IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFFS ALLERGAN, INC. AND ALLERGAN SALES, LLC'S REPLIES TO DEFENDANTS' OPPOSITIONS TO PLAINTIFFS' MOTIONS *IN LIMINE* 1-5

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TABLE OF CONTENTS

Page

I. REPLY IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF ANY CONTINUATION APPLICATIONS OF THE '834 PATENT 1

A. Argument 1

1. The later-filed continuation applications are legally irrelevant to the written description issue. 1

2. In order to shoehorn the CIP into evidence, Alcon recasts the invention of the '834 patent. 1

3. Alcon's new arguments about inherency make no sense. 3

B. Conclusion 3

II. REPLY IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE ALCON FROM OFFERING ANY EVIDENCE OR THEORY THAT IT DOES NOT INFRINGE THE '834 PATENT 4

A. Argument 4

1. Noninfringement arguments that Alcon may have as to the '337 patent do not give notice as to non-infringement arguments regarding the '834 patent. 4

2. Alcon mistakenly expects that a yet-unknown claim construction might open the door to a new, unidentified non-infringement defense. 5

B. Conclusion 5

III. REPLY IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE ALCON FROM PRESENTING PRIOR ART NOT RELIED ON OR EXPLAINED BY ALCON'S EXPERTS 6

A. Argument 6

1. Alcon concedes its experts' testimony must be limited. 6

2. Expert testimony is required for introducing prior art in this technologically-complex case. 6

B. Conclusion 8

TABLE OF CONTENTS (cont'd)

Page

IV. PLAINTIFFS' REPLY TO DEFENDANTS' OPPOSITION TO PLAINTIFFS' MOTION *IN LIMINE* TO PRECLUDE ALCON FROM HAVING MULTIPLE EXPERTS TESTIFY ON A SINGLE ISSUE 9

A. Introduction 9

B. Argument 9

1. Based on the plain language of the final pretrial order, Alcon should be limited to one expert's testimony as to the alleged invalidity of the '834 patent at trial. 9

C. Conclusion 11

V. REPLY IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE CERTAIN TESTIMONY FROM ALAN ROBIN, MD UNDER *DAUBERT* AND FEDERAL RULE OF EVIDENCE 702 12

A. Argument 12

1. Dr. Robin's questionable testimony does not rise to the level of helpfulness or credibility required. 12

2. Alcon does not adequately explain the lack of basis for Dr. Robin's opinion, nor do they adequately explain the actions by Alcon's counsel at his deposition. 14

B. Conclusion 14

TABLE OF AUTHORITIES

Page(s)

FEDERAL CASES

Calhoun v. Yamaha Motor Corp.,
350 F.3d 316 (3rd Cir. 2003) 14

Cooper v. Ford Motor Co.,
748 F.2d 677 (Fed. Cir. 1984) 7

Eli Lilly v. Aradigm Corp.,
376 F.3d 1352 (Fed. Cir. 2004) 5

THK America, Inc. v. NSK, Ltd.,
917 F. Supp. 563 (N.D. Ill. 1996) 10

Union Carbide Corp. v. American Can Corp.,
724 F.2d 1567 (Fed. Cir. 1984) 7

Yeti by Molly Ltd. v. Deckers Outdoor Corp.,
259 F.3d 1101 (9th Cir. 2001) 7

FEDERAL STATUTES

Fed. R. Civ. P. 26(a)(2)(C) 5, 7

I. REPLY IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF ANY CONTINUATION APPLICATIONS OF THE '834 PATENT

Despite Alcon's continuing arguments, the later-filed CIP application is not relevant to Alcon's written description defense. It is black-letter law that sufficiency of written description is based on the specification and claims at the time of filing. Apparently realizing that it cannot overcome the case law, Alcon shifts to a new and equally baseless argument that the later-filed CIP somehow proves that Allergan's original Alphagan formulation inherently anticipated the claims of the '337 patent. But whether PVA might act as an SEC in some later-developed formulations is not proof that it inherently acted as an SEC in the prior-art Alphagan formulation. Alcon's constantly shifting arguments as to the relevance of the CIP application only proves that it is not relevant at all.

A. Argument

1. The later-filed continuation applications are legally irrelevant to the written description issue.

Alcon's case citations do not change the law as set forth in Allergan's opening brief: written description is tested as of the time of filing the application. See Allergan Br. at pp 3-5 (D.I. 150). We refer the Court to the discussion in our opening brief, citing a number of cases that Alcon chooses not to address. Contrary to Alcon's assertion, the "weight" of the evidence found in a later application does not change the proper standard, and Alcon cites no case in support of that assertion.

2. In order to shoehorn the CIP into evidence, Alcon recasts the invention of the '834 patent.

In its written description arguments, Alcon continues to mischaracterize the '834 invention by equating the "0.15%" concentration limitation with the "invention." This

view misses the point entirely. The invention made by Dr. Olejnik and Dr. Kerslake was the ability to formulate compositions containing a therapeutically effective dosage of brimonidine tartrate in an opthalmically acceptable, aqueous solution at a pH greater than about 7.0. Original Alphagan was the state of the art prior to the invention claimed in the '834 patent. Alphagan was a therapeutically effective, opthalmically acceptable solution containing 0.2% brimonidine tartrate at a pH of about 6.4 It was also known that brimonidine tartrate's solubility drops precipitously at pHs greater than about 7.0 As a result, persons of skill in the art did not think it would be possible to formulate a therapeutically effective composition of brimonidine tartrate at these elevated pHs. Drs. Olejenik and Kerslake found that it was possible to formulate at these higher pHs and that the resulting compositions have less harmful side effects for patients. The invention of the '834 patent, therefore, is embodied in both Alphagan P with a target formulation of 0.15% brimonidine tartrate at a pH of 7.2 and in Allergan's recently approved product of Alphagan 0.1% with a target formulation of 0.1% brimonidine tartrate at a pH of 7.7.

The invention is thus not the mere selection of the "0.15%" concentration limitation—rather, that value is merely a convenient upper boundary selected by the inventors in light of the pre-existing Alphagan 0.2% formulation. Indeed, the limitation of claim 1 reads "up to about 0.15%." That the invention is broader than merely "0.15%" is perhaps why Alcon seems to have trouble finding the written description of the invention: Alcon misunderstands or purposefully misstates what invention is described and claimed in the '834 patent. There can be no "overreaching" as suggested by Alcon where the description of the invention is to an invention broader than what is claimed.

3. Alcon's new arguments about inherency make no sense.

After spending much of this litigation trying to argue the relevance of the CIP for the written description issue, Alcon's new claims that the application is relevant to the issue of anticipation by inherency are simply nonsensical. Whether Alphagan inherently had an SEC depends upon whether Alcon can demonstrate, by clear and convincing evidence, that the formulation inherently had an SEC based on what was known to those of skill in the art at the time. A patent application filed years after the fact cannot have any relevance to this inquiry as a matter of law. Accordingly, Alcon's efforts to shoe-horn the CIP application in on these grounds fail as well.

B. Conclusion

For the reasons set forth above and in Allergan's opening brief (D.I. 150), Plaintiff Allergan respectfully requests that the Court issue an Order precluding Defendants from introducing into evidence, or making any direct or indirect references to, the existence or content of any continuing patent applications filed after the filing date of the '834 patent.

II. REPLY IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE ALCON FROM OFFERING ANY EVIDENCE OR THEORY THAT IT DOES NOT INFRINGE THE '834 PATENT

Alcon does not argue – as it cannot – that it has advanced any non-infringement theory other than a long-since abandoned claim construction; it merely holds on to a false hope for some last-minute, never-before-advanced, claim construction to save them. As an act of mercy, that hope should be put to rest now. Having failed in their duty to disclose, or alternatively, having had nothing additional to disclose by way of a non-infringement theory, Alcon cannot be allowed to lie in wait until trial to unveil a new non-infringement theory.

A. Argument

1. Noninfringement arguments that Alcon may have as to the '337 patent do not give notice as to non-infringement arguments regarding the '834 patent.

Alcon, in its recitation of the "facts" performs a classic bait and switch by quoting from the '834 patent's claims and then introducing a non-infringement argument that applies only to the '337 patent. Even if there could be said to be a dispute as to the interpretation of "soluble" as posited by Alcon (which would be news to Allergan), Alcon still raises no non-infringement theory as to the '834 patent. There is no question that the brimonidine tartrate in Alcon's proposed product There is no question that Alcon's proposed product REDACTED There is no question that Alcon's proposed product REDACTED And each of these things is true REDACTED hat is all that is required for infringement of the '834 patent; Alcon's arguments that go to the '337 patent do not and cannot change that conclusion.

2. Alcon mistakenly expects that a yet-unknown claim construction might open the door to a new, unidentified non-infringement defense.

Alcon concedes that, not having "proffer[ed] a claim construction at the appointed time … [they] have waived [their] right to raise the claim construction." Alcon Opp. Br. (D.I. 161) at 6, citing Eli Lilly v. Aradigm Corp., 376 F.3d 1352, 1360 (Fed. Cir. 2004). And yet, Alcon continues to hope for some new, not-yet-proposed claim construction of "important claim terms (such as the term 'soluble') that is different from the ordinary meaning" to avoid a finding of infringement. *See* Alcon Opp. Br. at 7 (D.I. 161). Such hope at this late stage is a false hope, and is based on the premise that Alcon can continue to change its position at will at any time during this litigation – something of a theme with this defendant.

Not having advanced any non-infringement theory prior to trial, Alcon should not be allowed to ambush Allergan with a new theory once at trial. Such a sanction is automatic where there is a failure to comply with Fed. R. Civ. P. 26(a)(2)(C).

B. Conclusion

For the reasons set forth above and in Allergan's opening brief, Alcon should be precluded from offering testimony or evidence that it does not infringe the '834 patent.

III. REPLY IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE ALCON FROM PRESENTING PRIOR ART NOT RELIED ON OR EXPLAINED BY ALCON'S EXPERTS

Alcon concedes that Allergan's position, in the main, is correct and that its experts' testimony should be limited. An order to that effect is respectfully requested. The order should also reflect that the prior art not relied-on or explained by Alcon's experts should also be excluded.

A. Argument

1. Alcon concedes its experts' testimony must be limited.

Allergan appreciates Alcon's concession that "Alcon's experts *may not offer* any opinions regarding prior art that are not disclosed in their expert reports," that "Alcon's experts *will indeed limit* their testimony concerning prior art to the opinions, and bases therefore, set forth in their expert reports, and *do not intend to offer* opinions concerning prior art that are not supported by their pre-trial disclosures," Alcon Br. at 8 (D.I. 161), and that "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." Alcon Opp. Br. at 9 (D.I. 161) (emphases added). Allergan certainly expects that Alcon will stand by its promises and adhere to those statements and the Federal Rules of Civil Procedure that compel those concessions, but Allergan, in an abundance of caution, would request that an order be issued to ensure that there exists no temptation for last-minute sleight-of-hand by Alcon.

2. Expert testimony is required for introducing prior art in this technologically-complex case.

While it may be true that, under certain circumstances, expert testimony is not necessarily required to introduce and explain prior art references, it is respectfully

suggested that this case differs materially from the two cases cited by Alcon, which both referenced rather simple inventions: a locking automobile gas cap in Cooper and a dispenser for plastic bags in Union Carbide. See Cooper v. Ford Motor Co., 748 F.2d 677 (Fed. Cir. 1984) and Union Carbide Corp. v. American Can Corp., 724 F.2d 1567 (Fed. Cir. 1984). Indeed, in the Union Carbide case, the court discussed at length the fact that "the references and appellant's invention are easily understandable without the need for expert explanatory testimony" and that the level of skill was that of the "ordinary layman of average intelligence." Id. at 1573. It is also worthy of note that both of these cases reached the appellate court from decisions on summary judgment, where the evidentiary burdens and legal standards differ from those at trial.

In this case, it is submitted that the pre-trial introduction of technical references, alleged to be prior art, could only have been properly accomplished by the foundational testimony of an expert witness who is qualified to interpret and explain such documents. Without such testimony, the mere citation of these references in Alcon's interrogatory response leaves Allergan with no explanation as to their relevance, no explanation of Alcon's interpretation of the teaching of these references, and no explanation as to how such references might be combined or where the motivation for doing so might be found. The introduction of such references at trial, without any prior foundation, leaves Allergan at an unfair disadvantage, and leaves Alcon with an opportunity to "ambush" Allergan at trial. And it bears repeating that "Rule 37(c)(1) gives teeth to [the requirements of Fed. R. Civ. P. 26(a)(2)(C)] by forbidding the use at trial of any information required to be disclosed by Rule 26(a) that is not properly disclosed." Yeti by Molly Ltd. v. Deckers Outdoor Corp., 259 F.3d 1101, 1106 (9th Cir. 2001).

B. Conclusion

For the reasons set forth above and in Allergan's opening brief, Allergan requests an order limiting testimony by Drs. Amidon or Robin to the references adequately discussed in their expert reports, as listed in Allergan's opening brief, and that any prior art not relied on or explained by Alcon's experts should also be excluded.

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

A. Introduction

Alcon presents no reason why it should be allowed to violate this Court's rule, set forth in the Final Pretrial Order, that it is only allowed to have one expert testify on the issue of whether the claims of the '834 patent are supported by the written description. Alcon has chosen to have both its experts present highly similar opinions on the invalidity of the '834 patent in their expert reports. This is not a tactic that Alcon should be permitted to continue at trial.

B. Argument

1. Based on the plain language of the final pretrial order, Alcon should be limited to one expert's testimony as to the alleged invalidity of the '834 patent at trial.

The Court's Final Pretrial Order provides as follows:

> Only 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.

In Alcon's expert reports, Dr. Amidon and Dr. Robin both provide opinions that the '834 patent is invalid for lack of written description. Although Alcon attempts to paint these opinions as having entirely different focus, closer inspection demonstrates that is not the case. Alcon argues that Dr. Robin presents opinions about written description support for therapeutic effectiveness, while Dr. Amidon presents opinions about written description support for a 0.15% concentration. Based on their reports, however, both experts are plainly opining on both of those points. For example,

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[Marsden Decl., Ex. 1, para. 152 and Ex. 2, para. 69.] Also,

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REDACTED

[Marsden Decl., Ex. 1, para. 154 and Ex. 2, para. 62.] If both experts were to testify at trial as to the subject matter of the opinions in their reports, it would contravene the provision in the Final Pretrial Order allowing a party only one expert witness per subject.

Alcon even acknowledges that two proposed experts' trial testimony would overlap. The plain language in this Court's Final Pretrial Order, however, does not allow for such overlap, absent "good cause." Alcon cites to a case from the Northern District of Illinois, where that Court allowed two experts to testify. In that case, however, there was no overlap on specific issues as there is here. In that case one expert was to testify *generally* about patent office procedures, patent claims, and other basic issues, while the other was to testify *specifically* on the issues of infringement, inequitable conduct, and invalidity of particular patents. *THK America, Inc. v. NSK, Ltd.*, 917 F. Supp. 563, 576 (N.D. Ill. 1996) (emphasis added). They were not both planning to testify on a single ultimate issue, as Alcon plans to have its experts do here with the issue of written description support for the claims of the '834 patent.

Finally, Alcon attempts to show "good cause" for the testimony of multiple experts on written description, arguing that the "issue whether the '834 patent is invalid for lack of written description implicates more than one area of expertise." Alcon Opp. Br. (D.I. 161) at 11. Rather than offering the testimony of a single person of ordinary skill in the art, as is the standard in patent cases, Alcon apparently believes that there is no single person of skill for the '834 patent. It instead attempts to categorize this one patent as both a formulation patent and a patent directed to physicians, in an attempt to squeeze in testimony from two different experts.

But this asks the Court to accept, simply so that Alcon can offer multiple experts, that the inventors, who were formulators, did not have the requisite expertise for their

own patent. This line of argument defies logic and does not create good cause for presenting the testimony of two experts. One person of skill in the art has all the expertise required to opine as to the validity of the '834 patent. But even putting aside the complete lack of merit to this view, if this is Alcon's view, a person of skill in the art—and an expert—needs to have both areas of expertise. Offering two experts with differing expertise does not somehow solve this problem of Alcon's own creation. Rather, each expert is deficient and offering both's testimony does not cure the deficiency.

Accordingly, based on the language in the Court's Final Pretrial Order requiring that "[o]nly one expert witness on each subject for each party will be permitted to testify absent good cause shown," Alcon must choose one expert to testify as to the alleged invalidity of the '834 patent for lack of written description, as it cannot show good cause for having two experts testify on that single subject.

C. Conclusion

For the foregoing reasons, Allergan requests that the Court grant its motion and issue an order limiting Alcon from calling multiple experts to testify at trial about the alleged invalidity of the '834 patent.

V. REPLY IN SUPPORT OF PLAINTIFF'S MOTION *IN LIMINE* TO EXCLUDE CERTAIN TESTIMONY FROM ALAN ROBIN, MD UNDER *DAUBERT* AND FEDERAL RULE OF EVIDENCE 702

Far from being a "red herring," Allergan's criticism of Dr. Robin's lack of formulation experience (and other testimonial failings) goes to the heart of the issue – an expert should fail to make it past the gatekeeper when his proposed testimony does not fit the needs of the case. This is especially so when there are indicia that the witness lacks the proper expertise and lacks credibility.

A. Argument

1. Dr. Robin's questionable testimony does not rise to the level of helpfulness or credibility required.

As foreshadowed by Alcon, Dr. Robin's proposed testimony will go to the supposed expectation that a 0.15% brimonidine tartrate solution would be therapeutically effective at a pH between 7.0 and 7.5 because, according to him, the prior art had allegedly established the efficacy of 0.08% and 0.2% at different pHs. But even this testimony, as crafted by Alcon's counsel, shows the fallacy of allowing Dr. Robin to opine as an expert: these are formulation patents, invented by formulators, for formulators. As discussed in Allergan's opening brief in support this motion, the mere inclusion of the phrase "therapeutically effective" does not magically turn a formulation patent into a patent directed to clinicians. As evidence of the approach physicians take to such matters, consider Dr Robin's own testimony:

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[Marsden Decl., Ex. 3, Deposition Transcript of Dr. Alan Robin, page 108:1-5.]

It may not make any difference to Dr. Robin, but it certainly makes a difference to pharmaceutical chemists and those who are charged with making formulations that allow new therapies to flourish for such hard-to-formulate compounds. It most certainly makes a difference to those of skill in the proper art for the '834 patent. Such a laissez-faire attitude as evidenced by Dr. Robin is hardly appropriate in judging the standard of invention that brought a novel and useful treatment to clinicians, even if

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Alcon also argues that Dr. Robin would testify that the '834 patent's specification does not lead one of ordinary skill in the art to recognize that the inventors claimed a 0.15% concentration of brimonidine as therapeutically effective. But it is Dr. Robin's very lack of expertise that leads him to that erroneous conclusion. Because he is unable to understand the specification for what it teaches, how can Dr. Robin understand what a person of ordinary skill can glean from the disclosure? And although Alcon argues that Dr. Robin is not being offered as a "formulator" – indeed, he could not properly be – they gloss over the fact that such experience is relevant to the "helpfulness" of the proffered opinion. Both parties have presented evidence of what one of skill in the art – the art of pharmaceutical formulation – would understand the claims to mean, and such evidence is far more helpful and relevant than that of Dr. Robin.

Indeed, Alcon's pre-trial-preparation rationale that Dr. Robin can be presented and is qualified to discuss the written description issues of the '834 patent is an obvious attempt at revisionist history and claim construction. Alcon attempts to morph the '834 claims into something directed to clinicians when the disclosure and claims are directed

to pharmaceutical chemists and formulators like Allergan's inventors. And, as has been admitted numerous times, Dr. Robin is not a formulator.

2. Alcon does not adequately explain the lack of basis for Dr. Robin's opinion, nor do they adequately explain the actions by Alcon's counsel at his deposition.

Alcon is too dismissive of Allergan's other bases of challenge, stating that those matters go to weight, not admissibility. There comes a point along the spectrum, however, where so little weight can properly be accorded to testimony that it should be held inadmissible. This is the very role of the Court required by Federal Rule of Evidence 702. Allergan respectfully suggests this is such a case: Dr. Robin could offer no legally or factually relevant bases for his opinion of obviousness, he demonstrated a misunderstanding of the critical chemical behavior of brimonidine, and last, but certainly not least, had to be coached by Alcon's counsel in order to answer in accordance with Alcon's wishes. Under the totality of those circumstances, it is difficult to accept that Dr. Robin's testimony could be viewed as qualified, reliable or fit for this case. See Calhoun v. Yamaha Motor Corp., 350 F.3d 316, 321 (3rd Cir. 2003). Additionally, there is the fundamental question of fairness, and it would be patently unfair for a witness to arrive at trial after the opportunity for counsel to correct his testimonial failings and suddenly provide a basis for the conclusions which counsel would like to reach; bases which were not provided in an expert report and which could not be tested at deposition.

B. Conclusion

For the reasons stated above and in Allergan's opening brief, Plaintiff Allergan respectfully requests that the Court issue an order excluding the testimony of Dr. Alan Robin.

Dated: January 30, 2006 FISH & RICHARDSON P.C.

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CERTIFICATE OF SERVICE

I hereby certify that on January 30, 2006, I electronically filed with the Clerk of Court using CM/ECF, PLAINTIFFS ALLERGAN, INC. AND ALLERGAN SALES, LLC'S REPLIES TO DEFENDANTS' OPPOSITIONS TO PLAINTIFFS' MOTIONS *IN LIMINE* 1-5 which will send notification of such filing(s) to the following:

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