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 **REDACTED VERSION**

PLAINTIFFS' 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

Dated: May 23, 2005

William J. Marsden, Jr. (marsden@fr.com)
Sean P. Hayes (hayes@fr.com)
FISH & RICHARDSON P.C.
919 N. Market Street, Suite 1100
P.O. Box 1114
Wilmington, DE 19899-1114
Telephone: (302) 652-5070

Jonathan E. Singer
Michael J. Kane
Deanna J. Reichel
3300 Dain Rauscher Plaza
60 South Sixth Street
Minneapolis, MN 55402
Telephone: (612) 335-5070

Juanita Brooks
W. Chad Shear
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070

Attorneys for Plaintiffs
ALLERGAN, INC. and ALLERGAN SALES, LLC

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I. INTRODUCTION

Whether premised on a claim construction without basis in law—that the '337 patent is limited to "anionic" solubility enhancing components—or an evidentiary claim with no basis in fact—that the '874 patent does not disclose the concentration of active ingredient referenced in the claims ("about 0.15%")—Alcon's summary judgment motion fails in all respects and should be denied.

With respect to the '337 patent, that patent is plainly not limited to "anionic" solubility enhancing components, as claimed by Alcon. In contrast to the '210 patent, which is not asserted by Allergan here, the '337 patent does not use the term "anionic" in any of the asserted claims. Essentially, Alcon is asking the Court to rewrite the claims of the '337 patent and add the word "anionic." This request is based on a misleading and incomplete recitation of the prosecution history of the '337 patent, violates numerous canons of claim construction law and is an invitation for this Court to commit legal error.

As to the '834 patent, Alcon's motion: 1) fails even to mention the evidentiary standard to which its written description argument is subject—clear and convincing evidence—and 2) declines to inform the Court that the principal case upon which the summary judgment motion relies—*Purdue Phara, L.P. v. F.H. Faulding & Co.*—was decided after a full trial on the merits. Tellingly, the motion is based entirely on attorney argument, without any evidentiary support at all even though written description is a question of fact based on the views of those of ordinary skill. Moreover, the motion is principally based on a new argument for which Alcon never received permission to file summary judgment and that is conspicuously absent from both Alcon's discovery responses in this litigation, as well as its Paragraph IV certification provided to Allergan last summer.

The motions are unsupported in law or in fact, and the motion on the '834 patent violates fundamental procedural fairness. The Court should deny the motions forthwith.

II. NATURE AND STAGE OF THE PROCEEDING

This case concerns Alcon's infringement of Allergan's United States patents nos. 6,637,337 (the "'337 patent") and 6,641,834 (the "'834 patent"). In July, 2004, Allergan received notification from Alcon that it had filed a section 505(b)(2) application with the United States Food and Drug Administration for approval of a generic version of Allergan's widely sold glaucoma drug, Alphagan® P (0.15% brimonidine tartrate solution). Alcon's proposed generic formulation infringes both the '337 and '834 patents.

On November 30, 2004, the Court granted Alcon permission to file a summary judgment motion limited to the following two issues: "a) whether the claims of the '834 patent violate the written description requirement of 35 U.S.C. § 112 because they use the percentage '0.15%'; and b) whether the limitation 'solubility enhancing component' in the '337 patent should be limited to only anionic solubility enhancing components." Scheduling Order, at 4.

Apparently having realized that its original written description argument was doomed to failure, Alcon now raises in its summary judgment brief a new argument that the claims of the '834 patent are invalid for failure to comply with the written description requirement because there is no support for the 0.15% (w/v) concentration being "therapeutically effective," as recited in the preambles of the independent claims. Alcon makes this argument despite the fact that: (1) it is outside of the limited grounds for which the Court granted leave to file a summary judgment motion; (2) is not listed as one of its defenses to infringement in its interrogatory response served in this case or in its Paragraph IV certification; and (3) is outside the scope of the discovery that Allergan

took to respond to Alcon's motions. This new argument is an unfair surprise.[1] But like Alcon's two original arguments it is without merit nonetheless.

As demonstrated below, because the '337 patent is not limited to anionic solubility enhancing components ("SEC"), Alcon's proposed 0.15% brimonidine tartrate may not escape a finding of infringement on this ground. Moreover, because one of skill in the art would immediately recognize that the inventors of the '834 patent had possession of therapeutically effective concentrations of about 0.15% (w/v) 5-bromo-6-(2-imidizolidin-2-ylamino) quinoxaline tartrate ("brimonidine tartrate"), the '834 patent is not invalid.

III. SUMMARY OF THE ARGUMENT

1. The asserted claims of the '337 patent are not limited to anionic SECs, and Alcon's summary judgment motion should be denied. The plain language of the claims does not limit the claims to "anionic" SECs, and *all* the intrinsic evidence is consistent with this plain language. Alcon's motion misstates the applicable law to this case, as well as completely mischaracterizes the '337 patent's file history.

2. Because the specification of the '834 patent is clearly directed to therapeutically effective compositions, and the 0.15 % (w/v) concentration of brimonidine tartrate is explicitly disclosed to one of skill in the art in Figure 1 of the patent, as well as Table IV of the '834 patent, the asserted claims of the '834 patent are not invalid for failure to comply with the written description requirement of 35 U.S.C. § 112, ¶1. Moreover, because written description is an issue of fact based on the views of

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[1] Alcon's summary judgment motion also makes at least passing reference to still more invalidity arguments which are outside the scope contemplated by the Court's Order. At one point, Alcon suggests that the '834 patent could be invalid for a best mode violation. (*See* Alcon's Opening Brief, at 26 n. 45, D.I. 55.) At other points, Alcon suggests that the invention disclosed in the specification must include either a solubility enhancing component or a preservative. (*See, e.g.*, Alcon's Brief, at 21, D.I. 55.) These arguments are likewise improperly raised by Alcon. Allergan is filing contemporaneously herewith, a motion to strike Alcon's unfairly raised arguments.

those of ordinary skill, Alcon's failure to present competent evidence of the meaning of the disclosure of the '834 patent to a person of ordinary skill requires denial of its motion.

IV. STATEMENT OF FACTS

A. Brimonidine is a Powerful Glaucoma Medication, Brought to Market First by Allergan as ALPHAGAN®, a Generic Version of Which is Now Sold by Alcon

Open-angle glaucoma is an incurable disease of the eye that causes gradual vision loss and can lead to blindness. [Marsden Markman Decl. Ex. D, D.I. 58][2] Almost 70 million people worldwide suffer from glaucoma, which is the second leading cause of blindness worldwide. [*Id.*] Allergan is a leader in the development of pharmaceutical treatments for glaucoma, investing hundreds of millions of dollars annually in research and development. [*Id.*]

Although there is no cure, there are various pharmaceutical and surgical treatments that may slow the progression of glaucoma. One of these treatments is to lower the pressure of the fluid in the eye, known as intra-ocular pressure ("IOP"). Scientists and medical personnel believe that the elevated IOP found in glaucoma patients contributes to the gradual retinal deterioration and loss of vision that are characteristics of the disease.

Topically-applied brimonidine assists in the lowering of IOP. The drug was originally used to treat high blood pressure, but in the early 1990's, Allergan scientists discovered that it was also a powerful medication for lowering IOP.[3] After investing millions of dollars to prove the safety and efficacy of the drug, Allergan received approval from the FDA and launched the drug in 1996 under the tradename Alphagan®.

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[2] Several of the Exhibits that are referred to throughout this brief were submitted as exhibits to William J. Marsden's Declaration submitted with Allergan's Opening Brief in Support of Its Proposed Claim Construction. Therefore, the exhibits from that declaration will be referred to as "Marsden Markman Decl," while the Declaration of William J. Marsden that is submitted concurrently with this brief will be referred to as simply "Marsden Decl."

[3] Additionally, Allergan scientists discovered that Brimonidine protects the optic nerve.

Alphagan® was a 0.2% formulation of brimonidine at a pH range of 5.6-6.6. After the expiration of Allergan's five-year statutory exclusivity period, Alcon launched a generic version of Alphagan®, which Alcon sells to this very day. [Marsden Decl. Ex. A]

B. Allergan's Alphagan® P is a Significant Improvement Over Alphagan®, with over a 40% Reduction in Allergic Side Effects, for Which the FDA Granted Three Years of Market Exclusivity Under the Hatch-Waxman Act

Although brimonidine is very effective at treating glaucoma, it can cause significant side effects, including allergic conjunctivitis, a far more serious version of the familiar childhood ailment, "pinkeye." Accordingly, beginning in 1997, Allergan set out to design a new brimonidine product that provided the same or better efficacy as Alphagan® but with reduced side effects and an overall better tolerability profile.

The result of Allergan's development efforts was Alphagan® P, which contains 0.15% brimonidine, a twenty-five percent reduction in concentration over the original Alphagan® product. Alphagan® P was shown in clinical studies to have comparable efficacy to Alphagan®, but with a forty percent reduction in allergy rate. [Marsden Markman Decl. Ex. G, AGN0221650-658, D.I. 58] Because of this significant additional patient benefit, Allergan was awarded a three-year market exclusivity period by the FDA for Alphagan® P, above and beyond that which Allergan had received for Alphagan®. The FDA granted this exclusivity when it approved Allergan's New Drug Application ("NDA") for Alphagan® P on March 16, 2001.

Market exclusivities such as the one received by Allergan for Alphagan® and Alphagan® P (and those received by Alcon for its drugs, including, for example, a three-year exclusivity received by Alcon for its reformulation of its Betoptic® drug, Betoptic® S)[4] are one of the ways the Hatch-Waxman Act provides incentive to companies to

[4] In this regard, Alcon's repeated implication that Allergan has done something wrong by employing the system precisely as Congress intended should not be taken seriously. Alcon has received multiple market exclusivities for its pioneer drugs, and, through this litigation, hopes to gain an additional market exclusivity (albeit, a generic exclusivity) for its generic version of Alphagan® P. *See* 21 U.S.C. § (j)(5)(B)(iv)(I).

develop new drugs and improve on existing drugs. 21 U.S.C. 355 (c)(3)(E)(ii)[5]. If a company can demonstrate to the FDA that it has improved its drug, as Allergan did for Alphagan® P, the FDA will grant additional market exclusivity in addition to the exclusivity period the pioneer manufacturer may already have received for the original formulation. 21 U.S.C. 355 (c)(3)(E)(iii).

Another way the Hatch-Waxman Act provides incentives to pioneer manufacturers to develop and discover new drugs and drug formulations is through the strong protection of patent rights. Hatch-Waxman is, fundamentally, a compromise between the interests of pioneer drug manufacturers and generic drug manufacturers. *Andrx Pharms., v. Biovail Corp.*, 276 F.3d 1368, 1371 (Fed. Cir. 2002). Before the Hatch-Waxman Act, all drug manufacturers, both brand-name and generic alike, had to incur the cost to perform the clinical studies necessary to demonstrate that a drug was safe and effective for its intended use. *See Allergan, Inc. v. Alcon Laboratories, Inc.*, 324 F.3d 1322, 1325 (Fed. Cir. 2003). This significantly increased the amount of time that it took for generic drugs to reach the market.

The Hatch-Waxman Act eliminated the requirement that generic drug manufacturers perform these studies in most circumstances. The Act also provided generic drug manufacturers with the ability to use a pioneer drug or formulation claimed in a patent in order to prepare an application for FDA approval of a generic drug, without liability for infringement. 35 U.S.C. § 271(e)(1). That application can take one of two forms: (1) an Abbreviated New Drug Application ("ANDA"); or (2) a Section 505(b)(2) application, often called a "paper NDA." 21 U.S.C. § 355. An ANDA relies on the safety and efficacy results obtained by the innovator drug company by showing that the generic product is bio-equivalent to the approved drug. 21 U.S.C. § 355(j). To the extent

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[5] Alcon incorrectly cites to this section as 21 U.S.C. § 355(c)(3)(D)(ii), however, the Act was amended in 2003 and the correct citation for that section is now § 355(c)(3)(E)(iii). Congress created this initial five year market exclusivity period primarily to encourage the development of unpatentable pharmaceuticals. H.R. Rep. 98-857, pt. 1, at 29 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48.

that a generic company modifies the formulation in any way, it may file a paper NDA which may rely on not only the original safety and efficacy results from the pioneer but also published literature to demonstrate the safety and efficacy of the proposed formulation. In either form, the generic's cost in seeking approval of the drug is dramatically reduced.

But while permitting a generic manufacturer to use the pioneer's data and patents in the FDA application process, Hatch-Waxman does not permit the outright copying of valid patent rights by a generic manufacturer in the ultimately-marketed generic drug. Unfortunately, that is exactly what has happened here.

C.

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D. The Inventions of the Patents in-Suit Made Alphagan P Possible

1. The Nature of the Eye Presents Formulation Difficulties in Reducing the Concentration of Drug

In developing its generic formulation, Alcon copied the inventions of the patents-in-suit. These inventions are the key to formulators' ability to offer a brimonidine formulation at a lower concentration while at the same time maintaining efficacy and reducing side effects. Simply put, without these inventions, Alphagan® P would not have been possible.

As stated above, Allergan scientists began the research underlying the patents-in-suit in approximately 1997. This research faced significant hurdles because of certain physiological aspects of the eye. Because liquid very quickly drains off of the eye, medications applied in the form of eye-drops have a very short residence time on the eye. [Declaration of Valentino Stella ("hereinafter, Stella Decl.") submitted herewith, ¶ 8.]. Typically, only a small percentage of the drug that is placed on the eye is actually absorbed by the cornea where it can have therapeutic benefit. [*Id.*]. Thus, simply lowering the concentration of brimonidine in the same formulation was not an option, as this would have dramatically reduced the drug's effectiveness in a comparable amount. Accordingly, Allergan scientists had to come up with a different solution to the problem.

2. The invention of the '834 patent – Un-ionized drug, more concentrated at increased pH, most effectively passes into the eye where it can be of therapeutic benefit

The outer layer of the eye, the epithelial layer, contains lipid membranes that the drug must pass through to be therapeutically beneficial. As disclosed in the patents-in-suit, it is believed that un-ionized (i.e., neutral) forms of the drug more readily pass through these membranes, while ionized, or charged, forms may not. [Marsden Markman Decl. Ex. C, '834 Patent, Col. 1, ll. 34-43, D.I. 58]

Drugs like brimonidine exist in two states: (1) the protonated or charged (ionized) form; and (2) the neutral or un-ionized form. [Stella Decl. ¶10]. In solution,

both forms exist in equilibrium in concentrations that depend on the pH of the solution. pH is a measurement of the acidity or basicity (alkalinity) of a solution. Acidic solutions are those with pHs from zero to 7. Basic (or alkaline) solutions are those with pHs from 7 to 14.

For brimonidine, as the pH of the solution increases and approaches the pKa of the drug,[6] the concentration of the un-ionized form substantially increases. Accordingly, at higher pH's, more drug is in the un-ionized form. Because un-ionized forms of brimonidine diffuse better across the lipid membranes of the eye, the drug will be more bioavailable and may allow for use of lower concentrations of the drug without compromising efficacy. [See Stella Decl. ¶¶10-12; see also Marsden Markman Decl. Ex. C, '834 patent, Col. 1, lines 34-43, Col. 6, lines 8-16, D.I. 58.]

The '834 patent claims the use of these lowered concentrations of brimonidine at elevated pHs. *See generally*, Claim 1 of the '834 patent. Because about 0.15 % brimonidine is disclosed as roughly the solubility limit of brimonidine at the most preferred pHs in the patent (about 7.5), *see* Figure 1 and Table IV of the '834 patent, the claims are written with that concentration as an upper limit. Alphagan® P is formulated in this elevated pH range, as is Alcon's proposed generic formulation.

3. The invention of the '337 patent - A more robust formulation can be made using solubility enhancing components in the formulation.

Raising the pH of the formulation presented its own set of problems, however. As the pH goes up, brimonidine tartrate experiences a rapid drop in solubility. Figure 1 of both patents demonstrates the relationship between solubility and pH. To maintain the advantage of formulating at a higher pH, Allergan researchers also discovered that it was possible to use components known as "solubility enhancing components" to increase the

[6] The pKa of an acid or base is its "acid disassociation" constant, which measures the extent to which the hydrogen ions in an acid or base will disassociate from the acid or base.

solubility of the brimonidine in these solutions. [*See* Marsden Markman Decl. Ex. B, '337 Patent, Col. 2, lines 9-17, D.I. 58.]

The '337 patent claims the use of these SECs with alpha-2-adrenergic agonists such as brimonidine. *See generally*, Claim 1 of the '337 patent.[7] The patent specification discloses the use of a variety of SECs, including anionic SECs like the carboxymethylcellulose ("CMC") used by Allergan in Alphagan P, and non-anionic SECs like that proposed to be used by Alcon in its proposed generic formulation. Indeed, the SEC chosen by Alcon for its proposed generic formulation, povidone, which is also known as polyvinylpyrrolidone, is specifically listed in the patent specification as an SEC that may be used according to the teachings of the invention. [See Marsden Markman Decl. Ex. B, the '337 Patent, Col. 2, ll. 9-17, D.I. 58.]

The '337 and '834 patents have a common specification and descend from a provisional application that was filed on July 14, 2000 with 46 original claims directed to the various inventions encompassed within the specification. Contrary to Alcon's unsupported implication that the Examiner may not have been aware of the claims filed in related applications, all of the related applications that resulted in the '337 patent, the '834 patent, and the 6,627,210 (hereinafter "the '210 patent") patent were reviewed and examined by the same examiner. And while we address this prosecution history below, we also have addressed it in detail in our *Markman* briefs, which we specifically incorporate herein.

After its scientists discovered these inventions, Allergan submitted its NDA for Alphagan® P to the FDA on June 29, 2000. [Marsden Decl. Ex. I – AGN0000021-23]. This is two weeks before Allergan filed the provisional application that resulted in the '337 and '834 patents. At the time Allergan filed its provisional patent application,

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[7] *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1370 (Fed. Cir. 2003) ("[a]n invention may possess a number of advantages or purposes, and there is no requirement that every claim directed to that invention be limited to encompass all of them.")

Allergan had completed years of clinical trials and submitted a 60,000 page NDA to the FDA showing that Alphagan P was indeed a therapeutically effective, 0.15% brimonidine tartrate solution. And while not directly relevant to the legal standard for the written description defense, which is based on the teachings of this originally-filed provisional application, the close timing of the NDA filing and the patent filing counsels strongly against a finding in favor of Alcon.

V. ARGUMENT

A. The Asserted Claims of the '337 Patent Are not Limited to Anionic SECs and Alcon's Arguments Seeking to Read the Word "Anionic" Into the '337 Patent Claims Are Not Supported By the Intrinsic Evidence or By the Cited Case Law.

Alcon's Motion for Summary Judgment with respect to the '337 patent is based *entirely* on its untenable claim construction position that the claims of the '337 patent are limited to anionic SECs. As clearly set forth in Allergan's Response to Alcon's Memorandum in Support of Its Claim Construction, the claims of the '337 patent are not limited to anionic SECs, and we incorporate that brief by reference here. So that the record is complete, however, we address Alcon's arguments below, as well, as space allows.

Before doing so, however, we note that the independent claims of the '337 patent do not contain the term "anionic" in front of the term "solubility enhancing component." Accordingly, Alcon is asking this Court to read a word into the claims based entirely on a non-infringement position constructed after-the-fact that suffers from a fatal flaw—the statements from the '210 prosecution history upon which Alcon relies were all made with reference to claims that actually used the term "anionic." How such statements can limit later claims that specifically do not use the word "anionic" is not explained by Alcon. Indeed, the law and all the intrinsic evidence demonstrates that such "disclaimer" cannot occur in the circumstances presented by this case. Accordingly, Alcon's request that the

Court do so invites clear legal error and ignores multiple, binding Federal Circuit precedents.

1. The Ordinary Meaning and the Specification Both Demonstrate that the Invention Includes SECs of Any Ionic State.

Claims are presumptively entitled to carry the full scope of their ordinary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002). As demonstrated in Allergan's opening *Markman* brief, the ordinary meaning of the term "solubility enhancing component" is broad and reaches any component that increases the solubility of the alpha-2-adrenergic agonist component. Alcon does not argue otherwise.

This broad meaning is confirmed by the intrinsic evidence. The specification of the '337 patent explains that "[a]ny suitable SEC may be employed in accordance with the present invention" and goes on to list numerous examples of SECs, some of which are non-ionic and some of which are anionic. [*See* Marsden Markman Decl. Ex. B, '337 Patent, Col. 6, l. 17 – Col. 7, line 9, D.I. 58.] Indeed, one of the identified non-anionic SECs is polyvinylpyrrolidone (povidone), which Alcon uses in its proposed product. [*Id.*]

With respect to anionic SECs, the specification repeatedly refers to these substances as "preferred embodiments," not as the invention itself. *Id.*

> Any suitable SEC may be employed in accordance with the present invention. On one embodiment, the SECs include pyrrolinidone components. Examples of pyrrolinidone components are polyvinylpyrrolinidones and derivatives thereof. In a preferred embodiment, the SECs include polyanionic components.

[Marsden Markman Decl. B, '337 Patent, Col. 6, ll. 18-23, D.I. 58.][8] Accordingly, absent a 'clear disclaimer' of this subject matter, Alcon's request to limit the claims to "anionic" SECs violates a basic canon of claim construction by seeking to limit the claimed

[8] Anionic SECs need only have one negative charge but may have more. "Polyanionic" SECs, like CMC used in the preferred embodiment, must have multiple negative charges.

invention to the preferred embodiment. This is strictly forbidden by applicable Federal Circuit precedent. *See Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-87 (Fed. Cir. 1998).

2. The Statements from the '210 Patent Prosecution History Relied Upon by Alcon Were Directed to Claims that Had Already Been Narrowed to Include the Term "Anionic" and, as a Matter of Law, Cannot Limit the Scope of the Broader Term "Solubility Enhancing Component."

As demonstrated in Allergan's opening *Markman* brief, prosecution history statements may only be used to limit the claims if they demonstrate a clear and unmistakable surrender of subject matter. *See Storage Tech. Corp. v. Cisco Sys., Inc.*, 329 F.3d 823, 833-34 (Fed. Cir. 2003) (refusing to limit scope of claim term because the applicants' prosecution statements were not found "to be a clear and unambiguous disavowal of claim scope as required to depart from the meaning of the term provided by the written description"). The Federal Circuit has consistently declined to find disclaimer in cases where there is any ambiguity in the prosecution statements. *See, e.g., Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1347 (Fed. Cir. 2001) (refusing to limit the ordinary meaning of the claim because the alleged disclaimer in the file wrapper was at best "inconclusive"); *Vanguard Prods. Corp. v. Parker Hannifin Corp.*, 234 F.3d 1370, 1372 (Fed. Cir. 2000) (refusing to narrow the asserted claim based on prosecution disclaimer because "the prosecution history does not support [the infringer]'s argument that the Vanguard inventors 'expressly disclaimed' claim scope beyond products made by co-extrusion").

Here, there is not even any ambiguity to the file histories—there was no disclaimer at all. All the prosecution history statements from the parent file history that are relied upon by Alcon were made in support of claims that had already been narrowed to require anionic SECs, and relate to particular advantages of this preferred embodiment. Specifically, at the time of the statements relied upon by Alcon, all of the pending claims of the '210 patent had already been amended to contain either the term "polyanionic

solubility enhancing component" or "anionic solubility enhancing component." [Marsden Markman Decl. Ex. J, AGN0221893-903, D.I. 58] As a matter of law, these statements cannot restrict the scope of the broader term "solubility enhancing component." *See Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1305 (Fed. Cir. 2001) (refusing to limit claim to require that balloon be coaxial with guidewire lumen because, unlike the claims of the parent patents, the claims of the patent-in-suit did not contain that term).

As *Advanced Cardiovascular* teaches, the prosecution history of a related patent may only be used to limit a related patent if that prosecution history addresses a common claim term. *Id.* Here, however, the later patent does not contain the limitation ("anionic") that was added to the parent patent. As such, the parent prosecution history may not limit the claims of the later case. *See id.* at 1305-06; *Cf. Al-Site Corp. v. VSI Int'l, Inc.*, 174 F.3d 1308, 1322 (Fed. Cir. 1999) ("While in some cases, the prosecution history of a related application may limit application of the doctrine of equivalents in a later filed patent, in this case the specific limitation added in the claims of an earlier issued patent is not present in the claims of the later issued patents.").

Because of this lack of a common claim term between the parent case and the patent-in-suit, the cases cited by Alcon regarding prosecution disclaimer are simply not relevant. Each of those cases deal only with the application of the prosecution history of a parent application to a later patent that "contain[s] the same claim limitation." *See, e.g., Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999) (emphasis added). Alcon's disclaimer argument fails completely.

3. Alcon Mischaracterizes Allergan's Statements from the '210 Patent Prosecution to Fashion a Disclaimer that Never Occurred.

In addition to citing inapplicable case law, Alcon repeatedly mischaracterizes Allergan's statements in the prosecution of the '210 patent as saying that the non-ionic vehicles disclosed in Burke "would not function as SECs" and asserts that Allergan

"expressly disclaimed certain enumerated SECs." [*See e.g.*, Alcon's Opening Markman Brief, at 13, 15 and 20, D.I. 55] This is a blatant misrepresentation of the record of the PTO proceedings.

In Dr. Olejnik's declaration submitted during prosecution of the parent '210 patent, he stated that the "Burke patent discloses a multitude of different ingredients that may be contained in formulations containing brimonidine; among these are mentioned optional 'vehicles' which may include, without limitation, polyvinyl alcohol, povidone (polyvinylpyrrolidone), hydroxypropylcellulose, poloxamers, carboxymethylcellulose (CMC), and hydroxyethylcellulose." [Marsden Markman Decl. Ex. J, AGN0221902-903, D.I. 58] Dr. Olejnik further explained that CMC, the only anionic polymer on that list, "possesses the surprising advantages of both increasing the solubility of brimonidine in solution, as shown in Table 1, and causing such solutions to have superior adherence to cell surfaces, including ocular surfaces such as the cornea." [[Marsden Markman Decl. Ex. J, AGN0221893-899 (emphasis added), D.I. 58] Dr. Olejnik then went on to explain that the other vehicles in Burke would not possess the "surprising combination of advantages" of the anionic SECs recited in the narrow claims. [*Id.*]

Nowhere in this declaration is it stated or implied that the other vehicles disclosed in Burke would not be effective as solubility enhancing components. Dr. Olejnik simply stated that the anionic preferred embodiment, to which the amended claims were directed at that time, possessed an additional surprising advantage of increased adherence to the eye surfaces. This was surprising because it would have been expected that the anionic components would be repelled by the negatively charged surfaces, and therefore not adhere as well.

In the reply to the office action relied upon by Alcon, the point being made is the same. In the reply, Allergan argued that the other "vehicles" disclosed in Burke did not have the same characteristics as the claimed anionic SECs because the anionic SECs provided a surprising advantage in "adsorbing to cellular surfaces, such as the cornea ...

while simultaneously increasing solubility." [Marsden Markman Decl. Ex. J, AGN0221898-899, D.I. 58] Nowhere in the office action reply or the declaration did Allergan state that non-anionic components would not work as SECs or circumscribe the term "SEC" to include only anionic components. Rather, Allergan highlighted particular additional advantages of the anionic preferred embodiment covered by the amended claims. There is no disclaimer of any of the other "vehicles" disclosed in Burke.

Moreover, contrary to Alcon's suggestions [Alcon's Opening Markman Br. at 14], nothing that Allergan said during prosecution of the '337 patent was inconsistent with any of the earlier statements from the '210 parent prosecution. In support of the patentability of the broader '337 claims, Allergan argued to the examiner that "nothing in Burke discloses or suggests the use of a solubility enhancing component in combination with an alpha adrenergic agonist." [Marsden Markman Decl. Ex. K, AGN0221774, D.I. 58] This is entirely consistent with statements from the '210 prosecution history, which acknowledge that Burke discloses a list of potential "vehicles," but never says that Burke makes any reference to the potential effect of any of these vehicles on solubility or suggests an appropriate amount to use to affect solubility. Allergan did not reclaim subject matter that had been "disclaimed" during prosecution of the parent application.

4. Allergan Properly Amended the Claims to Speed Prosecution During the '210 Patent Prosecution and Resubmitted Broader Claims in a Later Application.

During prosecution of the '210 patent, Allergan made clear that the "claim amendments and cancellations have been made solely in order to enable early allowance of certain aspects of the invention; Applicants have cancelled and/or amended claims in this application with the understanding that they may present the unamended and non-cancelled versions thereof in a subsequent patent application." [Marsden Markman Decl. Ex. J, AGN0221897, D.I. 58] This one statement puts the lie to Alcon's claim that somehow Allergan "disclaimed" or "waived" subject matter at any time. Simply put, Alcon fails to tell the Court (though it undoubtedly knows it) that it is perfectly common

and acceptable practice for a patentee to obtain narrow claims in an earlier patent and seek broader claims in later continuing or divisional applications.

In *Liebel-Flarsheim Co. v. Medrad, Inc.*, 358 F.3d 898, 909 (Fed. Cir. 2004), the Federal Circuit refused to read a "pressure jacket" limitation into the asserted claims. The patents-in-suit derived from a common application, and during prosecution of both of them, the applicants replaced claims that included a pressure jacket limitation with claims not reciting that limitation. *Id.* According to the Federal Circuit, "[t]he omission of reference to a pressure jacket in many of the claims of the applications that matured into the [patents-in-suit] is a strong indication that the applicants intended those claims to reach injectors that did not use pressure jackets." *Id. See also Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1357-58 (Fed. Cir. 2004) (refusing to limit claims in a later patent to a predetermined method because the "progression, from 'predetermined time period' to 'predetermined incubation period' to 'suitably stable endpoint,' shows that LifeScan purposefully sought in the '162 patent claim scope broader than the predetermined timing method.") *Id.* at 1358.

Just as in *Home Diagnostics,* Allergan first obtained relatively narrow claims directed to a preferred embodiment—an anionic solubility enhancing component—in the '210 parent patent, and then later sought and obtained broad claims covering any type of solubility enhancing component other than a cyclodextrin in the '337 patent. This progression clearly demonstrates that the '337 patent cannot be limited to anionic SECs, and Alcon's Motion for Summary Judgment of Non-Infringement should be denied.

5. Alcon's Reliance on the Federal Circuit Decisions in *Wang, Microsoft,* and *Modine* is Misplaced.

Alcon's argument—that this case is controlled by the Federal Circuit decisions in *Microsoft*, *Wang*, and *Modine*—is just as wrong as its other arguments. These cases employ the prosecution history to confirm a narrow claim construction based principally on the patent specification. As demonstrated above, the specification in the '337 patent is

broad, encompassing both anionic and non-anionic SECs, including the specific SEC—povidone—that Alcon is using.

In *Microsoft Corp. v. Multi-Tech Systems, Inc.*, 357 F.3d 1340, 1348-49 (Fed. Cir. 2004), the Federal Circuit came to its narrow claim construction after examining the specification, which it concluded repeatedly characterized the invention as "communicat[ing] over standard telephone lines." *Id.* at 1348. These descriptions were not of preferred embodiments, but rather characterized the whole invention in that manner. *Id.* (noting that the statements "are not limited to describing a preferred embodiment, but more broadly describe the overall inventions of all three patents"). The Federal Circuit went on to explain that the prosecution history "confirms that Multi-Tech viewed its inventions as being limited to communications over a telephone line." *Id.* at 1349 (emphasis added). In prosecution, the applicants had characterized the specification as "disclos[ing] a communications system which operates over a standard telephone line" and "establishes a point-to-point connection between telephone equipment on each end of the line. *Id.* at 1349. The Federal Circuit concluded that the applicants' prosecution statements narrowly characterized the "invention" disclosed in the common specification of the patents in the family, confirming the narrow claim construction. *Id.*

Wang Laboratories, Inc. v. America Online, Inc., 197 F.3d 1377, 1383-84 (Fed. Cir. 1999) deals with a similar situation. In that case, the Federal Circuit primarily based its narrow claim construction on disclosure of a single embodiment in the specification—because the "only embodiment described in the ... specification [was] the character-based protocol, ... the claims were correctly interpreted as limited thereto." Again, the prosecution history simply confirmed that construction.

Similarly, *Modine Manufacturing Co. v. United States International Trade Commission*, 75 F.3d 1545, 1551 (Fed. Cir. 1996), deals with a situation where the supposed "preferred embodiment" was actually the only embodiment disclosed in the specification as part of the invention. At one point, the specification disclosed a range of 0.015 to 0.070 inches, but an amendment was made to the specification in response to an examiner rejection narrowing the range disclosed to 0.015 to 0.040 inches. *Id.* at 1551-52. The patentee was therefore limited to that range and could not recapture the range between 0.040 and 0.070. No analogies to this case can be made from the facts of *Modine*.

In contrast to *Microsoft*, *Wang*, and *Modine*, the specification of the '337 patent characterizes the invention broadly and places no limitations on the types of SECs that are covered. Any suitable SEC may be used. Furthermore, Allergan's statements in prosecution of the '210 parent patent do not characterize the "invention" narrowly. The statements are directed to the then "current claims" reciting the anionic SECs of the preferred embodiment, not to the broader invention relating to SECs in general. [Marsden Markman Decl., Ex. J, at AGN0221898, D.I. 58.] Neither the specification nor the file histories of the '210 parent patent or the '337 patent itself provide any basis for reading in an anionic limitation to the term "solubility enhancing component." Alcon's arguments should be rejected.

B. The Originally-Filed Claims and Specification of the '834 Patent Demonstrate to one of Skill in the Art that the Inventors of the '834 Patent Were in "Possession" of the Contested Claim Limitations

1. Written Description is An Issue of Fact, Subject to the Clear and Convincing Evidentiary Standard, and Alcon has Presented No Evidence to Meet the Standard

Despite Alcon's musings that "written description" is amenable to summary judgment, it is actually a highly factual inquiry that depends upon the teachings of the patent, the nature of the claimed invention, and, most importantly, how both of those would be interpreted by one of ordinary skill in the art. As stated by the Federal Circuit in *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562 (Fed. Cir. 1991):

> The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter.

Id. at 1563 (internal citations omitted) (emphasis added).

As Alcon concedes, in considering a written description claim, the Court must evaluate the entirety of the written description, as well as the originally-filed claims of the patent-in-suit. *Purdue Pharma L.P. v. Faulding, Inc.*, 230 F.3d 1320, 1323 (Fed. Cir. 2000); *see also*, Alcon's Brief in Support of Its Motion for Summary Judgment, page 20. The description includes all the drawings, figures and examples of the patent, as well as the written text. *See Space Sys./Loral, Inc. v. Lockheed Martin Corp.*, 2005 WL 901802 (Fed. Cir. 2005) (reversing grant of summary judgment of invalidity for failure to satisfy the written description requirement based on expert testimony and the teachings of a figure.); *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997) (holding that the written description requirement can be satisfied by "words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.").

Moreover, because a patent is presumed valid, "a party alleging that a patent is invalid for failure to comply with the written description requirement has the burden of establishing by clear and convincing evidence that the requirement was not met."

Intertool, Ltd. v. Texar Corp., 369 F.3d 1289, 1294 (Fed. Cir. 2004) (emphasis added). Notably, this evidentiary burden is wholly absent from Alcon's brief. Also absent is any acknowledgement of the hornbook law that, in the context of written description, where, as here, the Examiner did not reject the claims as "new matter" under 35 U.S.C. § 132, the fact that the patent complies with the written description requirement is entitled to "an especially weighty presumption of correctness." *Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555, 1575-76 (Fed. Cir. 1993); *In re Smythe*, 480 F.2d 1376, 1385 (CCPA 1973).

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In stark contrast, Allergan submits herewith the declaration of Dr. Valentino Stella, University Distinguished Professor of Pharmaceutical Chemistry at the University of Kansas that demonstrates, in simple terms, why the patent meets the written description requirement. [Stella Decl. ¶ 1-33] This declaration, combined with the complete absence of evidence from Alcon, alone raises a material issue of fact preventing the grant of summary judgment in this case. *Enzo Life Sciences, Inc. v. Digene Corp*, 305 F.Supp.2d 400, 404-405 (D. Del. 2004) (in denying the motion for summary judgment on written description grounds, the district court found that because plaintiff offered the declaration of "one allegedly skilled in the art," and defendant did not come forward with any evidence to support its contention that the specification fails to meet the written

description requirement of Section 112, there was a material issue of fact which prevented granting defendant's motion for summary judgment.).

Despite the complete failure of Alcon to satisfy even its burden of production, and its telling silence on the burdens to which its motion is subject, we nonetheless address Alcon's arguments below. We first address Alcon's new argument—that the patent fails to disclose the claimed concentrations as "therapeutically effective"—and then address the argument for which Alcon received permission to move for summary judgment—that the patent fails to disclose to a person of ordinary skill the concentration limitation listed in the claims.

2. The specification of the '834 patent clearly teaches that the disclosed compositions are "therapeutically effective concentrations."

The specification of the '834 patent states that the invention of the patent is directed to "therapeutically effective concentrations." In fact, the opening substantive paragraph of the '834 patent, the "Background of the Invention" section, reads:

> The present invention relates to compositions containing alpha-2-adrenergic agonist components. More particularly, the invention relates to such compositions in which the alpha-2-adrenergic agonist components have enhanced solubility at the ***therapeutically effective concentrations***.

[Marsden Markman Decl. Ex. C, '834 Patent, Col 1, ll.15-19, D.I. 58.]

Contested Claim 1 of the '834 patent is directed to a "therapeutic effective: aqueous ophthalmic composition" where the active ingredient is "soluble at about 21 degrees C." This is almost the same language from the first paragraph of the patent. To claim, as Alcon does, that the patent is not directed to "therapeutically effective" concentrations is simply wrong. This language tells one of ordinary skill in the art that the patent discloses and is directed to "therapeutically effective" concentrations of alpha-2-adrenergic agonists, of which brimonidine is one. [Stella Dec. ¶ 18]

As explained by Dr. Stella, the specification goes on to teach that in one preferred embodiment the alpha-2-adrenergic agonist is present in an amount to provide

"at least one therapeutic benefit," and that "the present compositions are ophthalmically acceptable, e.g. the compositions do not have deleterious or toxic properties which could harm the eye of the human or animal to whom the compositions are administered." [Marsden Markman Decl. Ex. C, '834 Patent, Col. 3, ll. 24-26 and 36-41, D.I. 58.] The specification further states that"[f]urthermore, solubilized alpha-2-adrenergic agonist compounds provide other benefits, for example, reduced irritation to tissues that interact with alpha-2-andrenergic agonists." [*Id.* Col. 1. ll. 48-52.] From this, it is clear not only to one of skill in the art, but also any layman looking at the patent, that the inventors of the '834 patent had within their possession compositions of therapeutically effective concentrations. [Stella Decl. ¶ 18.].

Indeed, the originally-filed claims of the provisional application were directed to therapeutically effective formulations. [Stella Decl. ¶ 19] Claim 1 of the originally filed provisional application required, inter alia:

> A composition comprising:
>
> > An alpha-2-adrenergic agonist component in an amount ***effective to provide a therapeutic benefit*** to a patient whom the composition is administered . . . .

[Marsden Markman Decl. Ex. H – Prosecution history of '834 patent, D.I. 58]

Accordingly, from the very beginning, the claims sought from the PTO related to compositions at therapeutically effective concentrations. From these claims and the repeated disclosure in the specification, a person of ordinary skill in the art would understand that the formulations disclosed in the patent were understood by the inventors to be compositions at therapeutically effective concentrations. [Stella Dec. ¶¶ 18-19.]

3. The specification and originally filed claims of the '834 patent clearly teach to one of skill in the art a concentration of 0.15%.

Given that the patent plainly discloses that it is directed to "therapeutically effective" concentrations of brimonidine, the only remaining issue is whether the patent points to the 0.15% concentration limitation. The patent does so repeatedly.

a. The'834 patent explicitly states that the most preferred pH is 7.5.

Ignored entirely by Alcon in its motion is the fact that the patent specifies that a pH of 7.5 is the most preferred pH for the compositions encompassed by the invention. As stated at Column 11, lines 3-6:

> The aqueous liquid carrier preferably has a **pH** in the range of about 6 to about 9 or about 10, more preferably about 6 to about 8, and still ***more preferably about 7.5***.

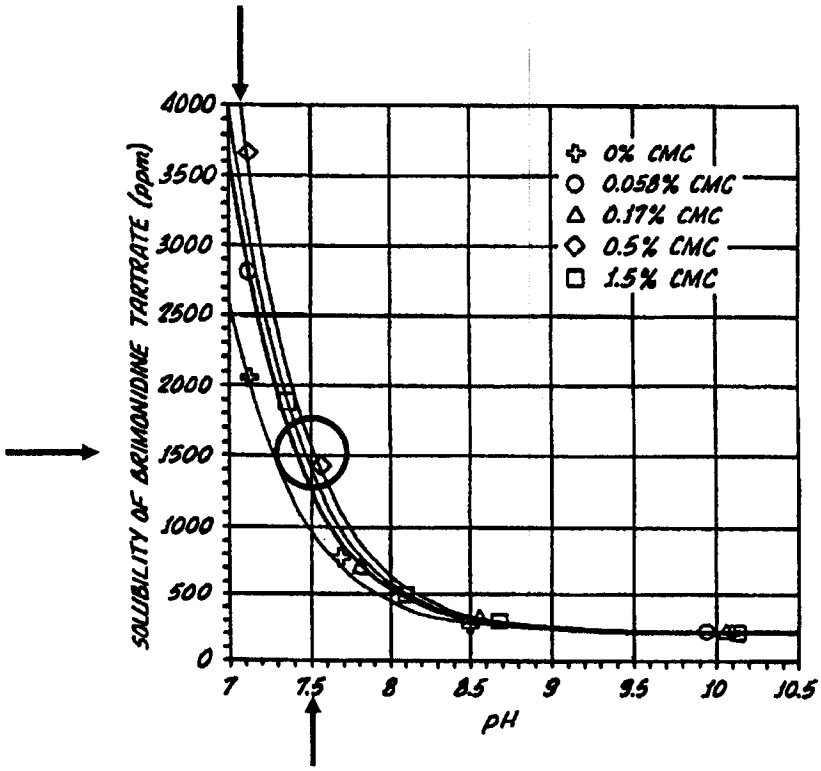
[Marsden Markman Decl. Ex. C. (emphasis added) , D.I. 58.] The "carrier" is simply the solution that the brimonidine is dissolved in so that it can be applied to the eye. [Stella Dec. ¶ 23]

b. At pH 7.5, the brimonidine concentration is 0.15% as evidenced by Figure 1, Table IV and Example 2.

i. Figure 1 of the '834 patent supports the 0.15% limitation

Also ignored entirely by Alcon is the fact that, at the preferred pH of 7.5, the concentration of brimonidine disclosed by each of Figure 1, Table IV and Example II is about 0.15%.

Figure 1 of the '834 patent is plot of solubility versus pH for brimonidine using different concentrations of CMC, a solubility enhancement component. The vertical axis of this graph is in parts per million ("ppm"). As demonstrated below, at pH of 7.5, the concentration limit of brimonidine is about 1500 ppm, which converts to 0.15 % w/v, the contested limitation. [See Stella Decl. ¶¶ 23-25]. Accordingly, Figure 1 itself satisfies the written description requirement.



ii. Table IV of the '834 patent Also Discloses the 0.15% limitation

The 0.15% limitation is also clearly expressed in Table IV of the '834 patent. Table IV of the '834 patent contains the data that was used to generate the curves in Figure 1.

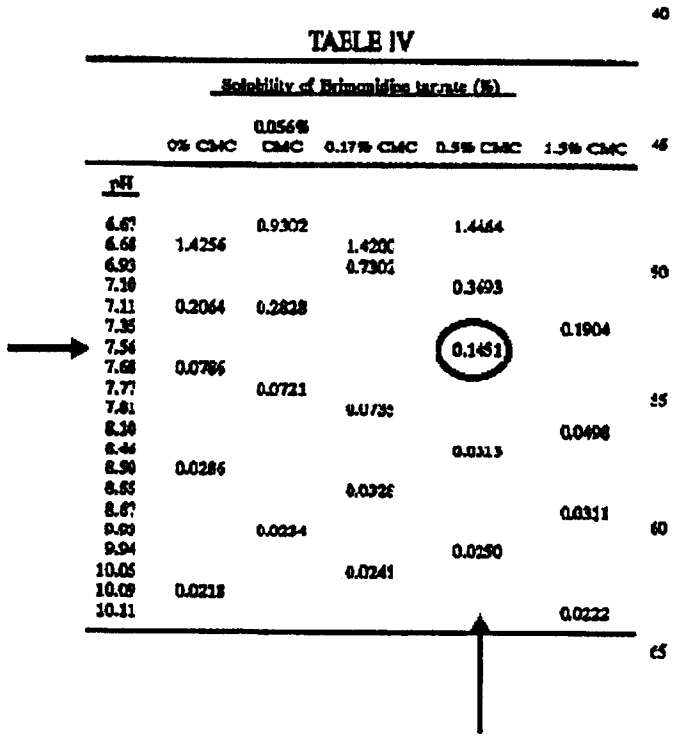


TABLE IV

Solubility of Brimonidine tartrate (%)

pH	0% CMC	0.05% CMC	0.17% CMC	0.5% CMC	1.5% CMC
6.67		0.9302		1.4464	
6.68	1.4256		1.4200		
6.93			0.7301		
7.10				0.3693	
7.11	0.2064	0.2828			
7.35					0.1904
7.54				0.1451	
7.68	0.0786				
7.77		0.0721			
7.81			0.0739		
8.10					0.0498
8.46				0.0313	
8.50	0.0286				
8.55			0.0326		
8.67					0.0311
8.89		0.0234			
9.04				0.0250	
10.05			0.0241		
10.09	0.0218				
10.11					0.0222

The graph in Figure 1 that showed the best solubility profile was a formulation containing 0.5% CMC (underlined in the figure above in yellow). One of skill in the art, knowing that the most soluble form of the drug would be the most preferred drug, a fact which is taught by the patent, would be instantly drawn to the 0.5% CMC column. [Stella Dec. ¶ 27.] Given that the most desirable pH in the patent is 7.5, the data point in the area of pH 7.5 in Table IV is 0.1451 % brimonidine tartrate. Under both parties' proposed claim construction 0.1451% is about 0.15%. Accordingly, one of skill in the art would again be directed to the "about 0.15 %" limitation by Table IV. [Stella Decl. ¶¶ 26-27, 30-33]

iii. Example 2 of the '837 Patent Also Points to the "About .15%" Limitation

Example 2 of the '834 patent also points one of skill to the contested limitation. Example 2 ends with a discussion of the solubility results of brimonidine tartrate at pH 7.5, the most preferred pH in the patent.

> FIG. 1 clearly shows that the solubility of Brimonidine tartrate tends to increase with increasing CMC concentrations. For example, at pH 7.5, the sample with 0% CMC resulted in 1000 ppm of Brimonidine tartrate; 0.056% CMC, 1300 ppm; 0.17% CMC, 1300 ppm; and 0.5%, 1600 ppm. At pH 7.5, the sample with 1.5% CMC resulted in about 1400 ppm, which is less than that of a similar solution with CMC at 0.5%.

[Marsden Markman Decl. '834 Patent Col. 16, ll. 1 – 3, D.I. 58.]

In this discussion, the inventors state that they believed that at most 1600 ppm (or 0.16 % w/v) of brimonidine tartrate could be dissolved in solution regardless of the amount of the SEC used. (CMC is one of the SEC's disclosed in the '834 patent.). And, as Dr. Stella notes, 1600 ppm is "about 0.15%). [Stella Decl. ¶ 28].

c. The .15% Concentration Taught by the Patent Corresponds to The Original Claims and the Specification of the '834 Patent Regarding Substantially Un-ionized Formulations.

Accordingly, from all of these factors, and as demonstrated in the declaration of Dr. Stella, one of skill in the art would be directed to the therapeutically effective 0.15% brimonidine formulation in the patent-in-suit. [Stella Decl. ¶¶ 18-29] This should hardly be surprising because this concentration simply reflects the discovery made by the inventors relating to preferred concentrations of the un-ionized forms of the drug.

As demonstrated above, the '834 patent teaches that one of the reasons that the disclosed formulations have therapeutic benefit is because of their increased un-ionized state.

> Additionally, the dispensed or administered alpha-2-adrenergic agonist components should advantageously be soluble in biological systems or environments, for example, for effective or enhanced in vivo diffusion through cell membranes or lipid bilayers. Some alpha-2-adrenergic

> agonist components with higher pKa's, for example, greater than about 7, tend to diffuse very well through lipid membranes at pH values near their pka, because in such circumstances they are predominantly unionized in neutral to alkaline biological environments.

[Marsden Markman Decl. Ex. C, '834 Patent, Col. 1, ll. 33-43, D.I. 58] Put simply, this means that at pH values at or near the drug's pKa, the amount of drug in the un-ionized form is increased, which is beneficial because it more readily passes through the lipid bilayers and into the cells of the body. And, as stated in the Summary of Invention, in one embodiment, the alpha-2-adrenergic agonist is un-ionized in the composition.

> In one embodiment, the alpha-2-adrenergic agonist components are ***unionized*** in the compositions. Preferably, the alpha-2-adrenergic agonist components are also ***unionized*** in the biological environment into which the compositions are administered.

[*Id.*, '843 Patent, Col. 2, ll. 48-52.]

And, just as with the "therapeutic effectiveness" limitation, the inventors sought from the beginning of prosecution to claim formulations relating to the un-ionized form of the drug. Claim 1 of the originally filed claims required, inter alia, an alpha-2-adrenergic agonist component in an amount effective to provide a therapeutic benefit. Claims 7 and 8 that depended from Claim 1 required, respectively, that the agonist of Claim 1 is "substantially unionized" and is "substantially unionized in a biological environment." [Marsden Markman Decl. Ex. H – Claims 1, 7 and 8 of the originally filed application; *see also* Stella Decl. ¶ 21-22]

Moreover, as demonstrated above, the concentration of the un-ionized form increases as the pH of the solution approaches the pKa of the drug. The pKa of brimonidine tartrate is 7.78. [Marsden Markman Decl. Ex. C, '834 Patent, Col. 13. l.16, D.I. 58.] The preferred pH in the patent is 7.5, near the pKa. Accordingly, the concentration at the preferred pH of 7.5 ("about .15%) is directly related to the "substantially un-ionized" invention originally claimed in the provisional application and disclosed as an embodiment of the invention in the Summary of Invention.

4. Analogous case law compels denial of Alcon's motion for summary judgment.

Dr. Stella's declaration and Alcon's lack of evidence compel denial of it Motion for Summary Judgment. Alcon's cases do not change that result.

In *Vas-Cath v. Mahurkar*, 935 F.2d 1555 (Fed. Cir. 1991), Mahurkar brought suit over two patents related to multi-lumened catheters. Based on argument alone, Vas-Cath brought a motion for summary judgment of invalidity for failure to comply with the written description requirement. The two patents that Mahurkar had brought suit under claimed priority to a design patent that had the same figures as the later utility patents but no discussion of those figures. Mahurkar put forth the declaration of an expert, Dr. Ash, who declared that one of skill in the art would recognize that the claimed invention was supported by those figures alone. In reversing the district court's grant of summary judgment, the Court held:

> Although the district court considered Dr. Ash's declaration, we believe its import was improperly disregarded when viewed through the court's erroneous interpretation of the law. We hold that the Ash declaration and Vas-Cath's non-refutation thereof, without more, gave rise to a genuine issue of material fact inappropriate for summary disposition.

Id. at 1567 (emphasis added).

Just like in *Vas-Cath*, Alcon has offered nothing more than argument to support its assertion that one of skill in the art would not recognize that the claimed invention is supported by the specification of the '834 patent. Therefore, just like *Vas-Cath*, summary judgment is inappropriate.

In *Enzo Life Sciences, Inc. v. Digene Corp*, 305 F.Supp.2d 400 (D. Del. 2004), the defendant, Digene, offering nothing but argument, moved for summary judgment that the patent-in-suit was invalid for failure to comply with the written description requirement. The plaintiff presented the declaration of its expert who cited to various sections of the

specification and opined that one of skill in the art would immediately recognize that the inventions claimed in the patent in suit are fully described by the specification. *Id.* at 404. The Court held that:

> Based on the evidence, the Court concludes that Digene has not established that it is entitled to summary judgment. The question of whether the specification makes disclosures to one of ordinary skill in the art sufficient to satisfy the written description requirement is an issue of disputed fact, and therefore, improper for resolution by summary judgment.

Id. (emphasis added). The same reasoning applies here.

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Purdue Pharma is of no help to Alcon. In *Purdue Pharma*, plaintiffs appealed the district court's bench trial judgment that the patent at issue was invalid for failure to meet the written description requirement of 35 U.S.C. § 112. *See id.* at 1322. In that case, the district court acted as a fact finder, weighing the evidence and making credibility determinations regarding plaintiffs' experts' testimony. *See id.* at 1324-25. Further, in that case, the district court made the factual determination that because plaintiffs had not provided sufficient "blaze marks," one of ordinary skill in the art would not be directed to the invention claimed. *Id* at 1326. The Federal Circuit affirmed the case finding that

there was sufficient evidence to support the district court's factual determination and that the district court had not committed clear error.

The issue before this Court is clearly distinguishable from *Purdue Pharma*. Here, the Court is not acting as a fact finder, and is not charged with weighing the evidence or making factual determinations. In deciding Alcon's instant motion, the standard the Court must apply is whether Alcon has provided clear and convincing evidence to show that there is no genuine issue of material fact, and that it is entitled to judgment as a matter of law. As discussed extensively herein, Alcon does not meet that burden, and *Purdue Pharma* has no application to Alcon's instant motion.

Moreover, in contrast to *Purdue Pharma*, it is conceded here that that patent specifically discloses a concentration of "about 0.15%." And while Alcon might not like it, this is the concentration at the most preferred pH in the patent, a fact which Alcon does not even mention, let alone discuss. How one of skill in the art is not pointed to the concentration resulting from the most preferred pH is difficult to comprehend.

Alcon's reliance on *In re Ruschig* is similarly misplaced. In *Ruschig*, the Board of Patent Appeals had rejected an application claim for "New Benzene Sulfonyl Ureas and Process for Their Preparation" because the claim had "no specific support in the disclosure." *Id.* at 991-92. The applicants appealed this decision, arguing that the disclosure clearly disclosed to one of skill in the art the compound claimed. In rejecting applicants' arguments, the Court of Customs and Patent Appeals noted that the "general disclosure of the application encompasses something like half a million possible compounds." *Id.* at 993. Further, the court in *Ruschig* made the factual determination that the applicant failed to "name or even mention in any manner" the compound being claimed, and that based on the myriad of possibilities encompassed by the broad disclosure (namely 500,000 possible compounds), the disclosure did not teach to one of skill in the art the compound claimed. *Id.* at 995-96.

In the instant case, Allergan specifically referenced and called out the 0.15% brimonidine concentration. Further, the court here is not charged with making a factual determination, but rather must determine if Alcon is entitled to judgment as a matter of law. Because it has failed to meet its burden, and Allergan has submitted evidence at least raising a material issue of fact, Alcon is not entitled to judgment.

Alcon's reliance on *University of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004) is also unavailing for several reasons. In *University of Rochester*, plaintiffs appealed the district court's grant of summary judgment that the patent-in-suit was invalid for failure to comply with the written description requirement. *Id.* at 917. In affirming the district court's grant of summary judgment, the Federal Circuit first noted that

> [t]ellingly, ... what plaintiff's experts' [sic] do *not* say is that one of skill in the art would, from reading the patent, understand what compound or compounds -- which, as the patent makes clear, are necessary to practice the claimed method -- would be suitable, nor would one know how to find such a compound through trial and error .... Plaintiff's experts opine that a person of ordinary skill in the art would understand from reading the '850 patent what method is claimed, but it is clear from reading the patent that one critical aspect of the method -- a compound that selectively inhibits PGHS-2 activity -- was hypothetical, for it is clear that the inventors had neither possession nor knowledge of such a compound.

Id. at 925-26 (internal citations omitted) (italics in original). Moreover, the Federal Circuit stated that the patent-in-suit "does not disclose *any compounds* that can be used in its claimed methods.... No compounds that will perform the claimed method are disclosed, nor has any evidence been shown that such a compound was known." *Id.* at 927 (emphasis added). The court further pointed out that the only claims that appear to be supported by the specification are claims to assay methods for screening compounds, but not the compounds themselves. *Id.* at 927-28. Thus, the Federal Circuit affirmed the district court's grant of summary judgment because plaintiffs failed to provide any

evidence that they had disclosed the claimed compound, or any compound that would have lead one of ordinary skill in the art to the claimed compound. *Id.* at 929.

The facts in *University of Rochester* are easily distinguishable from the disclosure in the '834 patent. First, as described in detail above, expert testimony clearly and unequivocally states that one of ordinary skill in the art would immediately understand that the specification and originally filed claims amply described therapeutically effective 0.15% concentrations of brimonidine. [Stella Decl. ¶ 29.] Second, unlike the utter lack of any recitation of compounds in *University of Rochester*, the 0.15% concentration limitation is explicitly disclosed in the specification. [Stella Decl. ¶¶ 25, 27, and 28]

Accordingly, Alcon's motion should be denied. Alcon has failed to even come forward with evidence close to that which would be necessary and the evidence presented by Allergan raises genuine issues of material fact for trial.

C. In the Alternative, the Court Should Deny Alcon's Motion for Summary Judgment for Failure to Comply with the Court's Scheduling Order.

The Court granted Alcon permission to file a summary judgment motion limited to two issues: "a) whether the claims of the '834 patent violate the written description requirement of 35 U.S.C. § 112 because they use the percentage '0.15%'; and b) whether the limitation 'solubility enhancing component' in the '337 patent should be limited to only anionic solubility enhancing components." Scheduling Order, at 4. As clearly set forth above, Alcon failed to comply with that Order as it relates to the '834 patent. And while Allergan has filed a Motion to Strike Alcon's Motion for Summary Judgment, the Court should alternatively deny Alcon's Motion for Summary Judgment of Invalidity for failing to comply with the Court's Scheduling Order.

VI. CONCLUSION

Based on the above, Allergan respectfully requests that the Court deny Alcon's Motion for Summary Judgment of non-infringement of the '337 patent and invalidity of the '834 patent.

Dated: May 23, 2005

FISH & RICHARDSON P.C.

By: */s/ William J. Marsden, Jr.*

William J. Marsden, Jr. (marsden@fr.com)
Sean P. Hayes (hayes@fr.com)
919 N. Market Street, Suite 1100
P.O. Box 1114
Wilmington, DE 19899-1114
Telephone: (302) 652-5070

Jonathan E. Singer
Michael J. Kane
Deanna J. Reichel
3300 Dain Rauscher Plaza
60 South Sixth Street
Minneapolis, MN 55402
Telephone: (612) 335-5070

Juanita Brooks
W. Chad Shear
12390 El Camino Real
San Diego, CA 92130
Telephone: (858) 678-5070

Attorneys for Plaintiffs
ALLERGAN, INC. and ALLERGAN SALES, LLC

CERTIFICATE OF SERVICE

I hereby certify that on May 23, 2005, I electronically filed with the Clerk of Court the REDACTED VERSION OF PLAINTIFFS' 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 using CM/ECF which will send notification of such filing(s) to the following:

Josy W. Ingersoll, Esq.
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building, 17th Floor
1000 West Street
P.O. Box 391
Wilmington, DE 19899-0391

I hereby certify that on May 23, 2005, I have sent by U.S. Mail, the above document to the following non-registered participants:

Brian D. Coggio, Esq.
Orrick, Herrington & Sutcliffe LLP
666 Fifth Avenue
New York, NY 10103-0001

/s/ William J. Marsden, Jr.
William J. Marsden, Jr.

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