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**

ALLERGAN, INC. AND ALLERGAN SALES, LLC'S RESPONSE TO MEMORANDUM IN SUPPORT OF ALCON'S PROPOSED CLAIM CONSTRUCTION

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I. INTRODUCTION

The claim constructions that Alcon has proposed in its opening *Markman* brief violate nearly all the basic rules of claim interpretation set forth by the Federal Circuit. Most glaring is Alcon's attempt to manufacture a noninfringement argument by inserting a word ("anionic") into the claims of the '337 patent that is simply not there. Alcon's proposed construction of "solubility enhancing component" wrongly limits the term to the disclosed preferred embodiment, while at the same time eliminates from the term several solubility enhancing components that are explicitly disclosed in the specification, including, not coincidentally, the component that Alcon has chosen to use in its proposed product, polyvinylpyrrilidone (or "povidone"). Similarly, on the '834 patent, Alcon attempts to impose artificial limits on the scope of the term "about," disregarding the already adjudicated ordinary meaning of the term in an effort to prop up its written description defense.

There is no basis in the intrinsic evidence for limiting the ordinary meaning of the claims. Accordingly, the Court should reject Alcon's proposed constructions and apply the ordinary meaning of the contested claim terms as proposed by Allergan.

II. SUMMARY OF THE ARGUMENT

A. The '337 Patent

The key claim term in dispute in the '337 patent is the term "solubility enhancing component" ("SEC"). The parties' proposed constructions of this term are set forth below:

Allergan's proposed construction	Alcon's proposed construction
The claimed composition contains a solubility enhancing component, which is a component that enhances the solubility of the alpha-2-adrenergic agonist	The term "solubility enhancing component" in the '337 patent refers only to an anionic component and does not include polyvinyl alcohol, povidone (polyvinylpyrrolidone),

component, and any solubility enhancing component other than a cylclodextrin is covered by the claim. [*See* Joint Claim Chart, D.I. No. 53.]	hydroxypropylcellulose, poloxamers or hydroxymethylcellulose, which were expressly disclaimed during prosecution. [Alcon Markman Br. at 2, D.I. 54]

Allergan's proposed construction of this term simply mirrors the plain language of the claims, whereas Alcon's proposed construction inserts an additional limitation ("anionic") that is nowhere to be found in the claim and that is contrary to the broad description in the specification. As stated in the patent specification, "any" solubility enhancing component ("SEC") may be used in the teachings of the invention, and the specification includes both anionic and non-anionic SECs. '337 Patent, col. 6, line 17 – col. 7, line 9 [Marsden Markman Decl., Ex. B, at AGN0065329-30, D.I. 58.]

The only proffered support for Alcon's claim construction is an ill-conceived prosecution history disclaimer argument that rests on statements from the prosecution history not of the patent-in-suit, but of the '210 parent patent, which Allergan did not assert in this case. But the portions of the '210 patent prosecution history Alcon cites are directed only to the claims of that patent, which claims a preferred embodiment containing an anionic SEC. The statements are not generalized statements about the scope of the invention or the disclosure in the specification, but rather are limited to the anionic claims that were sought (and ultimately allowed) in the '210 patent. In no way does anything that occurred in the prosecution of the '210 or '337 patents amount to a clear and unmistakable surrender of non-anionic SECs in the claims of the '337 patent. Alcon's arguments fail completely.

B. The '834 Patent

The key claim term in dispute in the '834 patent is "about." This term appears numerous times in the claims, and the parties' proposed constructions are set forth below:

Allergan's proposed construction	**Alcon's proposed construction**
The term "about" carries its ordinary meaning of "approximately" in all its uses in the claims of the '834 patent. [*See* Joint Claim Chart, D.I. No. 53.]	Alcon proposes that the term "about 0.15%" be interpreted to encompass the range of values that would be rounded up or down to 0.15% (i.e., 0.15% ± 0.005%). [Alcon Markman Br. at 28.] Alcon proposes that the term "pH of about 7.0" be interpreted to encompass the full range of values that would be rounded up or down to that number. [Alcon Markman Br. at 32.] Alcon proposes that the term "about 21° C" be interpreted as 21° C ± 0.5° C. [Alcon Markman Br. at 33, D.I. 54.]

As with the '337 patent, Allergan's proposed construction simply applies the plain language of the claim term, while Alcon's proposed construction seeks to read in limitations that are nowhere to be found in the language of the claim and not warranted by the specification or prosecution history. Notably, the Federal Circuit has already spoken to this issue, and, just a few months ago, held that the ordinary meaning of the word "about" is approximately. *See Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369-70 (Fed. Cir. 2005). Given that there is nothing in the specification suggesting an alternative meaning, this ordinary meaning applies and Alcon's arguments should be rejected.

III. ARGUMENT

A. Nothing in the Plain Language, Specification, or Prosecution History Supports Limiting The Asserted Claims of the '337 Patent to an Anionic SEC.

1. The Plain Language of the Claim Places No Limitations on the Type of SEC.

It is hornbook caselaw that 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). 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.

Claim 1 of the '337 patent, the asserted (and only) independent claim of the patent, reads as follows:

> 1. A therapeutically effective ophthalmic composition comprising:
>
> an alpha-2-adrenergic 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.

The contested limitation in the '337 patent is "a solubility enhancing component other than a cyclodextrin." As cannot be disputed, the word "anionic" does not modify "solubility enhancing component" and does not even appear in the claim. Alcon's argument thus seeks to add a word to the claim that is not there. Accordingly, the first and most important source of intrinsic evidence, the language of the claim, weighs strongly against Alcon's proposed construction. *See Renishaw PLC v. Marposs Societa' per Azioni*, 158 F.3d 1243, 1248 (Fed.Cir. 1998) ("[T]he claims define the scope of the

right to exclude; the claim construction inquiry, therefore, begins and ends in all cases with the actual words of the claim.").

2. The Specification Confirms the Plain Meaning of the Claim and Broadly Discloses That Any Type of SEC, Anionic or Non-Anionic Can Be Used to Practice the Invention.

The second source of intrinsic evidence, the specification, also supports the broad meaning of the claims. The specification, of course, is often the "best source" for construing the claims. *See Metabolite Labs., Inc. v. Lab Corp. of Am. Holdings*, 370 F.3d 1354, 1360 (Fed. Cir. 2004) ("In most cases, the best source for discerning the proper context of claim terms is the patent specification wherein the patent applicant describes the invention.").

The specification could not be more clear that "[a]ny suitable SEC may be employed in accordance with the present invention." '337 patent, col. 6, lines 17-18. [Marsden Markman Decl., Ex. B, at AGN0065329, D.I. 58.] The SECs themselves may be of any ionic state. The specification describes numerous examples of SECs, some of which are non-ionic and some of which are anionic. *Id.* at col. 6, line 17 – col. 7, line 9. [Marsden Markman Decl., Ex. B, at AGN0065329, D.I. 58.]

As can be seen, included among the disclosed SECs are pyrrolidone components, which are not anionic and include povidone. *Id.* This, of course, is the SEC chosen by Alcon. Alcon's argument is thus wholly transparent. In order to avoid infringement, Alcon asks the Court to insert the word "anionic" into the claims so that the claims do not cover povidone in spite of the specification listing it as a possible SEC. This approach is wholly improper. *See Union Oil Co. of Cal. v. Atl. Richfield Co.*, 208 F.3d 989, 995 (Fed. Cir. 2000).

Moreover, as if the disclosure that "any" SEC can be used weren't clear enough, polyanionic SECs are described as a "preferred embodiment" '337 patent, col. 6, lines 21-22, col. 2, lines 52-53 [Marsden Markman Decl., Ex. B, at AGN0065329, AGN0065327, D.I. 58], of the invention, and not the invention itself. And as demonstrated above, the patent discloses both anionic SECs, and non-anionic SECs. Alcon's effort to add the word "anionic" to the claims thus violates additional Federal Circuit precedent strongly disfavoring claim constructions limited to the preferred embodiment. *See Comark Communications, Inc. v. Harris Corp.*, 156 F.3d 1182, 1186-87 (Fed. Cir. 1998).

3. The Prosecution History Also Supports the Ordinary Meaning of the Claim and Makes Clear That The Claims Of The '337 Patent Are Not Limited To Anionic SECs.

The third source of intrinsic evidence, the prosecution history, confirms the conclusion compelled by the other two sources—that the term "solubility enhancing component" should be given the full breadth of its ordinary meaning.

(a) During the Prosecution Of The '210 Parent Patent, The Inventors Chose To Narrow The Claims To Anionic SECs, the Preferred Embodiment, But Specifically Reserved The Right To Seek Broader Claims Not Limited To Anionic SECs.

The '337 patent descends from the '210 patent, and both patents claim priority to provisional application no. 60/218,200, filed July 14, 2000. The '337 and '210 patents contain the same specification, but the claims are directed to different facets of the inventions disclosed in that specification, as evidenced by the prosecution histories. While the '337 patent broadly claims the use of any SEC, the '210 parent patent claims only "anionic" SECs. For this reason, Allergan did not assert the '210 patent here.

During prosecution of the application leading to the '210 patent, Allergan initially filed 46 claims directed to various aspects of the inventions. The examiner issued a restriction requirement, and Allergan elected to pursue claims in Group I, the broadest of which, claim 1, read as follows:

> 1. A 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;
>
> a solubility enhancing component 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; and
>
> a liquid carrier component.

[Marsden Markman Decl., Ex. J, at AGN0221871, AGN0221876, AGN0221851, D.I. 58.]

Examiner Bennett rejected all the elected claims as obvious over the Burke reference in view of Remington's Pharmaceutical Sciences, stating that "[a]bsent unexpected results, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Burke by adding carboxymethylcellulose in order to achieve the desired viscosity as taught by Remington." [Marsden Markman Decl., Ex. J., at AGN0221882.]]

In response to the rejection, Allergan did not make any arguments directed to the patentability of the broad claims rejected by the examiner or make any statements about the scope of any of the terms in the original claims. Rather, Allergan conducted an examiner interview to discuss proposed amendments to the claims. [Marsden Markman

Decl., Ex. J, at AGN0221886, D.I. 58.] After this interview, Allergan chose to narrow the claims to include only polyanionic or anionic SECs.[1] For example, Allergan amended as follows:

> 1. A therapeutically effective aqueous composition comprising:
>
> ~~an alpha-2-andrenergic agonist component~~ a therapeutically effective alpha-2-adrengergic agonist component selected from the group consisting of 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, a salt thereof, and an ester thereof in an amount effective to provide a therapeutic benefit to a patient to whom the composition is administered; and
>
> a polyanionic solubility enhancing component 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~~; and~~
>
> ~~a liquid carrier component~~.

[Marsden Markman Decl., Ex. J, at AGN0221893, D.I. 58.] Allergan similarly amended other claims to require an anionic as opposed to a polyanionic SEC. [*See, e.g.*, Marsden Markman Decl., Ex., J, at AGN0221895, and Ex. I, at AGN0064820, D.I. 58.] Allergan intentionally added the words "polyanionic" or "anionic" to the claims.

In its office action reply accompanying the narrowing amendments, Allergan carefully noted 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, at AG0221898, D.I. 58.] In other words, Allergan narrowed the claims to speed allowance of "certain aspects of the invention." But

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

Allergan was crystal clear that its understanding, after the interview with Examiner Bennett, was that it would be allowed to submit the broader claims in a subsequent application.

Allergan then went on to argue the patentability of the amended claims, which of course had been limited to anionic and polyanionic SECs. In the preface to its arguments on the patentability of the amended claims, Allergan stated that "[t]he current claims are directed to compositions comprising brimonidine and salts and esters thereof in combination with an anionic polymeric solubility enhancing component." [Marsden Markman Decl., Ex. J, at AGN0221898, D.I. 58 (emphasis added).] Allergan then made arguments in favor of unexpected results of the "currently claimed" anionic SECs, explaining that:

> the use of an anionic polymer solubility enhancing component such as CMC (as compared to, for example, hydroxypropyl methyl cellulose) has the advantage of adsorbing to cellular surfaces, such as the cornea of the eye, in a manner that retains any drug in solution with the CMC to be retained at the ocular surface for longer (and in a larger volume) than viscous formulations made with other, non-anionic polymers, while simultaneously increasing solubility.

[Marsden Markman Decl., Ex. J, at AGN0221898-99, D.I. 58.]

This statement simply points out the particular advantages offered by the anionic SECs recited in the newly amended claims—in addition to increasing solubility, anionic SECs provide the extra advantage of increasing residence time of the drug on the eye. It is by no means a general statement that anionic SECs must be used in order to practice the invention and it was specifically directed to the "current claims," which had been amended.

At the same time, Allergan also submitted a declaration from one of the inventors, Dr. Orest Olejnik, in support of the patentability of the newly amended claims. In that declaration, Dr. Olejnik 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, at AGN0221902-03, 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, at AGN0221903 (emphasis added)] Dr. Olesnik 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.* (emphasis added)]

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. Moreover, all of Dr. Olejnik's statements were made with respect to the

"presently claimed compositions," and not, as Alcon argues, to the "invention." In fact, Dr. Olejnik's declaration does not even use the word "invention."

Accordingly, during the prosecution of the '210 patent, Allergan intentionally narrowed the pending claims by adding the words polyanionic or anionic to the claims. The arguments made by Allergan and Dr. Olejnik's declaration were all made in support of these narrowed claims. Contrary to Alcon's position, the arguments and declaration submitted in support of the narrow claims cannot be used to interpret the scope of claims that do not include the words polyanionic or anionic. On May 23, 2003, Examiner Bennett allowed the claims as amended. [Marsden Markman Decl., Ex. J, at AGN0221908-10, D.I. 58.]

(b) After Obtaining The Allowance Of the Narrow Claims In The '210 Patent, Allergan Resubmitted The Broader Claims, Which Were Then Allowed And Issued As The '337 Patent.

While the prosecution of the '210 patent was occurring, Allergan was also prosecuting the application that led to the '337 patent. After receiving the Notice Of Allowability from Examiner Bennett on the narrower anionic claims in the '210 patent, Allergan did exactly what it said it would do. It amended the claims it was then prosecuting to resubmit broader claims that were not limited to polyanionic or anionic SECs. On June 13, 2003, less than one month after the notice of allowability for the narrow claims of the '210 patent, Allergan submitted the following broad claim to Examiner Bennett:

> 1. A therapeutically effective ophthalmic composition comprising:
>
> an alpha-2-adrenergic 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.

[Marsden Markman Decl., Ex. K, at AGN0221771, D.I. 58.]

As is readily apparent, Allergan chose not to use the word "anionic" or "polyanionic" in this claim, thus giving it a broader scope than the claims of the '210 patent. In support of this broad claim, Allergan pointed out that:

> nothing in Burke discloses or suggests the use of a solubility enhancing component in combination with an alpha adrenergic agonist. The present application, which also discloses the advantages of using such a component (such as greater flexibility with the concentration and pH at which such composition is formulated[)], is , to the Applicants' knowledge, the first reference to do so.

[Marsden Markman Decl., Ex. K, at AGN0221774, D.I. 58.]

This argument is plainly directed to the broad use of any SEC and says nothing about polyanionic or anionic SECs. Nor is it based on the previously noted particular advantages of anionic SECs, i.e., better adherence to the eye. Examiner Bennett considered these arguments made with respect to these broader claims and allowed the broader claims to issue as the '337 patent without any limitation to a polyanionic or anionic SEC.

Accordingly, all three sources of intrinsic evidence support the ordinary meaning of the limitation.

4. Alcon's Prosecution-History Based Arguments Seeking to Read a Word Into the '337 Patent Claims That is Not There Are Not Supported By the Intrinsic Evidence or By the Cited Case Law.

In contrast to this straightforward file history supporting the ordinary meaning of the claim, Alcon presents a cut and paste recitation of the file history in support of its proposed construction. But all of Alcon's prosecution-history based arguments to limit the claims of the '337 patent suffer from a fatal flaw—Alcon fails to recognize that the statements in the '210 prosecution history on which it so heavily relies refer to an entirely different claim term than the term "solubility enhancing component" at issue in the '337 patent. As demonstrated above, the limitations in the '210 patent expressly include the word "polyanionic" or "anionic." Consequently, the office action reply and accompanying declaration make arguments in favor of the patentability of claims with those words in them. The statements made do not purport to define the term "solubility enhancing component," but rather point out particular advantages of a preferred embodiment of the invention as recited in the amended claims.

Alcon's arguments thus also violate basic Federal Circuit precedent regarding prosecution history disclaimer. At the outset we note that 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").

Moreover, the prosecution history of a related patent may be relevant only if it addresses a common claim term. *Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc.*, 265 F.3d 1294, 1305 (Fed. Cir. 2001). Where the later patent does not contain the limitation that was added to the parent patent, as here, the parent prosecution history may not limit 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.").

Under these standards, there is no basis whatsoever to find prosecution history disclaimer. With respect to the '337 file history, there is no ambiguity. In its arguments, Allergan made no reference to anionic SECs or their advantages when it made its argument in support of the broader claims in the '337 patent. No clear and unmistakable surrender occurred that would allow Alcon to read the anionic limitation into the term "solubility enhancing component."

And as for the statements made during prosecution of the '210 patent, as demonstrated above, that patent contains limitations ("anionic") that are not claimed in the '337 patent-in-suit. As *Advanced Cardiovascular* teaches, the parent prosecution history does not apply in such a situation, when the later patent lacks a term that was present in the parent and to which the prosecution statements were directed. *See Advanced Cardiovascular*, 265 F.3d at 1305-06 (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 cannot be contested, the prosecution history statements 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 the anionic SEC preferred embodiment. Accordingly, the cases cited by Alcon are simply not relevant to this situation because they 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).

This case stands in stark contrast to the facts of *Biovail Corp. Int'l v. Andrx Pharms., Inc.*, 239 F.3d 1297, 1301-02 (Fed. Cir. 2001), in which the claim limitation was simply "admixture." Although none of the claims contained the term "homogenous," the Federal Circuit limited the claims to homogenous admixtures because the prosecution characterized the whole of the invention as homogenous. *Id.* at 1302. In contrast, only the claims of the '210 patent contain the term "anionic" or "polyanionic," and Allergan made a conscious choice to omit these terms in the '337 patent. As detailed above Allergan never characterized the whole of its invention as being directed to anionic

SECs, but carefully referred only to the preferred embodiment and directed its arguments during the '210 patent prosecution to the narrow claims being sought at that time.

Indeed, the weakness of Alcon's disclaimer argument is demonstrated by the lengths to which it goes to mischaracterize both the '210 and '337 patent file histories. In its brief, 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 Markman Brief, at 13, 15, 19, 20, D.I. 54] This is a blatant misrepresentation of the record of the PTO proceedings. Dr. Olejnik explained that CMC "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, at AGN0221903, D.I. 58.] He 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.* (emphasis added)]

Alcon's assertion that Dr. Olejnik stated that povidone "would not work in the invention" [Alcon Summary Judgment Br. at 16, D.I. 55] is patently false. Dr. Olejnik never made that statement, and the portion of his declaration cited by Alcon refers to "the presently claimed compositions," not to "the invention." Indeed, the declaration does not even use the word "invention."

Moreover, in its summary judgment briefing, Alcon states that Dr. Olejnik submitted his declaration and "thereafter" that Allergan was forced to narrow the claims by amendment. [Alcon Summary Judgment Br. at 8, D.I. 55.] In reality, Allergan

narrowed the claims and then submitted Dr. Olejnik's declaration in support of the narrowed claims. Alcon falsely suggests that Dr. Olejnik's declaration referred to the unamended claims and that only after submitting the declaration were the claims amended. Alcon deliberately attempts to mislead the Court. Nowhere in the declaration is it stated or implied that the other vehicles disclosed in Burke, including povidone, would not be effective as solubility enhancing components.

In the reply to the office action, the same is true. 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, at AGN0221898-99, 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, narrower claims. There is no disclaimer of any of the other "vehicles" disclosed in Burke, and Alcon's argument to the contrary is based on a fanciful recreation of the file history and not the actual statements made to the PTO.

Moreover, contrary to Alcon's suggestions [Alcon's 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] 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 most definitely did not reclaim subject matter that had been "disclaimed" during prosecution of the parent application.

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

Also highlighting the weakness of Alcon's position is the insinuation it makes that Allergan did something improper by going back to the PTO and obtaining its broad claims. Such a practice not only is common in patent prosecution proceedings—undoubtedly, Alcon, which has over 700 patents, has done it countless times—but it was done with the full knowledge of Examiner Bennett.

As demonstrated above, after the interview with Examiner Bennett during prosecution of the '210 patent, Allergan submitted its amended claims with the following proviso: 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, at AGN0221897, D.I. 58.] Alcon wholly ignores this statement.

Moreover, this reservation by Allergan was not only proper, but it was prudent practice. The Federal Circuit has approved of this practice. 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.*

Similarly, in *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1357-58 (Fed. Cir. 2004), the patentee had a family of patents, with the earlier ones containing narrow claims requiring a predetermined timing method. The Federal Circuit refused to limit claims in a later patent to a predetermined method, explaining that 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.

This case should be treated no differently. In prosecution of the '210 patent, Allergan obtained relatively narrow claims directed to a preferred embodiment—an anionic solubility enhancing component—but preserved its rights to later seek broader claims. Allergan did this and the PTO allowed the claims in the '337 patent-in-suit. Allergan's amendment practice is no basis for limiting the claims.

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

Alcon's final 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 Labs., 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 Mfg. Co. v. United States Int'l Trade Comm'n*, 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 '834 Patent Uses The Term "About" In Its Ordinary Sense, Meaning "Approximately."

Alcon's attempts to artificially limit the scope of the term "about" in the claims on the '834 patent are just as unavailing as its attempts to read a limitation into the '337

patent claims. Just as it does with the term "solubility enhancing component," Alcon seeks to impose limitations on the term "about" that run counter to its plain meaning of "approximately" and are not required by the specification or prosecution history.

1. The Adjudicated Ordinary Meaning of "About" is "Approximately."

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.

[Marsden Markman Decl., Ex. C, at AGN0068211, D.I. 58.] As can be seen, the claim uses the term "about" three times with reference to three different quantities: the concentration of the drug ("up to about 0.15%), the pH of the solution ("about 7.0 or greater) and the temperature ("about 21° C).

The ordinary meaning of the term "about" is "with some approach to exactness in quantity, number, or time: approximately." *Webster's Third New Int'l 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). Moreover, though his declaration is extrinsic evidence, Dr. Stella testifies that one of skill in the art would also understand the term to mean "approximately." [Stella Decl. ¶¶ 30, 34.]

As demonstrated above, a claim term should be construed to carry its ordinary meaning unless the specification or prosecution history clearly redefines the term more narrowly. *Johnson Worldwide Assocs. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 2000). As demonstrated in our opening brief, no such redefinition occurred in the specification or prosecution history of the '834 patent. Furthermore, a term that is used multiple times in the same patent should be interpreted consistently in each use, *see Phonometrics, Inc. v. N. Telecom, Inc.*, 133 F.3d 1459, 1465 (Fed. Cir. 1998), so "about" should be construed to mean "approximately" in all its uses in the '834 patent claims.

2. "About 0.15%" Means Approximately 0.15%.

Nothing in the specification of the '834 patent indicates that Allergan intended to deviate from this ordinary meaning of the term "about" with respect to the "about 0.15%" limitation. Much of Alcon's argument regarding the "about 0.15%" limitation in the specification is merely a reiteration of the written description argument from its summary judgment brief and should have no bearing on the proper claim construction. Indeed, 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 several of the solubility curves converging around 0.15%, and the examples further explain that around 0.16% brimonidine, estimated from the figure, was the most the inventors were able to solubilize with any amount of solubility enhancing component. [Marsden Markman Decl., Ex. C, at AGN0068203, AGN0068211, D.I. 58.]

Alcon's citations to the prosecution history also provide no basis for imposing Alcon's proposed numerical limitations on the term. According to Alcon, "[t]he 0.15%

concentration was at the core of Allergan's argument for the patentability of the claims," and therefore "about 0.15%" can reach only a minimal range. Tellingly, Alcon cites no case law to support its argument.

The limitation that Alcon seeks on the "about 0.15%" limitation, restricting it to 0.15% ± 0.005%, also has no basis in the "technologic and stylistic context" of the term." *See Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995); *see also W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 842 F.2d 1275, 1280 (Fed. Cir. 1988). Indeed, Alcon's position on this limitation is purely expedient, as it has shifted its position on this issue to suit its defense of the moment. In Alcon's initial claim chart, it sought to interpret "about 0.15%" at "within 0.0001%." [Ex. 1, at 5.] Now, Alcon claims that the margin of error is plus or minus 0.005%. Apparently, what is so "clear" to Alcon now was not clear to Alcon just weeks ago.

Either way, both of Alcon's positions lack any support in the context of the technology.

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If there is any numerical limit to be imposed on the term, plus or minus 10% would be the only appropriate choice. [Stella Decl. ¶¶ 31-32.] Alcon's arguments should be rejected.

3. "About 7.0 or Greater" Means Approximately 7.0 or Greater.

Alcon's arguments concerning the "about 7.0" limitation fare no better. Alcon seeks to limit this term to encompass only a pH of 6.95 to 7.05. This proposed construction once again ignores the "technologic and scientific context" of the invention,

as the pH of these types of drug formulations tends to vary throughout a greater range than this. Furthermore, the specification of the '834 patent, contrary to Alcon's suggestion, does not suggest, let alone require, such a restrictive interpretation. The specification 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. [Marsden Markman Decl., Ex. C, at AGN0068209, D.I. 58.] Also example 2 refers to measuring the pH "from about 7 to about 10." *Id.* at col. 15, lines 23-24. [Marsden Markman Decl., Ex. C, at AGN0068211, D.I. 58.] The pH measurements were actually taken over a range from 6.67 up through 10.11, significantly wider than the range of Alcon's proposed claim construction. *Id.* There is simply nothing in the plain language, specification, or prosecution history to indicate that "about 7.0" means anything other than "approximately 7.0."

4. "About 21° C" Means Approximately 21° C.

Finally, Alcon provides no reason deviate from the ordinary meaning of "about" in the term "about 21° C." Alcon proposes to limit the term to 21° C ± 0.5° C, alluding to some vague notion of scientific principles. Alcon, however, fails to provide the type of evidence required to overcome the "heavy presumption," *see CCS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002), in favor of the ordinary meaning of "approximately."

5. *B.J. Services* Does Not Support Alcon's Proposed Claim Construction.

Alcon cites *B.J. Services Co. v. Halliburton Energy Servs.*, 338 F.3d 1368 (Fed. Cir. 2003), for the proposition that "experimental error" is an appropriate way to construe

the term "about." [Alcon Markman Br. at 26, D.I. 54.] In *B.J. Services*, however, it was the patentee that sought a narrow construction of the term "about" to avoid the prior art and preserve the validity of its claims. *B.J. Servs.*, 338 F.3d at 1372-73. No such considerations are at issue in this case. Moreover, in that case the Federal Circuit did not comment on the ordinary meaning of the term because neither party had proposed it.

Notably, Alcon fails to provide any evidence as to what the experimental error would be in this case, and quickly switches to a completely unsupported, lawyer-made argument suggesting that "about" should only encompass a range that would be rounded to the precise number recited in the claims. As demonstrated by Alcon's and Allergan's NDA filings, and as is supported by Dr. Stella, brimonidine formulations are labeled at 0.15% (w/v) so long as they are within plus or minus 10% of this amount. [Exs. 2 and 3.] Accordingly, to the extent the Court wishes to consider experimental error, both parties are on record as applying a different number to the formulations in dispute than that proposed by Alcon's lawyers.

Nonetheless, nowhere does the patent require this or any other margin of error. Accordingly, the ordinary meaning of the term should control pursuant to *Merck v. Teva*, 395 F.3d at 1369-70.

IV. CONCLUSION

Allergan's proposed claim constructions are consistent with the ordinary meaning of the claim terms, while Alcon's proposed constructions ask the Court to read in artificial limitations that are contrary to the plain language and not required by the specifications or prosecution histories. Allergan therefore respectfully requests that the Court adopt the following claim constructions of the disputed terms:

Solubility enhancing component: The claimed composition contains a solubility enhancing component, which is 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.

About: The term "about" carries its ordinary meaning of "approximately" in all its uses in the claims of the '834 patent.

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CERTIFICATE OF SERVICE

I hereby certify that on May 23, 2005, I electronically filed with the Clerk of Court REDACTED VERSION OF ALLERGAN, INC. AND ALLERGAN SALES, LLC'S RESPONSE TO MEMORANDUM IN SUPPORT OF ALCON'S PROPOSED CLAIM CONSTRUCTION using CM/ECF which will send notification of such filing(s) to the following:

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