IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

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

**DEFENDANTS' REPLY BRIEF IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF ALLERGAN'S U.S. PATENT NO. 6, 673,337 AND INVALIDITY OF ITS U.S. PATENT NO. 6,641,834**

Josy W. Ingersoll (No. 3362)
John W. Shaw (No. 1088)
YOUNG CONAWAY STARGATT & TAYLOR, LLP
The Brandywine Building
1000 West Street
Wilmington, Delaware 19801
(302) 571-6600
jshaw@ycst.com
Attorneys for Alcon, Inc., Alcon Laboratories Inc. and Alcon Research, Ltd.

OF COUNSEL:

Daniel J. Thomasch
Brian D. Coggio
M. Veronica Mullally
ORRICK, HERRINGTON & SUTCLIFFE LLP
666 Fifth Avenue
New York, NY 10103
(212) 506-5000

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## I. INTRODUCTION

Allergan's opposition arguments to both of Alcon's summary judgment motions suffer from a common flaw: all start from a position developed in the context of litigation, and look back at the patents-in-suit and relevant prosecution histories through a litigation-oriented lens to focus the Court's attention on matters that played no role in the issuance of those patents. That is the wrong approach.

First, Allergan seeks to disassociate itself from its representations to the PTO in the prosecution of the parent application, where Allergan argued an "invention of selection" to cover CMC, and disclaimed povidone and the other non-ionic polymers disclosed in the Burke reference. In this Court, Allergan repeatedly refers to those unselected polymers as "non-anionic SEC's." That term is the artful creation of Allergan's litigation counsel: No such term was ever used by Allergan in the PTO. Burke disclosed, inter alia, six polymer vehicles to carry the active ingredient in an ophthalmic composition, including CMC (used in Allergan's product) and povidone (used in Alcon's product). In the prosecution of the parent application (which issued as the '210 patent) Allergan overcame an obviousness rejection based on Burke by making an "invention of selection" argument in the PTO. In that argument, Allergan characterized CMC alone among the six polymer vehicles disclosed in Burke as a "solubility enhancing component." The notion that some or all of the other five polymers are any type of "SEC" is flatly contrary to what went on in the relevant prosecution history of the parent application to the '337 patent. In designing its product in a non-infringing manner, Alcon had a right to rely on Allergan's "invention of selection" argument in the prosecution history to select a prior art polymer that Allergan disclaimed in obtaining a patent that covered CMC.

Second, in its written description argument for the '834 patent, Allergan relies on blatant hindsight and invites the Court to do the same. Allergan picks and chooses

fragments from here and there in the specification in a fruitless effort to piece together "support" for a claim to a concentration of brimonidine tartrate (the active ingredient) of "up to about 0.15%." That misses the point entirely in a case such as this, where the subject matter of the claims at issue was later-added during prosecution. The dispositive issue here is whether the disclosure (the specification and the original claims) contains a written description that evidences that the inventors had possession of, and actually described the invention they later claimed as of the priority date. As evidenced by the written description added to the specification in continuation-in-part ("CIP") applications that Allergan took from the '834 patent, such written description is not hard to write for an invention claiming a "0.15%" brimonidine composition. The specification of the '834 patent, however, makes clear that the dose of the active ingredient was not part of the invention that the inventors possessed as of the priority date. The invention at that time, as disclosed in the specification, concerned the presence and amount of a solubility enhancing component, which is not even required by the claims at issue. There is not a mention anywhere in the patent to indicate that the inventors had possession of an invention that involved the use of any particular dose of brimonidine tartrate, much less "up to about 0.15%" in particular. Nothing. That dose is simply not mentioned in the specification, a fact that does not require an expert affidavit to prove. The Court is well positioned to review the specification and, finding no teaching to use a dose of the active ingredient of "about 0.15%," to grant Alcon summary judgment under 35 U.S.C. §112 ¶ 1.

## II. ARGUMENT

### A. Alcon Is Entitled To Summary Judgment Of Non-Infringement Of The '337 Patent Because Allergan Disclaimed Non-Ionic Polymers, Including Povidone, Which Is Contained In Alcon's Proposed Product

Allergan does not dispute that Alcon is entitled to summary judgment of non-infringement on the '337 patent if the term "solubility enhancing component" is

construed as encompassing only anionic components, (consistent with Allergan's disclaimer of all non-ionic polymers). Allergan admits that Alcon's proposed product contains "povidone, [which is] not anionic."[1] Despite their admissions and its repeated disclaimer of all but anionic compounds, Allergan seeks to avoid summary judgment by arguing that the claims of the '337 patent should not be limited by its earlier representations in the prosecution of the parent application.

The Court's interpretation of the disputed claim term "solubility enhancing component" will be dispositive of Alcon's motion for summary judgment of non-infringement of the '337 patent. Allergan's opposition to the motion repeats the arguments it made in its opposition to Alcon's proposed claims construction essentially *verbatim*. Therefore, Alcon relies upon the detailed refutation of every one of Allergan's arguments in Alcon's Reply In Further Support Of Its Proposed Claims Construction ("Alcon's Markman Reply"), which is filed concurrently with this brief and is incorporated herein by reference.

Accordingly, for these reasons set forth in Alcon's submissions regarding claims construction, it is respectfully submitted that this Court should interpret the term "solubility enhancing component" as limited by Allergan's disclaimer of non-ionic polymers, including povidone, and grant Alcon's motion for summary judgment of non-infringement of the '337 patent.

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[1] Allergan, Inc. and Allergan Sales, LLC's Opening Markman Brief (D.I. 57) at 5 (emphasis added).

**B. The Claims Are Invalid As A Matter Of Law For Failure To Meet The Written Description Requirements Of 35 U.S.C. § 112 ¶ 1 Because Nothing In The Disclosure (Including The Original Claims) Of The '834 Patent Indicates That The Inventors Were In Possession Of An Invention Involving A Reduced Dose Of Active Ingredient As Of The Priority Date.**

**1. The Specification Makes Clear That The Inventors Did Not Possess The Claimed Invention As Of The Priority Date.**

As explained in Alcon's Opening brief, the specification is replete with descriptions of an invention that involves the use of so-called solubility enhancing components, "SECs," but there is no indication in the specification that, at the time the priority application was filed, the inventors had possession of the later-claimed invention.[2] Varying the concentration of active ingredient was simply not part of the subject matter that the inventors described in their application. The specification discloses "preferred," "more preferred," and "most preferred" values for concentrations of CMC – but nowhere is there any mention of a preferred concentration of active ingredient.[3] The patent describes a number of benefits that should accompany the use of an SEC and the formulation of the composition at higher pHs than would be achievable without an SEC – notably absent from such articulated benefits is any suggestion that a lower dose of active ingredient could, or would desirably, be used.

It stands to reason that, if the inventors had possession of the invention they seek to claim in the '834 patent, they could have easily described it just as Allergan did in its subsequently filed CIPs.[4] But, far from describing the later-claimed invention, the specification is inconsistent with those claims, as the only concentrations that the

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[2] Defendants' Opening Brief In Support Of Their Motion For Summary Judgment Of Non-Infringement Of Allergan's U.S. Patent No. 6,673,337 And Invalidity Of Its U.S. Patent No. 6,641,834 ("Alcon's Opening Brief") (D.I. 55) at 21-27.

[3] While not denominated as "preferred" the only concentration that is suggested to be therapeutically effective is 0.5% brimonidine tartrate. See '834 patent (Alcon's Opening Brief at Ex. B), col. 11, ll. 5-6; col. 3, ll. 13-17.

[4] See infra at 9 and n. 11.

specification actually discloses are 0.2% and 0.5%. The claims of the '834 patent are therefore invalid for lack of written description. See Lockwood, 107 F.3d at 1572.

**a. The Invention Described Relates To The Use Of An SEC.**

The specification focuses on the possibility of enhancing the solubility of the alpha 2-adrenergic agonist drug component (brimonidine) by using varying amounts of SECs, which are said to allow for greater solubility of the brimonidine at neutral to alkali pHs. As described in the patent, brimonidine is more soluble at a higher pH with an SEC than without an SEC. In the Background of the Invention, the specification describes the problems in the art that the invention addresses including: the fact that some alpha-2-adrenergic agonists components become insoluble at neutral to alkaline pHs and that such insolubility may decrease membrane diffusion capabilities, rendering the drug components less effective and/or their therapeutic effects more variable at a given dosage.[5] The invention disclosed in the specification of the '834 patent is directed to:

> aiding or assisting in solubilizing the alpha-2-adrenergic agonist components in the compositions, and preferably in environments to which the compositions are administered or introduced, for example, biological environments, such as the eye.[6]

The patent also describes the benefits of the invention in solubilizing compositions formulated at neutral to alkaline biological pHs (i.e., closer to the pH of the eye) and the benefits of the drug being solubilized at biological pHs are described as a possible improved ability to cross the lipid membranes relative to unsolubilized drug components and possible reduced irritation to sensitive tissues.[7] The described invention in the

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5 '834 patent (Alcon's Opening Brief at Ex. B), col. 1, ll. 43-50.

6 Id. at Summary of the Invention, col. 1, ll. 60-64.

7 Id. at col. 4, ll. 35-40 and 57-59.

specification of the '834 patent concerns the use of an SEC to keep the alpha-2-adrenergic agonist drug component from precipitating out of solution after the drug composition is introduced into the neutral to alkali biological environment of the eye. Thus, the described invention purports to make the therapeutic effect of the drug more predictable (i.e., less variable) at given dosages by ensuring that the amount of drug in solution remains constant even at the more alkaline pH encountered in the eye. However, the patent does not describe reducing the dose of active ingredient as a benefit or advantage of that invention. That is not what the inventors described as their invention at the time of filing the priority application.

**b. The Examples In the Specification Are Inconsistent With The Invention Claimed In The '834 Patent.**

The specification discloses experimental testing with starting compositions having different pHs and different amounts of SEC but it does not contain any testing that compares starting compositions with different amounts of brimonidine tartrate (or any potential active ingredient). Indeed, there are only two places in the specification where the concentration of the active ingredient is actually referenced. In Example 1, the solubility of 0.5% brimonidine is studied at different pHs to show that solubility decreases as pH increases; there is no comparison of compositions with different doses of brimonidine tartrate. In Example 2, solubility of brimonidine is studied in five compositions, all of which are identified as being 0.2% brimonidine, but which differ by the amount of amount of a solubility enhancing component, CMC, that is included in the compositions. The patent does not describe testing of any composition having a concentration of less than 0.2% brimonidine.

**i. Example 1.**

Significantly, Allergan does not attempt to rebut what Alcon pointed out in its opening brief on this motion – that the specification is entirely inconsistent with the

claimed invention.[8] Neither Allergan, nor Dr. Stella, offer any commentary on the clear statement in Example 1 of the specification: "it will be understood that concentrations of adrenergic agonists other than 0.5% may be used."[9] This language in the specification suggests that the inventors anticipated the use of compositions containing up to 0.5% brimonidine, therefore, they could not have regarded their invention as therapeutically effective compositions containing "up to about 0.15%" brimonidine at the time the priority application was filed. Moreover, by expressly noting that other doses could be used, without providing any preferred doses or any data relating dose to therapeutic effectiveness, it is unmistakable that the inventors did not consider the concentration of the active ingredient to be their invention.[10]

**ii. Example 2.**

Example 2 in the specification also provides no teaching of the claimed invention. Example 2 discloses five different compositions which each contain a different amount of CMC ranging from 0% to 1.5%. All, however, contain 0.2% brimonidine tartrate, as described in Table III. Figure 1, based on the data in Table IV, reveals how varying the pH of the composition affects the solubility of 0.5% brimonidine in the various compositions. Example 2 concludes with a discussion about the solubility of brimonidine and how it varies depending on the amount of CMC that is present and how it is unclear why more brimonidine is soluble in solution at pH 7.5 with 0.5% CMC than with 1.5% CMC. Thus, along with Example 1, Example 2 makes it unmistakably clear that the invention described in the priority application, was not the claimed invention at issue, but

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8 Alcon's Opening Brief at 9-10 and 21-24.

9 '834 patent (Alcon's Opening Brief at Ex. B), col. 13, ll. 19-21.

10 It is also very instructive that Allergan removed the "0.5%" language from the specification when it added the written description support for a 0.15% therapeutically effective composition in its subsequently filed CIP. U.S. Patent Application No. 10/851,266 ("the '266 CIP") (attached hereto as Ex. SJ9) at ¶ 0130.

rather relates to the use of CMC to enhance the solubility of brimonidine at pHs higher than pH 7.

Allergan argues that one skilled in the art could infer from Figure 1 and Table IV that under certain conditions less than 0.2% brimonidine would be soluble in the presence of preferred quantities of CMC. Even if true, that is not a written description of the use of 0.15% brimonidine tartrate in any composition, much less the claimed compositions, which do not require an SEC. Whether there are data in the patent that could potentially permit a skilled artisan to derive a product with a reduced concentration of the drug component is irrelevant – that is not the test. Written description is a question of whether the application necessarily discloses the particular invention. Purdue Pharma v. Faulding Inc., 230 F.3d 1320, 1327 (Fed.Cir. 2000). The written description must describe the invention with all of its limitations "not only what makes it obvious." Lockwood, 107 F.2d at 1572. Thus, even if, arguendo, the claimed invention in the '834 patent were obvious from the disclosures in the patent (which it is not), absent an actual written description of the claimed invention, the patent would still be invalid as a matter of law.

**c. The Text And Examples Added To The Specification Of The '834 Patent In Subsequent Continuation-In-Part Applications Reveals The Written Description That Is Missing From The '834 Patent.**

The specification of certain continuation-in-part applications derived from the '834 patent provides objective evidence of the written description that is missing from the '834 patent. In October 2003, just before the '834 patent issued, Allergan filed a continuation application Serial. No. 10/691,912 ("the '912 App.") with method-of-use claims for 0.15% compositions. Thereafter, on May 21, 2004, Allergan filed a CIP application of the '912 App. Serial No. 10/851,266 ("the '266 CIP") with claims drawn to compositions with "up to about 0.15% alpha-2-adrenergic agonist . . . wherein the composition has a pH of about 7.2 to about 7.7 or greater." Claims to 0.1% compositions

were also included.[11] Alcon learned of these patent applications because, even though Allergan abandoned the '912 App., and the '266 and '758 CIPs during the course of this litigation, each of the applications published.[12] The significance of this CIP application will be readily apparent to the Court because it provides a written description for "a therapeutically effective 0.15% composition" and it clearly evidences what is missing from the disclosure of the '834 patent. Although most of the specification of the '266 CIP remained the same as the specification in the '834 patent, certain very significant changes and additions were made. First among these is the addition of a paragraph describing that the invention is directed to compositions containing certain concentrations of brimonidine, including 0.15%:

> [0042] In a particularly preferred embodiment, the invention is directed to a composition comprising 5-brimo-6-(2-imidozolin-2-ylamino) quinoxaline, or salts thereof, wherein the solution is formulated at a concentration of less than 0.2% (w/v). Preferably the active ingredient is present in the composition at a concentration of preferably between 0.2% (w/v) and about 0.0001% (w/v), more preferably about 0.15% (w/v) or less, even more preferably between 0.15% (w/v) and about 0.001% (w/v), most preferably about 0.1% (w/v) or less.[13]

Example 4 was added to the specification of this CIP application to demonstrate how a composition of 0.15% brimonidine was found to be therapeutically effective to reduce ocular hypertension in humans:

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[11] Allergan subsequently filed two additional CIPs of the '912 App. In the second filed CIP (Serial No. 10/850,758 ("the '758 CIP")), three additional examples relating to 0.1% compositions at various pHs were added to the specification. In the third filed CIP (Serial No. 10/928,906 ("the '906 CIP")) an additional example was added and all the claims were drawn to 0.1% compositions formulated at pH 7.7.

[12] Significantly, Allergan did not produce any documents related to these applications in response to Alcon discovery requests.

[13] '266 CIP (Ex. SJ9) at ¶ 0042 (emphasis added).

Example 4

[0143] Brimonidine tartrate was formulated for ophthalmic topical delivery pH 7.2 and a concentration of 0.15% (w/v) in a aqueous solution containing PURITE® as a preservative. The ocular hypotensive efficacy of this formulation was determined in human clinical subjects, and compared to the efficacy of ALPHAGAN®, which contains 0.2% brimonidine tartrate, formulated in aqueous ophthalmic topical solution at pH 6.5 in a citrate buffer with 0.05% benzalkonium chloride as a preservative. A third formulation containing 0.2% (w/v) brimonidine tartrate and a PURITE® preservative was also included as a control . . .

* * *

[0145] At the end of the 12 month period, the results indicated that there was no significant difference in the hypotensive efficacy of a solution containing 25% less of the active ingredient (0.15% brimonidine) when formulated at pH 7.2, as compared to the ALPHAGAN® product (0.2% brimonidine formulated at pH 6.5). However, those subjects receiving 0.15% brimonidine reported a lower incidence of side effects, such as allergic conjunctivitis, oral dryness, conjunctivitis hyperemia, and eye discharge, as compared to the higher (0.2%) concentration of brimonidine. These differences are not seen in the 0.2% brimonidine solutions containing PURITE®, and thus are not attributable to the difference in preservatives.[14]

Thus, it is clear how an adequate written description for a 0.15% therapeutically effective composition of brimonidine should read, and it is equally clear that nothing like that appears in the '834 patent.

[14] '266 CIP (Ex. SJ9) at ¶¶ 0143-0149 (emphasis added).

**2. Allergan's Arguments Are The Product Of Improper Hindsight And Cannot Defeat Summary Judgment.**

**a. Written Description Is Evaluated In The Context Of The Invention As A Whole.**

That Allergan breaks Alcon's argument into two parts is very telling.[15] Under the guise of "first address[ing] Alcon's new argument" and "then address[ing] the argument [upon] which Alcon received permission to move," Allergan proceeds in a manner contrary to the proper way to evaluate written description – in terms of the claimed invention in its entirety. See Lockwood, 107 F.3d at 1572 (The written description inquiry evaluates whether "the claimed invention" is fully set forth in the disclosure) (emphasis added). By separately evaluating individual claim terms outside the context of the claimed invention, Allergan makes a superficial argument that ignores the applicable law. Allergan and its consultant's simplistic approach of matching words and numbers from the claim with the same or similar words and numbers in the specification, regardless of context, does nothing more than demonstrate the fact that Allergan is improperly utilizing hindsight to select parts of the specification that match the claim terms. That is not how compliance with the requirement of § 112 ¶ 1 is determined. See Fujikawa v. Wattanasin, 93 F.3d 1559, 1570 (Fed. Cir. 1996) (improper to use hindsight to confer a written description on a patent where no such description is clearly found in the first instance).

It is well recognized, that in pharmaceutical formulation cases in particular, there is a real risk that "hindsight picking and choosing" will be used to satisfy written description for later filed claims such as those in the '834 patent:

> courts have carefully scrutinized the patent application or specification in light of the claims to determine whether the applicant actually invented the compounds claimed or

[15] Plaintiff's Opposition To Defendants' Motion for Summary Judgment Of Non-Infringement of Allergan's U.S. Patent No. 6,673,337 And Invalidity Of Its U.S. Patent No. 6,641,834 ("Allergan's Opp. Brief") at 23.

> whether she was working backward by combining disparate portions of the specification in an attempt to justify a new claim to a chemical compound that was not within her possession at the time of her invention.[16]

This is precisely what Allergan and Dr. Stella did – picking and choosing support for individual claim limitations from disparate parts of the specification, and then combining them to arrive at a description of the claimed compositions. It is wholly improper to attempt to satisfy §112 by working backwards from the later-filed claims, as Allergan did. See In re Ruschig, 379 F.2d 990, 993 (C.C.P.A. 1967). The written description requirement is not satisfied even if each of the limitations of the claimed compositions were specifically disclosed somewhere in the specification. See Fujikawa, 93 F.3d at 1571. To satisfy that requirement, the disclosure must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the claimed invention as of the priority date. Purdue Pharma L.P., 230 F.3d at 1320.

**i. Mere Recitation Of The Words "Therapeutically Effective" In The Specification Does Not Provide Written Description For The Claimed Invention.**

Allergan's argument consists entirely of recitations of disparate references in the specification to the specific words "therapeutically effective." In a specification that is entirely focused on the invention of compositions containing solubility enhancing components,[17] Allergan points to language such as:

> The polyanionic component preferably is sufficiently anionic to interact with or otherwise affect, in particular increase, the solubility of the alpha-2-adrenergic components. This interaction preferably is sufficient to render the alpha-2-adrenergic components substantially

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[16] Joseph M. Manak, The Law of Written Description in Pharmaceutical and Biotechnology Patents, 23 Biotech L. Rep. 30, 35 (2004).

[17] Alcon's Opening Brief at 21-27.

> completely soluble at therapeutically effective concentrations.[18]

to assert the existence of written description for the claimed invention, notwithstanding the complete absence of any teaching that less than 0.5% brimonidine tartrate would be therapeutically effective. The specification goes on to say: "The amount of SEC in the composition preferably is in the range of about 0.1% (w/v) to 30% (w/v) . . ."[19] The range of the SEC, however, is not part of the claimed invention, which does not even require an SEC. More importantly, the specification says nothing comparable about preferable ranges of the active ingredient, which is the claimed limitation. Finally, the claims require that the claimed compositions actually work to treat disease. In the specification, the only concentration that is said to be therapeutically effective is 0.5%, almost three times the maximum claimed dose.[20] Allergan's bald repetition of the words "therapeutically effective," without further description of any type, does not establish that the inventors were in possession of a novel 0.15% composition that was actually therapeutically effective. See Fujikawa, 93 F.3d at 1571.

**ii. Among The Myriad Of Possible Compositions Disclosed By Figure 1 and Table IV, There Is No Teaching That A 0.15% Dose Is The Invention.**

As Alcon points out in its opening brief, the Federal Circuit in Purdue Pharma (citing In re Ruschig) likened the written description requirements to "blaze marks" necessary to guide the artisan through the forest of the specification to the individual tree

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18 '834 patent (Alcon's Opening Brief at Ex. B), col. 3, ll. 11-13; Allergan's Opp. Brief at 24; Stella Decl. at ¶ 18.

19 '834 patent (Alcon's Opening Brief at Ex. B), col. 3, ll. 13-14 (emphasis added).

20 "It will be understood that concentrations of adrenergic agonists other than 0.5% may be used, so long as they have therapeutic activity." '834 patent (Alcon's Opening Brief at Ex. B), col. 13, ll. 19-22.

that is the claimed invention.[21] The Federal Circuit specifically warned against the use of hindsight to meet the requirements of § 112 ¶ 1.

> [O]ne cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.

Id. at 1326-27 (emphasis added).

Having established that the patent contains the words "therapeutically effective" (but not that the patent discloses the claimed therapeutically effective 0.15% compositions), Allergan then turns to the "0.15%" limitation to complete the second half of its compilation by hindsight. It first points to a "most preferred" pH of 7.5 (not the pH limitation of the claims) and reads the concentration 0.15% from Figure 1.[22] Allergan's consultant, Dr. Stella provides arrows and circles, in full color, to direct the Court to that information on Figure 1. But the bright red arrows and the circle Dr. Stella transposed on to Figure 1, are not the sort of "blaze marks" that the Federal Circuit had in mind in Purdue Pharma.[23] Dr. Stella's attempts to supply "blaze marks" now only serves to prove that they were not originally in the specifications. Regardless of Dr. Stella's convenient conclusions, anyone can see that Figure 1 discloses a myriad of possible compositions. Notably, at about pH 7 (the pH used in the claims) compositions of over 0.4% are shown

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21 Alcon's Opening Brief at 29.

22 Allergan is inconsistent in its asserted ability to interpret Figure 1 since Allergan purports to do so here but was unable to do so in responding to Alcon's Requests to Admit Nos. 13-15. See Plaintiffs' Response To Defendants' First Set Of Requests For Admissions (Nos. 1-26) (attached hereto as Ex. SJ10) at 7-8 and Plaintiffs' Response To Defendants' Second Set Of Interrogatories (No. 12) (attached hereto as Ex. SJ11) at ¶¶ 15-17.

23 See Alcon's Opening Brief at 28.

to be possible in the presence of CMC, and compositions of up to 0.25% are possible without CMC.[24]

Even if pH 7.5 was the pH utilized in the claims (which it is not), at most Figure 1 shows only that certain amounts of brimonidine are soluble in compositions containing varying amounts of CMC – not that 0.15% is a therapeutically effective concentration of brimonidine which would be recognized from the specification as the invention.

**iii. Neither Figure 1 Nor Table IV Discloses The Claimed Invention.**

Moreover, even if Dr. Stella's disparate "blaze marks" were not the product of hindsight, as they most surely are, the invention claimed in the '834 patent is not an invention disclosed by Figure 1. At most Figure 1 discloses, at pH 7.5, a composition of 0.1% brimonidine without CMC or a composition of 0.15% brimonidine which must contain 0.5% CMC. There is no disclosure supporting the invention actually claimed – a composition of 0.15% brimonidine formulated at about pH 7.0 or greater, that does not require an SEC. Similarly, in Table IV the number that Dr. Stella points the Court to, is 0.1451% but if that number in Table IV discloses a composition at pH 7.56, that composition must also contain 0.5% CMC. Thus, even if there was teaching that 0.15% brimonidine tartrate and could be used instead of 0.2% (which there is not), whatever is disclosed by Figure 1 and Table IV at pH 7.5 and 0.5% CMC, it is not the claimed invention.

**iv. Dr. Stella's Theories And Conclusions Do Not Cure The Lack Of Written Description.**

Arguing the basis of its alleged invention, Allergan states that unionized forms of the drug formed at higher pH's "tend to diffuse well across lipid membranes" and "may

[24] The specification provides no explanation whatsoever for how more brimonidine tartrate could be reclaimed from the compositions (0.25% - 0.4%) than was originally in the compositions (0.2%).

allow for use of lower concentrations of the drug without compromising efficacy."[25] While the specification suggests certain advantages of formulating compositions at a higher pH, closer to the pKa of the drug, and the advantages of the resultant increase in the amount of unionized drug in solution, none of those advantages include using at least 25% less active ingredient. That Dr. Stella now advances his theory that unionized forms of the drug "may" allow the use of less drug is of no consequence; neither his theory, nor any similar teaching, is found in the '834 patent. See Lockwood, 107 F.3d at 1572 (the written description must describe the invention with all of its limitations "not only what makes it obvious."). Thus, any "invention" that Dr. Stella came up with after reading the patent is irrelevant to the written description determination if "invention" is not also described in the patent. Purdue Pharma, 230 F.3d at 1327 (written description is a question of whether the application necessarily discloses the particular invention). The conclusory statements of Allergan's hired expert do not cure the lack of written description in the '834 patent.

**b. The Absence Of A New Matter Rejection Is Not Determinative.**

Allergan misstates the law by asserting that the Examiner's failure to reject the claims of the '834 patent as new matter creates an "especially weighty presumption" that the patent complies with the written description requirement.[26] This is not the law. In ICN Photonics, Ltd. v. Cynosure, Inc., 73 Fed. Appx. 425 (Fed. Cir. 2003),[27] the Federal Circuit addressed this very point, stating:

> We should dispel the notion that the failure of the PTO to issue a new matter rejection automatically creates an "especially weighty presumption" of compliance with the written description requirement. Although there is dictum

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25 Allergan's Opp. Brief at 10 (emphasis added).

26 Allergan's Opp. Brief at 22.

27 A copy of this unpublished decision is attached hereto as Exhibit SJ10.

> in Brooktree Corp. v. Advanced Micro Devices, Inc., 977 F.2d 1555, 1574-75 (Fed.Cir.1992) . . . The presumption is far from determinative, however, and we have on occasion invalidated patent claims for including new matter, despite the PTO's having allowed those claims.

Id. at 430 (citations omitted). There simply is no such presumption.

**c. Allergan Has Not Raised A Material Issue of Fact By Submitting The Declaration Of Dr. Stella.**

Allergan argues that Alcon's motion should fail because Allergan has submitted the declaration of an expert witness, Dr. Stella,[28] while Alcon relies on the law, the disclosure of the '834 patent, the subsequently filed CIP, and common sense. But Allergan cannot raise an issue of material fact, ipso facto, by the submission of a strategic expert declaration. The Federal Circuit has on multiple occasions upheld grants of summary judgment in favor of the defendant where the plaintiff-patentee has submitted an expert declaration in an attempt to raise an issue of material fact and the defendant has submitted no declaration. See, e.g., Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 930 (Fed. Cir. 2004) (patentee's expert declarations were not sufficient to raise an issue of material fact to defeat motion for summary judgment of invalidity based on lack of written description); TurboCare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co., 264 F.3d 1111, 1119 (Fed. Cir. 2001) (conclusory statements of expert not sufficient to raise issue of material fact and defeat summary judgment of invalidity for lack of written description); Lockwood, 107 F.3d at 1572 (patentee's expert declaration was insufficient to raise an issue of material fact with respect to written description); see also Abbott Labs. v. Iverness Med. Tech., No. Civ.A. 98-10674-GAO, 2002 WL 1906533, at *1-*2 (D. Mass. Aug. 19, 2002) (affidavit of the patentee's expert witness was not sufficient to create a dispute of material fact regarding the sufficiency of the written description).

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[28] Allergan's Opp. Brief at 4, 22 and 30-34.

Moreover, contrary to Allergan's representation,[29] Alcon's motion does not rely on attorney argument. It provides the Court with compelling evidence of the lack of written description in the '834 patent. This evidence, explained in detail above, shows how Allergan, recognizing the fatal deficiencies in the specification, corrected it by adding text and Examples in a ("CIP"). These additions clearly identify the written description that is missing from the specification of the '834 patent and are strong evidence that the '834 patent lacks adequate written description for claims to therapeutically effective compositions of up about 0.15% brimonidine.

**d. Allergan's NDA Filing Does Not Provide The Necessary Written Description For The Claimed Invention.**

Allergan also argues, without benefit of citation, that because it filed its NDA for Alphagan®P two weeks before it filed the priority provisional application that "the close timing of the NDA filing and the patent filings counsels strongly against a finding in favor of Alcon."[30] As shown by the disclosure in the CIP and the prosecution history of the '834 patent, the basis for the 0.15% claimed invention was the Katz article[31] which reported clinical studies comparing 0.2% and 0.15% Brimonidine-Purite formulations to Allergan's existing 0.2% product. This article was not presented to the PTO until late 2002. Indeed, the Katz article was submitted for publication almost a full year after the provisional application resulting in the patents-in-suit was filed.

More importantly, the entire issue of FDA submissions is a red herring to the issue at hand: FDA submissions cannot provide written description for a patent. Adequate written description for the invention claimed in the '834 patent must be found

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29 Id. at 1.

30 Id. at 11-12.

31 L. Jay Katz, MD, Twelve-Month Evaluation of Brimonidine-Purite Versus Brimonidine in Patients With Glaucoma or Ocular Hypertension, prosecution history of the '834 patent ("'834 PH") (Alcon's Opening Brief at Ex. F), Declaration of Amy Batoosingh received March 24, 2003, Tab 7 at attached Katz article.

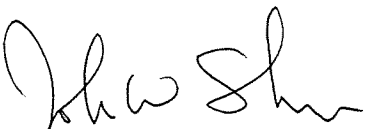
in the specification or the originally-filed claims of that patent. "To meet [the written description requirement], the disclosure of the earlier application, the parent, must reasonably convey to one of skill in the art that the inventor possessed the later-claimed subject matter at the time the parent application was filed." Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998) (emphasis added). For that matter, even if Allergan had made the claimed composition before its priority date, this would not have satisfied the written description requirement. "A showing of 'possession' is ancillary to the statutory mandate that '[t]he specification shall contain a written description of the invention,' and that requirement is not met if, despite a showing of possession, the specification does not adequately describe the claimed invention." Enzo Biochem, Inc., v. Gen-Probe Inc., 323 F.3d 956, 969 (Fed. Cir. 2002). Where, as here, the patent in suit entirely lacks an adequate description of the claimed invention, regulatory submissions or marketed products cannot save the patent from invalidity under 35 U.S.C. § 112 ¶ 1.

## III. CONCLUSION

For the reasons stated above, and on the authorities referenced herein, Alcon respectfully requests entry of summary judgment of non-infringement of U.S. Patent No. 6,673,337 and summary judgment of invalidity for lack of written description of U.S. Patent No. 5,641,834.

Respectfully submitted,

Young Conaway Stargatt & Taylor, LLP



Josy W. Ingersoll (No. 1088)
John W. Shaw (No. 3362)
The Brandywine Building
1000 West Street
Wilmington, Delaware 19801
(302) 571-6600
jshaw@ycst.com

Attorneys for Defendants
Alcon, Inc., Alcon Laboratories Inc.,
and Alcon Research, Ltd.

Of Counsel:

Daniel J. Thomasch
Brian D. Coggio
M. Veronica Mullally
Orrick, Herrington & Sutcliffe LLP
666 Fifth Avenue
New York, NY 10103
(212) 506-5000

Dated: May 23, 2005

**CERTIFICATE OF SERVICE**

I, John W. Shaw, Esquire hereby certify that on May 23, 2005, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

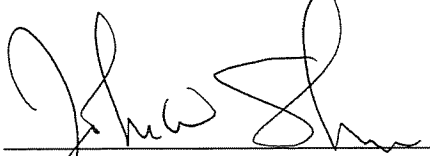
William J. Marsden, Jr., Esquire
Fish & Richardson, P.A.
919 N. Market Street, Suite 1100
Wilmington, DE 19801

I further certify that on May 23, 2005, I caused a copy of the foregoing document to be served on the following non-registered participants in the manner indicated:

**BY E-MAIL**

Jonathan E. Singer, Esquire
Fish & Richardson, P.A.
3300 Dain Rauscher Plaza
60 South Sixth Street
Minneapolis, MN 55402

YOUNG CONAWAY STARGATT & TAYLOR, LLP



Josy W. Ingersoll (No. 1088)
Karen E. Keller (No. 4489)
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, Delaware 19801
(302) 571-6600
kkeller@ycst.com
jshaw@ycst.com

Attorneys for Defendants