REDACTED VERSION – PUBLICLY FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., and ALLERGAN SALES, LLC., Plaintiffs, v. ALCON INC., ALCON LABORATORIES, INC., and ALCON RESEARCH, LTD., Defendants.	**Civil Action No: 04-968-GMS**

DEFENDANTS ALCON INC., ALCON LABORATORIES, INC., AND ALCON RESEARCH, LTD.'S MEMORANDA OF LAW IN OPPOSITION TO PLAINTIFFS' MOTIONS *IN LIMINE*

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I. MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF ANY CONTINUATION APPLICATIONS OF THE '834 PATENT

Alcon, Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively, "Alcon") respectfully submit this memorandum of law in opposition to the motion *in limine* of Plaintiffs Allergan, Inc. and Allergan Sales, LLC (collectively, "Allergan"), to exclude evidence of any continuation applications of U.S. Patent No. 6,641,834 (the "'834 Patent"). Allergan bases its motion on the argument that such continuation applications are irrelevant to the adequacy of the '834 patent's written description. However, evidence that Alcon would put forward in this case concerning continuation-in-part ("CIP") applications stemming from the '834 patent does not bear only on that written-description issue. For example, and most importantly, certain CIP applications contain various representations by witnesses for Allergan, including Edward D.S. Kerslake and Orest Olejnik, that are critical as regards anticipation of the other patent in suit (U.S. Patent No. 6,673,337, hereinafter the '337 patent), which shares the '834 patent's specification. Thus, Allergan's arguments in support of its motion are largely immaterial. The CIP applications are relevant and admissible not, in the main, as they relate to the sufficiency of the '834 patent's written description, but because they contain statements attributable to Allergan witnesses (and provide related evidence), pertaining to anticipation issues with respect to the '337 patent. That said, the CIP applications are not, as Allergan contends, irrelevant to the adequacy of the '834 patent's written description.

FACTS

The '834 patent is a continuation of Application Serial No. 09/904,018, which, in turn, stems from Provisional Application Serial No. 60/612, 200, filed July 14, 2000. The '834

patent claims the benefit of the July 14, 2000 filing date of the provisional application, whose specification appears, identically, in both the '834 patent and the '337 patent.

The issue of whether Allergan's Alphagan product anticipates U.S. Patent No. 6,673,337 (the '337 patent) turns in part on whether Alphagan contained a solubility enhancing component ("SEC"), as the claims of the '337 patent require. Dr. Olejnik, one of Allergan's witnesses, testified at his deposition that the polyvinyl alcohol ("PVA") in Alphagan is not a solubility enhancing component. CIP applications of the '834 patent, however, on which Dr. Olejnik is named as an inventor, identify PVA as an SEC, and, indeed, as a preferred SEC. E.g., Exhibit D, p. 4.

Additionally, the specifications of certain continuation-in-part applications of the '834 patent contain new matter concerning a 0.15% brimonidine composition, including a background statement noting as a basis for the invention a 2002 journal article indicating similar efficacy for 0.15% and 0.2% brimonidine solutions (e.g., Exhibit D, Application Serial No. 10/928,906 ("CIP") [0010]); a narrative statement providing a range of preferred concentrations of brimonidine that includes 0.15%, (e.g., CIP [0045]); an example setting forth the formula for a 0.15% brimonidine composition within the scope of the claims (e.g., CIP, [0147]); and clinical trial data comparing a 0.15% brimonidine composition within the scope of the claims to a composition outside the scope of the claims, together with a statement reflecting the inventor's preference for the claimed composition (e.g., CIP,[0148-149]). None of these items, which together constitute a proper written description in support of a 0.15% claim limitation, are included in the specification for the '834 patent.

ARGUMENT

Clearly, to the extent that the inventors identified in CIP applications stemming from the '834 patent made representations in those applications that are inconsistent with testimony they would offer in this case — for example Dr. Olejnik's representation that PVA is an SEC — the CIP applications are relevant to an assessment of witness credibility, and as an admission. In addition, the fact that the CIP applications disclose the use of PVA as a preferred solubility enhancing component suitable for use in various brimonidine formulations provides evidence that PVA is inherently solubility enhancing — a fact squarely relevant to the disputed issue whether PVA acted as an SEC in Allergan's prior-art Alphagan product, for purposes of the anticipation analysis with respect to the '337 patent. Therefore, Allergan's motion to exclude CIPs stemming from the '834 patent should be denied, because Allergan does not (and could not) argue that the CIPs are irrelevant to these issues.

Allergan's argument that the CIPs are not relevant to the written description analysis is, in any event, unfounded. "The policy behind the written description requirement is to prevent overreaching and *post hoc* claims that were not part of the original invention." Purdue Pharma, L.P. v. F.H. Faulding & Co., 43 F. Supp. 2d 420, 427 (D. Del. 1999), aff'd, 230 F.3d 1320 (Fed Cir. 2000). The Federal Circuit has accordingly held that "possession is a relevant factor in determining whether an invention is described" — although an inquiry into possession will not necessarily be dispositive. Enzo Biochem, Inc. v. Gen-Probe Inc., 323 F.3d 956, 973 (Fed. Cir. 2002). Evidence concerning CIP applications of the '834 patent is therefore relevant here because the disclosures set forth in those applications concerning the basis for the claimed invention — e.g., a journal article published in 2002 demonstrating efficacy of a 0.15% brimonidine solution — considered together with additional, new, subject matter in the CIP

specifications concerning a 0.15% brimonidine solution, provides strong evidence that Allergan was either not in possession of the claimed invention as of the priority date, or else chose not to provide any description concerning a 0.15% composition, because it did not deem that to be an "invention" at all. United States Steel Corp. v. Phillips Petroleum Co., 865 F.2d 1247 (Fed. Cir. 1989), which Allergan relies upon for the proposition that subsequent filings are irrelevant to the written-description analysis, did not involve similarly strong evidence and is therefore distinguishable. Similarly, the finding in Paperless Accounting, cited by Allergan, that the "mere filing of a CIP with additional matter or revised claims is not of itself an admission that the matter is 'new' or that the original application was legally insufficient to support the claims" (Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys 804 F.2d 659, 664 (Fed. Cir. 1986) (emphasis added)), does not suggest that a CIP with additional matter is irrelevant.

CONCLUSION

For the foregoing reasons, this Court should deny Allergan's Motion *In Limine* to Exclude Evidence of Any Continuation Applications of the '834 Patent.

II. MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE ALCON FROM OFFERING ANY EVIDENCE OR THEORY THAT IT DOES NOT INFRINGE THE '834 PATENT

Alcon respectfully submits this memorandum of law in opposition to Plaintiffs' Motion *in Limine* to Exclude Alcon from Offering Any Evidence or Theory that It Does Not Infringe the '834 patent. In support of its motion, Allergan argues that Alcon has waived any infringement defense with respect to the '834 patent, because, according to Allergan, the only defense disclosed in Alcon's interrogatory responses relies on a claim construction that Alcon did not advance to the Court. This argument is meritless. As a matter of law, failure to advance a particular claim construction at a *Markman* hearing amounts, at most, to a concession that the claim terms at issue carry their ordinary meaning to persons of skill in the art – not to a concession of infringement. Allergan still bears the burden to demonstrate by a preponderance of the evidence that Alcon's proposed brimonidine product meets each of the limitations of the asserted claims in light of their ordinary meaning.

It must be recognized, in addition, that the Court can and may still refine or alter its construction of the '834 patent's claims. In particular, Alcon anticipates that Allergan may present evidence at trial that is inconsistent with the ordinary meaning of those claims. Should the Court, as a result, choose to refine or modify its construction of those claims (as it is free to do), Allergan would bear the burden to demonstrate infringement on the basis of the claim construction adopted by the Court, while Alcon would have, and reserves, the right to raise any infringement defense appropriate to the adopted construction.

FACTS

Each of the asserted claims of the '834 patent depends from claim 1, which reads as follows:

> A therapeutically effective aqueous ophthalmic composition comprising:
> up to about 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate, the composition having a pH of about 7.0 or greater, and the 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate being soluble in the composition at about 21° C.

'834 patent, col. 16, lines. 45-54 (emphasis added).

It is not certain whether the Court will ultimately give all of the terms of this claim their ordinary meaning. As one example, Alcon has taken the position in this litigation that the term "soluble," as used in both of the patents in suit, carries its ordinary meaning, such that brimonidine is "soluble" if it can be fully dissolved within the composition to form a solution. On the basis of that position, Alcon has argued that its proposed brimonidine product does not infringe the '337 patent, because, while the limitations of that patent require a "solubility enhancing component," the brimonidine in Allergan's proposed product is already "soluble" (fully dissolvable into the solution), and, as a result, by definition, its solubility cannot be "enhanced." Allergan's expert witness, however, Dr. Valentino J. Stella, testified at his deposition that solubility, as used in the patents in suit, refers to "equilibrium solubility," which must be determined not on the basis of how much brimonidine is actually dissolved in the claimed invention (or in Allergan's allegedly infringing product), but by how much excess brimonidine could be added to the product and dissolved before some of it starts to precipitate out of the solution.

ARGUMENT

Where a party fails to proffer a claim construction at the appointed time, that party may be deemed to have waived its right to raise the claim construction, and thereby to have implicitly conceded that the claim terms at issue are clear and do not require construction. See

Eli Lilly v. Aradigm Corp., 376 F.3d 1352, 1360 (Fed. Cir. 2004). However, a concession that an asserted claim is clear is an entirely distinct matter from whether the claim has been infringed, and in no way amounts to a concession regarding infringement. The plain meaning of a claim may just as likely defeat or support an allegation of infringement, and the party alleging infringement therefore still bears the burden to demonstrate infringement by a preponderance of the evidence. Accordingly, Allergan's argument that Alcon has waived any defense to infringement of the '834 patent because it has supposedly waived its interpretation that the '834 patent's claims require an anionic SEC[1] has no basis whatsoever in law. Nor would it be fair to preclude Alcon, at this time, from offering any defense to infringement of the '834 patent, when it is still possible that the Court may adopt a definition of important claim terms (such as the term "soluble") that is different from the ordinary meaning (potentially requiring different proof of infringement from Allergan and giving rise to additional non-infringement defenses).

CONCLUSION

For the foregoing reasons, this Court should deny Allergan's motion *in limine* seeking to preclude Alcon from offering any evidence or theory that it does not infringe the '834 patent.

[1] Allergan does not even address the additional defense, disclosed in Alcon's interrogatory responses, that its proposed brimonidine product contains no SEC of any kind.

III. MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO EXCLUDE ALCON FROM PRESENTING PRIOR ART NOT RELIED ON OR EXPLAINED BY ALCON'S EXPERTS

Alcon respectfully submits this memorandum of law in opposition to Plaintiffs' Motion *In Limine* to Exclude Alcon from Presenting Prior Art Not Relied on or Explained by Alcon's Experts. To the extent that Allergan merely argues that Alcon's experts may not offer any opinions regarding prior art that are not disclosed in their reports, there is no dispute and Alcon's motion is moot. Alcon's experts will indeed limit their testimony concerning prior art to the opinions, and bases therefor, set forth in their reports, and do not intend to offer opinions concerning prior art that are not supported by their pre-trial disclosures. To the extent that Allergan also seeks an order excluding from evidence any prior art not relied upon or explained by Alcon's experts, however, Allergan's motion should be denied, because it rests on the erroneous assumption that expert testimony concerning a prior-art reference is required for the reference to be admissible and offers no argument as to why any particular prior-art reference identified in Alcon's interrogatory responses requires explanatory expert testimony. Finally, with respect to Allergan's argument that five of the prior art references discussed in Dr. Amidon's reports should be excluded — because the explanation regarding those references allegedly does not explain what they disclose and what would motivate one of skill in the art to combine them with others —Allergan's motion should be denied, because Dr. Amidon's explanations of those references is sufficient.

FACTS

In Alcon's Supplemental Response to Allergan's Interrogatory No. 1, Alcon identified approximately 70 prior art references that, separately or in various possible combinations, may invalidate the patents in suit. Alcon attached to that supplemental response

charts setting out detailed, side-by-side, comparisons of certain of those references with the patents in suit. See, e.g., Exhibit E, excerpts of Exhibits to Alcon's Supplemental Response to Allergan's Interrogatory No. 1. In addition, Alcon's expert witnesses, Drs. Gordon L. Amidon, Ph. D., and Alan L. Robin, M.D., provided explanatory opinions in their reports concerning 14 prior-art references.

Allergan has moved to preclude Alcon from presenting any prior-art references other than nine such references that it asserts are the only ones adequately discussed in Alcon's expert witness reports. Additionally, as to five of the references mentioned in Dr. Amidon's report — U.S. Patent Nos. 5,091,528; 5,776,445; 5,834,470; 5,663,205; and 5,212,196 – Allergan argues that those references should be excluded even though Dr. Amidon specifically identifies and relies upon them, because they are not adequately explained.

ARGUMENT

The only legal argument that Allergan offers in support of its motion is based on the provisions of Federal Rules of Civil Procedure 26 and 37 providing, respectively, for the disclosure of expert witness reports, and for the automatic exclusion of evidence that a party is required to disclose but does not. See generally, Fed. R. Civ. P. 26(a)(2)(B); Fed. R. Civ. P. 37; Plaintiffs' Motion *in Limine* To Exclude Alcon From Presenting Prior Art Not Relied on or Explained by Alcon's Experts, at pp. 1-3. Alcon does not dispute that its experts may offer opinions pertaining to prior-art only to the extent that such opinions are disclosed in their reports. To the extent that Allergan seeks an order in that regard, its motion *in limine* should therefore be denied as moot.

However, Allergan apparently seeks not only to preclude Alcon's experts from offering opinions pertaining to prior art that are not disclosed in their reports, but also to preclude

Alcon from presenting any prior-art references independently of expert testimony. Allergan offers no argument whatsoever in support of the latter effort, and Alcon is fully entitled to present references to prior art, for cross-examination purposes or otherwise, to the extent that their relevance can be demonstrated without an expert opinion. It is well established that explanatory expert testimony is not necessarily required for the admission of prior-art references. See Cooper v. Ford Motor Co., 748 F.2d 677 (Fed. Cir. 1984); accord, Union Carbide Corp. v. American Can Corp., 724 F.2d 1567 (Fed Cir. 1984). Accordingly, to the extent that Allergan's motion seeks broadly to preclude Alcon from offering as evidence any references to prior art not explained by Alcon's experts, Allergan's motion should be denied.

Allergan's additional argument that five of the references set forth in Dr. Amidon's report should be excluded because they are not adequately explained simply has no basis in fact. Allergan asserts that, with respect to U.S. Patent Nos. 5,091,528, 5,776,445, 5,834,470, 5,663,205 and 5,212,196, Dr. Amidon's report contains "nothing but a conclusory statement that they may be combined with some other reference . . . and no specific explanation as to what the reference discloses." That is simply not true. Dr. Amidon explains what each of these patents teaches and specifies references with which they may be combined. See Exhibit A, Amidon Report at ¶ 119. Moreover, Alcon's responses to Allergan's interrogatories included charts with detailed, side-by-side, comparisons of certain claims of these prior-art patents with claims of the patents in suit. See Exhibit E. No further explanation of the relevance of these five references is necessary, and there is accordingly no basis for their exclusion from evidence.

CONCLUSION

For the foregoing reasons, this Court should deny Allergan's Motion *In Limine* to Exclude Alcon from Presenting Prior Art Not Relied on or Explained by Alcon's Experts.

IV. MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE ALCON FROM HAVING MULTIPLE EXPERTS TESTIFY ON A SINGLE ISSUE

Alcon respectfully submits this memorandum of law in opposition to Plaintiffs' Motion *In Limine* to Preclude Alcon From Having Multiple Experts Testify on a Single Issue. The Court's standard form Final Pretrial Order permitting only one expert witness per subject for each party does not preclude Drs. Robin and Amidon from both testifying as to the validity of the '834 patent, because they will offer testimony focusing on different subjects bearing on the validity of that patent. The fact that there will be some degree of overlap in their testimony is no basis to bar either witness from testifying regarding the '834 patent, given that their testimony will not simply be cumulative. The issue whether the '834 patent is invalid for lack of written description implicates more than one area of expertise, establishing good cause for testimony from both witnesses.

FACTS

Alcon's expert witness, Gordon L. Amidon, Ph.D., is a Professor of Pharmacy and Pharmaceutics at the College of Pharmacy at the University of Michigan, and has 35 years of experience working on, teaching about, and studying drug formulations and drug delivery. Exhibit A, Amidon Report at ¶ 1. He is thus offered as an expert in pharmaceutics and pharmaceutical chemistry. A second expert witness for Alcon, Alan L. Robin, M.D, is an Associate Professor of Ophthalmology at Johns Hopkins University (in addition to holding other positions), and specializes in the treatment of glaucoma. Exhibit B, Robin Report at ¶ 1. He is offered as a physician with relevant knowledge concerning the evaluation and selection of ophthalmic products for the treatment of glaucoma. Only Dr. Amidon would offer testimony concerning the '337 patent, and there is therefore no dispute as to the use of multiple experts

with respect to the '337 patent. Additionally, only Dr. Robin would offer testimony concerning invalidity of the '834 patent due to obviousness under prior art. The only dispute, then, concerns whether Dr. Robin and Dr. Amidon may both offer testimony concerning invalidity of the '834 patent due to a failure of written description. In this regard, Dr. Amidon's proposed testimony focuses on the failure of the '834 patent's written description to include any reference at all to a 0.15% brimonidine limitation in concluding that the description would not lead an ordinarily skilled artisan to recognize a 0.15% brimonidine limitation as part of the claimed invention. E.g., Ex. A, Amidon Report at ¶ 152. Dr. Robin, on the other hand, as a physician, focuses on the failure of the written description to convey to a person of ordinary skill in the art that the inventors claimed any particular concentration of brimonidine below 0.5% as "therapeutically effective." See generally, Ex. B., Robin Report at ¶¶ 70-71. While Dr. Amidon states in his report that he agrees with Dr. Robin's conclusion regarding the failure of written description relevant to the "therapeutically effective" limitation, see Ex. A, Amidon Report at ¶ 160, Dr. Amidon does not address that limitation in the detail provided by Dr. Robin.

ARGUMENT

The Court's form Final Pretrial Order provides that "[o]nly one expert witness on each subject for each party will be permitted to testify absent good cause shown. If more than one expert witness is listed, the subject matter of each expert's testimony shall be specified." It does not appear that the Court has issued any written opinion construing this standing order. However, the United States District Court for the Northern District of Illinois has instructively addressed an identical standing order. In THK America Inc. v. NSK Ltd., the court found it unnecessary under the standing order to bar either of two proffered experts from testifying merely because there was some overlap in their opinions. See THK America, Inc. v. NSK, Ltd.,

917 F. Supp. 563, 576 (N.D.Ill 1996). The court held that "any doubts as to whether one or two experts should be employed should be resolved by allowing the additional expert." Id. at 576. This holding is consistent with the generally recognized principle that the "ultimate touchstone [of admissibility of expert testimony] is helpfulness to the trier of fact." United States v. Velasquez, 64 F.3d 844, 849-50 (3d Cir. 1995).

Although there is some overlap between the testimony of Drs. Robin and Amidon with respect to the adequacy of the '834 patent's written description, the overlap does not require that any testimony of either expert be barred. As Dr. Robin is a physician with particular expertise in evaluating and selecting glaucoma treatments based on their therapeutic efficacy, his opinion concerning the written description of the '834 patent properly focuses on its failure to support the "therapeutically effective" limitation of the claims regarding the specified 0.15% brimonidine product. Dr. Amidon, based on his general expertise in the formulation of pharmaceutical products, focuses more broadly on the failure of the '834 patent's written description to make any reference whatsoever to the 0.15% brimonidine limitation. Thus, the opinions of Drs. Amidon and Robin concerning the adequacy of the '834 patent's written description are not simply cumulative, and each witness provides helpful testimony reflecting his particular area of expertise. Good cause therefore exists to permit both witnesses to offer their anticipated testimony concerning the adequacy of the '834 patent's written description.

CONCLUSION

For the foregoing reasons, this Court should deny Allergan's Motion *In Limine* to Preclude Alcon From Having Multiple Experts Testify on a Single Issue.

V. MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO EXCLUDE CERTAIN TESTIMONY FROM ALAN ROBIN, MD UNDER *DAUBERT* AND FEDERAL RULE OF EVIDENCE 702

Alcon respectfully submits this memorandum of law in opposition to Plaintiffs' Motion *In Limine* to Exclude Certain Testimony from Alan Robin, MD Under *Daubert* and Federal Rule of Evidence 702. Allergan's argument that Dr. Robin is not an expert in "pharmaceutical formulation" is a red herring, as Dr. Robin is not proffered as an expert "formulator;" and it is not necessary that he be such an expert in order for his testimony to assist the Court in understanding relevant issues in this case. As an ophthalmologist for nearly two decades, specializing in the treatment of glaucoma, Dr. Robin has vast expertise in evaluating the therapeutic efficacy of, and selecting, pharmaceutical treatments for glaucoma or elevated intraocular pressure. That expertise is highly likely to benefit the Court in this case. For example, the issue whether an ordinarily skilled artisan would have expected the 0.15% brimonidine product claimed in the '834 patent to be "therapeutically effective" is an issue, relevant to obviousness, as to which Dr. Robin's training and experience qualifies him to offer helpful testimony. Similarly, whether the written description for the '834 patent discloses to a person of ordinary skill in the art a particular concentration of brimonidine that would provide optimal therapeutic benefit is squarely within Dr. Robin's expertise.

Aside from Allergan's baseless qualification challenge, Allergan also contends that Dr. Robin's anticipated testimony should not be considered credible and reliable, because of supposed factual error, uncertainty and equivocation in part of Dr. Robin's testimony during his deposition, and because counsel for Alcon encouraged Dr. Robin to review his expert report at points during the course of his deposition. Such matters, however, go to weight and credibility at most — not to admissibility. Furthermore, Allergan fails to call into question Dr. Robin's core

anticipated testimony concerning the knowledge and expectations of one of ordinary skill in the art with regard to the therapeutic efficacy of brimonidine products. Allergan, in any event, will have a full opportunity to cross-examine Dr. Robin at trial and bring to light any alleged bias or gaps in his knowledge. Alleging such deficiencies now is not enough to overcome the strong policy and express provisions of the Federal Rules in favor of admitting expert testimony that may assist a trier of fact in understanding relevant issues.

FACTS

As the Court knows, this case concerns patents on a claimed ophthalmic composition approved for the reduction of elevated intraocular pressure, such as occurs in glaucoma patients. Dr. Robin is an Associate Professor of Ophthalmology at the medical school of Johns Hopkins University, and also holds positions in ophthalmology at the University of Maryland and the Veterans Administration System in Baltimore, Maryland. Robin Report at ¶ 1. He specializes in glaucoma, has approximately 12,000 glaucoma patients under his care, and has served as a consultant for numerous companies in connection with their development of ophthalmic pharmaceuticals. Id. He has received a number of honors and awards relating to his work with glaucoma and has authored numerous articles in peer-reviewed scientific and medical journals, among other professional achievements. Id. at ¶¶3-6.

Dr. Robin is prepared to offer testimony concerning glaucoma and its treatment, generally, to assist the Court in understanding the relevant medical background to the patents-in-suit. Id. at ¶¶22-28. In addition, Dr. Robin would offer testimony as to the invalidity of the '834 patent. In that regard, in order to overcome concerns with regard to obviousness, Allergan, in prosecuting the '834 patent, made representations to the Patent and Trademark Office ("PTO") that the '834 patent's claims resulted from a "surprising," "unexpected," finding that a 0.15%

brimonidine composition could be as therapeutically effective as a 0.2% composition if the pH of the composition were raised a level above 7. Alcon expects that, at trial, witnesses for Allergan will make similar representations. Dr. Robin would testify, however, that a person of ordinary skill in the art would have expected, prior to publication of the '834 patent, that a 0.15% brimonidine solution, at a pH between 7.0 and 7.5, would be "therapeutically effective," because prior art had already established the efficacy of 0.08% and 0.2% brimonidine concentrations, such that efficacy of a brimonidine concentration in the range between 0.08% and 0.2% — including 0.15% — would have been entirely obvious. See generally, id., ¶¶33-35. Additionally, Dr. Robin would testify, with regard to the adequacy of the '834 patent's written description, that nothing in that description would lead one of ordinary skill in the art to recognize that the inventors claimed a 0.15% concentration of brimonidine as "therapeutically effective," and as a limitation of their invention, given the absence of, among other things, clinical data that a person of ordinary skill in the art would expect to see in support of such a claim. See generally, id., ¶¶70-71.

Allergan has moved to exclude Dr. Robin's testimony concerning the invalidity of the '834 patent on the basis of Dr. Robin's testimony at his deposition. In particular, Allergan asserts that Dr. Robin (1) conceded that he is "not a formulator;" (2) offered no probative testimony concerning obviousness; (3) misstated the effect of a change in pH on brimonidine solubility; and (4) failed to recall certain prior art and bases for his conclusions, and, in that connection, received prompting from Alcon's counsel to review portions of his report.

ARGUMENT

Federal Rule of Evidence 702 provides, in pertinent part, that "[i]f scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence

or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise." Fed. R. Evid. 702. Accord, Daubert v. Merrell Dow Pharmaceuticals, Inc., 509 U.S. 579, 592 n.10 (1993). Rule 702 embraces "a strong and undeniable preference for admitting any evidence having some potential for assisting the trier of fact." United States v. Velasquez, 64 F.3d 844, 849 (3d Cir. 1995) (internal quotations and citation omitted). Accordingly, courts have been careful to avoid applying the expert qualification and reliability requirements of that rule in an unduly strict manner, recognizing that the "ultimate touchstone [of admissibility] is helpfulness to the trier of fact." Id. at 850. More specifically, the threshold requirement that the proffered witness be an "expert" has been liberally construed to encompass a broad range of relevant knowledge. Id. at 849. Additionally, the Third Circuit has cautioned that "[t]he trial judge must be careful not to mistake credibility questions for admissibility questions." Kannankeril v. Terminix International, Inc., 128 F.3d 802, 809(3d Cir. 1997). Even substantive mistakes in an expert's testimony, moreover, have been deemed insufficient to justify exclusion of that testimony under Rule 702, where the expert nonetheless offers important, helpful, opinions. See, e.g., In re Paoli Railroad Yard PCB Litigation, 35 F.3d 717, 754 (3d Cir. 1994) (overturning trial courts' decision to exclude testimony as abuse of discretion, where few technical errors were "hardly surprising" and unlikely to prevent witness from expressing helpful opinion).

Allergan's argument that Dr. Robin is not qualified because he is not a "formulator" plainly applies an overly narrow view of Rule 702's requirement of expertise. Dr. Robin is not being proffered as a "formulator," but as a physician with extensive experience in evaluating and selecting pharmaceutical therapies for the treatment of glaucoma or elevated intraocular pressure. As such, he easily qualifies as an expert under the appropriate liberal

standard. Additionally, Dr. Robin's alleged uncertainty regarding certain matters, and the one alleged factual misstatement in his testimony, go to weight and credibility, and are no grounds for exclusion of any of his testimony. Finally, and most importantly, Dr. Robin's anticipated testimony concerning the knowledge of one of skill in the art regarding the therapeutic effectiveness of brimonidine products would be relevant, within Dr. Robin's expertise as a physician, and likely to assist the Court as the trier of fact.

CONCLUSION

For all the foregoing reasons, the Court should deny Allergan's Motion *In Limine* to Exclude Certain Testimony from Alan Robin, MD Under *Daubert* and Federal Rule of Evidence 702.

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Dated: January 17, 2006

REDACTED VERSION – PUBLICLY FILED

EXHIBIT A

REDACTED VERSION – PUBLICLY FILED

EXHIBIT A

REDACTED IN ITS ENTIRETY

REDACTED VERSION – PUBLICLY FILED

EXHIBIT B

REDACTED VERSION – PUBLICLY FILED

EXHIBIT B

REDACTED IN ITS ENTIRETY

REDACTED VERSION – PUBLICLY FILED

EXHIBIT C

REDACTED VERSION – PUBLICLY FILED

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ORIGINAL

ALLERGAN, INC., and ALLERGAN SALES, LLC.,	)
Plaintiffs,	)
v.	)
ALCON INC., ALCON LABORATORIES, INC., and ALCON RESEARCH, LTD.,	)
Defendants.	)

Civil Action No: 04-968-GMS

ALCON'S RESPONSES TO ALLERGAN'S
FIRST SET OF INTERROGATORIES (Nos. 1-7)

Pursuant to Rule 33 of the Federal Rules of Civil Procedure, defendants, Alcon Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively "Alcon"), hereby respond to the First Set of Interrogatories (Nos. 1-7) of plaintiffs, Allergan, Inc. and Allergan Sales, LLC (collectively "Allergan"), with the following objections and answers:

GENERAL OBJECTIONS

To the extent applicable, Alcon incorporates by reference the General Objections set forth in its responses to Allergan's First Set of Requests for Production of Documents and Things (Nos. 1-57), served concurrently herewith.

of the '445 patent and the Burke '991 patent. The Burke '991 patent equates clonidine, apraclonidine and brimonidine as "most preferred" imidazolidine-derived alpha-2 agonist compounds.

3. **Both Patents**

Individuals with pertinent information include the inventors of the patents-in-suit, attorneys who prosecuted the relevant applications, and authors of prior art references.

All non-privileged responsive documents sought by this interrogatory and plaintiffs' document requests will be produced.

Since discovery has just commenced, Alcon reserves the right to supplement this response to the extent further discovery or investigation reveals additional defenses to the validity of either asserted patent.

INTERROGATORY NO. 2

State fully and with particularity all the facts and reasons upon which Alcon bases the contentions made in the First and Third Counterclaims and the First and Fourth Affirmative Defenses of its Answer and Counterclaims that it will not infringe, either literally or under the doctrine of equivalents, or by inducement or otherwise, each of the patents-in-suit, including an identification of each element of each claim that Alcon alleges it will not meet, an identification of all evidence, both intrinsic and extrinsic, that Alcon intends to rely upon in support of any claim construction advanced to the Court, including an identification of any prosecution history of the patents-in-suit or prior art that Alcon intends to rely upon, an identification and explanation of any claim amendments, arguments, or other statements made during the prosecution history of the patents-in-suit that Alcon alleges estops Allergan from asserting any of the patents-in-suit against Alcon, an identification of each person with factual information that refers or relates to Alcon's allegations including the nature and extent of the information known to each person and an identification of all documents that refer or relate to Alcon's allegations.

RESPONSE TO INTERROGATORY NO. 2

As demonstrated in its Response to Interrogatory No. 1, both the '834 and '337 patents-in-suit are invalid and, accordingly, will not be infringed by Alcon's sale of its proposed product.

1. The '834 Patent

Even if valid, the '834 patent will not be infringed by Alcon's proposed product. Based on the specification and the prosecution history, all claims of the '834 patent should be construed as requiring an anionic solubility enhancing component. The specification of the '834 patent describes an invention wherein "[t]he present compositions contain certain materials which are effective in at least aiding or assisting in solubilizing the alpha-2-adrenergic agonist components in the compositions," Summary of the Invention col. 1, lns. 57-61, and "[t]he amount of SEC in the present composition is not of critical importance so long as solubility at [*sic*] the alpha-2-adrenergic agonist component is a t least somewhat increased and is present in a biologically acceptable amount." Col. 8, lns. 51-54. The specification also discloses only compositions of brimonidine that contain SECs. Therefore, the claims of the '834 patent must also be construed to require an SEC, and the prosecution history, as explained below, requires that that SEC must be an anionic SEC. Alcon's proposed product does not infringe these claims, either literally or under the doctrine of equivalents, because it does not have any solubility enhancing component, because as shown in Figure 1 and Table IV of the '834 patent, brimonidine 0.15% (w/v) is 100% soluble at pH 7.2. The composition of Alcon's proposed product is explicitly shown in Alcon's NDA, which has been provided to Allergan. In addition, Alcon's proposed product does not infringe these claims, either literally or under the doctrine of equivalents, because it does not contain an anionic solubility enhancing agent, the only type which, according to the inventors of the '834 patent, will function in the claimed invention. Rather, Alcon's proposed product contains povidone, an ingredient which, according to the inventors of the '834 patent, will not function in the claimed invention.

The '834 patent-in-suit is a continuation of the '210 patent and therefore the prosecution history of the latter patent limits the scope of the '834 patent-in-suit. In the prosecution history of the '210 patent (portions of which are also discussed with respect to the '337 patent), Allergan elected to prosecute initial Claims 1-30 in response to a restriction requirement made against the original forty-six claims. The Examiner rejected all thirty claims under 35 U.S.C. §103(a) as unpatentable over Burke (US 5,215,991) in view of Remington's Pharmaceutical Sciences. According to the Examiner, Burke discloses compositions of the same quinoxaline drugs that are recited in Allergan's claims and Burke discloses that those compositions contain solubility enhancing components such as polyvinyl alcohol, polyvinylpyrrolidone, hydroxypropylcellulose, poloxamers, carboxymethylcellulose and hydroxyethylcellulose. In response to this rejection, Allergan obtained an interview with the Examiner on February 25, 2003, and argued that the instant invention was "an invention of selection." In the Amendment submitted by Allergan dated March 11, 2003, Allergan amended independent Claims 1 and 20 so that all of the pending claims would be limited to compositions containing an anionic SEC. According to Allergan, "[t]he current claims are directed to compositions comprising brimonidine and salts and esters thereof in combination with an anionic polymeric solubility enhancing component." Allergan also argued as follows:

> Of the "vehicles" specifically disclosed by the Burke patent, all will function to increase the viscosity of a liquid aqueous composition. However, of these vehicles only carboxymethylcellulose (CMC) is an anionic polymer. All of the other polymers are non-ionic. They may act to increase the solution's viscosity, but they do not have the same characteristics as an anionic polymer such as CMC.

Response to Office Action dated March 11, 2003 at 6.

In connection with this argument, Allergan submitted a Declaration of Orest Olejnik, Ph.D., one of the inventors, asserting that "anionic solubility enhancing components such as CMC have surprising and beneficial properties in the solubilization of brimonidine as compared to non-ionic or cationic polymers." Although completely lacking any supporting data, Allergan argued to the Examiner that the Declaration stated that "the use of an anionic polymer solubility enhancing component such as CMC (as compared to the nonionic polymer hydroxypropyl methyl cellulose) has the advantage of adsorbing to cellular surfaces . . . in a manner that retains any drug in solution with the CMC to be retained at the ocular surface far longer (and in larger volume) than viscous formulations made with other, non-anionic polymers, while simultaneously increasing solubility." Allergan concluded its argument by emphasizing that the art cited by the Examiner "would not direct or motivate the person of ordinary skill in the art to select or want to select an anionic polymeric solubility enhancing component such as CMC from the list of optional viscous 'vehicles' contained in the [Burke] patent."

According to the prosecution history of the '210 patent, the anionic nature of the solubility enhancing component is critical. Although Allergan initially presented broad claims that required any "solubility enhancing component," the Examiner did not allow any claims until Allergan amended the claims to limit the solubility enhancing component to an anionic solubility enhancing component. Allergan secured issuance of the patent only after emphasizing that its invention was a selection invention and that anionic solubility enhancing components were surprisingly and unexpectedly different than nonionic or cationic polymeric solubility enhancing components. Accordingly, it is unquestionably clear, in view of the prosecution history of the '210 patent, the parent of the '834 patent, that Allergan is estopped from asserting

that the '834 patent's claims cover any compositions that do not contain an anionic solubility enhancing component.

Individuals with information include the inventors of the '834 patent-in-suit, and the attorneys prosecuting such patent application. Pertinent documents include the prosecution histories of the relevant patents and Alcon's NDA for its proposed product.

2. **The '337 Patent**

In view of the prosecution history, all claims of the '337 patent should be interpreted as requiring an anionic solubility enhancing component. Alcon's proposed product does not infringe these claims, literally or under the doctrine of equivalents, because it does not have a solubility enhancing component nor an anionic solubility enhancement component (see description above in section 1 of this interrogatory response). *See also* discussion of prosecution history of the '210 patent above.

The '337 patent issued from USSN 10/299,386, filed Nov. 19, 2002, which was a divisional application from USSN 09/904,018 (now U.S. Patent No. 6,627,210), filed on July 10, 2001. The '210 patent is discussed above. When the application that led to the '210 patent was filed, the Patent Office restricted the claims into four groups: I. Claims 1-30 drawn to a composition; II. Claims 31-33, drawn to a complex; III. Claims 34-39, drawn to an oligomer; and IV. Claims 40-46, drawn to a composition comprising an oxychloro component. In response, the applicants elected to pursue the invention of Group I in the application that led to the '210 patent. Allergan filed a divisional application, USSN 10/299,386, to pursue the invention of Group IV (original Claims 40 – 46, drawn to a composition comprising an oxychloro component).