IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

MEMORANDUM

I. INTRODUCTION

Allergan, Inc. and Allergan Sales, LLC (collectively, "Allergan") filed the above-captioned action against Alcon Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively, "Alcon") on August 24, 2004. Allergan's complaint alleges that Alcon is infringing U.S. Patent No. 6,673,337 (the "'337 patent") and U.S. Patent No. 6,641,834 (the "'834 patent").

Presently before the court is Alcon's Motion for Summary Judgment (D.I. 56). For the reasons that follow, the court will deny Alcon's motion.

II. BACKGROUND

A. Statutory Framework Under Which this Suit Arises

1. Regulatory Approval of Innovative Drugs

The Federal Food, Drug, and Cosmetic Act of 1938 (the "FDCA"), 21 U.S.C. §§ 1, et seq., governs the procedures for the approval of innovative and generic drugs. Under the current statutory scheme of the FDCA, an innovator pharmaceutical company seeking to manufacture and market a novel brand drug must file a new drug application ("NDA") with the Food and Drug Administration

(the "FDA"). 21 U.S.C. § 355(a)-(b)(1) (2005). An NDA is often costly and time intensive, as it is required to contain comprehensive and detailed clinical studies demonstrating the brand drug's safety and efficacy. *See id.* An NDA must also include a list of patents which claim the brand drug. 21 U.S.C. § 355(b)(1), (c)(2). If the FDA approves an NDA, it publishes or lists information about the brand drug, as well as the patents covering the drug, in a publication officially titled "Approved Drug Products with Therapeutic Equivalence Evaluations," but otherwise known as the "Orange Book."

Under the FDCA, NDA holders are awarded a five-year period of market exclusivity from the date of the brand drug's approval. 21 U.S.C. § 355(c)(3)(E)(ii). An additional three-year period of exclusivity is awarded to an NDA holder for obtaining FDA approval for a new use or new formulation of a previously approved brand drug. 21 U.S.C. § 355(c)(3)(E)(iii)-(iv). An NDA holder can further extend its period of market exclusivity by six months if it sponsors clinical trials to evaluate the drug's safety and efficacy in children. 21 U.S.C. § 355a(b)(1) (2005). During the exclusivity period, the FDA may not approve an application to market a generic or modified version of the brand drug. 21 U.S.C. § 355(c)(3)(E)(ii)-(iv).

2. Regulatory Approval of Generic Drugs

Under the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"), Pub. L. No. 98-417, 98 Stat. 1585 (1984), codified at 35 U.S.C. § 271, as modified by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare Act"), Pub. L. No. 108-173, 117 Stat. 2066 (2003), codified at 21 U.S.C. § 355, a generic drug manufacturer seeking approval to market a generic version of a previously approved brand drug may submit an Abbreviated New Drug Application ("ANDA") or paper New Drug Application

("paper NDA") to the FDA.[1] 21 U.S.C. § 355(j). In its paper NDA, the generic manufacturer may rely on the NDA's safety and efficacy clinical studies by demonstrating the generic drug's bioequivalence with the approved brand drug. 21 U.S.C. § 355(j)(2)(A). A paper NDA also must contain one of four certifications regarding each patent that is listed in the Orange Book for the brand drug: (I) that no patent information on the brand drug has been submitted to the FDA; (II) that the listed patent has expired; (III) that the listed patent will expire on a stated date; or (IV) that the listed patent is invalid or will not be infringed by the generic product. 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV). These options "are commonly referred to as paragraph I, II, III, and IV certifications." *Teva Pharms. USA, Inc. v. Pfizer Inc.*, 395 F.3d 1324, 1328 (Fed. Cir. 2005).[2]

A generic manufacturer that desires to sell its drug product before a listed patent has expired must file a paragraph IV certification. The manufacturer must also notify the owner of any patents listed in the Orange Book and the NDA holder, as well as provide them with a "detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." 21 U.S.C. §§ 355(j)(2)(B)(I)-(iv). In response, the patent owner or NDA holder has the option of bringing a patent infringement action against the generic manufacturer within forty-five days of the notice. 21 U.S.C. § 355(j)(5)(B)(iii). During the pendency of the forty-five days, the generic is barred from filing a declaratory judgment action based upon the filing of its paper NDA. *Id.* If the patent holder elects to bring suit, then the effective date of FDA approval of the paper NDA is delayed for thirty months, or until a court rules that the patent is not infringed or invalid,

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[1] The court will use the term paper NDA, as this is the type of application Alcon filed with the FDA.

[2] The court will focus only on the paragraph IV certification, as this is the type of certification Alcon filed with the FDA.

whichever occurs first. *Id.* However, if the patent holder fails to bring suit within the forty-five days, the FDA may approve the paper NDA. *Id.*

As an incentive to encourage early paper NDA filing, the first generic to file a paper NDA containing a paragraph IV certification is known as the "first filer," and is eligible for a 180-day exclusivity period. The exclusivity period ensures that the only generic drug on the market during the 180 days is that of the "first filer." 21 U.S.C. § 355(j)(5)(B)(iv). The exclusivity period is triggered by the earlier of: (1) the first date of the first commercial marketing of the generic drug by the "first filer"; or (2) a court decision of non-infringement or invalidity of the patent by any paper NDA filer. *Id.* Thus, an action involving a subsequent paper NDA filer resulting in a judgment of non-infringement or invalidity can trigger the exclusivity period. *See id.* As a result, any subsequent paper NDA filer must wait until the expiration of the exclusivity period before the FDA will approve its paper NDA.

B. Brimonidine Tartrate, Its Uses, and Allergan's Market Exclusivity

The patents in suit are directed to compositions containing the alpha-2-adrenergic agonist brimonidine tartrate. Alpha-2-adrenergic agonists, including brimonidine tartrate, are used to treat elevated pressure of the fluid in the eye, known as intraocular pressure ("IOP"). Elevated IOP tends to be found in patients with glaucoma, an incurable disease of the eye that causes gradual vision loss and can lead to blindness. (D.I. 72, at 4.) Scientists and medical personnel believe that elevated IOP in patients with glaucoma contributes to gradual retinal deterioration and loss of vision, which are characteristics of the disease. (*Id.*)

In the 1990's, Allergan scientists discovered that topically-applied brimonidine could assist in lowering IOP and was, therefore, a benefit to glaucoma patients. (*Id.*) In 1996, Allergan received

approval from the FDA to market brimonidine tartrate and began selling the drug under the trade name Alphagan®. The Alphagan® drug product formulation contained 0.2%(w/v) brimonidine tartrate, at a pH range of 5.6-6.6.

On March 16, 2001, Allergan obtained FDA approval of its NDA for Alphagan®P, a new formulation of the original Alphagan® product, which contains 0.15% brimonidine, a twenty-five percent reduction in concentration over the original Alphagan® product, at a pH of 7.0 or greater. According to Allergan, the 0.2% brimonidine was effective at treating glaucoma, but caused significant adverse side effects, including allergic conjunctivitis. (D.I. 72, at 5.) Thus, Allergan set out to design a brimonidine product that would maintain the efficacy of Alphagan®, with reduced adverse side effects and better tolerability. (*Id.*) Allergan received FDA approval for Alphagan® P because it was able to show through studies that Alphagan® P has comparable efficacy to Alphagan®, with a forty percent reduction in allergy rate. (*Id.*) As a result, Allergan's new formulation of its brimonidine enabled it to receive an additional three years of market exclusivity for Alphagan® P. Allergan's period of market exclusivity ended on September 16, 2004. (D.I. 55, at 12.)

C. The Patents at Issue

Allergan alleges that Alcon's proposed brimonidine tartrate drug product infringes the '337 patent and the '834 patent. Both of these patents derived from the same parent application and contain the same specification. The specification for both patents describes one of the continuing challenges of formulating compositions having alpha-2-adrenergic agonist components as rendering the components more effective. ('834 patent Col. 1, ll. 26-29; '337 patent Col. 1, ll. 26-29.) Thus, the patents state that "[t]here continues to be a need for new compositions containing alpha-2-

adrenergic components." ('834 patent Col. 1, ll.53-54; '337 patent Col. 1, ll. 52-53.) Each of the patents then claims new compositions containing alpha-2-adrenergic agonist components.

The '834 patent specifically claims a therapeutically effective composition of up to about 0.15%(w/v) brimonidine tartrate, at a pH of 7.0 or greater. (*See* '834 patent, Claim 1.) That is, the patent claims the use of lowered concentrations of brimonidine at elevated pHs.[3] According to Allergan, the invention is important because the goal of a formulator is to maximize efficacy while minimizing toxicity in a specific pharmaceutical product. (D.I. 73 ¶ 6.) Thus, achieving the same level of efficacy and safety at a lower concentration of brimonidine tartrate is advantageous because it will decrease adverse side effects caused by the toxicity of the brimonidine tartrate.

The '337 patent is also directed to compositions containing alpha-2-adrenergic agonist components. However, it differs from the '834 patent in that it claims compositions of brimonidine tartrate containing a solubility enhancing component ("SEC") in an amount effective to increase the solubility of the brimonidine tartrate. (*See* '337 patent, Claim 1.) The specification discloses a variety of different SECs, including carboxymethylcellulose ("CMC") and polyvinylpyrrolinidones[4], and notes that "[a]ny suitable SEC may be employed in accordance with the present invention." (*Id.*

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[3] The human eye presents unique problems when formulating any ophthalmic pharmaceutical product. (D.I. 73, Declaration of Dr. Valentino Stella to Motion of Summary Judgment ¶ 7.) The most convenient method of ophthalmic delivery is eye drops. (*Id.*) However, because the eye has a small amount of liquid on its outer surface, eye drops drain off quickly through the eye's drainage ducts. (*Id.*) Thus, to maximize efficiency of eye drops, formulators must design them in such a way that the most amount of drug is absorbed in the least amount of time. (*Id.* ¶ 8.) Having an elevated pH is preferable, therefore, because increasing the pH effects how much brimonidine tartrate the cornea can readily absorb. (*Id.* ¶ 13.)

[4] According to the '337 patent, CMC is an anionic SEC, which carries a negative charge. ('337 patent Col. 2, l. 53- Col. 3, l. 7.) Conversely, a non-ionic SEC does not carry a positive or negative charge – it is neutral. Polyvinylpyrrolinidones are examples of non-ionic SECs disclosed in the '337 patent.

Col. 6, ll. 18-19.) According to the specification, the claimed compositions enhance the effectiveness of brimonidine tartrate (and other alpha-2-adrenergic agonist components) by increasing its apparent water solubility at pHs higher than neutral, or 7.0. (*Id.* Col. 2, ll. 9-13.)

D. Alcon's Paper NDA

In April 2001, Alcon began work on a generic formulation of Alphagan® P. Alcon's work resulted in the product Brimonidine PQ, a brimonidine product for lowering IOP. According to Alcon, its proposed product is an aqueous topical solution containing 0.15% brimonidine as the active ingredient. (D.I. 55, at 13.) However, its formulation contains Polyquad®, rather than Purite®, as a preservative, and Povidone K-90 as a viscosity enhancing agent, instead of CMC, Allergan's SEC. (*Id.*) Alcon's proposed product was tentatively approved by the FDA on March 1, 2005, but has not received final approval because Allergan filed the instant infringement suit. (*Id.*)

E. Allergan's Patent Infringement Suit

On August 24, 2005, Allergan initiated the instant action. The complaint alleges that Alcon infringes the '337 and '834 patents, pursuant to 35 U.S.C. § 271(e)(2),[5] because it submitted a paper NDA to the FDA, seeking approval of its proposed generic brimonidine tartrate ophthalmic drug

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[5] Section 271(e)(2) states, in pertinent part:

> [i]t shall be an act of infringement to submit – an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug or veterinary biological product claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

35 U.S.C. § 271(e)(2)(A).

product. (Compl. ¶¶ 14-15, 17.) Allergan is requesting injunctive relief.[6]

On May 2, 2005, Alcon filed a motion for summary judgment of non-infringement, with respect to the '337 patent, and invalidity, with respect to the '834 patent. Alcon contends that its product does not infringe the '337 patent because the claims are limited to anionic SECs, which its product does not contain. Alcon further contends that the '834 patent is invalid for lack of written description.

III. STANDARD OF REVIEW

Summary judgment is appropriate "if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c); *see also Chimie v. PPG Indus. Inc.*, 402 F.3d 1371, 1376 (Fed. Cir. 2005). Thus, summary judgment is appropriate only if the moving party shows there are no genuine issues of material fact that would permit a reasonable jury to find for the non-moving party. *See Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). A fact is material if it might affect the outcome of the suit. *Id.* at 247-48. An issue is genuine if a reasonable jury could possibly find in favor of the non-moving party with regard to that issue. *Id.* at 249. The moving party bears the initial burden of demonstrating that there are no genuine issues of material fact. *See Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Additionally, "the evidence must be viewed in the light most favorable to the party opposing the motion, with doubts resolved in favor of the nonmovant." *AFG Indus., Inc. v. Cardinal IG Co., Inc.*, 375 F.3d 1367, 1371 (Fed. Cir. 2004) (citing *Crown Operations Int'l, Ltd. v.*

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[6] Allergan had previously asserted a claim for willful infringement, which the court concluded was not permitted, thereby striking it from the complaint. *See* D.I. 108.

Solutia Inc., 289 F.3d 1367, 1375 (Fed. Cir. 2002).

IV. Discussion

A. Alcon's Motion for Summary Judgment of Non-Infringement

Alcon first argues that its brimonidine product does not infringe the '337 patent. A patent is infringed when a person "without authority makes, uses or sells any patented invention, within the United States . . . during the term of the patent." 35 U.S.C. § 271(a). A patent infringement analysis entails two steps: "(1) claim construction to determine the scope of the claims, followed by (2) determination of whether the properly construed claim encompasses the accused device." *Bai v. L & L Wings, Inc.,* 160 F.3d 1350, 1353 (Fed. Cir. 1998) (citations omitted). The first step, claim construction, is a matter of law for the court to decide. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). The second step, the determination of infringement, is a question of fact. *Bai*, 160 F.3d at 1353. "Literal infringement of a claim occurs when every limitation recited in a claim appears in the accused device, i.e., when 'the properly construed claim reads on the accused device exactly.'" *KCJ Corp. v. Kinetic Concepts, Inc.*, 223 F.3d 1351, 1358 (Fed. Cir. 2000) (citation omitted). Thus, summary judgment on the grounds of literal infringement is proper when no reasonable jury could conclude that every limitation recited in the properly construed claim is present in the accused device. *See Karlin Tech., Inc. v. Surgical Dynamics, Inc.,* 177 F.3d 968, 974 (Fed. Cir. 1999).

Alcon contends that Allergan cannot establish infringement of the '337 patent because povidone, the "viscosity agent" in its proposed product, is not an SEC as that term is used in the '337 patent. According to Alcon, Allergan expressly disclaimed povidone, as well as all other non-ionic SEC's, during prosecution of the parent application from which the '337 patent derived. (D.I. 55,

at 14.) Alcon further contends that 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" support limiting the claim scope to anionic SECs. (*Id.* at 15.) Lastly, Alcon contends that the non-infringement ground for its summary judgment motion "can be resolved by the court's claim construction determination." (*Id.* at 14.)

The court agrees that Alcon's non-infringement ground for summary judgment is resolved by the court's claim construction. However, Alcon's argument fails because, in making it, Alcon presumed that the court would construe the term "solubility enhancing component other than an cyclodextrin" to exclude non-ionic SECs when, in fact it did not. In its July 26, 2005 Order (D.I. 109), the court construed the term "solubility enhancing component other than an cyclodextrin" to mean "a component that enhances the solubility of the alpha-2 adrenergic agonist component other than a cyclodextrin." (D.I. 109 ¶ 1.) In doing so, the court rejected Alcon's proposed construction of an SEC as being limited to anionic SECs. Accordingly, summary judgment of non-infringement is not appropriate.

B. Alcon's Motion for Summary Judgment Based on Failure to Satisfy the Written Description Requirement of 35 U.S.C. § 112

Alcon next argues that the '834 patent is invalid for indefiniteness. Specifically, Alcon contends that while the claims of the '834 patent require a "therapeutically effective" composition containing "0.15%(w/v)," "about 0.15%(w/v)," or "up to about 0.15%(w/v)" of active ingredient, neither the specification nor any of the original disclosure in the parent application disclose the critical 0.15% limitation. (D.I. 55, at 18.) Thus, according to Alcon, nothing in the '834 patent specification or original disclosure establishes that the inventors actually possessed the invention

when they filed the provisional application from which priority is claimed. (*See id.*) Alcon further contends that because Allergan's attorneys argued during prosecution that a "therapeutically effective" formulation of brimonidine at 0.15% would have been "*unexpected*" and "*surprising*," thereby securing allowance of the patent, it cannot now argue that the "unexpected" finding would have been understood from the '834 patent disclosure. (*Id.* at 18-19 (emphasis in original)).[7]

Whether a patent complies with the written description requirement is an issue of fact. *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 296 F.3d 1316, 1324 (Fed. Cir. 2002) (citation omitted). When a party challenges a patent's validity, the court begins with the statutory presumption of validity. 35 U.S.C. § 282 ("A patent shall be presumed valid."). Accordingly, "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." *Id.* Invalidity must be shown by clear and convincing evidence. *Robotic Vision Sys., Inc. v. View Eng'g, Inc.*, 189 F.3d 1370, 1377 (Fed. Cir. 1999). This evidentiary standard is relevant in the context of a motion for summary judgment because "the judge must view the evidence presented through the prism of the substantive evidentiary burden." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 254 (1986). As the Supreme Court elaborated,

> [W]here the . . . 'clear and convincing' evidence requirement applies, the trial judge's summary judgment inquiry as to whether a genuine issue exists will be whether the evidence presented is such that a jury applying that evidentiary standard could reasonably find for either the plaintiff or the defendant. Thus, where the factual dispute concerns [a material issue] . . . the appropriate summary judgment question will be whether the evidence in the record could support a reasonable jury finding either that the [movant] has shown [that material issue] by clear and convincing

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[7] The court will not address Alcon's contentions concerning whether 0.15%(w/v) is a "therapeutically effective" amount of brimonidine tartrate, as it previously issued an Order (D.I. 93), on June 13, 2005, striking that argument. Thus, the only issue for the court to determine with respect to invalidity is whether the claimed limitations that use 0.15%(w/v) are supported by the specification.

evidence or that the [movant] has not.

Id. at 255-56. Thus, Alcon must show that there is no genuine issue as to any material fact that is necessary for a finding, by clear and convincing evidence, of invalidity. If Alcon makes such a showing, Allergan may withstand summary judgment by adducing "specific facts" sufficient to create a genuine issue of material fact as to an essential element of Alcon's defense of invalidity. FED. R. CIV. P. 56(e); *see also Int'l Ass'n of Heat & Frost Insulators & Asbestos Workers Local Union 42 v. Absolute Envtl. Serv., Inc., et al.*, 814 F. Supp. 392, 401-02 (D. Del. 1993) (explaining summary judgment standard and burdens).

Section 112 of the patent statute describes what must be contained in the patent specification. Among other things, it must contain "a written description of the invention, and of the manner and process of making and using it . . . [such] as to enable any person of ordinary skill in the art to which it pertains . . . to make and use the same. . . ." 35 U.S.C. § 112 ¶ 1. The Federal Circuit has held that the written description requirement mandates an applicant to provide a description that "reasonably conveys" to one skilled in the art that the inventor was in possession of what is claimed as of the filing date sought. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (citation omitted). In order to show that one is "in possession," the applicant must describe the invention, with all of its claimed limitations, and not only that which makes it obvious. *Lockwood v. Am. Airlines, Inc.*, 107 F.3d 1565, 1572 (Fed. Cir. 1997). The applicant accomplishes this by using such descriptive means as "words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention." *Id.* Further, while it is not necessary for the applicant to describe the claimed subject matter in the same terms as used in the claims, "the specification must contain an equivalent description of the claimed subject matter." *Id.* (citing *Eiselstein v. Frank*, 52 F.3d 1035, 1038 (Fed.

Cir. 1995)). Lastly, "[a] description which renders obvious the invention for which an earlier filing date is sought is not sufficient" to satisfy the written description requirement. *Id.*

Alcon's contentions regarding lack of written description are based on the absence of the claim term "0.15%(w/v)" in the '834 patent specification, which the patent's prosecution history allegedly confirms. Applying the above-mentioned standards to Alcon's contentions, the court concludes that Alcon has not carried its burden with respect to invalidity, but also notes that this issue was extremely close.[8] First, as previously mentioned, the specification need only contain an "equivalent description" of the claimed subject matter, not the exact language used in the claims. *Lockwood*, 107 F.3d at 1572. Additionally, an applicant can show "equivalent description" through figures, diagrams, tables, etc. *Id.* Here, Allergan has proffered evidence, in the form of a declaration of one allegedly skilled in the art, Dr. Valentino Stella ("Dr. Stella"), in support of its contention that the language, Figure 1, and Table IV of the specification satisfy the written description requirement.

The court notes at the outset that the simple act of submitting an expert declaration, on its own, does not raise an issue of material fact. *See Univ. of Rochester v. G.D. Searle & Co., Inc.*, 358 F.3d 916 (Fed. Cir. 2004) (grant of summary judgment for the defendant affirmed even though the plaintiff submitted an expert declaration and the defendant did not); *Lockwood*, 107 F.3d at 1572 (same); *TurboCare Div. of Deman Delaval Turbomachinery Corp. v. Gen. Elec. Co.*, 264 F.3d 1111 (Fed. Cir. 2001) (same). However, *University of Rochester*, *Lockwood*, and *TurboCare* are distinguishable from the present case for the reasons that follow.

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[8] Indeed, the court was "on the fence" with respect to the written description issue for some time. However, in light of the evidence presented by parties and the fact that the trial of this matter will be a bench trial, the court is not willing to conclude at this juncture that the '834 patent is invalid for failure to satisfy the written description requirement.

In *University of Rochester*, the Federal Circuit concluded that the plaintiff's experts did not offer any evidence that the inventors were in possession of what was claimed. The court noted the district court's observation that the "'plaintiff's experts' [sic] do not say . . . that one of skill in the art would, from reading the patent, understand what compound or compounds – which, as the patent makes clear, are necessary to practice the claimed method – would be suitable nor would one know how to find such a compound except through trial and error. . . .'" *Univ. of Rochester*, 358 F.3d at 926 (citing district court opinion, *Univ. of Rochester v. G.D. Searle & Co., Inc.*, 249 F. Supp. 2d 216, 229 (W.D.N.Y. 2003)). In fact, the plaintiff's experts opined that one of skill in the art "would have known to start with existing [compounds] and would have used routine methods to make structural changes to lead compounds to optimize them." *Univ. of Rochester*, 358 F.3d at 919. The district court concluded, however, that the plaintiff's experts failed to point to any language in the patent that supported their opinions. *Id.* The Federal Circuit agreed with the district court and upheld its grant of summary judgment to the defendants.

Lockwood is distinguishable on similar grounds. In *Lockwood*, the Federal Circuit found that the plaintiff's expert in that case averred only that the disclosure, when combined with the knowledge of one of ordinary skill in the art, would lead one to determine what modifications the inventor envisioned, but failed to disclose. *Lockwood*, 107 F.3d at 1572. Moreover, the court noted that it was "undisputed" that one of the intervening applications from which the issued patent descended did not disclose the claimed features. *Id.* Thus, summary judgment of invalidity was appropriate.

Likewise, *TurboCare* is distinguishable from the instant case. In *TurboCare*, the plaintiff contended that one of ordinary skill in the art would recognized that the claimed subject matter was

"inherent in the original disclosure." *TurboCare*, 264 F.3d at 1119. To support its contention, the plaintiff offered "the conclusory statements of its expert witness." *Id.* The Federal Circuit disagreed with the plaintiff, pointing out that a disclosure was not inherent unless "the missing descriptive matter . . . [is] present in the [original] application's specification such that one skilled in the art would recognize such a disclosure." *Id.* (citation omitted). In the plaintiff's case, the disclosure was not inherent because the original specification was missing a description of the claimed embodiment. *Id.* Additionally, the court pointed out that the plaintiff admitted that the only support in the original disclosure for the claimed subject matter was language from one of the original, rejected claims. *Id.* Thus, the court agreed with the district court's finding that summary judgment for the defendant was appropriate.

In contrast, Dr. Stella concludes in the present case that "one of skill in the art would *immediately recognize* that the inventors of the '834 patent had possession of a therapeutically effective composition containing up to about 0.15% brimonidine tartrate as that claim limitation is clearly supported by the patent specification and the originally filed claims." (D.I. 73 ¶ 29.) (emphasis added). Dr. Stella then provides evidence from the '834 patent specification to support his conclusion. For example, Dr. Stella explains that Figure 1 of the patent, a solubility vs. pH plot, demonstrates that the concentration limit of brimonidine formulations represented by the graph is about 1500 ppm, or 0.15%(w/v), at the patent's most preferred pH, which is disclosed in the specification. (*Id.* ¶¶ 24-25.) Dr. Stella also states that the 0.15% amount is "clearly expressed in Table IV of the '834 patent." (*Id.* ¶ 26-27.) Because Dr. Stella points to specific language, figures and tables included in the original disclosure to support his opinions (*Id.* ¶¶ 24-28), the present case is readily distinguishable from *University of Rochester* and *Lockwood*, in which the plaintiffs'

experts concluded only that one of skill in the art would be able to speculate what the claimed subject matter was from the disclosure.

The present case is also distinguishable from *TurboCare*, for several reasons. First, Allergan does not contend that the claimed subject matter is "inherent" in the original disclosure. Rather, Allergan contends that the original disclosure repeatedly points to the 0.15%(w/v) concentration. Therefore, unlike the plaintiff in *TurboCare*, Allergan has not admitted that support for the claimed 0.15%(w/v) concentration is lacking in the original disclosure. Further, the statements in Dr. Stella's declaration are not merely "conclusory statements" of an expert witness because, as previously stated, he points to parts of the specification which allegedly offer support for his opinions. Thus, based on the evidence raised in Dr. Stella's declaration, the court concludes that a genuine issue of material fact exists with respect to whether the specification discloses to one skilled in the art the meaning of the claim term "0.15%(w/v)." Accordingly, the court will deny Alcon's motion for summary judgment.

Dated: December 6, 2005

UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

ORDER

For the reasons stated in the court's Memorandum of this same date, IT IS HEREBY ORDERED that:

1. The defendants' 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 (D.I. 56) is DENIED.

Dated: December 7, 2005

UNITED STATES DISTRICT JUDGE