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 RESPONSE TO ALLERGAN'S OPENING MARKMAN BRIEF

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Dated: May 16, 2005

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I. PRELIMINARY STATEMENT

Under the guise of advocating the "plain meaning" of the disputed terms, Allergan purposely and improperly ignores the prosecution history of the '210 patent where, to overcome a § 103 rejection for obviousness, Allergan characterized anionic polymers such as CMC as "solubility enhancing components" ("SEC") that have "surprising and beneficial properties in the solubilization of brimonidine as compared to non-ionic or cationic polymers."[1] Indeed, Allergan went further, describing the solubility enhancing properties of the anionic polymer, CMC, as an "invention of selection" over prior art that discloses CMC and certain non-ionic polymers (including povidone) in similar compositions. It is basic patent law that such representations in the prosecution of a parent application are fully applicable to the construction of the claims of a continuation or divisional patent. See Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 980 (Fed. Cir. 1999). Nevertheless, Allergan now argues that the claim term "solubility enhancing component" should also encompass the very non-ionic polymers it so clearly disavowed in its selection invention argument to the PTO. That should not be allowed, as the public (including Alcon) has a right to rely on clear representations in the relevant prosecution history, and Allergan has no right to claim that its invention also comprises the non-ionic polymers that it distinguished to avoid the prior art.

In addition, Allergan's proposed interpretations of "similar compositions" in the '337 patent and "about" in the '834 patent, which are also allegedly based on the terms' "plain meanings," give no useful guidance as to the scope or purpose of those terms in the claims.

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[1] Memorandum in Support of Alcon's Proposed Claims Construction ("Alcon's Opening Brief"), Exhibit D (Prosecution History of the '210 Patent ("'210 PH")) Reply to Office Action mailed March 11, 2003, Tab 10 at 6. (Exhibits A-M accompany Alcon's Opening Brief, whereas Exhibits N-P accompany this submission).

Allergan's proposed interpretations of the claim terms-in-dispute (to they extent they can be characterized as interpretations at all) should therefore be rejected.

II. ARGUMENT

A. Allergan's Proposed Construction Of "Solubility Enhancing Component" Ignores Relevant Prosecution History

Allergan argues that the term "solubility enhancing component" should be interpreted consistent with its ordinary meaning to mean any component that enhances solubility. Although its simplicity is alluring, Allergan's purported reliance on "ordinary meaning" ignores the Federal Circuit's admonition that "the ordinary and customary meaning of a term does not govern if the intrinsic record contains clear lexicography or disavowal of claim scope." C.R. Bard, Inc. v. U.S. Surgical Corp., 388 F.3d 858, 863 (Fed. Cir. 2004) (emphasis added). Allergan's brief glosses over Allergan's unmistakable disavowal of non-ionic polymers as SECs without even mentioning that the same broad claims to compositions containing an SEC were rejected in the parent application under § 103 as obvious over the Burke '991 patent.[2] With reference to the parent application, Allergan admits amending the claims of the '210 patent to require a polyanionic or anionic SEC but omits any discussion as to why that amendment was necessary.

Revising history, Allergan now characterizes its arguments during the prosecution history as distinguishing anionic SECs from non-anionic SECs.[3] That is not what occurred in the PTO – the phrase "solubility enhancing component" had no accepted meaning, but instead was coined by Allergan to give the appearance of novelty to a prior art polymer vehicle for ophthalmic compositions, as described in Burke. Indeed, the term "non-anionic SEC" was never used in the

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2 Allergan, Inc. and Allergan Sales, LLC's Opening Markman Brief ("Allergan's Opening Brief") at 5.

3 Id.

prosecution history. In reality, Allergan argued to the PTO for the patentability of the basic concept of a component (specifically CMC) that surprisingly could enhance the solubility of brimonidine compared to the prior art compositions that were the basis for the PTO's initial rejections of the patentability of compositions with SECs.

Significantly, Allergan's brief does not mention any of the arguments Allergan made to the Examiner about its "invention of selection." Indeed, the critical words "invention of selection" are simply not present anywhere in Allergan's Opening Brief. As explained in detail in Alcon's Opening Brief, Allergan gained allowance of the '210 patent only after it argued for an "invention of selection" to overcome the rejection over Burke.[4] Burke discloses ophthalmic compositions formulated at up to pH 7.5 that contain alpha-2-adrenergic agonists in combination with any one of a group of polymer vehicles which are known viscosity enhancers.[5] The polymer vehicles disclosed in Burke include CMC (and povidone, which Alcon's proposed product contains). To obtain a patent on its claimed compositions over Burke, Allergan argued that CMC could be selected out of the group of polymer vehicles disclosed on the basis of unexpected results because Allergan had discovered that CMC had surprising properties in solubilizing brimonidine due to it being an anionic polymer.[6] Allergan specifically stated that the remaining non-ionic polymers also disclosed in Burke did not have the same characteristics.[7] In summarizing the inventor's supporting declaration to the Examiner, Allergan stated:

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4 See Alcon's Opening Brief at 11-13, 15-20; id., '210 PH (Exhibit D), Tab 10 at 7.

5 See id., Burke reference (Exhibit H) at col. 5, ll. 5-34.

6 The fact that Allergan argued that CMC had an additional advantage of causing superior adherence to cell surfaces in an effort to further persuade the Examiner that CMC is different from the other polymers recited in Burke is of no matter. No such advantage was disclosed in the specification or required by the claims at issue. In re Davies, 475 F.2d 667, 670 (C.C.P.A. 1973) ("property or utility must be disclosed in order for affidavit evidence of unexpected properties to be offered."). Here, only the solubility enhancing properties of CMC were disclosed and claimed.

> 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.[8]

Notably, neither Allergan nor its inventor characterized any of the non-ionic polymers (including povidone) from which CMC was distinguished as an "SEC" at any time during the prosecution of the parent application. No test data of any type was provided to the Examiner in connection with Allergan's "invention of selection" argument. The only test data that Allergan provides in the specification to support the concept of an SEC relates solely to CMC. Certainly, Allergan has never claimed to possess any evidence of comparative testing of the solubilizing properties of "anionic SECs" versus "non-anionic SECs." Thus, it is not surprising that there is no mention or suggestion anywhere in the relevant prosecution history of a "non-anionic SEC," as that term is a creature of this litigation. Consistent with its inventor's express statement, and implicit in the characterization of its "invention of selection," Allergan persuaded the PTO that the other polymers disclosed in Burke, including povidone, are incapable of functioning as SECs in the claimed invention.[9] Thereafter, in order to obtain issuance of claims in the '210 patent, Allergan was forced to narrow the claims by adding the limitation "anionic."

In its brief, Allergan admits that it later "resubmitted claims to the general use of SECs, anionic and non-anionic" in the prosecution of the '337 patent.[10] Allergan's brief also describes the prosecution of the '337 as "straightforward"[11] and states that "Allergan responded to the lone rejection by amending the broad claim covering the use of any SEC only as it related to the

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7 Alcon's Opening Brief, '210 PH (Exhibit D), Tab 10 at 6-7 and Tab 11.

8 Id., Tab 10 at 6.

9 See Alcon's Opening Brief at 15-20.

10 Allergan's Opening Brief at 6 (emphasis added).

11 Id. at 7.

exclusion of cyclodextrins, and not in any other fashion."[12] This simply is not true. As explained in Alcon's Opening Brief,[13] the application from which the '337 patent derived was filed as a divisional application that claimed compositions of an alpha-2-adrenergic agonist in combination with an oxy-chloro preservative and that were substantially free of cyclodextrins. After the claims of the parent application had been limited to require that the SEC be anionic, Allergan converted the claims of the divisional by making various amendments (including adding an SEC requirement and dropping the oxy-chloro requirement), until the claims were essentially the broad claims the Examiner had refused to grant in the parent application.[14] Thereafter, although the claims were rejected on the bases of: double patenting, and sections 112 and 103, and notwithstanding that the parent application had claimed the same compositions, Allergan persuaded the Examiner that this was the first application to suggest the concept of using an "SEC" in combination with an alpha-2-adrenergic agonist.

Allergan should not be permitted now to recapture the subject matter that it surrendered during prosecution notwithstanding broad statements in the specification or the fact that the '210 parent patent issued with narrower claims before the '337 patent.[15] Though the specification refers to "[a]ny suitable SEC," this does not control claim construction, since it is well established that applicants can surrender subject matter during prosecution. See e.g., Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323 (Fed. Cir. 2003) ("The doctrine of prosecution disclaimer is well established in Supreme Court precedent, precluding patentees from recapturing through claim interpretation specific meanings disclaimed during prosecution.") (citations

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12 Id. at 14 (emphasis added).

13 Alcon's Opening Brief at 13-14.

14 Id. at 15-17.

15 Allergan's Opening Brief at 14-15.

omitted). Allergan's reliance on the "common practice" of seeking allowance of narrow claims first (such as those in the parent '210 patent) and then pursuing broader claims in a later application (such as those in the '337 patent) [16] is also unavailing. In fact, the one case Allergan cites in support of this proposition cautions repeatedly that a "broad" claim does not cover all that it appears to when there has been a disavowal. Home Diagnostics, Inc. v. Lifescan, Inc., 381 F.3d 1352, 1357-58 (Fed. Cir. 2004) ("A patentee may claim an invention broadly and expect enforcement of the full scope of that language absent a clear disavowal . . . . Absent a clear disavowal . . . the patentee is entitled to the full scope of its claim language.") (emphasis added).

It would be legally erroneous to adopt Allergan's proposed "ordinary meaning," and thereby interpret the claims of the '337 patent to encompass subject matter that Allergan surrendered in order to obtain the '210 patent. Ordinary 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 (referring to the use of dictionaries as evidence of ordinary meanings). Accordingly, Allergan's proposed interpretation of "solubility enhancing component," which ignores Allergan's clear disavowal of non-anionic polymers as SECs, should be rejected.

B. Allergan's Proposed Construction Of "Similar Composition" Is Contrary To Basic Scientific Principles And The Intrinsic Evidence

Allergan also addresses the parties' disagreement with respect to the following limitation in claim 1 of the '337 patent:[17]

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16 Id.

17 Similarly, claim 6 of that patent provides: "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." (emphasis added).

> . . . a solubility enhancing component other than a cyclodextrin in an amount effective to increase the solubility of the alpha-2-adrenergic agonist component in the composition relative to the solubility of an identical alpha-2-adrenergic agonist component in a similar composition without the solubility enhancing component. (emphasis added).

Allergan argues that no interpretation of "similar composition" is needed because its meaning is clear.[18] It then plucks the word "identical" out of its context in Alcon's proposed construction, which actually says "otherwise identical," and argues that "similar" is not the same as "identical."[19] Allergan's proposed construction, which fails to ascribe any useful meaning to "similar composition," ignores the sense of the claim limitation, basic scientific principles, and other relevant intrinsic evidence. Allergan directs the Court to the use of the term "similar compositions" in the specification and explains how the inventors understood the difference between "similar" and "identical."[20] But Allergan leaves the Court (and potential competitors) guessing as to the defining properties of "similar" compositions.

Alcon reasonably proposes that the disputed limitation be interpreted, consistent with the sense of the claim limitation and fundamental scientific principles, to mean that the two compositions selected for comparison – one with an SEC and the other without it – are "otherwise identical." This interpretation reflects a properly-controlled experiment that would accurately determine whether the SEC has its claimed effect (i.e., enhancing the solubility of the alpha-2-adrenergic component). Such head-to-head comparisons are not performed under undefined "similar" conditions, having more than one variable, because under such

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18 Allergan's Opening Brief at 15.

19 Id. at 15-16. In the Joint Claims Construction Statement, Alcon proposed that the limitation be interpreted such that the composition must contain an anionic SEC that is "in an amount effective to increase the solubility of the alpha-2-adrenergic agonist component in the composition relative to the solubility of the alpha-2-adrenergic agonist component in an otherwise identical composition without the [SEC]." See Joint Claim Construction Statement, a copy of which is annexed hereto as Exhibit N.

circumstances any variable (or combination of variables) could produce the observed effect. Rather, they are performed under "otherwise identical" conditions, with just one variable.[21] Only in this way can it be determined whether that single variable has any effect.

The specification of the '337 patent supports Alcon's proposed interpretation. The specification's only exemplification of a composition containing an SEC (i.e., CMC) and an alpha-2-adrenergic agonist (i.e., brimonidine tartrate), compared the solubility of brimonidine tartrate with and without CMC in "otherwise identical" compositions (i.e., compositions that varied in only this one respect).[22] The experiments did not use "similar" compositions with different components, or even the same components at different concentrations of active ingredient.[23] Such experiments would provide meaningless results.

Accordingly, it is Alcon's position that "similar compositions" in the claims of the '337 patent should be interpreted to mean "otherwise identical compositions," i.e., compositions that are different only with respect to the presence or absence of the purported SEC.

C. Allergan's Proposed Definition Of "About" Ignores The Context Of The Alleged Invention

Allergan's proposed construction of the term "about" to mean "approximately" provides no meaningful guidance as to what the claims of the '834 patent cover.[24] Contrary to Allergan's assertion, Merck & Co. v. Teva Pharm., 395 F.3d 1364 (Fed. Cir. 2004) does not construe "about" to mean "approximately" as a matter of black letter law. It merely reflects the peculiar

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20 Allergan's Opening Brief at 15-16.

21 See, e.g., American Heritage College Dictionary 312 (4th ed. 2002) (defining "control experiment" as "An experiment that isolates the effect of one variable on a system by holding constant all variables but the one under observation.").

22 See, e.g., '337 Patent, col. 15, ll. 45-66; col. 16, ll. 10-22.

23 See id. at col. 15, ll. 5-23 (only varying the amount of CMC, with the other components present in each composition at the same concentration).

24 See Alcon's Opening Brief at 25-33.

facts of the Merck case – where the patentee argued that "about" means "exactly." This is illustrated by Hybritech, Inc. v. Abbott Labs., 849 F.2d 1446, 1455 (Fed. Cir. 1988), another case relied upon by Allergan.[25] There, in interpreting the term "about," the district court used the error inherent in the particular measurement to evaluate the scope of that term. See Hybritech, Inc. v. Abbott Labs., 4 U.S.P.Q.2d 1001, 1013 (C.D. Cal. 1987), aff'd, 849 F.2d 1446 (Fed. Cir. 1988). The court did not pretend to have discharged its duties in interpreting the term "about" by merely identifying its synonym. Indeed, in Hybritech, as in numerous other cases, the Federal Circuit has "repeatedly rejected" interpreting claim terms without considering their context. 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.'") (quoting De Marini Sports, Inc. v. Worth, 39 F.3d 1314, 1324 (Fed. Cir. 2001)).

In addition to this basic misunderstanding of the relevant law, Allergan mischaracterizes the intrinsic evidence. For example, Allergan contends that "the specification of the '834 patent is entirely consistent with [the] ordinary meaning" of the term "about" because:[26]

> 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."

Yet Allergan does not cite any "reference in the specification" in support this argument. This is not all together surprising since, as Allergan well knows, nothing in the specification "points to a formulation of up to about 0.15%." Allegedly in further support, Allergan goes on to argue:[27]

> At the most preferred pH of 7.5, Figure 1 shows a convergence of points about 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.

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25 Allergan's Opening Brief at 17.

26 Id. (emphasis added).

27 Id. (emphasis added).

Allergan's representations are not consistent with the facts.[28] Figure 1 does not teach that the "most preferred pH" is 7.5. Nor does Figure 1 show a "convergence of points about 0.15%." In fact there is only one data point anywhere near that concentration (assuming arguendo that 0.15% w/v corresponds to 1500 ppm). Neither Figure 1 nor the examples "explain" that the inventors were "unable to solubilize more than 0.16%" with any amount of SEC.[29] Also, Figure 1 purports to show that concentrations of brimonidine much higher than 0.16% were achieved both with and without an SEC.[30] Allergan's desperation is evident from its after-the-fact attempt to transform an "unclear" observation at a single pH into an invention.[31] In actuality, there is no support for Allergan's proposed construction of the term "about 0.15% (w/v)."

In regard to pH, Allergan abandons its reliance on Figure 1 and the examples to argue that the specification refers to pH in "approximate terms."[32] In so doing, Allergan seeks to avoid the devastating impact of the examples reporting pH to a precision of one-hundredths of a unit and Figure 1 (and the claims) reporting pH to tenths of a unit. Moreover, Allergan's brief supports Alcon's proposed construction of the term "a pH of about 7.0 or greater." In discussing the alleged invention of the '834 patent, Allergan's counsel state:

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28 Allergan's statements about what Figure 1 shows are indeed surprising, since Allergan denied Alcon's Request to Admit Nos. 15-17 on the ground that Figure 1 could not be interpreted where Table IV does not provide a specific data point. See Plaintiffs' Responses To Defendants' First Set Of Requests To Admit (Nos. 1-26) (Exhibit O) and Plaintiffs' Response To Defendants' Second Set Of Interrogatories (No. 12) (Exhibit P) respectively. Yet, Table IV provides no data point corresponding to 0.16% and Allergan purports to have derived this information from Figure 1.

29 Allergan's Opening Brief at 16.

30 See, e.g., '834 Patent, Figure 1, all values greater than 1600 ppm, which we assume arguendo corresponds to 0.16% (w/v).

31 Allergan appears to refer to the statement in its specification that "[a]t pH 7.5, the sample with 1.5% CMC resulted in about 1400 ppm, which is less than that of a similar solution with CMC at 0.5%. It is unclear at this point what the cause of this observation may be." ('834 Patent, col. 16, ll. 3-26) (emphasis added).

32 Allergan's Opening Brief at 17-18.

> 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 . . . .[33]

If, as Allergan argues, the critical discovery underlying the alleged invention of the '834 patent is a reduced concentration of brimonidine tartrate at a pH "above 7.0," Alcon's proposed construction of the disputed term as encompassing "a pH of 6.95 and above" provides a generous scope to this claim limitation.

Finally, Allergan bounces back to the examples again in a vain effort to argue that measurements of temperature are not subject to precise definition either. Allergan, however, chose to make the temperature of the claimed compositions a claim limitation, but advances no argument or evidence to provide any tangible parameters to this limitation. Saying "about" means "approximately" in this context is meaningless. Alcon's proposed construction of the temperature limitation as 21°C ± 0.5°C comports with sound scientific principles and is fully consistent with the intrinsic evidence.[34]

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33 Id. at 3 (first emphasis in original).

34 See Alcon Brief at 25-33.

III. CONCLUSION

For the foregoing reasons and those stated in Alcon's opening brief, the Court should construe the disputed claim terms in accordance with Alcon's proposed constructions.

Dated: May 16, 2005

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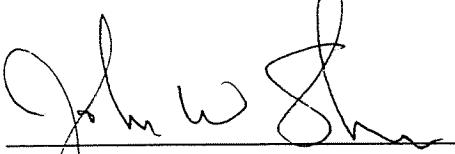
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