IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

ALCON'S REPLY BRIEF IN FURTHER SUPPORT
OF ITS PROPOSED CLAIMS CONSTRUCTION

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I. PRELIMINARY STATEMENT

Four straightforward questions govern the construction of the claim term "solubility enhancing component" ("SEC") in the '337 patent: (i) Does a disclaimer during prosecution allow for a claim construction that differs from the "plain meaning" of the term-at-issue as set forth in the claims and specification; (ii) does Allergan's "invention of selection" argument, made to overcome the prior art, limit it from now asserting that the '337 patent covers one of the components in the prior art that Allergan chose not to select and, in fact, affirmatively disclaimed during prosecution; (iii) does the disclaimer in the prosecution of the '210 patent limit the construction of the disputed term in the '337 divisional patent (i.e., SEC), where the claims in the two patents employ the exact same limitation (i.e., a "solubility enhancing component"), but only the earlier-issued patent from the parent application contains the modifier "anionic"; and (iv) does Allergan's disclaimer limit the scope of the resulting claims despite its ancillary arguments to the contrary? Alcon asserts that all four questions are properly answered in the affirmative and, thus, none of the arguments raised by Allergan provides a reasonable basis to reject Alcon's proposed construction of the '337 patent.

With respect to the '834 patent, the primary terms in dispute all relate to the word "about." Allegan proposes that "about" means "approximately" regardless of context, and proposes no more specific construction. Conversely, Alcon proposes that context must be considered in every case and that its proposed constructions are both logical and consistent with the intrinsic evidence. On that basis, Alcon respectfully request that its proposed claims constructions be adopted in full.

II. ALLERGAN HAS FAILED TO REBUT ALCON'S POSITION THAT THE CLAIMS OF THE '337 PATENT ARE SUBJECT TO A DISCLAIMER

A. Allergan's Disclaimer During The Prosecution Of The '210 Patent Is Not Undermined By The "Plain Meaning" Of The Claims Or Teachings In The Specification Of The '337 Patent

Much of Allergan's argument focuses on the fact that the claims of the '337 patent do not contain the word "anionic." While that is true, Alcon has never argued the word "anionic" is in the claims, nor does Alcon seek "to add a word to the claim that is not there." Rather, Alcon's position is that it, and the public at large, have the right to rely on what Allergan said its "invention" was and, more importantly, what its "invention" was not, during prosecution. See, e.g., Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 957 (Fed. Cir. 2000) (Ignoring prosecution disclaimers would be "inimical to the public notice function provided by the prosecution history" upon which competitors are "entitled to rely."); Digital Biometrics, Inc. v. Identix, Inc., 149 F.3d 1335, 1347 (Fed. Cir. 1998) ("The public has a right to rely on such definitive statements made during prosecution."). Allergan would not have obtained the '210 patent without representing to the United States Patent and Trademark Office that non-ionic polymers, including povidone, are not within the scope of its "invention," and these representations are relevant to, and limit the scope of, the claims of the '337 patent. See, e.g., Southwall Techs., Inc. v. Cardinal IG Co., 54 F.3d 1570, 1576 (Fed. Cir. 1995) ("The prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.").

1. Allergan's Reliance On The "Plain Meaning" Of The Claims Is Misplaced

Allergan relies heavily on "plain meaning" to imply that the Court can only examine the words in a claim to interpret it.[1] According to Allergan, since the word

[1] See, e.g., Allergan, Inc. And Allergan Sales, LLC's Response To Memorandum In Support Of Alcon's Proposed Claim Construction ("Allergan's Response Brief") (D.I. 71) at 4-5.

"anionic" is not in the claims, the claims cannot be so limited. That is not true. The Federal Circuit has pointedly cautioned that "the ordinary and customary meaning of a term does not govern if the intrinsic record contains clear . . . disavowal of claim scope." C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 863 (Fed. Cir. 2004) (emphasis added); see also Pall Corp. v. PTI Techs. Inc., 259 F.3d 1383, 1392 (Fed. Cir. 2001) ("Even where the ordinary meaning of the claim is clear, it is well-established that '[t]he prosecution history limits the interpretation of claim terms so as to exclude any interpretation that was disclaimed during prosecution.'" (citations omitted), vacated on other grounds, 535 U.S. 1109 (2002)). Indeed, "plain meaning" does not "somehow trump or override the intrinsic record in determining the meaning of a claim term." C.R. Bard, 388 F.3d at 862. The intrinsic evidence in this case requires the same distinction between povidone and CMC that Allergan advanced to its benefit in the PTO.

2. Allergan's Reliance On The Specification Is Also Misplaced

Allergan's reliance on the specification's reference to the use of "[a]ny suitable SEC" and a laundry list of compounds that purportedly could enhance solubility is also misplaced.[2] Statements in the specification, which were obviously made before prosecution even began, cannot be the basis to reclaim, in litigation, subject matter that was disclaimed during prosecution. Accordingly, Allergan's statements in the specification cannot override its subsequent disclaimer in the prosecution . See, e.g., Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1327 (Fed. Cir. 2002) (rejecting express definition of a disputed claim term in the specification because the patentee disclaimed that interpretation during prosecution).

Allergan's slavish reliance on the specification only serves to accentuate its disclaimer. If, as Allergan asserts, the specification's recital of "pyrrolinidone components" refers to povidone and characterizes it as an SEC, that would only

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[2] Allergan's Response Brief at 5-6.

underscore the knowing nature of Allergan's subsequent disclaimer in the prosecution of the parent application. When faced with a rejection over a prior art reference that disclosed both CMC and povidone, Allergan selected CMC as a key component in its invention and disclaimed povidone.

B. The Prosecution History Clearly Evidences Allergan's Disclaimer

1. Allergan Mischaracterizes The Prosecution History

a. The Prosecution Of The '210 Patent Contains A Clear And Unequivocal Disclaimer

Allergan admits, as it must, that it initially sought allowance of broad claims (which were not limited to anionic SECs) during prosecution of the '210 patent and that those claims were immediately rejected by the Examiner. But Allergan then puts a fanciful "spin" on the fact that it abandoned the broad claims because pursuing them was so obviously futile. Allergan says it did not make any arguments or statements in support of the original claims and simply "chose" to pursue narrow claims after an interview with the Examiner.[3] But, in the Reply that it filed immediately after that interview, Allergan admitted that it "discussed the outstanding rejections," and Allergan's brief indicates that the claims were narrowed "[a]fter this interview."[4] Clearly, Allergan had no choice but to narrow the claims – the broad claims were unpatentable in light of, inter alia, the Burke reference.

Likewise, while Allergan accurately states that it amended the claims in its Reply to the Office Action by including, among other things, the words "polyanionic" or "anionic" to expressly modify "solubility enhancing component," it omits any reference to the statements at the heart of its disclaimer. Allergan says nothing of the fact that it

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[3] Id. at 7-8.

[4] Prosecution history of the '210 patent ("'210 PH") (Alcon's Opening Brief at Exhibit D) (D.I. 54), Reply to Office Action mailed March 12, 2003, Tab 10 at 5, and Allergan's Response Brief at 8, respectively.

specifically selected CMC from the list of other compounds disclosed in the prior art Burke reference, thus distinguishing the others (including providone) as they relate to its "invention." Moreover, it all but completely ignores its representation that "anionic solubility enhancing components such as CMC have surprising and beneficial properties in the **solubilization** of brimonidine as compared to non-ionic or cationic polymers."[5]

Instead, Allergan tries to divert the Court's attention by emphasizing its ancillary argument in the Reply that anionic SECs had some purported advantage in "adsorbing" to the surface of the eye.[6] It then carries this argument forward in characterizing the Declaration of Dr. Olejnik as focusing entirely on an alleged combination of advantages provided by CMC (and other anionic SECs) because it could purportedly increase the solubility of brimonidine and, at the same time, better adhere to the eye.[7] But Allergan uses crop-quoting to avoid Dr. Olejnik's statement that the other compounds disclosed in Burke (including povidone) "would not possess" these properties.[8] Significantly, the claims of the '210 patent do not contain, nor did they ever contain, any limitation to the alleged "adherence" property that Allergan now urges was so important to the patent's allowance. In striking contrast, each and every claim of that patent is limited with respect to solubility.

b. Allergan's Clear Disclaimer Is Not "Trumped" By Its Boilerplate Statements

Allergan's post hoc rationalization of its disclaimer is further emphasized by its reliance on a boilerplate statement in the prosecution of the '210 patent. Allergan posits that its boilerplate statement that it "may" pursue prosecution of "unamended and non-

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5 See '210 PH (Alcon's Opening Brief at Exhibit D), Reply to Office Action mailed March 12, 2003, Tab 10 at 6 (emphasis added).

6 Allergan's Response Brief at 9.

7 Id. at 10.

8 '210 PH (Alcon's Opening Brief at Exhibit D), Declaration of Orest Olejnik, Ph.D., Tab 11 at ¶ 8 (emphasis added).

cancelled versions" of "cancelled and/or amended claims" (whatever that means) made it "crystal clear" that it intended to "submit the broader claims in a subsequent application."[9] But only the most extreme form of hindsight could transform this vague statement into a "crystal clear" one. Moreover, instead of filing an entirely new "subsequent" application to pursue the abandoned claims, Allergan "resubmi[ted]" the claims in a co-pending divisional application which, at that time, claimed a wholly distinct class of subject matter.[10]

If Allergan intended to pursue claims to any "solubility enhancing component" unencumbered by its limiting representations in its co-pending divisional application, it could and should have said so. Allergan cannot erase its clear disclaimer now, years later, by suggesting that its boilerplate statement somehow "trumps" the express representations that it made to secure the '210 patent.[11] See Bai v. L & L Wings, Inc., 160 F.3d 1350, 1355 (Fed. Cir. 1998) (finding that a boilerplate statement allegedly reflecting the applicant's intent in making an amendment did not rebut a surrender of claim scope).

The cases Allergan cites as allegedly condoning such boilerplate recitations as a "prudent practice," do no such thing.[12] In fact, boilerplate reservations have nothing to do with either case. Unlike here, the patentee in Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 909 (Fed. Cir. 2004) removed a claim limitation and affirmatively

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9 Allergan's Response Brief at 8-9.

10 See Alcon's Opening Brief at 13-15.

11 Allergan's related assertion that its boilerplate reservation was made to "speed prosecution" also rings hollow. If, as Allergan proposes, the broad claims of its '337 patent were patentable all along, Allergan actually slowed prosecution by dropping its broad claims from the '210 prosecution, submitting narrower claims for examination, then "resubmit[ting]" the broad claims in the '337 prosecution. The "broad" claims of the '337 patent were allowed over essentially the same rejections that were made months earlier in the prosecution of the '210 patent. Of course, it is clear that the "broad" claims of the '337 patent were no more patentable than the broad claims offered during prosecution of the '210 patent, absent Allergan's having disclaimed all but anionic SECs.

12 Allergan's Response Brief at 18-19.

precluded a narrow reading of the claim by specifically stating that the pending claims were no longer limited by the former limitation. Allergan never made such a representation. To the contrary, as noted above, Allergan admits that it "most definitely did not reclaim the subject matter that had 'disclaimed.'" (emphasis added). Home Diagnostics, Inc. v. LifeScan, Inc., 381 F.3d 1352 (Fed. Cir. 2004) does not address a boilerplate reservation either. Moreover, disclaimer was not even at issue in Leibel-Flarsheim or Home Diagnostics.

c. Allergan Did Nothing To Mitigate The Disclaimer In The Prosecution Of The '337 Patent

Allergan's mischaracterization of the prosecution history of the '337 patent does not provide a basis to construe the claims to include that which Allergan excluded during prosecution of the parent application. Allergan argues that it "did exactly what it said it would do" by "resubmit[ing]" its broad claims for allowance in the '337 patent.[13] But, as noted in the last section, Allergan did not say whether it would pursue any claims, what those claims might be, or where it might do so. It certainly gave no indication that it would completely reconfigure the claims of its co-pending divisional application.[14] Nor did it suggest this tact in its Reply to the Examiner's outstanding rejection of the then-pending claims in the '337 patent.

If anything, the entirety of Allergan's Reply suggested that prosecution was continuing on the former claims with only minor amendments. Allergan first remarked that it had received the Examiner's Office Action and "[f]ollowing a careful review, the Applicants have the following comments."[15] With respect to the Examiner's outstanding obviousness rejection, Allergan stated that it had amended the claims to set forth "the

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13 Allergan's Response Brief at 11.

14 Alcon's Opening Brief at 13-15.

15 '337 PH (Alcon's Opening Brief at Exhibit E), Reply to Office Action dated June 13, 2003, Tab 5 at 4.

invention in a preferred embodiment thereof" – drawing attention to the fact that it had amended the claims to cover a "therapeutically effective ophthalmic" composition by underlining that phrase (but not so indicating that the bulk of the claim was completely different).[16] It then paraphrased the Examiner's outstanding rejections on the formerly pending claims with respect to the Burke and Beck patents, and assured the Examiner that the Beck patent was no longer an issue because Allergan had "amended the claims to remove the necessity for a preservative."[17] And Allergan "maintain[ed]" that "nothing in Burke discloses or suggests the use of a solubility enhancing component in combination with an alpha adrenergic agonist."[18] This, of course, was simply and completely wrong. Burke disclosed CMC (an anionic polymer), which Allergan itself characterizes as a "solubility enhancing component," and Burke also disclosed its potential use in combination with brimonidine tartrate (an alpha-2-adrenergic agonist).

Allergan did not inform the Examiner that it had "resubmit[ted]" the broad claims that the Examiner had rejected earlier during the prosecution of the parent '210 patent over Burke. Nor did it suggest in any way that the reconfigured claims should not be limited by its unequivocal disclaimer of all but anionic SECs. Nor did it provide any new arguments or evidence that could have secured allowance over the Examiner's rejection (which was essentially the same as his rejection of the broad claims in the prosecution of the '210 patent).[19] Had Allergan truly intended the claims of '337 patent to be unrestricted by its disclaimer during prosecution of the '210 patent, it should have attempted to retract or modify its prior representations that disclaimed all but anionic SECs. It did not. If anything, Allergan did the opposite: representing that its resubmitted

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16 Id. at 5.

17 Id.

18 Id.

19 Compare '210 PH (Alcon's Opening Brief at Exhibit D), Office Action dated January 9, 2003, Tab 7 with '337 PH (Alcon's Opening Brief at Exhibit E), Office Action dated March 3, 2003, Tab 3.

claims were to a "preferred embodiment," which is how the specification refers to polyanionic SECs.[20]

2. Allergan's Attacks On Alcon's Disclaimer Arguments Lack Merit

a. There Is No Requirement That Claims In Different Patents Contain The Exact Same Limitation For A Disclaimer To Exist

Allergan takes the untenable position that there can be no prosecution history disclaimer unless the claims-at-issue contain the same limitation, ipsissimis verbis. Allergan argues that since the claims of the '210 patent contained the term "polyanionic solubility enhancing component" and the claims of the '337 patent only contain the term "solubility enhancing component," without an express recitation of the word "polyanionic" (or "anionic"), the limitations in the different claims are not the same and a disclaimer cannot exist.

However, the '210 and '337 patents do recite the same claim term: "solubility enhancing component." That this term is expressly modified by "polyanionic" (or "anionic") in the claims of the '210 patent, but not in the claims of the '337 patent, does not expunge Allergan's express disclaimer. Indeed, the doctrine of prosecution history disclaimer rests on the absence of an express limitation in the claims. The issue of disclaimer would not arise if the limitation were present in the claim. Allergan's suggestion to the contrary is absurd.

The cases that Allergan relies on for this proposition do not support its hyper-literalist view of "same limitation." Unlike here, in Advanced Cardiovascular Sys., Inc. v. Medtronic, Inc., 265 F.3d 1294, 1305-06 (Fed. Cir. 2001), "there [were] no common claim terms in dispute" and the defendant provided "no plausible reason" why the earlier prosecution histories were relevant. Likewise, in Al-Site Corp. v. VSI Int'l, Inc., 174

[20] '337 Patent, col. 6, ll. 21-22.

F.3d 1308, 1322 (Fed. Cir. 1999), it was argued that prosecution history estoppel applied merely because the patents "arose from related applications." And it is particularly surprising that Allergan would rely on Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979-80 (Fed. Cir. 1999). There, the Federal Circuit held that there was a disavowal despite the fact that the words of the relevant limitation were not completely identical in the two patents (one claim referred to a "feed tube" whereas the other referred to a "feed probe.") None of these cases support the proposition that the words used in claim limitations must be identical for a disclaimer to have occurred.[21]

The Federal Circuit has soundly rejected the very sort of hyper-literalist argument that Allergan makes. In Jonsson v. Stanley Works, 903 F.2d 812, 818-19 (Fed. Cir. 1990), for example, the Federal Circuit held that a downstream patent was limited by representations in its parent application even though the patentee argued the limitation had been "expressly deleted" from the downstream patent and was "glaringly absent" from it. Jonsson is not an aberrational case. To the contrary, it was one of the key cases relied upon by Advanced Cardiovascular, and the only case relied upon by Elkay, (two decisions Allergan relies upon) for the proposition that patents must contain the "same claim limitation." Advanced Cardiovascular, 265 F.3d at 1305; Elkay, 192 F.3d at 980. Clearly, Allergan is distorting the sense of this statement. This conclusion is fortified further by numerous other decisions rejecting Allergan's position. See, e.g., Alloc, Inc. v. Int'l Trade Comm'n, 342 F.3d 1361, 1371-72 (Fed. Cir. 2003) (relying on patentee's disavowal in parent application, which contained limitation, to narrowly construe claims of offspring patents that did not); Wang Labs., Inc. v. Am. Online, Inc., 197 F.3d 1377, 1384 (Fed. Cir. 1999) (limiting scope of claims of continuation patent that lacked key

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[21] Likewise, Allergan's effort to distinguish Biovail Corp. Int'l v. Andrx Pharms., Inc., 239 F.3d 1297 (Fed. Cir. 2001) because its disclaimer involved the entire invention also misses the mark. Allergan's Response Brief at 15-16. Allergan's prosecuting attorney and one of its inventors both disclaimed the use of non-ionic compounds as not being part of Allergan's entire invention as well. Allergan cannot reclaim that subject matter now, in litigation.

limitation based on representation made in parent because it applied to "common subject matter"); Modine Mfg. Co. v. Int'l Trade Comm'n, 75 F.3d 1545, 1551 (Fed. Cir. 1996) ("[I]t is incorrect to construe a claim as encompassing the scope that was relinquished in order to obtain allowance of another claim, despite a difference in the words used.") (emphasis added); Builder's Concrete, Inc. v. Bremerton Concrete Prods. Co., 757 F.2d 255, 259-60 (Fed. Cir. 1985) (limiting scope of claim based on arguments made in association with narrowing amendment of related claim to which an express limitation was added).

b. A Disclaimer During Prosecution Is Just As Effective As A Disclaimer In Both The Specification And The Prosecution

Allergan also criticizes Alcon for citing Microsoft, Wang Labs, and Modine because "[t]hese cases employ the prosecution history to confirm a narrow claim construction based principally on the patent specification."[22] In making this criticism, Allergan is apparently suggesting that disclaimers cannot be based on statements in the prosecution history alone; they must also be accompanied by a narrow construction mandated by the specification. This is simply not true. The fact that a claim is limited by both the specification and the prosecution does not mean, as Allergan suggests, that a disclaimer appearing only in the prosecution does not also limit the claim. See, e.g., Rheox, 276 F.3d at 1327 (rejecting express definition of term in the specification because patentee disclaimed interpretation during prosecution); Hockerson-Halberstadt, Inc., 222 F.3d at 956-57 (finding disclaimer from prosecution history where none existed in the specification).

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[22] Allergan's Response Brief at 19-21.

c. Allergan's Statements Regarding "Adherence" Do Not Vitiate Its Disclaimer With Respect to "Solubility"

Allergan improperly accuses Alcon of "blatant[ly] misrepresent[ing]" the prosecution history of the '210 patent because of Alcon's observation that Allergan expressly disclaimed the non-ionic compounds disclosed in the Burke reference by arguing that they would not function as SECs.[23] Allergan bases this accusation on misleading crop-quotes from Dr. Olejnik's declaration and its accompanying Reply to the Office Action. According to Allergan, the declaration distinguished anionic SECs from the non-ionic polymers in Burke because CMC was allegedly more soluble and adhered better to the cornea. Similarly, it asserts that its Reply distinguished Burke "because the anionic SECs provided a surprising advantage in 'absorbing to cellular surfaces, such as the cornea . . . while simultaneously increasing solubility.'"[24] Thus, according to Allergan, it "highlighted particular additional advantages of the anionic preferred embodiment covered by the amended, narrower claims."[25]

Allergan assiduously avoids any reference to the fact that it selected CMC and discarded povidone (and other non-ionic or cationic polymers from the disclosure in the Burke reference). Allergan expressly argued that anionic SECs, and specifically CMC, constituted an "invention of selection." It made this point several times. For example, at an interview with the Examiner, Allergan's "attorney explained the instant invention was an invention of selection."[26] In its Reply to the Office Action, Allergan said ". . . no disclosure [in the prior art] would direct or motivate the person of ordinary skill in the art to select or want to select an anionic polymeric solubility enhancing component such as

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23 Id. at 16.

24 Id. at 17.

25 Id.

26 '210 PH (Alcon's Opening Brief at Exhibit D), Summary of Interview dated February 25, 2003, Tab 8.

CMC from the list of optional viscous 'vehicles' contained in the '991 patent."[27] And Dr. Oljenik, Allergan's Vice President of Pharmaceutical Sciences and one of the named inventors, opined that neither prior art reference "discloses that CMC would have any characteristics that would motivate a person of ordinary skill in the art to choose it over other polymers in formulating a brimonidine solution."[28] Although it seeks to avoid it, Allergan must now live with that choice.

Allergan also eschews any reference to Dr. Olejnik's statement that the non-ionic polymers disclosed in Burke (which included povidone) "would not possess" the alleged combination of unexpected advantages and its unequivocal statement in the Reply that the prior art was not pertinent because anionic compounds were different "in the solubilization of brimonidine as compared to non-ionic or cationic polymers."[29] These representations could lead to no other conclusion than that Allergan expressly disavowed non-ionic and cationic polymers, including povidone.

Indeed, contrary to Allergan's representation to this Court, both "solubility" and "adherence to corneal surfaces" were not "covered by the amended, narrower claims" of the '210 patent. Only "solubility" is recited in the claims. Significantly, no limitation requiring "adherence to corneal surfaces," which Allergan now asserts is a key distinction from the prior art, is present in any of the claims. See, e.g., In re Kulling, 897 F.2d 1147, 1149-50 (Fed. Cir. 1990) (affirming rejection of claims that were not limited by unexpected property); In re Lindner, 457 F.2d 506, 508 (C.C.P.A. 1972) ("It is well established that the objective evidence of nonobviousness must be commensurate in scope with the claims.").[30] Likewise, the specification of the '337 patent (which is the

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27 Id., Reply to Office Action mailed March 12, 2003, Tab 10 at 7 (emphasis added).

28 Id., Declaration of Orest Olejnik, Ph.D., Tab 11 at ¶ 6.

29 Id., Reply to Office Action mailed March 12, 2003, Tab 10 at 6 (emphasis added).

30 See South Corp. v. United States, 690 F.2d 1368, 1370 (Fed. Cir. 1982) (The Federal Circuit adopted the decisions of the C.C.P.A. as precedential.).

same in the '210 patent) does not even refer to "adherence." Cf. In re Herr, 304 F.2d 906, 909 (C.C.P.A. 1962) ("if 'that advantage is not disclosed in [the patentee's] application he is 'not in a favorable position to urge it was a basis for the allowance of claims.'" (citation omitted)). Accordingly, Allergan's assertions that its ancillary arguments with respect to "adherence" somehow diminish its arguments with respect to solubility and negate its disclaimer are baseless.

As discussed above, Allergan did nothing during the prosecution of the '337 patent to mitigate its clear disavowal of non-ionic and cationic compounds during prosecution of the '210 patent. Thus, its disclaimer remained effective. See, e.g., Alloc, Inc., 342 F.3d at 1372 (noting that after allowance of identical claims but for one additional limitation, the applicant failed to "retract or modify" its limiting representations); Watts v. XL Sys., Inc., 232 F.3d 877, 883-84 (Fed. Cir. 2000) (stating that it was "irrelevant" that the patentee's comments were directed to a different claim "because there is no clear indication that they were not," and limiting the claims of related claims based on the representation as well).

Accordingly, Alcon respectfully requests that the term "solubility enhancing component" be interpreted, consistent with Allergan's disclaimer during prosecution of the parent application, to be limited to anionic compounds (and thereby exclude non-ionic polymers, such as povidone).

III. ALLERGAN PROVIDES NO COGENT REASON WHY ALCON'S PROPOSED CONSTRUCTION OF "ABOUT" SHOULD BE REJECTED

Allergan continues to refuse to provide any meaningful interpretation of the word "about" in the '834 patent.[31] Instead, it accuses Alcon of trying to impose limitations on the term that "run counter to its plain meaning of 'approximately' and are not required by

[31] Alcon's position with respect to the disputed term "similarly" in the '337 patent is set forth in Alcon's Response to Allergan's Opening Markman Brief at 6-8 (D.I. 67).

the specification or prosecution history."[32] Allergan's evasive tactics should not be tolerated, and the Court should adopt Alcon's proposed constructions. Alcon and the public at large are entitled to have a meaningful interpretation of the term "about" as it is used in the claims of the '834 patent.

A. The Merck Case Does Not Define The Meaning Of "About" In The '834 Patent

Once again, in its Responding Brief, Allergan cites Merck & Co., Inc. v. Teva Pharms. USA, Inc., 395 F.3d 1364 (Fed. Cir. 2004) for its discredited position that the Federal Circuit has construed the term "about" for all time, and under all circumstances, as "approximately." Allergan suggests that the Merck court somehow decided the meaning of "about" in the '834 patent – notwithstanding the fact that Merck involved a completely different type of claim (a method rather than a composition), a different technology, a different patent, and an obviously untenable proposed claim interpretation by the patentee for the term "about" (i.e. "exactly"). In so doing, Allergan urges this Court to construe the disputed term in a vacuum, which runs contrary to Federal Circuit precedent. See Medrad, Inc. v. MRI Devices Corp., 401 F.3d 1313, 1319 (Fed. Cir. 2005) ("We cannot look at the ordinary meaning of the term . . . in a vacuum." (citation omitted) (emphasis added)).

In contrast, Alcon proposes that the Court interpret the term "about" consistent with its "technologic and stylistic" context. See, e.g., Pall Corp. v. Micron Separations, Inc., 66 F.3d 1211, 1217 (Fed. Cir. 1995). As Alcon noted in its opening brief, and Allergan has not contested, one accepted means of interpreting claim terms consistent with their context is to round-up the value in the claim that "about" modifies.[33] In addition, Alcon's Opening Brief notes that the Federal Circuit, in an effort to provide a

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[32] Allergan's Response Brief at 21-26.

[33] Alcon's Opening Brief at 26-27.

meaningful scope to the claims, has also approved the use of experimental error to interpret the range of values encompassed by the word "about."[34]

B. The Meaning Of "About 0.15%"

As pointed out in Alcon's Opening Brief, the specification provides no guidance as to the meaning of "about 0.15%." In fact, the specification does not even contain the "0.15%" value. Allergan does not appear to contest this fact. Instead, it refers cryptically to "references in the specification that point to a formulation containing up to about 0.15%" and "solubility curves converging around 0.15%."[35] As explained in Alcon's Response to Allergan's Opening Brief, these statements are just as meaningless as they appear.[36]

In contrast, as explained in Alcon's Opening Brief, the prosecution history of the '834 patent is extremely informative.[37] The 0.15% value did not appear until a Preliminary Amendment was filed, and that limitation was critical to the claims of the '834 patent. Tellingly, Allergan's Responsive Brief does not rebut the substance of Alcon's argument.[38]

Finally, without any explanation, Allergan states that Alcon's proposed construction is "purely expedient." It criticizes Alcon for modifying its preliminary claim construction of "about 0.15%" ("0.15 ± 0.0001%"), which was created solely for the parties' meet-and-confer, to its almost identical, but slightly more expansive,

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[34] Id. at 26. Allergan's attempt to distinguish one (of the two) cases that Alcon relied upon for this proposition is unavailing. Allergan's Response Brief at 25-26. Contrary to Allergan's implication that the ordinary meaning of "about" was not considered in B.J. Servs. Co. v. Halliburton Energy Servs. Inc., 338 F.3d 1368, 1373 (Fed. Cir. 2003), it was agreed that the jury was to "to give 'about 0.06' its plain and ordinary meaning." This fact was noted, and apparently relied upon, in the Federal Circuit's decision.

[35] Allergan's Response Brief at 23.

[36] Alcon's Response to Allergan's Opening Markman Brief at 9-10.

[37] Alcon's Opening Brief at 28-29.

[38] Allergan's Response Brief at 23-24.

proposed construction ("0.15 ± 0.005%"). Then, in the very next paragraph, Allergan proposes – for the first time anywhere in this litigation[39] – that "about 0.15%" should be interpreted to mean "0.15% ± 10%."[40] Allergan does not pretend that this construction is supported by intrinsic evidence, nor does it provide any meaningful explanation for why this new interpretation should be adopted. Instead, it merely states that "[u]nder Food and Drug Administration ("FDA") regulatory specifications, the concentration of brimonidine in Alphagan®P and Alcon's proposed product, both labeled as containing 0.15% bromonidine, can vary in concentration from 0.15% ± 10%."[41] Whether that would have been a reasonable basis to so define the term in specification or not, Allergan chose not to do so. Dr. Stella's Declaration, which accompanies Allergan's Responsive Brief, does not explain why this newly-proposed interpretation should be read into the claims. Indeed, Allergan's Opening Brief acknowledges that extrinsic evidence, such as this, has little value in claims construction.[42]

C. The Meaning Of "About 7.0 Or Greater"

Allergan ignores the support that Alcon provided for its proposed construction of "about 7.0 or greater" because Allergan cannot rebut it. Instead, Allergan states, without attribution, that Alcon's construction ignores that "the pH of these types of drug formulations tends to vary through a greater range than this."[43] Alcon and the Court are left to wonder what "greater range" Allergan might be referring to, or why that "range"

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39 See, e.g., Allergan, Inc. And Allergan Sales, LLC's Opening Markman Brief ("Allergan's Opening Markman Brief") (D.I. 57), which makes no reference whatsoever to this newly-minted interpretation.

40 Allergan's Response Brief at 24.

41 Id.

42 Allergan's Opening Markman Brief at 12 ("By now, it is beyond dispute that extrinsic evidence plays little role in the claim construction process. . . . [I]t 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." (citations omitted)).

43 Allergan's Response Brief at 24-25.

might be relevant to the disputed term. Similarly, Allergan points to statements in the specification referring to various pHs modified by the word "about," none of which are "about 7.0," with no explanation as to why any of this would be relevant to interpreting the disputed term.

In contrast, Alcon's unrebutted explanation of its proposed interpretation informs the Court exactly why any interpretation of "about 7.0 or greater" less than pH 6.95 would contradict the claims' plain meaning and ignore the specification's pertinent teachings. Alcon also provided an unrebutted discussion of Allergan's clear disclaimer of lower pHs during prosecution of the '834 patent.[44] Indeed, even Allergan's Opening Brief noted that it was critical to its present "discovery" that the pH of the resulting formulation be "elevated above 7.0."[45]

D. The Meaning Of "About 21°C"

Allergan does not attempt to rebut Alcon's arguments with respect to its proposed interpretation of "about 21°C," other than to rely on its automatic use of the synonym "approximately," without further definition. This is a misuse of the Merck case. Accordingly, Alcon's proposed interpretation of this term should be adopted as well.

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[44] Alcon's Opening Brief at 29-32.

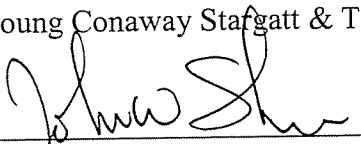
[45] Allergan's Opening Markman Brief at 3 (emphasis added).

IV. CONCLUSION

For the forgoing reasons, and those set forth in Alcon's Opening Brief and its Response to Allergan's Opening Brief, the Court should construe the disputed claim terms in accordance with Alcon's proposed constructions.

Respectfully submitted,

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CERTIFICATE OF SERVICE

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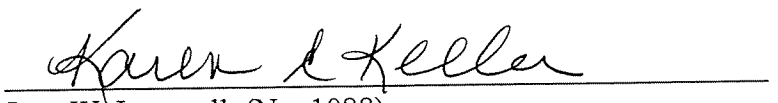
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