REDACTED VERSION – PUBLICLY FILED

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** **CONFIDENTIAL – FILED UNDER SEAL**

DEFENDANTS' OPENING BRIEF IN SUPPORT OF THEIR MOTION FOR SUMMARY JUDGMENT OF NON-INFRINGEMENT OF ALLERGAN'S U.S. PATENT NO. 6, 673,337 AND INVALIDITY OF ITS U.S. PATENT NO. 6,641,834

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Defendants, Alcon, Inc., Alcon Laboratories, Inc, and Alcon Research, Ltd. (collectively "Alcon"), respectfully submit this memorandum in support of their motion under Fed. R. Civ. P. 56(b) for summary judgment holding that U.S. Patent No. 6,673,337 asserted by plaintiffs, Allergan, Inc. and Allergan Sales, Inc. (collectively "Allergan"), is not infringed by Alcon's proposed generic drug product and that U.S. Patent No. 6,641,834 is invalid for failing to satisfy the written description requirement of 35 U.S.C. § 112.

I. NATURE AND STAGE OF THE PROCEEDING

This infringement action, instituted on August 24, 2004, is an attempt by Allergan to prevent the United States Food and Drug Administration ("FDA") from issuing final approval of Alcon's generic version of the glaucoma drug Alphagan®P sold by Allergan.[1] Allergan alleges that Alcon has infringed its U.S. Patents Nos. 6,673,337 ("the '337 patent") and 6,641,834 ("the '834 patent") under 35 U.S.C. § 271(e)(2) by seeking FDA approval of its proposed generic drug product.[2] On September 3, 2004, Alcon answered the complaint and raised various defenses and counterclaims disputing the validity and infringement of the patents-in-suit. Because of the filing of this suit, FDA approval of Alcon's new drug application ("NDA") has been stayed for up to 30 months or until the suit is resolved in Alcon's favor. By maintaining this suit, Allergan has extended its market exclusivity for Alphagan®P (which should have ended on September 16,

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[1] Alcon's NDA for its proposed brimonidine product has been tentatively approved by the FDA since March 1, 2005. See Ex. SJ1.

[2] For the convenience of the Court, unless otherwise indicated, the relevant patents and prosecution histories cited in this brief and in Alcon's brief on claims construction are assembled in one compilation. The exhibits are numbered in accordance with the order of their citation in Alcon's claims construction brief. Other exhibits, denoted "SJ," et seq., are compiled in a separate exhibit volume that is pertinent only to this motion.

2004) beyond the three and a one half years to which it was entitled under the Hatch-Waxman Act.

Alcon believes that there is no justification for further delay of final approval for its proposed product because this suit can be resolved on a single dispositive ground for each patent: the '337 patent is not infringed because the claims are limited to anionic SECs, which Alcon's product does not contain, and the '834 patent is invalid for lack of written description. On these bases, Alcon requested an early summary judgment[3] and the Court, on February 11, 2005, entered a Scheduling Order that expressly authorizes Alcon to file for summary judgment at this time. See Scheduling Order, Docket No. 30 at ¶ 8(a). The Court's Scheduling Order also provides that oral argument on these motions will be heard on the same day as the Markman hearing, June 7, 2005. Id.

II. SUMMARY OF ARGUMENT

1. The asserted claims of the '337 patent will not be infringed by Alcon's proposed brimonidine product because the prosecution history limits the claims to compositions containing anionic SECs, which do not include povidone, the non-ionic viscosity agent in Alcon's product that was expressly disclaimed by Allergan during prosecution of the '337 patent. See Microsoft Corp. v. Multi-Tech System, Inc., 357 F.3d 1340, 1349 (Fed. Cir. 2004); Omega Eng'g Inc. v. Raytek Corp., 334 F.3d 1314, 1323-24 (Fed. Cir. 2003); Biovail Corp. Int'l v. Andrx Pharm., Inc., 239 F.3d 1297, 1302 (Fed. Cir. 2001).

2. The asserted claims of the '834 patent are invalid because they fail to satisfy the written description requirement of 35 U.S.C. § 112 . The invention claimed in the '834 patent includes a critical 0.15% (w/v) "therapeutically effective" concentration of active ingredient that

is not mentioned anywhere in the specification and, indeed, is a wholly different invention from that described in the specification, which calls for compositions containing a solubility enhancing component and/or an oxy-chloro preservative. See Univ. of Rochester v. G.D. Searle & Co., Inc., 358 F.3d 916, 927 (Fed. Cir. 2004); Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323-25 (Fed. Cir. 2000).

III. STATEMENT OF FACTS

Three simple pertinent facts cannot be disputed and require that Alcon's motions for summary judgment be granted. First, the use of povidone as a viscosity agent in ophthalmic compositions containing brimonidine tartrate was known in the prior art. Second, to overcome such prior art during prosecution of the parent application of the '337 patent, Allergan expressly distinguished anionic solubility enhancing components ("SECs") (notably CMC, which is exemplified in the patent and used in Allergan's product) from non-ionic viscosity agents (including povidone, which is used in Alcon's proposed product), and, in so doing, disclaimed non-ionic agents from the class of claimed SECs. Third, nowhere in the specification or original disclosure of the application from which the '834 patent claims priority is 0.15% (w/v) identified as a therapeutically effective amount of active ingredient.

In the background that follows, Alcon summarizes the history of the parties' disputes related to brimonidine products, the prosecution histories of the patents-in-suit, the statutory framework of the Hatch-Waxman Act, and describes Allergan's NDA and Alcon's proposed product. Alcon believes that the facts in this background statement are not reasonably subject to dispute and that the Court will find it useful to have knowledge of the broader context in which

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[3] In exchange for this opportunity to obtain expedited resolution of the case by early summary judgment, Alcon agreed to file no other summary judgment motions in this case.

this action arises.

A. Allergan's Strategy To Protect Its Brimonidine Franchise

In 2000, when Allergan filed the provisional application from which the patents-in-suit claim priority, it was well known in the art that alpha-2-adrenergic agonists, including brimonidine tartrate, could be used to treat elevated intraocular pressure. In fact, Allergan had been marketing a product (Alphagan®) that contained 0.2% (w/v) brimonidine tartrate since 1996. As the five-year period of FDA-conferred market exclusivity for that product was close to expiring, Allergan did its utmost to protect its exclusive market for Alphagan® from competitors, including Alcon. Thus, in 2002, Allergan instituted an infringement action under 35 U.S.C. § 271(e)(2) in the Central District of California arguing that Alcon's proposed generic 0.2% brimonidine product would infringe two method-of-use patents. As a result, the FDA was required to stay its approval of Alcon's generic 0.2% brimonidine product until after Alcon summarily prevailed in that action.[4]

While the appeal of the foregoing action was pending, Allergan instituted a second infringement action against Alcon's generic 0.2% brimonidine product. Again, the FDA was required to suspend its approval of Alcon's generic application for up to 30 months or until Alcon prevailed in the new litigation. This time Allergan brought suit in the District of Delaware, but this Court promptly transferred the case to Judge Carter who, once again, granted Alcon's motion for summary judgment of non-infringement.[5] Thereafter, the FDA stay of

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[4] District Court Judge Carter granted Alcon's motion for summary judgment of non-infringement of both patents and that decision was affirmed by the Federal Circuit. Allergan, Inc. v. Alcon Labs., Inc., 200 F. Supp. 2d 1219 (C.D. Cal. 2002), aff'd, 324 F.3d 1322 (Fed. Cir.), cert. denied, 540 U.S. 1048 (2003).

[5] Alcon Labs., Inc. v. Allergan, Inc., 256 F. Supp. 2d 1080 (C.D. Cal. 2003).

approval was withdrawn, and Alcon's generic 0.2% brimonidine drug product was launched into the market. [6]

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[6] It is not surprising that the FTC condemned the ability of patentees to obtain multiple stays of FDA approval. See "Generic Drug Entry Prior To Patent Expiration: An FTC Study" (July 2002). Shortly thereafter, Congress, in the Medicare Prescription Drug and Modernization Act of 2003, changed the Hatch-Waxman Act to prevent such abuses.

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This is precisely the path pursued by Allergan, which ultimately modified its existing product in four respects: (1) it changed the preservative to utilize its patented oxy-chloro preservative, Purite®; (2) it eliminated the viscosity agent, polyvinyl alcohol (PVA), in favor of sodium carboxymethylcellulose ("CMC"), which Allergan characterizes as an SEC; (3) it increased the pH of the composition from 6.6 to 7.2; and (4) it reduced the concentration of active ingredient from 0.2% to 0.15%. As claimed in the provisional application and the parent application to which the '337 and the '834 patents both claim priority, the essence of Allergan's invention was the use of an SEC to allow for the increase in pH and/or the use of Purite® to improve the product's adverse reaction profile. Various benefits were claimed to flow from these changes to the prior art product, but nowhere in the original disclosure was it stated that the concentration of active ingredient could be reduced to 0.15% or less in a composition with or without an SEC and be therapeutically effective. Those claims of the issued '834 patent (which in fact do not require an SEC or a preservative) were first advanced more than two years after the original application was filed.

B. Allergan's Patents

The new formulation that is Alphagan®P contains Allergan's proprietary oxy-chloro preservative Purite® and a well-known viscosity modifier, CMC, which Allergan characterizes as an SEC. Allergan sought patent protection on compositions formulated to include either or both of those ingredients and avoided its existing prior art 0.2% product by claiming the combination of brimonidine with an oxy-chloro preservative (see U.S. Patent No. 6,562,873[11]) and the alleged

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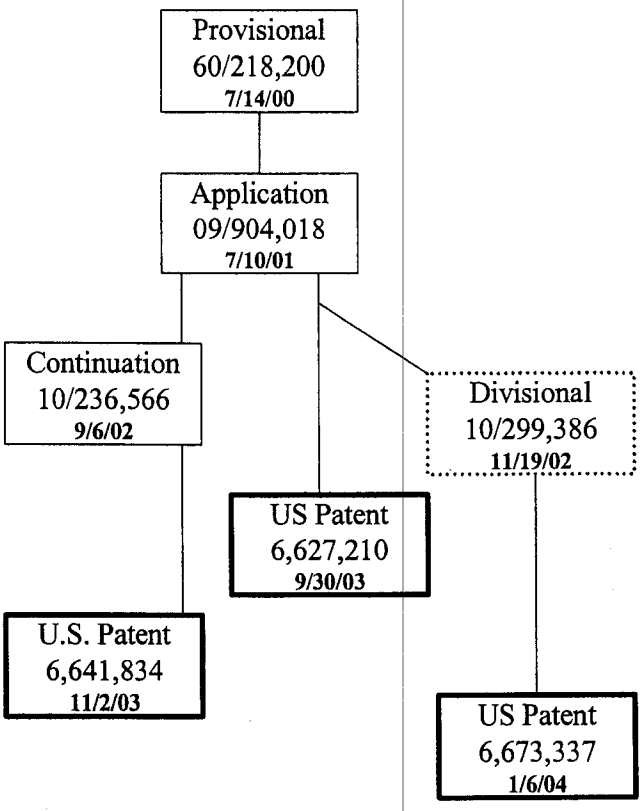
11 U.S. 6,562,873 patent is at Ex. M

solubility enhancing attributes of CMC (see the '210 patent).[12] Neither the '873 nor the '210 patent are asserted here because Alcon's proposed product does not have the same formulation as Alphagan®P. Alcon's proposed product contains neither CMC nor an oxy-chloro preservative. Instead, this action specifically involves Allergan's allegations that Alcon's proposed brimonidine tartrate drug product will infringe claims the '337 patent and the '834 patent, both of which derived from the Parent Application that issued as the '210 patent and both of which improperly attempt to cover subject matter well beyond any invention conceived of when Allergan made its new brimonidine-Purite® formulation (Alphagan®P).

The application resulting in the '337 patent is a divisional and the application resulting in the '834 patent is a continuation of Application Serial No. 09/904,018 ("the Parent Application"), now the '210 patent, which, in turn, stems from Provisional Application Serial No. 60/218,200, filed July 14, 2000. All three patents share a common specification. The chart below illustrates the relationship between the asserted patents and the related applications:

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12 The '210 patent is at Ex. C.



1. The '210 Patent

Although not asserted, the '210 patent is relevant here because during prosecution of the underlying Parent Application, Allergan expressly defined the scope of its invention and disclaimed certain subject matter to overcome a rejection for obviousness under § 103. In distinguishing its invention over a prior art patent to Burke, Dr. Olejnik, one of the inventors, stated that only anionic SECs confer the unexpected benefits of the invention and that the other non-ionic polymers disclosed by Burke, including povidone (the viscosity agent contained in Alcon's composition), do not work in the invention. Thereafter, Allergan was forced to narrow the claims by amendment to expressly recite the "anionic" limitation to the SEC claim term.

2. The '337 Patent

Not content with the narrowed claims it had secured in the '210 patent, Allergan turned to

its co-pending divisional application for a second chance to obtain the broad claims that the Examiner had refused to allow in the Parent Application. When the Examiner rejected the claims of the divisional for obviousness and double patenting, Allergan seized the opportunity to transform them into essentially the same broad claims that the Examiner had previously refused to allow in the '210 patent. Allergan amended the claims to delete the oxy-chloro component (despite it being the sole basis for the filing of the divisional application) and inserted broad language claiming compositions with any SEC. Surprisingly, the Examiner did not require Allergan to limit the SEC term to anionic SECs. Rather, she allowed the broad claims she had expressly rejected during the prosecution of the '210 patent.

3. The '834 Patent

Like the '210 and '337 patents, the '834 patent also derived from the Parent Application. However, the claims cover compositions containing a therapeutic amount of up to 0.15% (w/v) brimonidine tartrate at pH 7.0 or greater. This subject matter appeared for the first time in claims contained in a preliminary amendment filed a full two years after the filing of the provisional application from which the '834 patent claims priority. Thereafter, throughout further prosecution of the application that led to the '834 patent, Allergan described its "invention" to the Examiner as compositions of up to 0.15% (w/v) formulated at pH 7.0 or greater and argued that the claimed compositions showed "unexpected results." Indeed, the PTO was specifically informed that "[t]he present invention is the result of the surprising finding that increasing the pH of a brimonidine solution to a pH of greater than about 7.0 leads to similar efficacy at 25% lower concentration (from 0.2% (w/v) to about 0.15% (w/v) or less)" than the prior art brimonidine compositions.[13] However, the specification teaches away from this limitation

[13] '834 PH (Ex. F), Reply to Office Action mailed March 17, 2003, Tab 6 at 4 (emphasis added).

because all concentrations of active ingredient disclosed in the examples are 0.2% (w/v) or more and nothing in the specification points to 0.15% (w/v) or less as the therapeutically effective concentration of active ingredient required in the invention. Nor is there any mention of the 0.15% limitation in the originally-filed claims of the Parent Application. Nothing in the specification, or in the original disclosure, suggests that, at the time the provisional application was filed, Allergan's inventors were in possession of the invention the '834 patent now seeks to claim. Thus, the '834 patent is invalid for lack of written description. Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1563-64 (Fed. Cir. 1991).

C. Statutory Framework

The Hatch-Waxman Act (the "Act") amended the Federal Food, Drug, and Cosmetic Act (codified at 21 U.S.C. §§ 301 et. seq. (1994)) (the "FDCA") as well as the patent laws. As amended, Section 355 (§ 505 of the FDCA) authorizes the filing of abbreviated new drug applications ("ANDAs"), which substantially reduces the time and money needed to obtain FDA approval for generic drugs. The ANDA applicant is permitted to substitute bioequivalence data for the extensive safety and efficacy studies that must accompany a full new drug application ("NDA"). In addition, Section 355(b)(2) (§ 505(b)(2) of the FDCA) was amended to authorize a second type of abbreviated new drug application – a so-called "paper NDA." The paper NDA relies on published literature to demonstrate the safety and efficacy of the proposed new drug. This type of application is filed when the proposed drug product is a modified version rather than a generic copy of a brand name drug. In this case, Alcon's drug product contains the same active ingredient (0.15% brimonidine tartrate), but has a formulation that differs from that of Allergan's approved product.

Under the Act, NDA holders are awarded a five-year period of market exclusivity from the date of a new drug's approval. 21 U.S.C. § 355(c)(3)(D)(ii). In certain cases, a three-year period of exclusivity is awarded for obtaining FDA approval for a new use or new formulation of an already approved drug. The period of market exclusivity is extended by six months when the NDA holder sponsors clinical trials to evaluate the drug's safety and efficacy in children. Id. § 355a(a)(1). During the period of market exclusivity, no applicant can obtain FDA approval to market a generic or modified version of the approved drug. Id. § 355(c)(3)(D)(ii).

The Act also provides a mechanism to determine whether the proposed generic drug will infringe patents relating to the brand name drug before the generic product is approved for marketing. This scheme requires the drug maker to file with the FDA the serial number and expiration date of any patent which claims the drug that is the subject of the NDA or an approved method of using such drug. See id. § 355(b)(1). Upon approval of the NDA, the FDA publishes the patent information in "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book."

Toward the end of the period of exclusivity for the brand name drug, potential manufacturers of generic or modified versions of that drug can submit an ANDA or a paper NDA to the FDA. Such applications must contain one of four possible certifications with respect to each patent listed in the Orange Book for that drug: (i) "that such patent information has not been filed," (ii) "that such patent has expired," (iii) that commercial marketing will not begin until after "the date on which such patent will expire," or (iv) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Id. § 355(b)(2)(A). If the applicant makes either the first or second certification, FDA approval can be made effective immediately. Id. § 355(c)(3)(A). If the applicant makes

the third certification, approval can be made effective when the listed patent expires. Id. § 355(c)(3)(B). If the applicant makes the fourth certification (a paragraph IV certification), the effective date of FDA approval depends on the outcome of further events.

An applicant who makes a paragraph IV certification must give notice to the patent owner stating that an application has been filed seeking approval to market a generic version of the approved drug before the expiration of the listed patent. Such notice must contain a detailed statement of the factual and legal bases for the applicant's opinion that the listed patent is invalid or not infringed. Id. § 355(b)(3)(D)(ii). If the patent owner does not initiate an infringement suit within 45 days of receiving the notice, the abbreviated application may be approved immediately. However, if the patent owner institutes suit under 35 U.S.C. § 271(e)(2), FDA approval may not be made effective until the court rules that the patent-in-suit is invalid or not infringed or until the expiration of 30 months, whichever occurs first. See id. § 355(c)(3)(C). Thus, there is every incentive for brand name drug makers to list patents in the Orange Book and to institute suits to stay FDA approval and delay marketing of generic versions of drugs. As explained above, Allergan is no stranger to these strategies.

D. Allergan's NDA For Alphagan®P

On March 16, 2001, Allergan obtained FDA approval for its ophthalmic drug, Alphagan® P, for the single indication of "lowering IOP [intraocular pressure] in patients with open-angle glaucoma or ocular hypertension." Alphagan®P is an aqueous solution formulated at pH 7.2 containing 0.15% brimonidine tartrate as the active ingredient, an oxy-chloro preservative (Purite®), Na carboxymethylcellulose ("CMC") and additional excipients that are not relevant here. Allergan's three years of market exclusivity and additional six months of pediatric exclusivity for Alphagan®P ended on September 16, 2004.

E. Alcon's NDA For Its Proposed 0.15% Brimonidine Product

Alcon seeks approval of a paper-NDA covering its proposed brimonidine product for the same indication for which Alphagan® P has been approved, lowering IOP. Like Alphagan® P, Alcon's proposed product is also an aqueous topical solution containing 0.15% brimonidine as the active ingredient. However, Alcon's formulation does not contain Allergan's patented preservative, Purite® or Allergan's so-called SEC, CMC. Rather, Alcon's proposed product contains Polyquad® (Polyquaternium-1) as a preservative and Povidone K-90 as a viscosity enhancing agent.[14] As stated above, Alcon's proposed product was tentatively approved by the FDA on March 1, 2005, and final approval cannot issue until this action has been resolved.

IV. ARGUMENT

Summary judgment is appropriate when the moving party demonstrates that there is "no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c). Courts have not hesitated to grant summary judgment of noninfringement and/or invalidity in Hatch-Waxman cases brought under § 271(e)(2). See, e.g., Allergan, 200 F. Supp. 2d at 1221 (aff'd by Allergan, 324 F.3d at 1332); Warner-Lambert Co. v. Apotex Corp., 316 F.3d 1348, 1351 (Fed. Cir. 2003); Novartis Corp v. Ben Venue Labs., Inc., 271 F.3d 1043, 1044-45 (Fed. Cir. 2001); Eli Lilly & Co. v. Barr Labs., 251 F.3d 955, 972 (Fed. Cir. 2001) (holding that one of plaintiff's patent claims was invalid for obviousness-type double patenting); Bayer AG v. Elan Pharm. Research Corp., 212 F.3d 1241, 1244 (Fed. Cir. 2000); Alcon Labs., 256 F. Supp. 2d at 1081; In re Buspirone Patent Litig., 185 F. Supp. 2d 340, 363

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[14] Allergan has produced no evidence establishing that povidone or anything other than CMC, functions as an SEC in any composition containing brimonidine. Such documents were requested by Alcon's Document Request Nos. 15, 17 and 21 and no responsive documents were produced by Allergan.

(S.D.N.Y. 2002); In re Omeprazole Patent Litig., 2001 U.S. Dist. LEXIS 7103, *38 (S.D.N.Y. May 31, 2001). As the moving party, Alcon bears the initial burden of demonstrating the absence of a genuine issue of material fact. See Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986).

A. The Claims Of The '337 Patent Are Limited To The Scope Of The "Invention" Defined By The Patentee In The Prosecution History And Will Not Be Infringed By Alcon's Proposed Product

In making a determination on allegations of infringement, the fact finder compares the properly construed claim with the allegedly infringing product. Kemco Sales, Inc. v. Control Papers Co., 208 F.3d 1352, 1359 (Fed. Cir. 2000). Infringement requires the patentee to show that the accused product contains or performs each limitation of the asserted claim, Mas-Hamilton Group v. LaGard, Inc., 156 F.3d 1206, 1211 (Fed. Cir. 1998), or an equivalent of each limitation not satisfied literally, Warner-Jenkinson Co. v. Hilton Davis Chem. Co., 520 U.S. 17, 39-40 (1997). The first ground for Alcon's motion for summary judgment can be resolved by the Court's claim construction determination. Accordingly, Alcon hereby incorporates its concurrently filed "Memorandum in Support of Alcon's Proposed Claims Construction" ("Alcon's Markman Brief") into this memorandum.

Allergan alleges that povidone, the viscosity agent in Alcon's proposed product, is an SEC as that term is used in the '337 patent.[15] However, no laboratory testing is necessary to prove that Alcon's product does not infringe any of the claims of the '337 patent, because Allergan expressly disclaimed povidone as an SEC during prosecution of the Parent Application from which the '337 patent derived and Allergan cannot now recapture matter that it

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[15] See Plaintiffs Allergan, Inc. And Allergan Sales, LLC's Supplemental Responses To Defendants' Interrogatories Nos. 1 And 5 (Ex. SJ6) at 3.

affirmatively disavowed during prosecution.[16] Moreover, Alcon had the right to rely on Allergan's representations to the PTO in formulating its proposed product. As explained in Alcon's Markman Brief at § IV(A)(3), the scope of the claims of the '337 patent is limited by Allergan's unambiguous statements and the representations of one of the named inventors characterizing the invention during prosecution of the Parent Application from which the '337 patent is derived. The express statements in the relevant prosecution history disclaiming non-ionic SECs mandate that claims of the '337 patent must be limited to anionic SECs. See Microsoft Corp., 357 F.3d at 1349 (claims cannot be construed to cover subject matter broader than that which the patentee itself regarded as its invention and represented to the PTO). Because the claims of the '337 patent cannot be construed to cover more than that which Allergan itself regarded as comprising its invention, the claim term "SEC" must be construed to include only anionic SECs, which do not include povidone. Because povidone is not an anionic SEC, Alcon's proposed product does not infringe the '337 patent.[17]

As set forth in the accompanying Markman brief, during the prosecution of the Parent Application, Allergan was forced to distinguish its invention over a prior art patent to Burke which specifically discloses ophthalmic compositions containing brimonidine in combination with certain preferred vehicles including: povidone (polyvinylpyrrolidone), hydroxypropylcellulose, poloxamers, carboxymethylcellulose (CMC), and hydroxyethylcellulose.[18] To overcome a rejection for obviousness, Allergan argued that its "invention" was "an invention of selection" and stated that only CMC, the single anionic vehicle

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16 In the event that this case were to proceed to trial, Alcon would prove that povidone does not act to increase the solubility of its formulation, which is already 100% soluble without it.

17 Alcon's Markman Brief at § IV(B).

18 U.S. Patent No. 5,215,991 (Ex. H), Detailed Description of the Invention, col. 5, ll. 28-34.

disclosed in Burke, would work in the invention. In connection with this argument, Allergan submitted the Declaration of Orest Olejnik, Ph.D., one of the inventors. Dr. Olejnik describes the cited Burke patent as disclosing:[19]

> 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. See Burke, column 5, lines 28-34. (emphasis added).

Dr. Olejnik stated that the prior art does not disclose that CMC has characteristics that would motivate a person of ordinary skill in the art to choose it over the other vehicles disclosed in Burke to formulate a brimonidine composition. He further asserted, "Unlike the other listed polymers (polyvinyl alcohol, povidone, (polyvinylpyrrolidone), hydroxypropylcellulose, poloxamers, and hydroxyethylcellulose), CMC is anionic at pH7" and as such, "CMC possesses the surprising advantages of both increasing the solubility of brimonidine in solution . . . and causing such solutions to have superior adherence to cell surfaces, including ocular surfaces such as the cornea."[20] In conclusion, Dr. Olejnik stated that the other vehicles, including povidone, that Burke disclosed would not work in the invention:[21]

> It is also my belief that brimonidine solutions made using the other "vehicles" mentioned in the Burke patent would not possess this surprising combination of advantages. Therefore, the disclosures of Burke and Remington's in no way would render the presently claimed compositions obvious to the worker of ordinary (or even extraordinary) skill in the art.

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19 '210 PH (Ex. D), Declaration of Orest Olejnik, Ph.D. received March 17, 2003, Tab 11 at ¶ 4.

20 Id. at ¶ 7.

21 Id. at ¶ 8 (emphasis added).

To overcome Burke, Allergan amended all of the claims by adding the limitations "polyanionic" or "anionic" to the term SEC and distinguished its invention from the prior art on that basis: [22]

> Of the "vehicles" specifically disclosed by the Burke patent, all will function to increase the viscosity of a liquid aqueous composition. However, of these vehicles only carboxymethylcellulose (CMC) is an anionic polymer. All of the other polymers are non-ionic. They may act to increase the solution's viscosity, but they do not have the same characteristics as an anionic polymer such as CMC. (emphasis added).

Thus, as explained in Alcon's Markman Brief at § IV(B), Allergan's counsel's and its inventor's unambiguous disavowal of non-ionic SECs in the prosecution history of the '210 patent limits the claims of the '337 to the same scope. Microsoft Corp., 357 F.3d at 1350. ("Any statement of the patentee in the prosecution of a related application as to the scope of the invention [is] relevant to claim construction, and the relevance of the statement . . . is enhanced by the fact that the statement [is] made in an official proceeding in which the patentee [has] every incentive to exercise care in characterizing the scope of its invention."). In light of the unambiguous statements in the prosecution history, Allergan cannot now seriously contend that povidone, so explicitly disclaimed as an SEC in Parent Application, be considered an SEC within the scope of the invention claimed in the '337 patent which derived from the same Parent Applicant. Because Alcon's proposed product does not contain an anionic SEC as required by the asserted claims of the '337 patent, Alcon's product will not infringe that patent and Alcon's motion for summary judgment of non-infringement of the '337 patent should be granted

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[22] '210 PH (Ex. D), Reply to Office Action mailed March 12, 2003, Tab 10 at 6.

B. The '834 Patent Is Invalid Under 35 U.S.C. § 112 For Lack Of Written Description Because It Claims An Invention That Is Not Supported By The Specification Or Original Disclosure

The '834 patent also derived from the Parent Application that led to the '210 patent. The claims of the application that led to the '834 patent were added by a Preliminary Amendment that accompanied the filing of the application in September 2002, two years after the filing of the provisional application from which the patents-in-suit both claim priority. It was in the new claims added by the Preliminary Amendment that the 0.15% (w/v) limitation appeared for the first time. Each claim of the '834 patent requires a "therapeutically effective" composition containing "0.15%(w/v)," "about 0.15%(w/v)" or "up to 0.15%(w/v)" of active ingredient. Claim 1 is representative, and reads:[23]

> 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.

Neither the specification of the '834 patent nor any of the original disclosure (including the original 46 claims) in the Parent Application disclose the critical 0.15% limitation.[24] There is nothing in the '834 patent's specification or original disclosure to establish that the inventors actually possessed such invention when they filed the provisional application from which priority is claimed. That fact alone mandates summary judgment. Moreover, since Allergan's attorneys repeatedly argued during prosecution of the '834 patent that a "therapeutically effective" formulation of brimonidine at this concentration would have been "unexpected" and "surprising"

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[23] The '834 patent is attached hereto as Ex. B (emphasis added).

and secured allowance on that very basis, Allergan cannot now argue that this "unexpected" finding would have been immediately understood from the disclosure of the '834 patent, which lacks any pertinent teaching whatsoever. Accordingly, each claim of the '834 patent should be held invalid for failure to satisfy the written description requirement.

1. The Written Description Requirement Prohibits Applicants From Patenting Later "Inventions"

"The United States Supreme Court [has] acknowledged written description as a statutory requirement distinct not only from the best mode requirement but also from enablement." Univ. of Rochester, 358 F.3d at 921 (citing Festo Corp. v. Shotketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 736 (2002)). "The policy behind the written description requirement is to prevent overreaching and *post hoc* claims that were not part of the original invention." Purdue Pharma, L.P. v. F.H. Faulding & Co., 48 F. Supp. 2d 420, 427 (D. Del. 1999), aff'd, 230 F.3d 1320 (Fed. Cir. 2000); see also, Univ. of Rochester, 358 F.3d at 920, quoting Reiffin v. Microsoft Corp., 214 F.3d 1342, 1345 (Fed. Cir. 2000) (noting that the written description requirement is designed to "ensure that the scope of the right to exclude, as set forth in the claims, does not overreach the scope of the inventor's contribution to the field of art as described in the patent specification").

To satisfy the written description requirement, the disclosure does not have to provide *in hac verba* support for the claimed subject matter, but it must convey with reasonable clarity to those skilled in the art that the inventor was in possession of the claimed invention as of the priority date. Purdue Pharma L.P., 230 F.3d at 1320. In other words, "one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims." Id. (emphasis added); see also Regents of the Univ. of California v. Eli Lilly & Co., 119 F.3d

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[24] See U.S. Provisional Application Serial No. 60/218,200 (Ex. SJ7); '210 PH (Ex. D), Application as Filed July 10, 2001, Tab 1; '834 PH (Ex. F), Application as Filed September 6, 2002, Tab 1.

1559, 1566 (Fed. Cir. 1997) (quoting Lockwood v. Am. Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997)) (an invention must be described "in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention'.")).

Although compliance with the written description requirement is a factual inquiry, it is one that is amenable to summary judgment. See Univ. of Rochester, 358 F.3d at 927; Turbocare Div. of Demag Delaval Turbomachinery Corp. v. Gen. Elec. Co., 264 F.3d 1111, 1119-20 (Fed. Cir. 2001); Lockwood, 107 F.3d at 1572; GFI, Inc. v. Franklin Indus., 27 F. Supp. 2d. 686, 692 (N.D. Miss. 1998); Carnegie Mellon Univ. v. Hoffman-LaRoche Inc., 1999 WL 33298545, *7 (N.D. Cal. 1999); Abbott Labs. v. Inverness Med. Tech., 2002 WL 1906533 (D. Mass. 2002).

As discussed in detail below, the original disclosure of the '834 patent is devoid of any express or implied teaching of the criticial "0.15% (w/v)" concentration or that concentration's therapeutic effects. And the prosecution history demonstrates that such teachings were not provided in the patent's disclosure. These are classic circumstances under which summary judgment for lack of written description should be granted. Because it is improper to make a hindsight determination of whether the inventors had possession of the invention claimed in the '834 patent, the Court should look only to the original disclosure of the Parent Application (the common specification and the original 46 claims[25]) and must ignore the later filed claims which cannot provide their own written description. A reading of the common specification along with original claims 1-46, as filed, makes it clear that the Allergan's inventors did not contemplate or disclose as their invention (as of the priority date they now claim) a composition having a concentration of about of the active ingredient, brimonidine tartrate.

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[25] '210 PH (Ex. D), Application as Filed July 10, 2001, Tab 1 at 1-39.

2. There Is No Support For The 0.15% (w/v) Limitation In The Disclosure Of The '834 Patent

The specification of the '834 patent does not teach a "therapeutically effective" amount of brimonidine up to a maximum of "0.15% (w/v)" as required by the claims. The specification discloses compositions that purportedly achieve certain benefits by virtue or the combination of the drug with an SEC or an oxy-chloro preservative or both. There is no indication in the specification that the invention is to use a reduced amount of active ingredient in a composition that does not include either a solubility enhancing component or a preservative. Indeed, the specification teaches away from such a composition. In the Summary of the Invention the specification states:[26]

> New alpha-2-adrenergic agonist component-containing compositions have been discovered. The present compositions contain certain materials which are effective in at least aiding or assisting in solubilizing the alpha-2-adrenergic agonist components in the compositions, and preferably in environments to which the compositions are administered or introduced, for example, biological environments, such as the human eye. Preferably, solubilization of the alpha-2-adrenergic agonist components in accordance with the present invention facilitates transport of such components across lipid membranes. Also, preferably such solubilization allows the provision of more reliable and reproducible dosage forms of the drug. In addition, alpha-2-adrenergic agonist component-containing compositions have been discovered which include preservatives which provide substantial advantages, for example, reduced adverse interactions with the alpha-2-adrenergic agonist components and/or with the patients to whom the compositions are administered, while maintaining preservative effectiveness.

In the Detailed Description of the Invention the specification reads:[27]

> [I]t is believed that solubilized alpha-2-adrenergic agonist components are better able to cross the lipid membranes relative to unsolubilized alpha-2-adrenergic agonist components. It is further believed that the solubilized alpha-2-adrenergic agonist components are physically smaller and are therefore more able to physically permeate or diffuse through the lipid membranes.

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[26] '834 Patent (Ex. B), Summary of the Invention, col. 1, l. 57 – col. 2., l. 8 (emphasis added).

[27] Id., Detailed Description of the Invention, col. 4, ll. 34-40 (emphasis added).

Thus, the Summary of the Invention and the Detailed Description of the Invention attribute benefits to the invention such as enhanced solubility allowing provision of "more reliable and reproducible dosage forms of the drug," preservatives which allow "reduced adverse interactions," and enhanced solubility making the drug component smaller and more readily able to permeate lipid membranes. However, none of the benefits expressly attributed to the invention include lowering the therapeutic concentration of the drug by at least 25%, as later claimed.

The specification also devotes three columns to a description of SECs (see '834 patent, col. 6, l. 18 – col. 9, l. 22), but there is no teaching in the specification with respect to the "therapeutic effect" of any particular concentration of the active ingredient (e.g., brimonidine tartrate). Indeed, the specification's only teaching with respect to particular concentrations of active ingredient is limited to rudimentary solubility tests of brimonidine tartrate solutions at concentrations of 0.5% (w/v) and 0.2% (w/v).[28] In Example 1, a solubility profile of a 0.5% brimonidine solution was prepared that purportedly demonstrated "the solubility of Brimonidine is highly pH-dependent and spans more than two orders of magnitude over the pH range of 5-8. The solubility decreases sharply as the pH increases."[29] In Example 2, pH-solubility profiles of 0.2% brimonidine tartrate solutions containing CMC and oxy-chloro components were determined. The specification concludes from these experiments that "the solubility of Brimonidine tartrate tends to increase with increasing CMC concentrations".[30] Neither solubility

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[28] This should not be confused with the specification's teaching with respect to possible concentrations for "solubility enhancing agents" (SECs) or preservatives. See e.g., '834 Patent (Ex. B), Summary of the Invention, col. 3, ll. 13-17 (offering suggested concentrations of SEC); Detailed Description of the Invention, col. 9, ll. 43-49 (offering suggested concentrations of preservatives).

[29] Id., Example 1, col. 14, ll. 19-22.

[30] Id., Example 2, col. 15, l. 66 – col. 16, l. 1.

study provides any indication as to what concentrations of active ingredient might be therapeutically effective.

In fact, the specification affirmatively teaches away from the 0.15% (w/v) limitation. At column 13, lines 19-22, the specification states: "It will be understood that concentrations of adrenergic agonists other than 0.5% may be used, so long as they have therapeutic activity." This statement makes it clear that the inventors did not consider any particular dosage (or any dosage reduced from that in the prior art) to be part of their invention. It is undisputed that concentrations greater than 0.15% (w/v) have therapeutic effect; indeed, Allergan's own prior art product used 0.2% brimonidine tartrate. Thus, while indicating that dosage is not critical as long as it is therapeutically effective, it is notable that the specification does not suggest or disclose, much less identify, how much brimonidine tartrate is actually necessary to achieve a therapeutic effect either with or without an SEC. It is beyond dispute that there is no teaching in the patent that 0.15% brimonidine tartrate is therapeutically effective.

As a matter of law, the fact that Allergan introduced the 0.15% limitation in new proposed claims of a Preliminary Amendment[31] does not provide the necessary written description for the continuation application. Allowing applicants to introduce new subject matter during prosecution would undermine the prohibition against "overreaching and post hoc claims" that the written description requirement was designed to prevent. Purdue Pharma, 48 F. Supp. 2d at 427 (D. Del. 1999), aff'd, 230 F.3d 1320 (Fed. Cir. 2000); see also, In re Wright, 866 F.2d 422, 424 (Fed. Cir. 1989) ("When the scope of a claim has been changed by amendment in such a way as to justify an assertion that it is directed to a different invention than was the original claim, it is proper to inquire whether the newly claimed subject matter was described in the

[31] See '834 PH (Ex. F), Preliminary Amendment dated September 6, 2002, Tab 2 at 2-3.

patent application when filed as the invention of the applicant. That is the essence of the so-called 'description requirement' of § 112, first paragraph . . . .") (emphasis added to "newly").

3. The '834 Patent's Prosecution History Confirms The Absence Of A Proper Written Description

Allergan's efforts to rationalize the newly added "critical" 0.15% limitation during prosecution only accentuates the fact that an ordinarily skilled artisan could not have even inferred that limitation from the patent's original disclosure. As discussed below, Allergan repeatedly stated that a therapeutically effective 0.15% brimonidine composition would have been "unexpected" and could not even tell the Examiner where the application supported such a composition.

Immediately after introducing the 0.15% limitation into the claims in a Preliminary Amendment,[32] the Examiner rejected all of the claims as obvious because the newly introduced 0.15% concentration fell squarely within the preferred concentration range reported in the prior art and that an ordinarily skilled artisan could have determined the most efficacious dose by merely carrying out a dose response curve.[33] At a telephonic interview shortly thereafter, Allergan's attorney argued that a composition comprising up to about 0.15% (w/v) of brimonidine tartrate at a pH of 7.0 or greater would have been "unexpected" and agreed to file a declaration showing "unexpected results."[34]

In a written response mailed March 17, 2003, Allergan amended the claims and reiterated its "unexpected results" argument.[35] Allergan amended the claims to require that the compositions be "therapeutically effective aqueous ophthalmic" compositions, urging that this

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32 Id.

33 '834 PH (Ex. F), Office Action dated December 10, 2002, Tab 4.

34 '834 PH (Ex. F), Summary Interview dated February 25, 2003, Tab 5 (emphasis added).

amendment was supported by the application.[36] But the portions of the application to which Allergan referred contained absolutely no teaching of a therapeutically effective 0.15% brimonidine tartrate composition.[37] Thus, Allergan, itself, could not find pertinent teaching in the application to support its claimed "invention."

Moreover, in that response, Allergan reiterated its position that therapeutically effective compositions with brimonidine at concentrations of about 0.15% or less would have been "surprising."[38] To set the stage, Allergan noted – for the first time anywhere in the prosecution – that it was "important to understand that previous brimonidine solutions for ophthalmic use have been formulated at a pH of about 6.3-6.5 and a concentration of 0.2% (w/v)" and that that "formulation was approved for marketing in the United States and foreign countries under the trade name Alphagan®."[39] It utilized this representation in an effort to distinguish the prior art compositions:[40]

> The present invention is the result of the surprising finding that increasing the pH of a brimonidine solution to a pH of greater than about 7.0 leads to similar efficacy at a 25% lower concentration (from 0.2% (w/v) to about 0.15% (w/v) or less) than is seen in a brimonidine solution at a pH of about 6.6-6.8.

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35 '834 PH (Ex. F), Reply to Office Action mailed March 17, 2003, Tab 6 at 3-5.

36 Id. at 3.

37 See '834 Patent (Ex. B), Background of the Invention, col. 1, ll. 22-23 and Summary of the Invention, col. 2, l. 5 – col. 4, l. 34, which corresponds to the cited portions "e.g., at page 1, lines 15-16 and page 3-7 [sic]" ('834 PH (Ex. F), Reply to Office Action mailed March 17, 2003, Tab 6 at 3), respectively.

38 '834 PH (Ex. F), Reply to Office Action mailed March 17, 2003, Tab 6 at 4 (emphasis added).

39 Id. (emphasis added).

40 Id. (emphasis added).

Indeed, Allergan also characterized its claimed composition elsewhere in its response in even stronger terms, as "particularly surprising" and "truly unexpected."[41]

The "surprising" findings that Allergan was relying upon in its response were disclosed in the accompanying declaration of Amy Batoosingh and the Katz article.[42] Ms. Batoosingh disclosed the pHs of the formulations used in the Katz article and concluded, based on the results of that article, that "brimonidine 0.2% and brimonidine-Purite 0.15% showed comparable efficacy when each was used for the treatment of ocular hypertension in glaucoma and/or ocular hypertensive human patients over a 12 month period...."[43] Whether that is in fact the case is of no moment to this motion, as the Katz article was submitted almost a full-year after the provisional application resulting in the patents-in-suit was filed. The Katz article was not cited in that application, nor is any data of any type contained therein that would evidence that 0.15% concentration is therapeutically effective.[44] This, coupled with the absence of any information in the specification that discloses the significance of the 0.15% concentration, strongly suggests that the inventors did not possess the reduced concentration until well after the priority application was filed.[45] In any event, no one skilled in the art could read the original disclosure and understand that the inventors considered a 0.15% concentration of the active ingredient, without

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41 Id. (emphasis added).

42 Id.; see also, '834 PH (Ex. F), Declaration of Amy Batoosingh received March 24, 2003 and accompanying Katz article, Tab 7.

43 '834 PH (Ex. F), Declaration of Amy Batoosingh received March 24, 2003, Tab 7 at ¶ 4.

44 Indeed, the Katz article would not be enough to support a concentration of up to 0.15% because it expressly identifies 0.15% as the lowest effective concentration tested, which attains the desired therapeutic effect. See '834 PH (Ex. F), Declaration of Amy Batoosingh received March 24, 2003, Tab 7, at Katz article at 120.

45 If this were not the case, the '834 patent would be invalid (and possibly unenforceable for inequitable conduct) for failure to disclose the inventors' best mode.

need for an SEC or an oxy-chloro preservative, to be their invention. It simply would be impossible to derive such an understanding.

4. Allergan Cannot Salvage The '834 Patent By Arguing That The Claimed 0.15% (w/v) Brimonidine Compositions Could Be Determined Empirically Or Would Have Been Obvious

Even if one skilled in the art thought to perform experiments that would identify 0.15% as a therapeutic concentration of brimonidine at pH 7.0 or greater, the disclosure would still be inadequate because "[t]he adequacy of the written description (i.e., the disclosure) is measured from the face of the application; the requirement is not satisfied if one of ordinary skill in the art must first make the patented invention before he can ascertain the claimed features of that invention." New Railhead Mfg., L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1295 (Fed. Cir. 2002); see also, e.g., Purdue Pharma, 230 F.3d at 1327 ("It is 'not a question of whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure . . . Rather it is a question whether the application necessarily discloses that particular device.'") (quoting Jepson v. Coleman, 314 F.2d 533, 536 (C.C.P.A. 1963)).

Indeed, the Federal Circuit has cautioned that "one skilled in the art, reading the original disclosure, must immediately discern the limitation at issue in the claims." Purdue Pharma, 230 F.3d at 1223, 1323 (emphasis added). Courts do not just give this immediacy requirement lip-service. This maxim was recently relied upon in granting summary judgment of invalidity:

> Immediacy is important because it guarantees that the insight belongs to the author of the specification and appears at once to the intelligent educated reader. It is a different matter, however, if the language of the specification triggers an insight that belongs to the reader, who, having thought about the extent of what was actually disclosed by the specification, concludes, "This also could be done another way." In that circumstance, the reader is conceiving of an "obvious variant" of what is actually described, and that is not enough to satisfy the written description requirement.

Abbott Labs., 2002 WL 1906533 at *2 (citing Lockwood, 107 F.3d at 1572).

The Federal Circuit's recent holding in Purdue Pharma is particularly apposite to the facts of this case. There, the claims-at-issue contained the limitation "a maximum plasma concentration (Cmax) which is more than twice the plasma level of said opioid at about 24 hours after administration of the dosage form [C24] . . . ." 230 F.3d at 1323. The court noted that the claims were invalid for lack of written description because:

> [a]lthough the examples provide the data from which one can piece together the Cmax/C24 limitation, neither the text accompanying the examples, nor the data, nor anything else in the specification in any way emphasizes the Cmax/C24 ratio. The district court therefore reasonably concluded that one of ordinary skill in the art would not be directed to the Cmax/C24 ratio as an aspect of the invention.

Id. at 1326 (emphasis added). The court illustrated the issue by noting that:

> [O]ne cannot disclose a forest in the original application, and then later pick a tree out of the forest and say here is my invention. In order to satisfy the written description requirement, the blaze marks directing the skilled artisan to that tree must be in the originally filed disclosure.

Id. at 1326-27 (emphasis added).

Here, just as in Purdue Pharma, there are no "blaze marks" in the specification to lead the skilled artisan to the 0.15% limitation. Id. at 1326 (quoting In re Ruschig, 379 F.2d 990, 994-95 (C.C.P.A. 1967)). In fact, the 0.15% limitation cannot even be pieced-together from the disclosure because that number does not exist in the disclosure. Even if it were, there is no guidance in the specification that would lead one to select 0.15% over other concentrations of brimonidine, much less any indication that such concentration of brimonidine would be "therapeutically efficacious."

In sum, no reasonable fact finder could find that Allergan's original disclosure would enable one of skill in the art to recognize that Allergan's inventors then possessed the invention later claimed in the '834 patent through subsequent amendment. Thus, all of the claims of the

'834 patent are invalid under § 112 as a matter of law, and summary judgment is properly entered in favor of Alcon.

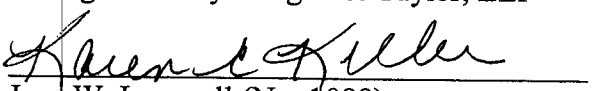
V. CONCLUSION

For the reasons stated above, and on the authorities referenced herein, Alcon respectfully requests entry of summary judgment of non-infringement of U.S. Patent No. 6,673,337 and summary judgment of invalidity for lack of written description of U.S. Patent No. 5,641,834.

Dated: May 2, 2005

Respectfully submitted,

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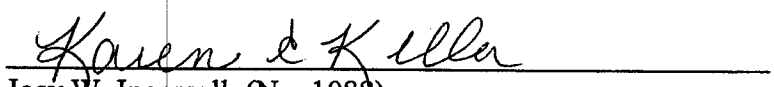
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