practice and recent lens manipulations." Dr. Cohen's statement is attributed in part to an internal, non-peer reviewed document of B & L's titled *Inhibitions of Bacterial Attachments to Contact Lens Surfaces* in which the authors concluded that the consequences of not disinfecting lenses was an increased risk of infection, including bacteria, fungi and Acanthamoeba. Based on these reports, Dr. Cohen concluded that contact lens contamination is a predisposing factor in the pathogenesis of infectious keratitis.

In a more recent article titled *Contact Lens Solutions: Part of the Problem* that she authored, Dr. Cohen discussed the Fusarium outbreak associated with ReNu ML, concluding that standards for multipurpose solutions need to be modified and improved to increase efficacy. The article has not yet been published, but has been accepted for publication.

Dr. Cohen also referred to *in vitro* studies by B & L on the impact of noncompliant behaviors on the efficacy of ReNu ML. These *in vitro* studies included:

1) Report For the Bioburden Evaluation of Opened/Used ReNu w/MoistureLoc Bottles From Various Locations, July 2006;

2) MoistureLoc Cycling Study-Residual Alexidine Concentrations, May 2006;

3) Biocidal Testing of Varying Concentrations of Alexidine in BL-400-NRC07 Using Fusarium Solani Containing Dried Films of BL-400-NRC07 Excipients (no Alexidine), May 2006;

4) Study on the Effect of five different Hand Soaps on the Antimicrobial Efficacy of ReNu with MoistureLoc, June 2006;

5) Biocidal Efficacy of Concentrated ReNu with MoistureLoc and ReNu MultiPlus Solutions, May 2006;

6) Study on the Effect of Testing the Biocidal Efficacy of Samples of ReNu with MoistureLoc in HDPE bottles, ReNu with MoistureLoc in PET bottles (S2001label adhevise) and ReNu with MoistureLoc in PET bottles (S692 label adhesive) after Storage at 400 C, 500 C and 60° C (all at 45% RH);

7) Report for the Effect of Testing the Biocidal Efficacy of Samples of ReNu with MoistureLoc after Storage at 600 C/45% RH.

Dr. Cohen focused on B & L's findings that under conditions mimicking noncompliance, the solution could evaporate and polymers contained in ReNu ML could form a polymer film that

allowed at least one strain of Fusarium to survive subsequent disinfection.[4] In this respect, ReNu ML performed differently than other contact-lens solutions on the market. B & L also found that ReNu ML loses biocidal efficacy against Staphylococcus bacteria (Staph) when half of the water is removed from the solution or three-fourths of the water is removed from the solution. This study was one step in the experimentation that led to the company's published polymer-film theory. The portion of the study results concerning staph was not published.

Dr. Cohen also reviewed B & L's comprehensive report detailing thousands of tests done during its Fusarium investigation and the conclusions reached by the investigators. This report, titled *Contact Lens Related Fusarium Keratitis Investigation Summary* (the Fusarium Investigation Report), is nearly 1000 pages long and attaches a multitude of test reports and data considered by B & L in reaching its conclusions. A further study she relied on is a B & L document titled *Bausch and Lomb Research and Development, Why Fusarium?*, in which B & L commented that non-Fusarium infections might not be reported by clinics as much as Fusarium infections because bacterial infections are more easily treated through the use of antibiotics. Dr. Cohen agreed that you can have a moderate increase of a common and successfully treatable condition of bacterial infection without particularly noticing.

On cross-examination, Dr. Cohen admitted that she had not done any testing of ReNu ML, that she had not notified the CDC or the FDA of any increase in non-Fusarium infections during the time ReNu ML was on the market and that none of her published work had focused on the issue of non-Fusarium infections as related to ReNu ML. She was not aware of any evidence

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[4]There are at least two types of Fusarium. ReNu ML, under noncompliant conditions, worked against one strain of Fusarium.

linking ReNu ML, as opposed to other contact lens solutions, to an outbreak of Acanthamoeba or to a 4-fold increase in pseudomonas and 8-fold increase in staph in 2005 and 2006. Nor was she aware of any case control study quantifying an increased risk, if any, between ReNu ML and non-Fusarium infections.

Dr. Cohen further agreed that there was no unique presentation for a patient suffering from an infection related to ReNu ML as opposed to other contact lens solutions, and that although *in vitro* testing is relevant to compliant use, more testing is necessary to prove the applicability of any resulting hypothesis to humans. She could not say if there was an increased rate, as opposed to risk, of infection resulting from the use of ReNu ML because she did not have the data. She had not reviewed four B & L studies regarding keratitis showing either that there had not been an increase of non-Fusarium infections when ReNu ML was on the market or that they had decreased.

2. *Dr. Michael Robert Withington Brown*

Dr. Brown is a Professor of Pharmaceutical Microbiology at the University of Wolverhampton in the United Kingdom. His areas of specialty include the study of microbial survival, focusing on environmental survival and antimicrobial resistance to pathogens. Dr. Brown has had a long and illustrious career as a research scientist, teacher and author. His overarching research theme has been the study of microbial survival. Areas of expertise have mainly centered around environmental survival and antimicrobial resistance of pathogens, including preservation of formulations for the eye. His contributions have included consulting for Alcon and for the UK Department of Health, and helping accelerate the move towards single

dose, sterile preparations. He has developed an expertise in biofilms and desiccation survival and has worked with and published on cationic antimicrobial agents including biguanides such as chlorhexidine as a preservative for ophthalmic solutions and also PHMB as an antibacterial and an anti-protozoal agent.

Of the numerous scholarly scientific publications authored by him, none address the association of ReNu ML with infection of the cornea. Prior to his involvement in this litigation, Dr. Brown had absolutely no research interest in ReNu ML or the investigation into the Fusarium keratitis outbreak. He has done no experimentation with ReNu ML. Nonetheless, Dr. Brown opines that the following possible mechanism-of-actions explain how ReNu ML could have caused Fusarium and non-Fusarium infections: 1) a number of mechanisms that resulted in the reduction of ReNu ML's biocidal efficacy and/or 2) the impact of biofilm and polymers promoted microbial growth.

Dr. Brown's Hearing Testimony

Dr. Brown had reviewed the various B & L studies, the CDC's epidemiological study and other reports. He explained that evaporation of ReNu ML facilitates a biofilm, which could harbor Fusarium as well as other microorganisms. There is nothing selective about the polymer package found in ReNu ML. Organisms would be facilitated by the gel, and as it dried, the organisms would have a comfortable home within the gel. He believes that ReNu ML's loss of efficacy against an organism means there is going to be a loss of efficacy for all organisms.

On cross-examination, Dr. Brown admitted that he was just a consultant for B& L, that he had not been asked to and had not done any of his own testing and that his report and

supplemental report were based on the documents and research provided by counsel. He could not point to any study or data indicating that a non-Fusarium microorganism survived in ReNu ML film and resulted in an infection. He explained it is not that the film causes infection, but that it allows germs to multiply, which becomes a danger. He agreed that his opinion was only an hypothesis.

3. *Dr. Gerald McGwin, Jr.*

Dr. McGwin is an epidemiologist who provided an expert opinion and was deposed regarding his opinion that ReNu ML is capable of causing Fusarium infections. He testified briefly at the hearing, stating that there is no epidemiological evidence either for or against an association between ReNu ML and non-Fusarium keratitis. He further agreed there are other lines of scientific evidence that can be looked to in determining whether or not an exposure increases the risk of an outcome.

The court precluded plaintiffs from questioning Dr. McGwin at the hearing about studies B & L was claiming showed there was no association between ReNu ML and non-Fusarium infections. The basis for the court's ruling was that Dr. McGwin had not addressed the studies in his previously exchanged expert report. Plaintiffs had further represented that Dr. McGwin would at some point opine that ReNu ML is capable of causing non-Fusarium infections, but prior to the hearing, they failed to exchange a supplemental report by Dr. McGwin containing such an opinion.

B. *B & L's Evidence*

Four publications looked at non-Fusarium microbial infections during the time that

ReNu ML was on the market from August 2004 through April 2006. None of these studies demonstrated any increased incidence of non-Fusarium keratitis. For example, Acanthamoeba is an organism that can cause keratitis. There was a reported increase in the incidence of Acanthamoeba keratitis. The University of Illinois at Chicago collected and analyzed data relating to the outbreak and determined that another contact-lens solution, not ReNu ML, was associated with that outbreak.

Studies from three major eye centers in the country, the Cullen Eye Institute at Baylor College of Medicine, the Bascom-Palmer Eye Institute at the University of Miami School of Medicine and the University of California at San Francisco, surveyed keratitis during the time ReNu ML was on the market. All three institutions documented an increase in Fusarium keratitis, but none reported an increase in non-Fusarium keratitis during that time period. In fact, some of the studies showed a decrease in non-fungal infections during this period.

B & L presented reports by experts, studies and published articles. B & L has established that it conducted an extensive investigation into the possible root cause of the Fusarium outbreak. The investigation focused on three main areas: 1) Identifying any possible contamination or sterility problems with the manufacturing and production of MoistureLoc; 2) Identifying any efficacy problems with the MoistureLoc formula as packaged; and 3) Identifying any consumer-use practices that could impact the efficacy of MoistureLoc.

Because it initially appeared that many of the reported Fusarium cases stemmed from ReNu ML manufactured at B & L's facility in Greenville, South Carolina, B & L investigated the facility. There was no evidence of Fusarium contamination at the Greenville facility. Retain

(unsold solution) testing confirmed that no product from the affected lots had been contaminated in Greenville. The FDA also investigated the Greenville manufacturing facility and reached the same conclusion.

Additionally, B & L conducted thousands of biocidal-efficacy tests on ReNu ML, including testing on retains, field returns and consumer returns. This testing confirmed that ReNu ML was biocidally effective against Fusarium. Testing of unopened bottles confirmed that the solution passed FDA standards for biocidal efficacy. Opened bottles returned from consumers and from the field killed Fusarium. Testing further confirmed that ReNu ML met chemistry specifications and was stable during its shelf life.

B & L then tested the impact of noncompliant behaviors on the efficacy of the product. Anecdotal reports from Singapore and Hong Kong suggested that noncompliance was a common factor among Fusarium-infected patients in those countries. The CDC case-control study also showed that re-use of the solution was a statistically significant noncompliant behavior among Fusarium patients. B & L found that under conditions mimicking noncompliance, the polymers contained in ReNu ML could form a polymer film that allowed at least one strain of Fusarium to survive subsequent disinfection with the same product. No test data suggested that any organism other than Fusarium could survive in the dried-down polymer film.

These study results were peer-reviewed and published in December 2006 in the journal Eye and Contact Lens. B & L's conclusion was supported by an additional peer-reviewed, published study conducted by researchers at Georgia State University. In addition to its peer-reviewed publication, B & L prepared a comprehensive report detailing the thousands of tests done during the Fusarium investigation and the conclusions reached by the investigators. This

report, entitled Contact Lens Related Fusarium Keratitis Investigation Summary (the Fusarium Investigation Report), is nearly 1000 pages long and attaches a multitude of test reports and data considered by B & L in reaching its conclusions. The Fusarium Investigation Report was submitted to the FDA.

In one of the expert reports submitted by B & L, a chemical engineer named Stephen Spiegelberg commented on the theories offered by plaintiffs' experts as to why ReNu ML was associated with a higher rate of Fusarium keratitis compared to other multipurpose solutions. He refers to tests where ReNu ML components were microbially- challenged as to Fusarium solani, as well as other microorganisms. He concluded that ReNu ML was efficacious against multiple microorganisms when used according to the package label. As stated by Dr. Spiegelberg,

> The Plaintiffs' experts set forth multiple theories based on a set of mechanisms for the deactivation of MoistureLoc's preservative, Alexidine, resulting in too-little Alexidine for adequate *Fusarium* and other microorganism killing ... The various Alexidine inactivation theories proposed by the Plaintiffs' experts are all disproven by the simple experimental result that field-returned and retained bottles of MoistureLoc showed the required biocidal efficacy against all microorganisms tested.[5]

1. *Hearing Testimony of Dr. Oliver B. Schein*

Dr. Schein is both a Professor of Ophthalmology with the Wilmer Eye Institute at Johns

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[5] Dr. Spiegelberg explained that "Two hundred eighty three returns were tested for *Fusarium*, and all showed greater than 2 log kill (BL002144896-921). Testing for C. *albicans* (49 returns tested) and S. *aureus (50* tested) showed that MoistureLoc was highly effective. Eighteen hundred retained samples were tested for *Fusarium* in the bottle, and all came back negative, while 1,785 of these retains were tested for *Fusarium* killing efficacy, and all showed greater than 2.0 log kill; 99.2% showed greater than 3 log kill (BL002144836-895). Similar results were obtained for these retained samples challenged with S. *aureus,* C. *albicans, P. aeruginosa* and S. *marcescens* (BL002144836-895)."

Hopkins University and a professor of the Department of Epidemiology at Bloomburg Johns Hopkins School of Public Health. He is board certified in both internal medicine and in ophthalmology. His clinical expertise is in cornea and external disease. He spends approximately 60 % of his time taking care of medical and surgical conditions, and 40 % in research and administration with his focus on epidemiology and public health clinical trials. The primary focus of his research career has been the epidemiology of eye diseases, with the principle areas being infections related to contact lenses, cataracts, and dry eye. He has published extensively.

Dr. Schein has been a consultant for B & L for ten or eleven years. He was familiar with ReNu ML before he became an expert in this litigation. After reports of Fusarium infections started coming in, he advised B & L to undertake a case control study. However, the CDC undertook such a study first. At the request of Dr. Levy from B & L, Dr. Schein put together a panel of people with expertise in corneal disease and fungi.

During the course of the panel's investigation, it never learned of reports of increased incidents of non-Fusarium infections or anything other than Fusarium associated with ReNu ML. In Dr. Schein's opinion there is no evidence of an association between ReNu ML and non-Fusarium infections in humans. Such an association is not generally accepted in the scientific community. He has not even heard of an hypothesis to that effect outside of the legal context. Dr. Schein conceded that you could miss less serious and more easily treated infections, but explained there was not even speculation of an outbreak of more serious non-Fusarium infections outside of this litigation.

He described the various studies and reports that support his opinion. Singapore had reported an outbreak of Fusarium and Acanthamoeba, but not Staph, Strep, Serratia,

Pseudomonas, Candida or Aspergillus. It also did not report a link between ReNu ML and Acanthamoeba. In a study at the Bascom and Palmer Eye Institute, it was reported there had been a decrease in non-fungal infections during the relevant period. In a study at the Cullen Eye Institute, it was reported that only Fusarium infections had been detected. In a mathematical modeling study at the University of California at San Francisco going back 20 years at a single institution (the Sansanayudh article), only Fusarium and Acanthamoeba outbreaks were picked up. In a study on Acanthamoeba at the University of Illinois, they detected an excess risk associated with the contact lens solution AMO Complete Moisture Plus, but not with B & L solutions. In data from the Hong Kong Center for Health Protection, it reported an excess of only Fusarium cases. In another paper, it was reported that in a single hospital in Hong Kong, fungal infections had increased and bacterial infections had decreased.

With respect to B & L's *in vitro* studies, Dr. Schein explained that extrapolating from *in vitro* testing to human clinical disease is not generally accepted in the scientific community. He had no problem with the concept of reducing the bioburden, but he did have a problem with the concept that you can predict who will get an infection from either preclinical testing or from the fact that you have a high rate of contamination in contact lens cases.

The cross-examination of Dr. Schein focused on the *in vitro* studies and the study by B & L's Dr. Levy that yielded data showing an increase in Staph. On being asked why the Staph component of Levy's study was not published, Dr. Schein responded, "I think companies are much more likely not to publish internal laboratory work than to publish it." Dr. Schein also acknowledged the limited nature of the studies demonstrating that there had not been an increase of non-Fusarium infections.

III. *Conclusions of Law*

In determining the admissibility of questioned expert testimony at trial, New York continues to adhere to the standard set forth in *Frye v. United States*, 293 F. 1013 (D.C. Cir. 1923). *People v. Wesley*, 83 N.Y.2d 417, 424, n.2 (1994) (Court specifically noted *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993) standard was not applicable in New York). As the *Frye* Court stated, "when a scientific principle or discovery crosses the line between the experimental and demonstrable stages . . . the evidential force of the principle must be recognized, and while courts will go a long way in admitting expert testimony deduced from a well-recognized scientific principle or discovery, the thing from which the deduction is made must be sufficiently established to have gained general acceptance in the particular field in which it belongs." From this discussion grew the evidentiary *Frye* test, permitting an expert to testify regarding novel scientific principles, procedures or theories if they have gained general acceptance in the relevant scientific community. *See People v. Wernick*, 89 N.Y.2d 111, 114 (1996); *Zito v. Zabarsky*, 28 A.D.3d 42 (2d Dept. 2006).

The issue of admissibility here does not concern a novel scientific technique, but rather a novel theory of causation. Plaintiffs' experts have opined that ReNu ML is capable of causing non-Fusarium infections when there are no scientific studies or case reports even suggesting such a possibility. They seek to extrapolate from *in vitro* and Fusarium studies to establish their theory of general causation. Under these circumstances, the inquiry focuses on whether the methodologies employed by the plaintiffs' experts lead to a reliable theory or opinion on causation. *See Parker v. Mobil Oil*, 7 N.Y.3d 434, 447-448, *rearg. denied* 8 N.Y.3d 828 (2007). This inquiry "is more akin to whether there is an appropriate foundation for the experts' opinions,

rather than whether the opinions are admissible under *Frye*." *Id.*; *cf. Matter of Neurontin Prod. Liab. Litig.*, 2009 N.Y. Misc. LEXIS 1777 (N.Y. Sup. Ct. May 15, 2009) (court found plaintiffs' expert opinions, that neurontin capable of causing plaintiffs or decedents to undergo suicide-related events, sufficiently reliable) (Friedman, J.).

Cases considering the admissibility of a plaintiff's theory of causation, both before and after *Parker*, have adopted the formulation that the plaintiff's burden is to prove that her "expert's theory is generally accepted" in the relevant scientific community. *Lara v. New York City Health & Hosps. Com.*, 305 A.D.2d 106 (1st Dept. 2003) (theory that precipitous delivery can cause infant cerebral palsy); *Marsh v. Smyth*, 12 A.D.3d 307 (1st Dept. 2004) (theory that hyperabduction of arm was cause of nerve palsy); *Pauling v. Orentreich Med. Gp.*, 14 A.D.3d 357 (1st Dept.), *lv. denied* 4 N.Y.3d 710 (2005) (theory that facial injections of silicone can cause silicone toxicity); *Heckstall v. Pincus*, 19 A.D.3d 203 (1st Dept. 2005) (theory that Bupropion, a smoking cessation aid, can cause arrhythmia); *Fraser v. 301-52 Townhouse Com.*, 57 A.D.3d 416 (1st Dept. 2008) (theory that mold can cause respiratory diseases).

The courts have consistently held that the *Frye* requirement of a generally accepted theory does not impose a rule "that a jury may hear only theories that are either 'conclusively established' by the scientific literature or unanimously supported by the scientific authorities." *Fraser, supra*, 57 AD3d at 418 n 2 (internal brackets omitted). Thus, "general acceptance does not necessarily mean that a majority of the scientists involved subscribe to the conclusion. Rather it means that those espousing the theory or opinion have followed generally accepted scientific principles and methodology in evaluating clinical data to reach their conclusions." *Zito v Zabarsky, supra*, 28 A.D.3d at 44 (causation opinion on whether Zocor can cause autoimmune disease), quoting

Matter of Rezulin Litigation , 2002 NY Slip Op 40431[U] * 6-7 (Sup. Ct., New York County) (Freedman, J.) (causation opinion on whether Rezulin can cause cirrhosis of liver). *Accord Matter of Bextra & Celebrex*, 2008 N..Y Misc Lexis 720 (Sup. Ct., New York County) (Kornreich, J.) (causation opinion on whether Celebrex increases risk of heart attacks or strokes at various doses).

As originally stated in *Frye* and reaffirmed in *Wesley*, the court must determine whether the experts' deductions are "based upon a scientific principle or procedure which has been sufficiently established to have gained general acceptance in the particular field in which it belongs." *Marso v. Novak*, 42 A.D.3d at 378, quoting *Wesley*, 83 NY2d at 423. The court must guard against the danger of allowing unreliable information or "junk science" to go before a jury, without imposing "an insurmountable standard that would effectively deprive toxic tort plaintiffs of their day in court." *Parker, supra,* 7 N.Y.3d at 447.

A. *Are Plaintiffs' Experts Qualified?*

"The admissibility and scope of ... [expert] testimony is addressed to the trial court's sound discretion." *Hudson v Lansingburgh Cent. School Dist.*, 27 AD3d 1027, 1028-1029 (3d Dept. 2006). An expert must not only be qualified (*see Frye supra),* the expert must be qualified in the *specific* area in which she is offering an opinion. *See Rosen v. Tanning Loft*, 16 A.D.3d 480, 481 (2d Dept. 2005) (excluding opinion testimony of engineer who, although licensed, had no "specialized knowledge, experience, training, or education with regard to tanning equipment so as to qualify him as an expert in the area").

B & L argues that while Dr. Cohen is qualified in ophthalmology and Dr. Brown in pharmaceutical microbiology, any testimony beyond their areas of expertise should be excluded.

However,"[n]o precise rule has been formulated and applied as to the exact manner in which [an expert's] skill and experience must be acquired. Long observation and actual experience, though without actual study of the subject, qualify a witness as an expert in that subject." *Meiselman v. Crown Heights Hosp.*, 285 N.Y. 389, 398 (1941); *see also Caprara v. Chrysler Corp.*, 52 N.Y.2d 114, 121, *rearg. denied* 52 N.Y.2d 1073 (1981) (expert's competency can be derived just as well "from the real world of everyday use" as from laboratory).

Plaintiffs' experts have long and impressive *curricula vitae*. Dr. Cohen is a respected clinician with a specific expertise in diseases of the cornea. She has authored numerous articles that required her to review and comprehend complex data and research studies. The fact that she is not a research scientist herself does not preclude her from testifying as an expert in this case where the issues involve potential causes for certain diseases of the cornea. Nor will the court exclude Dr. Brown who is a world renowned microbiologist. The real issue facing the court is the paucity of evidentiary substantiation for these experts' opinions, not their qualifications to render them in the first instance.

B. *Reliability of Plaintiffs' Expert Opinions*

Plaintiffs' experts have not cited a single case report, clinical study, epidemiological study, or published and peer reviewed article, concluding as they do, that ReNu ML is capable of causing non-Fusarium infections. Indeed, Dr. Brown admitted that his opinion is nothing more than an hypothesis. The inquiry could end here. *See Pauling v. Orentreich Med'l. Group*, 14 A.D.3d 357 (1st Dept.), *lv. denied* 4 N.Y.3d 710 (2005) (plaintiff failed to meet burden of proof at *Frye* hearing where no medical literature submitted to support theory and no scientific or medical board recognized causal relationship); *Marsh v. Smyth*, 12 A.D.3d 307(1st Dept. 2004)

(*Frye* test met where expert's deductions were supported by medical literature); *Saulpaugh v. Krafte*, 5 A.D.3d 934 (3d Dept.), *lv. denied* 3 N.Y.3d 610 (2004) (broad statement of scientific acceptance without accompanying support, insufficient to establish scientific acceptance of theory); *Lara v. N.Y.C. Health and Hosp. Corp.*, 305 A.D.2d 106 (1st Dept. 2003) (*Frye* test not met where no reported medical cases or formal studies supported theory); *Selig v. Pfizer, Inc.*, 290 A.D.2d 319 (1st Dept.), *lv. denied* 98 N.Y.2d 603 (2002) (where clinical data did not support expert's theory of causal link and expert failed to set forth other scientific evidence based on accepted principles to support causal link, expert precluded); *Stanski v. Ezersky*, 228 A.D.2d 311 (1st Dept.), *lv. denied* 89 N.Y.2d 205 (1996) (absence of single reported case supporting expert's theory required dismissal of case). Nonetheless, the court will briefly address plaintiffs' theories.

Plaintiffs attempt to bootstrap their experts' opinions by extrapolating from scientific data and published reports and studies showing an association between ReNu ML and Fusarium, *in vitro* studies and general theories that an increase in the microbial load can result in an increased risk of infection. For the reasons stated below, this exercise is more a leap of faith than a scientifically reliable analysis. The end product is the very "junk science" that the court is required to exclude.

Foremost, the extrapolation theories upon which plaintiffs' experts rely are not generally accepted in the relevant scientific community. First, Dr. Cohen and Dr. Brown extrapolate from in vitro testing by B & L to real world causation in formulating their opinions. Both plaintiffs' and B & L's experts, however, agreed that in vitro tests are only the first step; animal studies followed by human trials are necessary to determine the applicability of an hypothesis to humans. Indeed, Dr. Brown termed his opinion an hypothesis. Further, in all but one of the *in vitro* tests,

the reduction in efficacy occurred with other contact lens solutions and not just ReNu ML. Plaintiffs also attempt to establish that non-Fusarium infections were caused by ReNu ML by extrapolating from the scientific tests and data showing that ReNu ML is capable of causing Fusarium infections. Proof of one is not proof of the other. *See Matter of Bextra & Celebrex*, 2008 N..Y Misc Lexis 720 (Sup. Ct., New York County) (rejecting extrapolation of general causation from other COX-2 drugs to Celebrex, and from higher doses of Celebrex to lower doses). In fact, only one type of Fusarium survived in the polymer film when treated with a fresh dose of ReNu ML.

Nor is Dr. Cohen's loss of efficacy hypothesis reliable or generally accepted. Because some tests showed that under certain conditions ReNu ML loses efficacy as to some microbial organisms, Dr. Cohen opined that the risk of infection is increased. This, however, does not establish that ReNu ML is capable of causing non-Fusarium infections. Plaintiffs have not established a threshold microbial level or "load" necessary to actually cause the onset of a non-Fusarium infection. *See Matter of Bextra & Celebrex, supra,* (finding evidence insufficient to show general causation of cardiovascular injury at 200 mg dose of Celebrex); *see also Fraser, supra,* 57 A.D.3d at 419-420 (experts not establish threshold level of mold capable of causing alleged injuries).

Dr. Cohen admits that she does not have the data to establish that an increase in contamination resulted in an increase in infection. Her published literature demonstrates her recognition that there is no general acceptance of her theory. In an article co-authored by Dr. Cohen, entitled *Methods of Disinfecting Contact Lenses to Avoid Corneal Disorders*, the authors discuss contamination of lens-care systems with microorganisms, noting the high rate of

contamination among contact-lens wearers. The authors observe "contamination is not consistently correlated with a higher rate of microbial keratitis."

Plaintiffs' experts were provided with samples of ReNu ML by B & L, but they failed to conduct their own tests. Indeed, Dr. Brown, a leading microbiologist, testified that he was hired by plaintiffs to testify but was not asked to do any testing. Nor were tests done by B & L or the CDC or anyone else to determine whether ReNu ML was causing non-Fusarium infections. Those tests were not done for the simple reason that there was no reported outbreak of non-Fusarium infections.

Finally, the testing that was done did not yield data showing any association between ReNu ML and non-Fusarium infections. The drying down polymer test that B & L's Dr. Levy published showed only that one type of Fusarium could survive in the resulting polymer film. Plaintiffs' experts, in fact, ignored testing that supports the lack of an association between ReNu ML and non-Fusarium infections. In thousands of tests conducted by B & L as part of its Fusarium investigation, ReNu ML remained biocidally effective against a multitude of organisms. Four separate studies showed that although the use of ReNu ML resulted in an increase of Fusarium infections, it did not result in an increase in non-Fusarium infections and those infections were reduced in one study. For these reasons, the general causation opinions by plaintiffs' experts do not meet the *Frye* standard.

C. *Exclusion of Dr. Cohen's Affidavit*

The court does not reach the merits of this issue because inclusion of the challenged evidence does not change the result of B & L's motion. Accordingly, it is

ORDERED that defendant Bausch & Lomb's motion to exclude the general causation opinions of plaintiffs' experts as to non-Fusarium infections is granted; and it is further

ORDERED that defendant Bausch & Lomb's application to exclude the affidavit of Dr. Cohen is denied as moot.

ENTER

J.S.C.

Date: July 14, 2009