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

ALLERGAN, INC. AND ALLERGAN SALES, LLC'S
OPENING MARKMAN BRIEF

Dated: May 2, 2005

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I. INTRODUCTION

The claim construction process in this patent case is very straightforward. The terms of the asserted claims are simple and easy to understand based on their ordinary meaning. Accordingly, Allergan proposes constructions consistent with established Federal Circuit precedent emphasizing the plain and ordinary meaning of claim terms considered in light of the patent specifications and file histories. In contrast, Alcon proposes result-oriented constructions that violate numerous settled rules of claim construction law. Accordingly, Allergan respectfully requests that the Court adopt the proposed constructions provided herewith in Exhibit A.

II. NATURE AND STAGE OF THE PROCEEDINGS AND STATEMENT OF FACTS:

Pursuant to the Court's Scheduling Order [DI No. 30], this is Allergan' s opening brief in support of its proposed constructions of the disputed claim terms. Relevant facts supporting Allergan's proposed constructions are set forth in the Background that follows, as well as in the Argument.

III. BACKGROUND

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

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"). [Exhibits B and C][1] 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.

Alphagan® P is used by doctors to treat open-angle glaucoma. Open-angle glaucoma is an incurable disease of the eye that causes gradual vision loss and can lead to blindness. Almost 70 million people worldwide suffer from glaucoma, which is the second leading cause of blindness worldwide. Allergan is a leader in the development of pharmaceutical treatments for glaucoma, invests heavily in research and development. [Exhibit D, at 7]

Although there is no cure, there are various pharmaceutical and surgical treatments that may slow the progression of glaucoma. One of these 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, among other things, assists in the lowering of IOP. The drug was originally thought to be merely a blood-pressure medication, but in the early 1990's, Allergan scientists discovered that it was a powerful medication for lowering IOP, as well. 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®.[2] Alphagan® was a 0.2% formulation of brimonidine at a pH range of 5.6-6.6. [Exhibit E] After the expiration of Allergan's statutory exclusivity period, Alcon launched a generic version of Alphagan®, which Alcon sells to this very day.

B. Allergan's Alphagan® P is a Significant Improvement Over Alphagan®, with over a 40% Reduction in Allergic Side Effects

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

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[1] All exhibits are attached to the Declaration of William J. Marsden filed herewith.
[2] Brimonidine is what is known as an "alpha-2-adrenergic agonist," hence, the tradename ***Alpha***gan®. (emphasis added).

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. [*See* Exhibit F] Alphagan® P was shown in clinical studies to have comparable efficacy to Alphagan®, but with a forty-one percent reduction in allergy rate. [Exhibit G, at AGN0211650-58] 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®.

C. The Patents-in-Suit Claim the Inventions that Enabled the Formulation of Brimonidine in the Lowered, More Tolerable Concentration Contained in Alphagan® P

The successful development of Alphagan® P hinged on the inventions claimed in the patents-in-suit. Because of the observed side effects of Alphagan®, researchers recognized that it would be advantageous to formulate the drug in a significantly lower concentration, if efficacy was not compromised. Nonetheless, simply lowering the concentration of brimonidine in the same formulation was not an option, as this would be expected to dramatically reduce the drug's effectiveness by a comparable amount.

The patents-in-suit claim Allergan's solutions to this problem, which allow formulators to make stable, pharmaceutically acceptable preparations of drugs like brimonidine at significantly lower concentrations while maintaining the same efficacy. Allergan scientists discovered that it was possible to use the desired lower concentration of brimonidine tartrate and maintain effectiveness ***if*** the pH of the formulation was elevated above 7.0. These higher pHs are closer to the pKa of brimonidine tartrate, a point at which the brimonidine is substantially un-ionized.

(At the lower pH used in the Alphagan® product, brimonidine was present in a highly ionized form.) Un-ionized forms of brimonidine diffuse better across the lipid membranes of the eye, making the drug more bioavailable and allowing for use of a lower concentration than in previous drugs. *See* '834 patent, col. 1, lines 34-43, col. 6, lines 8-16. [Exhibit C, at AGN0068204, AGN0068206]

The '834 patent claims the use of these lowered concentrations of brimonidine at elevated pHs. *See generally* '834 patent, claim 1. [Exhibit C, at AGN0068211] Because about 0.15 % brimonidine is roughly the solubility limit of brimonidine at the most preferred pHs, the claims are written with that concentration either by itself or as an upper limit. Alphagan® P is formulated in this elevated pH range, as is Alcon's proposed generic 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. [Exhibit C, at AGN0068203; Exhibit B, at AGN0065326] 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 solubility of the brimonidine in these solutions. *See* '337 patent, col. 2, lines 9-17. [Exhibit B, at AGN0065327]

The '337 patent claims the use of these solubility-enhancing components ("SECs") with alpha-2-adrenergic agonists such as brimonidine. *See generally* '337 patent, claim 1. [Exhibit B, at AGN0065334] 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. *See* '337 patent, col. 6, line 17 to col. 9, line 22. [Exhibit B, at AGN0065329-31] Indeed, the

SEC chosen by Alcon for its proposed generic formulation, polyvinylpyrrolidone ("povidone"), is specifically listed in the patent specification as an SEC that may be used according to the teachings of the invention. '337 patent, col. 6, lines 18-21. [Exhibit B, at AGN0065329]

D. The Prosecution of the Patents-in-Suit

In July 2000, Allergan filed for patent protection on the discoveries that enabled it to make Alphagan® P. Both of the patents-in-suit ultimately descend from an original provisional application filed at that time. *See* U.S. Prov. Pat. App. No. 60/218,200. [Exhibit H]

1. The Parent Patent to the Patents-in-Suit, U.S. Patent No. 6,627,210, Claims the Use of Anionic SECs with Alpha-2-Adrenergic Agonists Like Brimonidine

The first patent to issue from this original filing was U.S. Patent No. 6,627,210, the application for which is the parent to both the '337 and '834 patents. Allergan did not assert the '210 patent in this litigation because the '210 patent claims only the use of *anionic* SECs, such as the CMC used by Allergan in Alphagan® P. [Exhibit I, at AGN0064819-20] By contrast, the SEC being employed by Alcon in its proposed generic formulation, povidone, is not anionic.

The '210 patent was limited in this fashion during its prosecution. As filed, the broadest original claims of the '210 parent patent covered both anionic and non-anionic SECs. [Exhibit J, at AGN0221851-857] In response to a rejection by the examiner, Allergan amended the claims to require specifically a polyanionic or an anionic SEC. [Exhibit J, at AGN0221893-896] In support of that amendment, one of the inventors of the patents-in-suit, Orest Olejnik, submitted a declaration explaining the special advantages he believed anionic SECs had over non-anionic SECs—namely, that, in addition to enhancing solubility, anionic SECs adhered better to the eye. [*See* Exhibit J, at AGN0221902-903] After reviewing the amended claims and the arguments made in support of claims limited to anionic SECs, the PTO issued a Notice of Allowability on May 23, 2003. [Exhibit J, at AGN0221908-910]

The issued claims of the '210 patent thus recite a therapeutically effective amount of an alpha-2-adrenergic agonist and a polyanionic or anionic SEC. [Exhibit I, at AGN0064819-20]

2. The '337 Patent-in-Suit Claims the Use of Any SEC with an Alpha-2-Adrenergic Agonist Like Brimonidine, Other than One Containing Cyclodextrin

After receiving the Notice of Allowability for the claims limited to the use of an anionic SEC, Allergan resubmitted claims to the general use of SECs, anionic and non-anionic, in patent application No. 10/299,386 on June 13, 2003. [Exhibit K, at AGN0221770-74] In support of these claims to the general use of SECs, Allergan argued that its patent application was the first reference to disclose the advantages of using an SEC with an alpha-2-adrenergic agonist. [Exhibit K, at AGN0221774] After considering the claim language and Allergan's arguments, the PTO issued a Notice of Allowability. [Exhibit K, at AGN0221777-78] Claim 1 of the '337 patent reads as follows:

> 1. A therapeutically effective ophthalmic composition comprising:
> an alpha-2-andrenergic agonist component in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered; and
> a solubility enhancing component other than a cyclodextrin in an amount effective to increase the solubility of the alpha-2-andrenergic agonist component in the composition relative to the solubility of an identical alpha-2-andrenergic agonist component in a similar composition without the solubility enhancing component.

[Exhibit B, at AGN0065334] As is readily apparent from the plain language of the claim, claim 1 of the '337 patent claims a therapeutically effective amount of an alpha-2-adrenergic agonist and ***any*** type of SEC except for cyclodextrins. The claims are not limited to anionic solubility enhancing components in any fashion.

3. The '834 Patent Claims the Use of the Lowered Concentrations or Brimonidine at Elevated pHs.

The '834 patent also descends from the '210 patent, but the claims are directed at a very different aspect of the invention. The '834 patent addresses Allergan's surprising discovery that formulating at a higher pH allows one to reduce the concentration of the drug, while nonetheless

maintaining therapuetic effectiveness. The specification explains Allergan's belief that "the un-ionized forms of the adrenergic components facilitate their permeation across membrane lipid bilayers," '834 patent, col. 6, lines 13-16 [Exhibit C, at AGN0068206], thus allowing a larger proportion of the adrenergic component to reach the desired site of action. As explained above, the un-ionized form of brimonidine occurs at high pH, near its pKa. *See* '834 patent, col. 1, lines 38-41. [Exhibit C, at AGN0068204]

The claims of the '834 patent cover this invention. Claim 1 of the '834 patent reads as follows:

> 1. A therapeutically effective aqueous ophthalmic composition comprising:
> up to about 0.15% (w/v) of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate, the composition having a pH of about 7.0 or greater, and the 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate being soluble in the composition at about 21° C.

[Exhibit C, at AGN0068211]

As with the '337 patent, prosecution of the '834 patent was straightforward. Allergan submitted claims directed to aqueous compositions with up to about 0.15% of active ingredient at a pH of about 7.0 or greater, and the active ingredient being soluble at 21° C. [Exhibit G, at AGN0221622-25] After the examiner originally rejected these claims as obvious over prior art [Exhibit G, at AGN0221633-34], Allergan responded to the rejection by submitting a declaration and article explaining the surprising advantages provided by the 0.15% brimonidine formulation over prior formulations. [Exhibit G, at AGN0221642-58] As Allergan explained in its response, when formulating near the pKa of brimonidine:

> . . . a larger proportion of the molecules are electrostatically neutral, and thus less lipophobic than the polarized molecule. As such, a greater amount of the active drug is able to enter the cornea of the eye at a given solution concentration; this effect counters the effects of decreased brimonidine solubility at the higher pH.

[Exhibit G, at AGN0221645] As further explained in the article, the new formulation had the same ability to lower IOP in patients, but resulted in a 41% in reduction in allergic conjunctivitis. [Exhibit G, at AGN0211650-58][3]

Following this amendment, the examiner allowed the claims of the '834 patent to issue, which Allergan has asserted here against Alcon's proposed product.

IV. LEGAL STANDARDS FOR CLAIM CONSTRUCTION

Claim construction is a matter of law exclusively for the Court. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 391 (1996). The Federal Circuit, following the Supreme Court's opinion in *Markman*, has established well-settled principles for ascertaining the proper meaning and scope of patent claims. The relevant principles are explained below.

A. Claim Terms Are Presumed to Carry Their Ordinary Meaning.

Citing more than a century of Supreme Court precedent, the Federal Circuit very recently reiterated that "[i]t is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Innova/PureWater, Inc. v. Safari Water Filtration Systems, Inc.*, 381 F.3d 1111, 1115 (Fed. Cir. 2004). "In construing claims, the analytical focus must begin and remain centered on the language of the claims themselves, for it is that language that the patentee chose to use to 'particularly point[ ] out and distinctly claim[ ] the subject matter which the patentee regards as his invention.'" *Interactive Gift Express, Inc. v. Compuserve, Inc.*, 256 F.3d 1323, 1331 (Fed. Cir. 2001).

The words used by the patentee to claim his invention are presumed to carry their ordinary and customary meaning. *CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002) ("Generally speaking, we indulge a 'heavy presumption' that a claim term

[3] In addition, Allergan amended the claims to make clear that the invention was directed to therapeutically effective aqueous ophthalmic compositions. [Exhibit G, at AGN0221643]

carries its ordinary and customary meaning."); *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 2000) ("A court must presume that the terms in the claim mean what they say, and, unless otherwise compelled, give full effect to the ordinary and accustomed meaning of claim terms."); *Rexnord Corp. v. Laitram Corp.*, 274 F.3d 1336, 1342 (Fed. Cir. 2001) ("All terms in a patent claim are to be given their plain, ordinary and accustomed meaning to one of ordinary skill in the relevant art."). Accordingly, "the claim construction inquiry ... begins and ends in all cases with the actual words of the claim." *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1324 (Fed. Cir. 2002) (quoting *Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed. Cir. 1998)).

B. The Ordinary Meaning of Claim Terms May Be Found in a Dictionary.

"It has been long recognized in our precedent and in the precedent of our predecessor court, the Court of Customs and Patent Appeals, that dictionaries, encyclopedias and treatises are particularly useful resources to assist the court in determining the ordinary and customary meanings of claim terms." *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1202 (Fed. Cir. 2002). "The ordinary meaning of a claim term may be determined by reviewing a variety of sources, including ... dictionaries and treatises ...." *Teleflex*, 299 F.3d at 1325 (internal citations omitted). "For such ordinary meaning, we turn to the dictionary definition of the term." *Optical Disc Corp. v. Del Mar Avionics*, 208 F.3d 1324, 1334-35 (Fed. Cir. 2000). Although dictionaries technically fall within the category of extrinsic evidence, it is appropriate to "rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1584 n.6 (Fed. Cir. 1996).

Dictionaries typically include multiple definitions, and different dictionaries may provide different definitions for a claim term. The ordinary meaning of a claim term should not be

limited by any particular definition. Instead, it should encompass all definitions not inconsistent with the intrinsic record. *See Tex. Digital*, 308 F.3d at 1202. Thus, "by further utilizing the intrinsic record to select from those possible meanings the one or ones most consistent with the use of the words by the inventor, the full breadth of the limitations intended by the inventor will be more accurately determined and the improper importation of unintended limitations from the written description into the claims will be more easily avoided." *Id.* at 1205. Ultimately, the claim term "is to be given its broadest ordinary meaning consistent with the written description." *Int'l Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1373 (Fed. Cir. 2004).

C. The Scope of a Claim Term May Not Be Limited by Reading in Limitations from the Specification.

The rule against importing limitations into claims is succinctly explained as follows: "[i]f everything in the specification were required to be read into the claims, or if structural claims were to be limited to devices operated precisely as a specification-described embodiment is operated, there would be no need for claims." *SRI Int'l v. Matsushita Elec. Corp. of Am.*, 775 F.2d 1107, 1121 (Fed. Cir. 1985). Patentees are not required to include within each of their claims all of the advantages or features described as significant or important in the written description. *Golight, Inc. v. Wal-Mart Stores, Inc.*, 355 F.3d 1327, 1331-1332 (Fed. Cir. 2004). This must be the case because "[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." *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1370 (Fed. Cir. 2003). Similarly, "[a]n applicant is not necessarily required by 35 U.S.C. § 112, ¶ 1, to describe more embodiments than its preferred one, and [the Federal Circuit has] outright rejected the notion that disclosure of a single embodiment necessarily limits the claims." *Golight*, 355 F.3d at 1332; *see also Teleflex*, 299 F.3d at 1327 (stating that "the number of embodiments disclosed in the

specification is not determinative of the meaning of disputed claim terms"). Thus, "particular embodiments appearing in the written description will not be used to limit claim language that has broader effect." *Innova*, 381 F.3d at 1117.

D. Any Alleged Disavowal of the Ordinary Meaning from the Prosecution History or Patent Specification Must be Clear and Unequivocal.

Regardless of the number or ways or detail with which features are described in the written description, the Federal Circuit has circumscribed the ways in which a court may constrict the ordinary meaning of a claim term, based on either the patent specification or prosecution history. As to the specification, the written description may only be used to restrict the scope of the claims if "the patentee demonstrated an intent to deviate from the ordinary and accustomed meaning of a claim term by redefining the term or by characterizing the invention in the intrinsic record using words or expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope." *Teleflex*, 299 F.3d at 1327. The patent's written description may not be used to narrow the scope of the claimed invention absent a clear disclaimer. *Brookhill-Wilk 1, LLC v. Intuitive Surgical, Inc.*, 334 F.3d 1294, 1301 (Fed. Cir. 2003) ("Absent a clear disclaimer of particular subject matter, the fact that the inventor anticipated that the invention may be used in a particular manner does not limit the scope to that narrow context."). In short, the presumption in favor of the broad construction of a claim term will only be overcome where the patentee, acting as his or her own lexicographer, has clearly set forth an explicit definition of the term different from its ordinary meaning. *See In re Paulsen*, 30 F.3d 1475, 1480 (Fed. Cir. 1994); *Intellicall, Inc. v. Phonometrics, Inc.*, 952 F.2d 1384, 1387-88 (Fed. Cir. 1992).

As to the prosecution history, the Federal Circuit has consistently declined to find any disclaimer based on prosecution history unless the alleged disavowal of claim scope is "clear and

unmistakable." *Omega Eng'g, Inc. v. Raytek Corp.*, 334 F.3d 1314, 1325-26 (Fed. Cir. 2003). If the disclaimer is ambiguous, disavowal will not be found. *Id.* ("We have, however, declined to apply the doctrine of prosecution disclaimer where the alleged disavowal of claim scope is ambiguous."); *N. Telecom Ltd. v. Samsung Elecs. Co.*, 215 F.3d 1281, 1293-95 (Fed. Cir. 2000) (refusing to limit scope of claims where inventors' statements were amenable to multiple reasonable interpretations); *Rexnord*, 274 F.3d 1336, 1347 (refusing to limit the ordinary meaning of the claim because the alleged disclaimer in the file wrapper was at best "inconclusive"). Disclaimers from parent applications are particularly disfavored, if the term in the child application is not of identical scope. *See Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1306 (Fed. Cir. 2001) (explaining that prosecution history of parent not relevant because claims terms in dispute were not common—the child patent did not contain the same limitation as the parent).

E. Extrinsic Evidence Should Rarely Be Used to Interpret the Claim, and May Not be Used to Alter the Claim's Meaning

By now, it is beyond dispute that extrinsic evidence plays little role in the claim construction process. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583 (Fed. Cir. 1996). While a court may accept extrinsic evidence to explain the technology, a court may not employ such evidence to interpret the claim terms where their meaning is clear from the intrinsic sources. *See Playtex Prods., Inc. v. Procter & Gamble Co.*, 400 F.3d 901, 907-08 (Fed. Cir. 2005). Moreover, it is black-letter law that a Court may not vary the terms of the patent from their ordinary meaning based on extrinsic evidence, such as expert declarations, inventor testimony or documents from either party. *See Intel Corp. v. VIA Techs., Inc.*, 319 F.3d 1357, 1367 (Fed.Cir.2003) ("When an analysis of intrinsic evidence resolves any ambiguity in a disputed claim term, it is improper to rely on extrinsic evidence to contradict the meaning so ascertained.").

Based on the above recited standards, the disputed claim limitations should be interpreted consistent with their ordinary meaning, as proposed by Allergan.

V. DISPUTED CLAIM TERMS

Allergan is asserting independent claims 1 and 10 and dependent claims 2-6, 8-9, 11-14, 17-18, and 20 from the '834 patent, and independent claim 1 and dependent claims 2-4, 6, 9, and 10 from the '337 patent. The terms in these claims are all straightforward and require little in the way of claim construction. All terms should be construed to encompass the full scope of their ordinary meaning. Asserted claims containing the disputed terms set forth in the parties Joint Claim Chart are reproduced below in the sections relating to each patent, with the disputed limitations highlighted:

A. Disputed Terms of the '337 Patent

1. A therapeutically effective ophthalmic composition comprising:
an alpha-2-andrenergic agonist component in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered; and
a solubility enhancing component other than a cyclodextrin in an amount effective to increase the solubility of the alpha-2-andrenergic agonist component in the composition relative to the solubility of an identical alpha-2-andrenergic agonist component in a *similar* composition without the solubility enhancing component.

6. The composition of claim 1 wherein the *solubility enhancing component* is effective to increase the solubility in a biological environment of the alpha-2-adrenergic agonist component relative to the solubility in a biological environment of an identical alpha-2-adrenergic agonist component in a *similar* composition without the solubility enhancing component.

1. "Solubility enhancing component" should be interpreted to mean "a component that enhances the solubility of the alpha-2-adrenergic agonist component," and any solubility enhancing component other than a cylclodextrin is covered by the claim

The disputed limitation "solubility enhancing component other than a cyclodextrin" should be construed to mean a component that enhances the solubility of the alpha-2-adrenergic agonist component, and any solubility enhancing component other than a cylclodextrin is covered by the claim. This construction is straightforward and simply follows the ordinary

meaning of the terms in the claim, the meaning the terms are presumed to have. *See Johnson Worldwide*, 175 F.3d at 989.

This ordinary meaning is consistent with the patent specification, which describes numerous possible SECs as useful with the invention, explaining that "[a]ny suitable SEC may be employed in accordance with the present invention." '337 patent, col. 6, lines 17-18. [Exhibit B, at AGN0065329]

This ordinary meaning is also consistent with the prosecution history, during which Allergan responded to the lone rejection by amending the broad claim covering the use of any SEC only as it related to the exclusion of cylcodextrins, and not in any other fashion. Moreover, Allergan received the broad claim only after receiving allowance of its narrower claim in the '210 patent.

In contrast to this straightforward ordinary meaning, Alcon has proposed a construction requiring that the solubility enhancing component be anionic, and that the component "cannot be polyvinyl alcohol, povidone (polyvinylpyrrolidone), hydroxypropylcellulose, poloxamers or hydroxymethylcellulose." While the reason Alcon has proposed this construction is clear—because it creates a non-infringement defense where none is otherwise apparent—the legal rationale is not. And while we await Alcon's brief to see this rationale in full, we note that that there simply is no support for imposing these limitations on the claim. The '337 patent descends from the '210 patent, which specifically claims anionic solubility enhancing components. In the '337 patent, by contrast, Allergan did not add the anionic limitation and instead obtained broader claims covering any type of solubility enhancing component other than cyclodextrins.

This progression from earlier narrow claims reciting an anionic limitation to later broad claims not reciting that limitation is common practice and shows that Allergan deliberately

sought broader claim scope encompassing all varieties of solubility enhancing components. *See Home Diagnostics, Inc. v. Lifescan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004) (noting the progression of claim breadth in family of patents and construing the claims of the later patent broadly). There is no clear disavowal of claim scope in either the specification or prosecution history that would allow the Court to grant Alcon's request to read a word into the claim that is plainly not present. The Court should adopt Allergan's proposed ordinary meaning.

2. "Similar composition": "Similar" means "similar," not "identical"

The ordinary meaning of the limitation "similar composition" should be applied as well. The asserted claims recite a comparison in solubility between the alpha-2-adrenergic agonist in a composition with a solubility enhancing component and a "similar" composition without the solubility enhancing component. It is Allergan's position that there is no construction needed here because the plain meaning of the term "similar" is clear—the comparison is made between similar compositions. To the extent any construction is required, the dictionary definition of "similar" is adequate. "Similar" is defined as "having characteristics in common: very much alike: comparable." *Webster's Third New International Dictionary* 2120 (1993).

This definition is consistent with the patent specification, which explains that, "[p]referably, the alpha-2-adrenergic agonist components are more soluble in the present compositions having, for example, pH's of about 7 or greater, relative to *similar* compositions without the SECs." '337 patent, col. 2, lines 17-20 (emphasis added). [Exhibit B, at AGN0065327] The specification plainly explains that the solubility comparison is to be made between similar compositions.

As with its construction of "solubility enhancing component," Alcon's proposed construction seeks to change the claim. As if by magic, Alcon's proposed construction changes the word "similar" to "identical." And while we await Alcon's brief to respond to the arguments

for such a construction, we note that, again, there is no support for changing the claim in such a fashion.

Moreover, the asserted claims demonstrate that the inventors understood the difference between the words "similar" and "identical." Claim 6 of the '337 patent uses the word "identical" just five words before it uses the word "similar." Plainly, the inventors understood the difference between these two words as evidenced by the use of the two different words in such close juxtaposition.

Simply put, the word that modifies the term "composition" is "similar." The claim should therefore be construed to require a comparison of similar compositions.

B. Disputed Terms of the '834 Patent

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

3. The composition of claim 1 which includes *about 0.15% (w/v)* of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate.

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

12. The composition of claim 10 which includes *about 0.15% (w/v)* of the component.

1. "About" Should be Construed Consistent with its Adjudicated Ordinary Meaning as "Approximately"

There are several disputed limitations in the '834 patent claims: "up to about 0.15%, "about 7.0 or greater," and "about 21° C" in claims 1 and 10 and "about 0.15%" in claims 3 and 12. The dispute, however, centers on the meaning of the straightforward term "about." Under

Allergan's proposed construction, the term "about" carries its adjudicated ordinary meaning of "approximately" in all its usages in the '834 patent claims. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369-70 (Fed. Cir. 2005) (holding that the ordinary meaning of "about" is "approximately"). The Court should apply this ordinary meaning.

As demonstrated above, claim terms are presumed to take on their ordinary meaning, and there is nothing in the specification or the file history to indicate that "about" is being used in any other way. The ordinary meaning of the term "about" is "with some approach to exactness in quantity, number, or time: approximately." *Webster's Third New International Dictionary* 5 (1993). The Federal Circuit recently confirmed that "approximately" is the ordinary meaning of the term "about," reversing an overly restrictive construction of the term. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369-70 (Fed. Cir. 2005); *see also Conopco, Inc. v. May Dep't Stores Co.*, 46 F.3d 1556, 1561 n.2 (Fed. Cir. 1994) (noting that ordinary meaning of "about" is approximately); *Hybritech, Inc. v. Abbott Labs.*, 849 F.2d 1446, 1455 (Fed. Cir. 1988) (holding that "at least about 10^8 liters/mole" is literally satisfied by 4.8 x 10^7 liters/mole and 7.1 to 7.5 x 10^7 liters/mole).

The specification of the '834 patent is entirely consistent with this ordinary meaning, and there is nothing to indicate that the term should be interpreted differently. The references in the specification that point to a formulation containing up to about 0.15% brimonidine fully support a construction of "about" as "approximately." At the most preferred pH of 7.5, Figure 1 shows a convergence of points around 0.15%, and the examples explain that the inventors were unable to solubilize more than 0.16%, estimated from the figure, with any amount of solubility enhancing component. [Exhibit C, at AGN0068203] The specification also repeatedly refers to the pH of the formulation in approximate terms, for example, explaining that the carrier has a pH

of "about 6 to about 9 or about 10, more preferably about 6 to about 8, and still more preferably about 7.5." *See* '834 patent, col. 11, lines 3-6. [Exhibit C, at AGN0068209] Finally, there is nothing to indicate that the use of "about" to modify the temperature was intended to mean anything other than "approximately." '834 patent, col. 15, lines 23-26. [Exhibit C, at AGN0068211]

In contrast to this simple ordinary meaning, Alcon proposes constructions of "about" with a variety of numerical limits. Currently, Alcon proposes a construction under which "up to about 0.15%" means "up to 0.155% (w/v) (the upper limit of 0.15 ± 0.005% (w/v)) brimonidine tartrate," "about 0.15%" means "0.145% to 0.155%", "up to about 7.0 or greater" requires "a pH of 6.95 (the lower limit of 7.0 ± 0.05) or greater," "about 21º C" means 21 ± 0.5C", and "about 0.15%" means "0.15 ± 0.005% (w/v)." [DI No. 53]

These proposed constructions by Alcon ignore the broad ordinary meaning of "about," and instead attempt to impose artificial limits on the terms that cannot be found anywhere in the patent specification. And while we await the alleged rationale for such an approach in Alcon's briefing, a similar approach was specifically rejected by the Federal Circuit in the *Merck* case, just three months ago.

Accordingly, the Court should apply the adjudicated meaning of the term "about", which is "approximately." *See Merck*, 395 F.3d at 1369-70.

VI. CONCLUSION

For all the reasons stated above, and those to be stated in later briefing and at argument, Allergan respectfully requests that its proposed claim constructions be adopted.

Dated: May 2, 2005

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CERTIFICATE OF SERVICE

I hereby certify that on May 2, 2005, I electronically filed with the Clerk of Court ALLERGAN, INC. AND ALLERGAN SALES, LLC'S OPENING MARKMAN BRIEF using CM/ECF which will send notification of such filing(s) to the following:

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