Return Date: October 9, 2001

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

PHARMACIA CORPORATION, PHARMACIA AB, PHARMACIA ENTERPRISES S.A. AND PHARMACIA & UPJOHN COMPANY, Plaintiff, v. ALCON LABORATORIES, INC., Defendant.	Civ. No. 01-1539 (WGB)

MEMORANDUM IN SUPPORT OF MOTION IN LIMINE TO EXCLUDE EXPERT OPINION TESTIMONY

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PRELIMINARY STATEMENT

Rather than submit the kind of the factual evidence required by courts in trademark injunction proceedings, Pharmacia relies on five expert opinions. It does so because its allegations about irreparable harm -- the wave of confusion and medication errors that was supposed to ensue once Alcon's TRAVATAN glaucoma treatment reached the market -- have not come to pass. In the six months that Pharmacia's Xalatan and Alcon's TRAVATAN prescription medications have coexisted, Pharmacia has been unable to identify a single instance of confusion or medication error.

This "alternative" evidence, however, is inadmissible because Pharmacia's five "expert" opinions do not pass muster under the Supreme Court's test for expert testimony as applied in this Circuit. *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 592-93 (1993); *Elcock v. Kmart Corp.*, 233 F.3d 734, 741 (3d Cir. 2000); *Milanowicz v. Raymond Corp.*, 148 F. Supp. 2d 525, 532-22 (D.N.J. 2001). Even accepting this testimony, but giving it little weight, would set an unfortunate precedent in trademark law: There are ***no*** reported decisions in which opinions of the sort offered by Pharmacia were accepted as a substitute for marketplace facts of either trademark dilution or confusion.[1]

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[1] A ruling by the Court on this motion *in limine* in advance of the December 17, 2001 return date also will significantly clarify the respective burdens of the parties in connection with the preliminary injunction hearing. Moreover, Alcon reserves the right to later challenge the qualifications of Pharmacia's experts but, for purposes of this motion *in limine*, assumes they meet the standards of Fed. R. Evid. 702.

I. BACKGROUND

The first of Pharmacia's experts, Dr. Stephen Obstbaum, has been a Pharmacia consultant for 14 years and is currently paid $190,000 per year for his services. Hogan Decl. Ex. 1 (Obstbaum Tr. 43-44, 105). Dr. Obstbaum opines that:

- "the TRAVATAN name is very similar to the XALATAN name," Hogan Decl. Ex. 2 (Obstbaum Decl. ¶ 14);
- "there is a likelihood that medication substitution could occur, because of the substantial similarity" of the names, *id.* ¶ 15; and
- "a medication error by which a pregnant woman patient receives TRAVATAN rather than XALATAN can pose a health risk to that patient." *Id.* ¶ 16.

Dr. Obstbaum's deposition confirmed what is apparent from his slender declaration. In formulating these opinions, he conducted absolutely no empirical or other research: They are based solely on his "subjective belief." Obstbaum Tr. 59-61 (subjective opinion regarding name similarity); 72-74 (subjective belief regarding possibility of medication error). In fact, although willing to volunteer his personal view about the purported risk to pregnant women from TRAVATAN, he actually had "no idea" about the actual nature of this risk; "I have not done this research myself [and] have no experience using the drug . . . nor have I done any of the animal studies." *Id.* at 149-50. His opinion was based solely on the warning language "in the [TRAVATAN] package insert." *Id.* at 150.[2]

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[2] ***Both*** TRAVATAN and Xalatan are characterized by the FDA as Pregnancy Category C medications. *See* 21 C.F.R. § 201.57(f)(6)(i)(c) (studies on animals show adverse effects on fetus; use in pregnant women only if "potential benefit justifies potential risk to the fetus"); Hogan Decl. Ex. 15 (package inserts for both

Dr. Eisenberg, another physician with an undisclosed business relationship with Pharmacia, Hogan Decl. Ex. 3 (Eisenberg Tr. 35, 43-49), opined that:

- "it is not unreasonable to anticipate a confusion between XALATAN and TRAVATAN" and
- that the FDA's approval of the TRAVATAN was based on "reasoning" that "no longer holds." Hogan Decl. Ex. 4 (Eisenberg Decl. ¶¶ 5-6).

Dr. Eisenberg admitted, however, that he conducted no empirical investigation regarding confusion and had no experience in trademark matters or the FDA name-clearing process. Eisenberg Tr. 66-67, 100-03. In short, he too based his opinion solely on his subjective evaluation of the trademarks and a summary FDA report given to him by Pharmacia's lawyers.[3] Eisenberg Tr. 95-96.

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products). Despite Pharmacia's suggestions to the contrary, there is no evidence that the pregnancy risk of TRAVATAN is any greater than that of Xalatan. *See, e.g.*, Obstbaum Tr. 151-52, 154 (admitting to having "no idea" of the risks of Xalatan to pregnant women and to having prescribed Xalatan to pregnant women); Hogan Decl. Ex. 16 (Harfstrand Tr. 30-31) (Pharmacia's characterization of the risk was based only on "what it says in the [TRAVATAN] package insert").

[3] This report was prepared by the FDA's Office of Post-Marketing Drug Risk Assessment ("OPDRA") when Alcon was considering launching with two concentrations – .0015% and .004% travoprost solution. Eisenberg Decl. Ex. 2. That Alcon went to market with only one concentration -- which the FDA knew, as it approved only one concentration of TRAVATAN -- in no way invalidates the FDA's research showing no likelihood of confusion. The OPDRA report makes clear that, even when no concentration is specified, (a) TRAVATAN was correctly interpreted 91% of the time and (b) at no time were there any "*erroneous interpretations of this proprietary name with other U.S. marketed drug products*," including Xalatan. *See id.* at 4 ("D/C TRAVATAN today").

George Di Domizio, the third of Pharmacia's experts, is a retired trademark manager.[4] In his opinion:

- "[t]he name TRAVATAN is similar to XALATAN," Hogan Decl. Ex. 5 (First Di Domizio Decl. ¶ 14);
- "[t]his similarity . . . leads me to conclude that medication errors between the two products are likely to occur," *id.*; and
- "[t]here is no reasonable basis to assume that [Alcon's] decision to use ATAN was accidental or coincidental." Hogan Decl. Ex. 6 (Second Di Domizio Decl. ¶ 7).

Mr. Di Domizio's declaration is a remarkable document. He opines on the ultimate legal issue the Court must decide in this case, likelihood of confusion, Even though he has only a layperson's understanding of infringement. (Di Domizio Tr. 23). He opines on that legal issue unencumbered by any facts regarding the efforts Alcon took to clear the TRAVATAN mark. (Di Domizio Tr. 124). Moreover, Mr. Di Domizio, like Drs. Obstbaum and Eisenberg, engaged in no empirical research in making his judgments about name similarity and Alcon's good faith. In fact, his declaration does not even address the prevalence of the "TAN" and "AN" suffixes in the pharmaceutical industry or possible confusion among healthcare professionals.[5]

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[4] The deposition of Mr. Di Domizio was set for September 12, 2001 in Manhattan. For obvious reasons, it had to be postponed until Friday, September 14 and was moved to Pharmacia's New Jersey offices. Rough transcript citations from Mr. Di Domizio's deposition are attached to the Declaration of Michael Potenza. ("Potenza Decl." Ex. 1).

[5] For example, "AN" is the ninth most common suffix among generic names for pharmaceutical products and the sixth most common suffix among registered trademarks in U.S. Category 018 (Medicines and Pharmaceutical Preparations) and

The opinion offered by Pharmacia's fourth expert, Dr. Bruce Lambert, also goes to the ultimate legal issue in this case. Hogan Decl. Ex. 11 (Lambert Decl. ¶ 8). Dr. Lambert's views differ from Mr. Di Domizio's only in that they appear to have a veneer of scientific certainty because they purport to be based on a statistical model. In fact, Dr. Lambert's published work concedes that the real world predictive value of his model is "poor." More importantly, no reported trademark opinion has ever admitted, much less relied on, this type of abstract model as a substitute for marketplace facts, particularly when, as here, those facts show no confusion has occurred. Admitting and relying on Dr. Lambert's opinion would effectively second-guess the FDA, which approved the TRAVATAN mark only after conducting tests that simulate real world clinical conditions in order to determine whether confusion would be likely.

Pharmacia's fifth expert opinion is that of Walter McCullough, who conducted a survey purporting to measure whether TRAVATAN dilutes the Xalatan mark.[6] In that survey, 199 ophthalmologists were shown a box of TRAVATAN and asked what other products, if any, were brought to mind. Hogan Decl. Ex. 13 (McCullough Decl. Ex. 1, at 5). Should a respondent answer Xalatan, they repeatedly were asked "why" Xalatan

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International Category 005 (Pharmaceuticals). Hogan Decl. Ex. 7 (Bruce L. Lambert et al., "Descriptive Analysis of the Drug Name Lexicon," 56 Drug Information J. 163, 170 Tbl. 3 & 171 Tbl. 4 (2001)).

6 Incredibly, despite also claiming in its complaint that the TRAVATAN mark will cause confusion, Pharmacia did not commission a survey to measure the likelihood of confusion -- a form of survey that is widely used in trademark infringement litigation and regularly accepted by courts.

came to mind. *Id.* Any answers that indicated "name similarity" -- even those indicating the similarity was based on the respective generic names of the products -- were coded in Pharmacia's favor as dilution responses.

The survey also had a much smaller control cell, where 112 ophthalmologists were shown a box of Lumigan, a competing drug marketed by Allergan, Inc. *Id.* at 6. After netting out the dilution or "noise" results of the control cell, Mr. McCullough opined that 14.5% of respondents thought TRAVATAN brought Xalatan to mind because of similarities in the trade names. *Id.*; Hogan Decl. Ex. 8 (McCullough Tr. 134).

Mr. McCullough's opinion must be excluded because, under black letter law, fundamental flaws in his survey render its results unreliable and inadmissible. First, it was not conducted in a true double-blind fashion in that at least two interviewers were aware of this litigation. Second, because the generic names for TRAVATAN (travoprost), Xalatan (latanoprost) and Lumigan (bimatoprost) all end in "oprost" and are prominently displayed on the front of the product packages, it was impossible for Mr. McCullough to know which of the trademark "dilution" responses were based on the "name similarity" of the generic names, as opposed to the brand names. Moreover, the survey excluded important elements of the market population and was not designed to ensure a representative sample of that population. McCullough Tr. 208-9, 213-14.

II. ARGUMENT

Rule 702 permits the admission of expert testimony only if "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue" and if "(1) the testimony is based upon sufficient facts or data,

(2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." Under *Daubert* and *Kumho Tire Co. v. Carmichael*, 526 U.S. 137 (1999), the expert must be qualified to express an expert opinion, the opinion must fit expertise to facts and the opinion must be reliable. *See Elcock*, 233 F.3d at 741; *Milanowicz*, 148 F. Supp. at 530-31.

A. The Expert Opinions Of Mr. Di Domizio, Dr. Obstbaum And Dr. Eisenberg Are Inadmissible.

1. The Opinions Are Based Solely On Subjective Belief.

"An expert's opinion is ***reliable if*** it is ***based on*** the methods and procedures of ***science rather than on subjective belief*** or unsupported speculation; the expert must have good grounds for his or her belief." *Elcock Corp.*, 233 F.3d at 745 (quoting *In re Paoli R.R. Yard PCB Litig.*, 35 F.3d 717, 742 (3d Cir. 1994) (emphasis added) and *Daubert*, 509 U.S. 579, 590 (1993)) (internal quotation marks omitted). An expert must "show how his conclusion . . . is grounded in – follows from – an expert study of the [issue]." *Navarro v. Fuji Heavy Industries, Ltd.*, 117 F.3d 1027, 1032 (7th Cir. 1997). If it is without any actual study of the issue, it is, by definition, "not one based on expert knowledge and [not] entitled to the dignity of evidence." *Id.* at 1031.

Pharmacia's so-called expert testimony regarding confusion epitomizes the type of "subjective belief" and "unsupported speculation," *Elcock*, 233 F.3d at 734, that the Court, in its gate-keeper role, should exclude. Indeed, the admittedly subjective

evaluations of Drs. Obstbaum and Eisenberg[7] left them unable to evaluate the confusion potential between Xalatan and Pharmacia's yet-to-be approved glaucoma drug "Xalcom," even though Xalcom has as many, if not more, of the characteristics they identify as making confusion between Xalatan and TRAVATAN likely.[8] *See* Obstbaum Tr. 143-44 (any prediction would be "purely speculative"); Eisenberg Tr. 92-93 (unsure whether pharmacist could misread Xalatan for Xalcom). Their professed inability to evaluate the confusion that might result from Xalcom means the methodology they applied to evaluate TRAVATAN cannot be relied on. *See Elcock*, 233 F.3d at 747-48 (methodology unreliable when expert does not explain how he or she excludes other variables and results could not be reproduced); *In re TMI Litig.*, 193 F.3d 613, 703-04 (3d Cir. 1999) (expert's unexplained weighing of various factors is subjective and unreliable). Their opinions, therefore, do nothing to assist the finder of fact and are inadmissible. *Elcock*, 233 F.3d at 747-48 (finding vocational rehabilitationist's testimony unreliable where

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7 Obstbaum Tr. 59-61 ("subjective opinion" regarding name similarity); 72-74 ("subjective belief" regarding possibility of medication error and name similarity); 149-50 ("no idea" whether TRAVATAN has greater adverse effect among pregnant women than Xalatan); Eisenberg Tr. 73-79 (opinion not based on any research or other empirical investigation); *cf. In re TMI Litig.*, 193 F.3d 613, 680 (3d Cir. 1999) (expert whose only knowledge of health effects was literature reviewed for litigation "plainly" unqualified). Mr. Di Domizio's views suffer from the same subjective analysis. Di Domizio Tr. 70 – 72 (agreeing his view of confusion between TRAVATAN and Xalatan was a "judgment call" on which "different people" could "reach different judgments.")

8 In addition to starting with the same prefix and being prescribed for the same condition as Xalatan, Xalcom also has the same manufacturer's label and is stored in the same area of the pharmacy as Xalatan, unlike TRAVATAN, *which does not require refrigeration.*

witness did not explain standards used to reach his conclusion); *Milanowicz*, 148 F. Supp. at 540-41 (D.N.J. 2001) (finding expert testimony that "employed no defined methodology and did not provide 'good grounds' for the conclusion" unreliable and therefore inadmissible); *Lithuanian Commerce Corp., Ltd. v. Sara Lee Hosiery*, 179 F.R.D. 450 (D.N.J. 1998) (finding an expert opinion had "an inadequate foundation" and therefore "unreliable and inadmissible"); *Huey v. United Parcel Serv., Inc.*, 165 F.3d 1084, 1087 (7th Cir. 1999) ("expertise" in a topic is insufficient to make "expert" opinion admissible; expertise must be applied in analysis).[9]

2. The Experts Have No Specialized Trademark Knowledge.

"[A]t a minimum, a proffered expert witness . . . must possess skill or knowledge greater than the average layman." *American Tech. Resources v. United States*, 893 F.2d 651, 656 (3d Cir. 1990); *see also Aloe Coal Co. v. Clark Equip. Co.*, 816 F.2d 110, 114 (3d Cir. 1987); *Surace v. Caterpillar, Inc.*, 111 F.3d 1039, 1055 (3d Cir. 1997) (a proffered witness fails to qualify as an expert if he or she does not possess the requisite training or experience in the particular area for which he or she is being offered to give testimony).

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[9] *See also McMahon v. Bunn-O-Matic Corp.*, 150 F.3d 651, 657 (7th Cir. 1998) (rejecting, as an inadmissible "naked opinion" testimony of a qualified expert who offered "only a bare conclusion" without any supporting data or rationale); *Minasian v. Standard Chartered Bank,* PLC, 109 F.3d 1212, 1216 (7th Cir. 1997) ("legal analysis in the guise of [medical] expertise" defines "everything that is bad about expert witnesses in litigation"); *id.* ("an expert's report that does nothing to substantiate th[e] opinion is worthless, and therefore inadmissible").

Although they may be qualified to opine on ophthalmic issues, neither Dr. Obstbaum nor Dr. Eisenberg has had any experience in trademark-related matters or in the FDA clearance process for pharmaceutical trademarks. Obstbaum Tr. 66-67; Eisenberg Tr. 96, 100-04. Neither surveyed or conducted any other empirical research on the reactions of ophthalmologists, optometrists or pharmacists, Obstbaum Tr. 59-61; Eisenberg Tr. 73-75, and neither has knowledge of the number of similar pharmaceutical trademarks, Obstbaum Tr. 60; Eisenberg Tr. 74. Neither was familiar with the major medical error reporting systems that track and evaluate medical errors. Obstbaum Tr. 73-74; Eisenberg 78-79. In fact, notwithstanding the view he expressed in his declaration regarding the FDA's reasons for approving the TRAVATAN mark, Dr. Eisenberg was unwilling to state that the FDA would have reached a different conclusion had it evaluated the mark in connection with only one concentration of the drug: He simply did not know. Eisenberg Tr. 100-101.

Similarly, Drs. Obstbaum and Eisenberg lack any specialized knowledge regarding whether medication errors are likely to be caused by optometrists or by pharmacists misfilling prescriptions. *See* Obstbaum Tr. 62 (admitting that he would not "under normal circumstances" hear of such pharmacist medication errors); Eisenberg Tr. 70-72, 74 (no surveys of pharmacists; no opinions on whether ophthalmologists or optometrists would be confused); *see also In re TMI Litig.*, 193 F.3d at 671-72, 680 (affirming district court's exclusion of meteorologist's testimony "about issues other than the relevant weather conditions" because meteorologist was not an expert in such areas as radiation dose reconstruction). As for the cryptic references by Dr. Eisenberg and Mr. Di

Domizio to other medication errors, it is clear from their declarations that they are conveying anecdotal evidence and not opinions based on scientific or methodological research. Neither offers anything empirical in connection with this issue. *See also In re TMI Litig.*, 193 F.3d at 673-74 (opinion based on anecdotal evidence properly excluded).[10]

3. The Expert Testimony Impermissibly Opines On The Ultimate Legal Issue.

The testimony of Dr. Obstbaum, Dr. Eisenberg and Mr. Di Domizio regarding trademark confusion also should be excluded because they opine on the ultimate legal issue in this case – the likelihood of trademark confusion.

Under Fed. R. Evid. 702 and 704(a), an expert can testify as to any ***factual*** issues, even ultimate factual issues, provided that the testimony is helpful to the trier of fact and otherwise admissible. "Neither rule, however, permits expert witnesses to offer conclusions of law." *C.P. Interests, Inc. v. California Pools, Inc.*, 238 F.3d 690, 697 (5th Cir. 2001) (Garza, J.) (error to admit expert testimony on "ultimate issues to be decided by the jury" in trademark case).

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[10] Dr. Obstbaum's unique take on this issue, which he characterizes as "medication substitution," Obstbaum Decl. ¶ 15 -- *i.e.*, doctors knowingly prescribing TRAVATAN instead of Xalatan because both treat glaucoma, Obstbaum Tr. 72 -- is irrelevant to any issue in this trademark case and therefore inadmissible. *In re TMI Litig.*, 193 F.3d at 665 (admissibility depends on connection between expert testimony and disputed fact).

Dr. Obstbaum, Dr. Eisenberg and Mr. Di Domizio all cross this line.[11] Obstbaum Tr. 75-76 (opining that it is "possible" doctors will be confused by names); Eisenberg Decl. ¶ 6 ("it is not unreasonable to anticipate a confusion between XALATAN and TRAVATAN"); Di Domizio Decl. ¶¶ 11, 14 (opining on likelihood of "confusion over the similarity of drug names"). Because there can be no dispute that likelihood of confusion is a legal issue – indeed, the central legal issue in a trademark case – these opinions should be excluded. *See Playboy Enters., Inc. v. Terri Welles, Inc.*, 78 F. Supp. 2d 1066, 1081-82 (S.D. Cal. 1999) ("Expert testimony consisting of legal conclusions regarding the 'likelihood of confusion' or Ms. Welles' 'descriptive use' are inappropriate subjects for expert testimony and as such, are inadmissible"); *see also Whitmill v. City of Philadelphia*, 29 F. Supp.2d 241, 246 (E.D. Pa. 1998) ("As a general rule an expert's testimony on issues of law is inadmissible").

B. The Lambert Statistical Model Is Unreliable.

In addition to opining on the ultimate legal issue, Lambert Decl. ¶ 7, Dr. Lambert's opinion should be excluded because it is unreliable. One critical measure of reliability of scientific evidence it its "error rate." *Daubert*, 509 U.S. at 580. Dr. Lambert has admitted in published articles that the very same methods he employed in reaching his opinion in this case have "poor positive predictive value" and error rates that are "too high" to be relied on "as the sole basis for regulatory decisions." Hogan Decl.

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[11] Dr. Lambert's testimony, discussed *infra*, should be excluded for this reason as well. *See* Lambert Decl. ¶ 7 ("I concluded the similarities"... are substantial... "suggesting a strong likelihood of confusion").

Ex. 12 (Bruce L. Lambert et al., "Similarity as a Risk Factor in Drug-Name Confusion Errors," 37 Medical Care 1214, 1223 (1999) (hereinafter "Lambert 1999")). It is difficult to conceive of a more direct admission of unreliability. For this reason alone, Dr. Lambert's opinion should be excluded.

Dr. Lambert's declaration attempts to fudge this issue by claiming his model can distinguish "error pairs" from "closely matched control pairs" with 99% accuracy. Lambert Decl. Ex. 2 at 5, 7. This does ***not*** mean that it can predict whether TRAVATAN and Xalatan ever will be confused in the real world, as Dr. Lambert conceded at his deposition. Hogan Decl. Ex. 9 (Lambert Tr. 145). Putting aside the myriad real world factors, such as differences in prescribing physicians' handwriting, that no mathematical model ever can capture, *see* Lambert Tr. 184-92, Dr. Lambert admits in a "caveat" that there are over 2,350,000 name pairs that are more similar than TRAVATAN and Xalatan. Lambert Decl. Ex. 2, at 4. At most, only 1127 of ***all possible name pairs*** ever have resulted in error or have been "reported to be confusing," Lambert Decl. ¶ 6. Lambert Decl. Ex. 2, at 4. That means that, even accepting all the figures in Dr. Lambert's report, his model is right at best $^{1,127}/_{2,350,000}$ times, translating into an error rate of 99.96%. Any methodology so demonstrably unreliable lacks any probative value and perfectly exemplifies the kind of evidence that should be excluded.

Under *Daubert* and *Kumho Tire*, the lack of predictive ability of Dr. Lambert's model cannot be ignored. *See Daubert*, 509 U.S. at 594 (courts should consider error rate of scientific technique); *Kumho Tire*, 526 U.S. 153-54 (question is not whether method is useful in general, but whether method is reasonable in reaching conclusion about specific

event at issue); *General Electric Co. v. Joiner*, 522 U.S. 136, 146 (1997) ("[A] court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."). Moreover, Dr. Lambert's failure fully to disclose these issues, despite their admittedly critical importance to predictive value, Lambert 1999, at 1167; Lambert Tr. 216-17, deprives the Court of any way in which to evaluate the probative value of his calculations. *See Navarro v. Fuji Heavy Indus., Ltd.*, 117 F.3d 1027, 1032 (7th Cir. 1997) ("An expert's affidavit must be sufficiently complete to satisfy the criteria of the *Daubert* decision. . . ."); *In re TMI Litig.*, 193 F.3d at 695 (opinion missing critical variable inadmissible and unreliable).

In addition to these flaws, Dr. Lambert's litigation mindset is demonstrated by his denial, in deposition, that his report was about "medication errors," Lambert Tr. 76, 205. He instead insisted that its purpose was to opine on the legal issue of "likelihood of confusion," *id.* at 61-62, despite all of his prior articles making clear that his model is entirely limited to medication errors. *See* Hogan Decl. Ex. 14 (Bruce L. Lambert, "Predicting Look-Alike and Sound-Alike Medication Errors," 54 Am. J. Health-Sys. Pharm. 1161 (1997) (hereinafter "Lambert 1997")); Lambert 1999, at 1214.[12]

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[12] His denial is likely influenced by trademark law, which requires confusion by the relevant consumers – here, prescribing ophthalmologists and optometrists – rather than mistakes by non-consumers, such as pharmacists or nurses, who are not potential prescribers. *Versa Prods., Inc. v. Bifold Co.*, 50 F.3d 189, 200 (3d Cir.) ("[C]onsumer confusion is, of course, at the heart of trademark law...."), *cert. denied*, 516 U.S. 808 (1995); *Lang v. Retirement Living Publ'g Co.*, 949 F.2d 576, 583 (2d Cir. 1991) (Lanham Act only protects against "mistaken purchasing

Dr. Lambert also admitted that his opinion was based on mixing two different models and that neither he nor anyone else ever tested those two models together. Lambert Tr. 65-66 (phonological model); *id.* at 133-39 (orthographic model; tested different pronunciation measures); *see Elcock*, 233 F.3d at 748 ("arbitrary admixture of two widely used methods" was "nothing more than a hodgepodge . . . permitting [the expert] to offer a subjective judgment"). Further, he admitted that his list of "error pairs" had not been verified as actual errors, that he could not identify which had been subjectively chosen by others and that his calculations were likely to be biased because of voluntary reporting. *See* Lambert Tr. 203, 206-07, 210-11; Lambert 1997, at 1170; *see also In re TMI Litig.*, 193 F.3d at 671, 705 (unverified data cannot be basis for reliable opinion); *Paoli*, 35 F.3d at 762 (uncorroborated reports of health problem where over-reporting was likely were unreliable).

In short, nothing has changed since Dr. Lambert wrote, in a peer-reviewed publication, that his model should not be used to make regulatory decisions. Lambert 1999 at 1223; Lambert Tr. 225 (agreeing that report was subject to same criticisms as earlier published work). The flaws and uncertainties in his model make it particularly unsuited as a substitute for actual confusion or consumer survey evidence. Courts routinely require one or the other, and Pharmacia can identify no case accepting such a formula in lieu of real-world evidence. *See also* Lambert Tr. at 33 (Lambert did not

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decisions," not against confusion generally); RESTATEMENT (THIRD) OF UNFAIR COMPETITION § 20 cmt. b, at 210 (1995) (same).

evaluate names in context of packaging and advertising). For these reasons, his opinion must be excluded.

C. **Pervasive Flaws In The McCullough Survey Warrant Its Exclusion.**

Survey evidence is reliable only if elicited through the use of generally-accepted survey techniques. *Pittsburgh Press Club v. United States*, 579 F.2d 751, 758 (3d Cir. 1978). Accordingly, courts scrutinize survey evidence closely to determine whether it meets well-established standards assuring its reliability. MANUAL FOR COMPLEX LITIGATION 3d § 21.493 (Federal Judicial Center 1995).[13] Although McCullough admitted familiarity with such standards and professed adherence to them, McCullough Tr. 7, his survey fails to meet them in at least four ways.

First, although the survey purports to be "double-blind," it is not. McCullough Tr. 91, 229; *see* Shari Seidman Diamond, *Reference Guide on Survey Research*, REFERENCE GUIDE ON SCIENTIFIC EVIDENCE at 238 (Federal Judicial Center 2000)

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[13] These standards include:

- A properly chosen and defined survey population ("universe");
- A survey sample that is representative of that population;
- Accurate reporting of gathered data;
- Analysis of the data gathered in accordance with accepted statistical principles;
- Survey questions that are clear and not leading;
- Proper procedures, overseen by qualified persons; and
- Precautions to ensure objectivity (e.g., surveys conducted by people who have no knowledge of the litigation or the purpose for which the survey is being conducted).

Id. at 102; *see also* Shari Seidman Diamond, *Reference Guide on Survey Research*, REFERENCE GUIDE ON SCIENTIFIC EVIDENCE (Federal Judicial Center 2000).

("potential bias" is eliminated when both "interviewers and respondents [are] blind to the purpose and sponsorship of the survey"). To the contrary, two respondents explicitly noted the pendency of the lawsuit during their interview, McCullough Tr. 98-99, 101-03, resulting in at least two of the interviewers being made aware of the litigation as well. Once a respondent mentioned the lawsuit to an interviewer, precautions should have been taken to ensure that any further responses elicited by that interviewer were scrutinized for any anomalies and, if any appear, were excluded. *Paco Sport v. Paco Rabanne*, 86 F. Supp. 2d 305, 323 (S.D.N.Y. 2000) ("[T]he experts on both sides agree that for survey results to be reliable, interviewers should not be aware of the purpose of the survey . . . or the answers the sponsor wants to receive. Interviewers occasionally fabricate answers instead of completing interviews, and knowledge of the desired responses makes cheating easier."); *Pittsburgh Press Club*, 579 F.2d at 758.

Here, far from adjusting the data for such anomalies, Pharmacia relies on them. The answers obtained by interviewer Susan Boyd during or after the interview in which she gained knowledge of the lawsuit make up almost 25% of Pharmacia's total "dilution" responses. McCullough Tr. 223-24 (Boyd's knowledge); 239-40 (acknowledging Boyd's 24% "dilution" responses and high 50% "success rate" in obtaining answers that help Pharmacia).

Significantly, before being confronted with Ms. Boyd's verbatim answers, Mr. McCullough's initial deposition testimony was that the type of results she obtained -- highly specific responses referring to "ATAN" -- should have raised the possibility that her work did not objectively report the results of actual interviews. *See* McCullough

Tr. 168-69 (surveyor should be suspicious "[i]f you start getting answers that are different than what one might expect from the other answers you read and they're very consistent with one particular interview; identical wording from questionnaire to questionnaire, with the same interviewer who's done interviews sequentially; particularly if the kind of wording is such that it's kind of an unusual thing that's being said"); 225-26 (admitting that a response identifying the –TAN or –ATAN ending would be "extremely detailed and very unusual" and "I would have suspected the physician was an attorney"); 232-40 (reviewing Boyd's answers).

After the anomalies created by her work were pointed out to him, McCullough Tr. 263-64 (admitting that Ms. Boyd got detailed answers, including seven of the ten responses specifically identifying ATAN as the reason for name similarity); *id.* at 258 (admitting that she conducted 5 interviews in 2 ½ hours, an unusual number), Mr. McCullough admitted to "concerns" about her answers, *id.* at 259-60, 265-66. He would not agree, however, that it was appropriate to make further inquiries into the objectivity and validity of the results Ms. Boyd obtained without receiving the advice of Pharmacia's counsel. *Id.* at 258-59. That extraordinary response starkly illustrates an inappropriate level of involvement by counsel with Mr. McCullough's supposedly independent opinion. *Greenpoint Financial Corp. v. Sperry & Hutchingson Co. Inc.*, 116 F. Supp.2d 405 (S.D.N.Y. 2000) (rejecting probative value of McCullough dilution survey because, *inter alia*, of "the involvement of Plaintiff's law firm"). Whether based on that, or because of the fundamental failure to avoid the bias created by the lack of

double-blinding, *see Paoli*, 35 F.3d at 762, 768 (opinions based on biased or unreliable data properly excluded), this Court should not rely on Mr. McCullough's work.

Second, Mr. McCullough's survey asks a question that triggered ambiguous answers. Despite that it purported to measure trademark dilution, the survey asks which "***products***" (not what "***names***" or "***brands***") come to mind. This is a significant error because all three drugs tested in the survey – TRAVATAN, Xalatan and Lumigan (the control) – are in the same class of drugs. By explicitly focusing the respondent on "***products***," rather than trademarks, names or brands, many doctors made associations based on ***drug class*** similarity rather than solely ***trademark*** similarity. *See WGBH Educational Foundation v. Penthouse Int'l Ltd.*, 453 F. Supp. 1347, 1351 (S.D.N.Y. 1978) (criticizing survey for directing attention to "word" rather than "name"), *aff'd*, 598 F.2d 610 (2d Cir. 1979). Indeed, Mr. McCullough admitted that this first question was likely to elicit association responses based on similarity between class of drugs rather than similarity between brand names. McCullough Tr. 171-72.

This error, which produced many ambiguous answers, was greatly exacerbated by McCullough's failure to control for the similarity in the generic names of the drugs tested, all of which end in "oprost" (latanoprost, bimatoprost, travoprost). As a result, responses that do no more than say "similar names" or "similar endings" are simply unclear about ***which*** names -- the generic name or the trademark -- the respondent

intended.[14] *See* McCullough Tr. 213 (admitting that answers would have been clearer if the respondent had identified –TAN or –ATAN as being the source of the "name similarity"). *Church & Dwight Co., Inc. v. S.C. Johnson & Son, Inc.*, 873 F. Supp. 893, 910 (D.N.J. 1994) (according "little weight" to survey where there were "numerous ambiguities and discontinuities" in coding the responses); *Simon & Schuster, Inc. v. Dove Audio, Inc.*, 970 F. Supp. 279, 290-91 (S.D.N.Y. 1997) (significantly reduced weight accorded to survey where ambiguous questions produced ambiguous answers); *Pebble Beach Co. v. Laub America Corp.*, 1985 WL 5584, at *22 (N.D. Cal. Dec. 27, 1985) (discounting ambiguous answers); *General Motors Corp. v. Cadillac Marine & Boat Co.*, 226 F. Supp. 716, 735-38 (W.D. Mich. 1964) (faulting survey for counting ambiguous answer).[15]

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[14] It appears from many of the verbatim responses that respondents coded as giving "dilution" answers in the test cell actually answered with either the class of drug or generic name in mind. *See* McCullough Decl., Ex. 1 at Ex. A (n.p.) (test cell response 122 ("Name sounds similar and are similar in their chemical structure"); 128 ("it's the ***same class*** of drug and the name sounds familiar"); 129 ("Because of the name and I'm familiar with TRAVATAN and it's a glaucoma drop of the ***prostaglandin*** group."); 140 ("The ***medical name*** is similar. The last three letters are the same."); 177 ("***Prostaglandin*** analogue – same basic type of drug. The name is very similar."); 193 ("[I]t is the ***same class*** of drugs. The name itself is reminiscent."); 229 ("Name similarity."); 234 ("They are in the same category. They are ***prostaglandin*** or agonist. The names sound alike."); 282 ("The endings the same; same medication; ***same type drug***."); 290 ("The concentration is similar. The name is almost the same."); 348 ("***Similar product***. Similar name. Does the same thing.") (emphasis added.)).

[15] If these ambiguous answers are discounted, the purported dilution level drops to 6-7%, a clearly inadequate percentage. Moreover, this is not the first time McCullough has been criticized for designing surveys that elicit ambiguous answers. *See Westchester Media Company v. PRL USA Holdings, Inc.*, 1998 U.S. Dist. LEXIS

Mr. McCullough's coding of these ambiguous responses adds to this problem because he did not apply the same standard to the test and control cells. For the test cell, where it would benefit Pharmacia, Mr. McCullough counted as a dilution answer any response that noted name similarity ***unless*** it specifically mentioned the generic name. McCullough Tr. at 286-88, 290-93; 304-05 ("the name itself is reminiscent," "they both sound the same," "similar name" all coded as dilution in test cell; coded test cell on assumption that similarity response referred to trademark absent response "clearly indicating" that respondent meant generic).[16] By contrast, in the control cell, where it benefited Pharmacia to exclude ambiguous answers, Mr. McCullough excluded two answers that noted a name similarity even though they did ***not*** specify whether the similarity was in the brand or generic names. *Id.* at 283-85, 289-90 ("similar endings" and "similar names" not coded as dilution in control cell); McCullough Decl. Ex. 1 at Ex. A (n.p.) (control cell responses 175 & 267). *See also* McCullough Tr. 205 (admitting that his coding of name "familiarity" as name "similarity" was based on a "subjective

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11737 (S.D. Tex. July 2, 1998) (characterizing another McCullough survey as "equivocal" for producing ambiguous answers), *aff'd*, 214 F.3d 658 (5th Cir. 2000).

[16] Mr. McCullough eventually admitted to having miscoded at least one such response, McCullough Tr. 292-93, but refused to admit that this same error was made with respect to many such responses. Notably, simply by omitting that one, concededly wrongly coded response, the controlled dilution percentage drops to 14%. McCullough Decl., Ex. 1 at Ex. A (verbatim responses showing 36 – now 35 – of 199 "dilution" responses in test cell and 4 of 112 "dilution" responses in control cell).

determination"). The disparate treatment of test and control responses brings into sharp focus the unreliability of Mr. McCullough's subjective coding.

Third, the survey excluded important elements of the market population. Despite the fact that optometrists in all but 3 states nationwide prescribe glaucoma medications, Mr. McCullough surveyed ophthalmologists only. McCullough Tr. 23-26. That ophthalmologists may write a majority of glaucoma prescriptions does not excuse this design flaw: a proper survey universe includes "all . . . individuals . . . whose characteristics or perceptions the survey is intended to represent." Diamond at 239; *see also American Home Products Corp. v. Barr Laboratories, Inc.*, 656 F. Supp. 1058, 1070 (D.N.J.), *aff'd*, 834 F.2d 368 (3d Cir. 1987); *Starter Corp. v. Converse, Inc.* 170 F.3d 286, 297 (2d Cir. 1999). McCullough's survey fails this basic test entirely by excluding optometrists. *See Gillette Co. v. Norelco Consumer Prods. Co.*, 69 F. Supp. 2d 246, 261 (D. Mass. 1999) (study unreliable where "universe of consumers surveyed was improperly limited in that it excluded important segments of the universe of prospective purchasers"); *Winning Ways, Inc. v. Holloway Sportswear, Inc.*, 913 F. Supp. 1454, 1467 (D. Kan. 1996) (excluding survey that ignored important market segment; exclusion "extinguishes the probative value of the survey"); *Hutchinson v. Essence Communic., Inc.*, 769 F. Supp. 541, 560 (S.D.N.Y. 1991) (survey that excluded significant portion of relevant consumers was unreliable); *Rolodex Corp. v. Rubbermaid Commerce Prods. Inc.*, Civ. A. No. 84-3303, 1986 WL 9719, at *6 (D.N.J. May 14, 1986) (same).

Fourth, McCullough did not take any steps to ensure that the sample drawn from this incomplete universe was representative of the marketplace. He did nothing to screen

for respondents' years of experience and the size of their practices, McCullough Tr. 87, a flaw Pharmacia itself characterized as the antithesis of good market research practices. Hogan Decl. Ex. 10 (Gurreri Tr. 219).[17] As a result, there is no way to test whether the survey respondents are a representative sample, even of ophthalmologists. *Harold's Stores, Inc. v. Dillard Dep't Stores, Inc.*, 82 F.3d 1533, 1544 (10th Cir. 1996) (court should exclude survey "when the sample is clearly not representative of the universe it is intended to reflect"); *Dick's Sporting Goods, Inc. v. Dick's Clothing & Sporting Goods, Inc.*, 188 F.3d 501 (4th Cir. 1999) (table; text in Westlaw) (same); *Arche, Inc. v. Azaleia, U.S.A., Inc.*, 882 F. Supp. 334, (S.D.N.Y. 1995) (excluding survey where "the sample of respondents interviewed was not representative of any reproducible group because no objective selection criteria were used"); *Boehringer Ingelheim G.m.B.H. v. Pharmadyne Labs*, 532 F. Supp. 1040, 1058 (D.N.J. 1980) (excluding "haphazard" survey where doctors chosen simply based on prescription volume).

The pervasiveness of these flaws means the survey should be excluded in its entirety, *see Universal City Studios, Inc. v. Nintendo Co.*, 746 F.2d 112, 118 (2d Cir. 1984) (excluding confusion survey because it was "so badly flawed that it cannot be used"); *Johnson & Johnson-Merck Consumer Pharmaceuticals Co. v. Rhone-Poulenc Rorer Pharmaceuticals, Inc.*, 19 F.3d 125, 134 (3d Cir. 1994) ("'The probative value of a

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[17] In addition, the size of the sample cell was half the size of the control cell, meaning that the sample cell was much more unreliable. McCullough Tr. at 107-08. The inability of McCullough's survey to compare similarly-sized cells further increases its unreliability.

consumer survey is a highly fact-specific determination and a court may place such weight on survey evidence as it deems appropriate.'") (citation omitted).

III. CONCLUSION

Pharmacia asks this Court to issue preliminary injunctive relief based on a series of short-cuts. Rather than conduct a confusion survey, it relies on opinions about confusion. Rather than develop marketplace evidence of confusion, it relies on an opinion based on an abstract and unprecedented statistical model. Rather than produce proper evidence of dilution, it relies on an opinion derived from a survey that violates the most fundamental rules of survey research: asking the right questions of the right respondents in a double blinded manner. That Pharmacia felt compelled to rely on such poor substitutes for actual facts tells as much about its case as did its failure, in its *ex parte* application, to disclose the lengthy delay that preceded this motion and the FDA's specific approval of the TRAVATAN mark.

For that reason, as well as those set forth above, defendant Alcon Laboratories, Inc. respectfully requests that certain testimony of George Di Domizio, Dan L. Eisenberg, M.D., Stephen A. Obstbaum, M.D., Dr. Bruce Lambert and Walter J. McCullough be excluded.

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