d. Allergan represented and/or clearly implied that its alleged invention was patentable as an "invention of selection." That representation and/or implication was false and/or misleading because the invention of selection argument was inapplicable.

e. Allergan represented and/or clearly implied that the other "vehicles" disclosed in Burke did not have solubility enhancing properties, when it believed otherwise.

f. On information and belief, Allergan suppressed, and failed to disclose to the PTO, the best mode contemplated by the inventor(s) of carrying out the invention. Among other things, Allergan had filed a New Drug Application ("NDA") for a commercial product, which reflected the subject matter claimed by the '210 patent, shortly before filing the earliest application giving rise to the '210 patent. Whereas the NDA disclosed, *inter alia*, a "therapeutically effective aqueous composition" with brimonidine "in an amount effective to provide a therapeutic effect" and a polyanionic SEC "in an amount effective to increase the solubility of" the brimonidine, that composition was not disclosed in the '210 patent.

g. On information and belief, Allergan suppressed, and failed to disclose to the PTO, the existence of prior published information contradicting its representations with respect to adhesive properties of the "vehicles" disclosed in Burke, including, but not limited to:

   i. Greaves et al., 1992, *STP Pharma Sci.*, 2:13-33

   ii. J.D. Smart, 1984, *J. Pharmacol.*, 36:295-299

   iii. M.F. Saettone, 1984, *Int'l J. Pharmaceutics*, 20:187-202

h. On information and belief, Allergan suppressed, and failed to disclose to the PTO, information contradicting its representations with respect to the solubilizing properties of the "vehicles" disclosed in Burke.

i. On information and belief, Allergan suppressed, and failed to disclose to the PTO, other information contradicting its representations with respect to adhesive properties of the "vehicles" disclosed in Burke.

71. At the time of filing, and during the prosecution of '834 patent application, Allergan made misrepresentations and/or omissions of material facts to the Patent Examiner and the United States Patent Office, including, but not limited to:

a. Allergan represented and/or clearly implied that it was "surprising" that the concentration of active ingredient in a therapeutically effective composition could be reduced by adjusting the composition's pH closer to the pKa of the active ingredient. That representation and/or implication was false.

b. Allergan represented that it was "truly unexpected" that "a therapeutically effective dosage could be provided by a composition containing about 0.15% or less of brimonidine" at a pH greater than about 7.0. That representation was false.

c. On information and belief, Allergan suppressed, and failed to disclose to the PTO, the best mode contemplated by the inventor(s) (whether named on the '834 patent or not) of carrying out the invention. Among other things, Allergan had filed an NDA for a commercial product, which reflected the subject matter claimed by the '834 patent, shortly before filing the earliest application giving rise to the '834 patent. Whereas the NDA disclosed, *inter alia*, a therapeutically effective aqueous ophthalmic composition with 0.15% brimonidine, that composition was not disclosed in the '834 patent.

d. On information and belief, Allergan suppressed, and failed to disclose to the PTO, the existence of prior published information demonstrating the efficacy of brimonidine at concentrations of "up to about 0.15%," including, but not limited to:

i. Derick et al., 1997, *Ophthalmol.*, 104:131-136

ii. Walters T, 1996, *Survey of Ophthalmol.*, 41:S19-S26

e. On information and belief, Allergan suppressed, and failed to disclose to the PTO, the existence of prior published information demonstrating the effect of pH on drug bioavailability, including, but not limited to:

i. Olejnik, O., 1992, Ophthalmic Drug Delivery Systems (Ashim Mitra, ed.) pp. 177-198.

ii. Wilson et al., 1981, *J. Pharm. Pharmacol.*, 31:749-53.

iii. Small et al., 1997, *Int'l J. Pharmaceutics*, 149: 195-201.

iv. Chien et al., 1990, *Current Eye Res.*, 9:1051-1059.

72. At the time of filing, and during the prosecution of the '337 patent application, Allergan made misrepresentations and/or omissions of material facts to the Patent Examiner and the United States Patent Office, including, but not limited to:

a. Allergan represented that "nothing in Burke discloses or suggests the use of a solubility enhancing component in combination with an alpha adrenergic agonist." Allergan clearly understood that Burke disclosed an alpha adrenergic agonist in combination with a "vehicle," and failed to disclose its belief that nearly all of the "vehicles" disclosed in Burke functioned as solubility enhancing components (albeit not labeled as such).

b. Allergan represented and/or clearly implied that its patent application was, to the Applicants' knowledge, the first reference to disclose the advantages of using a solubility enhancing component, "such as greater flexibility with the concentration and pH at which such composition is formulated." That representation and/or implication was false.

c. On information and belief, Allergan suppressed, and failed to disclose to the PTO, the best mode contemplated by the inventor(s) of carrying out the invention. Among other things, Allergan had filed an NDA for a commercial product, which reflected the subject matter claimed by the '337 patent, shortly before filing the earliest application giving rise to the '337 patent. Whereas the NDA disclosed, *inter alia*, a "therapeutically effective aqueous composition" with brimonidine "in an amount effective to provide a therapeutic effect" and an SEC "in an amount effective to increase the solubility of" the brimonidine, that composition was not disclosed in the '337 patent.

d. On information and belief, Allergan suppressed, and failed to disclose to the PTO prior published information contradicting its representation that, to the Applicants' knowledge, the '337 patent's specification was the first reference to disclose the advantages of using a solubility enhancing component, "such as greater flexibility with the concentration and pH at which such composition is formulated," including, but not limited to, the references identified in paragraphs 70 and 71.

73. The representations and/or omissions set forth in paragraphs 70, 71 and 72 were false and/or misleading.

74. The representations and/or omissions set forth in paragraphs 70, 71 and 72 were material to the prosecution of the '210, '834 and/or '337 patents.

75. The representations and/or omissions set forth in paragraph 70 were material to the prosecution of the '210, '834 and '337 patents.

76. The representations and/or omissions set forth in paragraph 71 were material to the prosecution of the '210, '834 and '337 patents.

77. The representations and/or omissions set forth in paragraph 72 were material to the prosecution of the '337 patent.

78. The representations and/or omissions set forth in paragraphs 70, 71 and 72 were known, or should have been known, by Allergan to be false and/or misleading prior to the issuance of the '210, '834 and/or '337 patents.

79. Allergan knew, or should have known, that the representations and/or omissions set forth in paragraphs 70, 71 and 72 were material to the prosecution of the '210, '834 and/or '337 patents.

80. The representations and/or omissions set forth in paragraphs 70, 71 and 72 were made with the intent to, and/or did, deceive the PTO, and were intended to, and/or did, induce the issuance of the '210, '834 and/or '337 patents.

81. Allergan (including, without limitation, its inventors, attorneys, and/or others involved in the filing and/or prosecution of the '210, '834 and/or '337 patents) owed a duty of candor and good faith to the United States Patent and Trademark Office.

82. The first named inventor of the '210, '834 and '337 patents, Orest Olejnik, owed a duty of candor and good faith to the United States Patent and Trademark Office.

83. An attorney who prosecuted the '210, '834 and '337 patents for Allergan, Carlos A. Fisher, owed a duty of candor and good faith to the United States Patent and Trademark Office.

84. Allergan (including, without limitation, its inventors, attorneys, and/or others involved in the filing and/or prosecution of the '210, '834 and/or '337 patents) breached that duty of candor and good faith.

85. The first named inventor of the '210, '834 and '337 patents, Orest Olejnik, breached his duty of candor and good faith to the United States Patent and Trademark Office.

86. An attorney who prosecuted the '210, '834 and '337 patents for Allergan, Carlos A. Fisher, breached his duty of candor and good faith to the United States Patent and Trademark Office.

First Counterclaim For Declaratory Relief

87. Alcon repeats and realleges the allegations of paragraphs 33 through 86 hereof as though fully set forth herein.

88. Alcon's proposed brimonidine product will not infringe, contribute to, or induce infringement of any claims of the '834 patent, literally or under the doctrine of equivalents.

Second Counterclaim For Declaratory Relief

89. Alcon repeats and realleges the allegations of paragraphs 33 through 86 hereof as though fully set forth herein.

90. The '834 patent is invalid for failure to comply with one or more requirements of Title 35, U.S.C. sections 102, 103, 112 and/or 256.

Third Counterclaim For Declaratory Relief

91. Alcon repeats and realleges the allegations of paragraphs 33 through 86 hereof as though fully set forth herein.

92. The '834 patent is unenforceable for inequitable conduct and/or unclean hands.

Fourth Counterclaim For Declaratory Relief

93. Alcon repeats and realleges the allegations of paragraphs 33 through 86 hereof as though fully set forth herein.

94. Alcon's proposed brimonidine product will not infringe, contribute to, or induce infringement of any claims of the '337 patent, literally or under the doctrine of equivalents.

Fifth Counterclaim For Declaratory Relief

95. Alcon repeats and realleges the allegations of paragraphs 33 through 86 hereof as though fully set forth herein.

96. The '337 patent is invalid for failure to comply with one or more requirements of Title 35, U.S.C. sections 102, 103, and/or 112.

Sixth Counterclaim For Declaratory Relief

97. Alcon repeats and realleges the allegations of paragraphs 33 through 86 hereof as though fully set forth herein.

98. The '337 patent is unenforceable for inequitable conduct and/or unclean hands.

Seventh Counterclaim For Declaratory Relief

99. Alcon repeats and realleges the allegations of paragraphs 33 through 86 hereof as though fully set forth herein.

100. Allergan is barred from recovery for unclean hands.

DEMAND FOR JUDGMENT

WHEREFORE, Alcon respectfully requests:

A. On the Complaint of Allergan, Inc. and Allergan Sales, LLC. (collectively "Allergan") against Alcon:

1. that judgment be entered against Allergan, and in favor of Alcon;

2. that Allergan not be awarded any of the relief it seeks in this action;

3. that no Order be issued under 35 U.S.C. §271(e)(4)(A) affecting FDA approval of Alcon's NDA No. 21-764;

4. that no injunction be entered against Alcon, its officers, agents, servants or employees;

5. that judgment be entered declaring that Alcon has not infringed, and will not infringe, and is not and will not be liable for any infringement of, any claim of United States Patent No. 6,641,834 (the "'834 patent") as the result of the making , using or selling of its proposed brimonidine product;

6. that judgment be entered declaring that Alcon has not infringed, and will not infringe, and is not and will not be liable for any infringement of, any claim of United States Patent No. 6,673,337 (the "'337 patent") as the result of the making , using or selling of its proposed brimonidine product;

7. that judgment be entered declaring the '834 patent is invalid;

8. that judgment be entered declaring the '834 patent is unenforceable;

9. that judgment be entered declaring the '337 patent is invalid;

10. that judgment be entered declaring the '337 patent is unenforceable;

11. that judgment be entered declaring Allergan is barred from recovery for unclean hands.

B. On Alcon's First Counterclaim, that judgment be entered declaring that Alcon has not infringed and will not infringe, and is not and will not be liable for any infringement of, any claim of United States Patent No. 6,641,834 (the "'834 patent")

C. On Alcon's Second Counterclaim, that judgment be entered declaring that each claim of United States Patent No. 6,641,834 (the "'834 patent") is invalid;

D. On Alcon's Third Counterclaim, that judgment be entered declaring that United States Patent No. 6,641,834 (the "'834 patent") is unenforceable;

E. On Alcon's Fourth Counterclaim, that judgment be entered declaring that Alcon has not infringed and will not infringe, and is not and will not be liable for any infringement of, any claim of United States Patent No. 6,673,337 (the "'337 patent");

F. On Alcon's Fifth Counterclaim, that judgment be entered declaring that each claim of United States Patent No. 6,673,337 (the "'337 patent") is invalid;

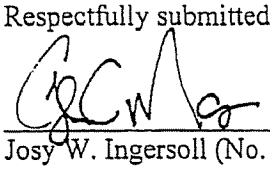
G. On Alcon's Sixth Counterclaim, that judgment be entered declaring that United States Patent No. 6,673,337 (the "'337 patent") is unenforceable;

H. On Alcon's Seventh Counterclaim, that judgment be entered declaring that Allergan is barred from recovery for unclean hands;

I. That this case be declared exceptional and that Alcon be awarded its attorney's fees, costs, and expenses; and

J. That Alcon be awarded such other and further relief as this Court may deem just and proper.

Respectfully submitted,



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July 25, 2005

EXHIBIT B

REDACTED IN ITS ENTIRETY

EXHIBIT C

COPY

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC., and ALLERGAN SALES, LLC,	)	
Plaintiffs,	)	Case No.
vs.	)	04-968-GMS
ALCON, INC., ALCON LABORATORIES, INC., and ALCON RESERACH, LTD.,	)	
Defendants.	)	

VIDEOTAPED DEPOSITION OF CARLOS A. FISHER

Irvine, California

Wednesday, July 20, 2005

Reported by Jana J. Bommarito, CSR No. 10880

11:54:55 BY MR. THOMASCH:

11:54:55 Q Do you know -- yes or no, do you know what
11:54:57 work was done or directed by Dr. Olejnik as being
11:55:02 made reference to in the Declaration that you cite
11:55:06 in your Reply?

11:55:10 MS. BROOKS: Same -- same objection and
11:55:11 instruction.

11:55:12 THE WITNESS: I -- I cannot disclose any
11:55:15 information concerning that because it involves
11:55:22 privileged attorney-client communications.

11:55:26 BY MR. THOMASCH:

11:55:26 Q I'm only asking you whether you know what
11:55:28 it is, not what it is.

11:55:31 MS. BROOKS: But the content is implicit in the
11:55:34 question, and, therefore, the attorney-client
11:55:36 privilege applies. If he were to answer that
11:55:41 question --

11:55:42 MR. THOMASCH: Are you directing him not to
11:55:43 answer?

11:55:44 MS. BROOKS: If -- if -- I am cautioning the
11:55:45 witness if he can answer without revealing
11:55:47 attorney-client communications, he should feel free
11:55:50 to do so. If not, then I am instructing him not to
11:55:53 answer.

11:55:54 THE WITNESS: And I cannot.

EXHIBIT D

OIPE JC54 MAR 17 2003

DOCKET NO. 17361 (AP)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of Olejnik, et al.

Serial No: 09/904,018

Filed: July 10, 2001

For: COMPOSITIONS CONTAINING ALPHA-2-ADRNERGIC AGONIST COMPONENTS

Group Art Unit: 1626

Examiner: Bennett, R.

RECEIVED
MAR 24 2003
TECH CENTER 1600/2900

DECLARATION OF OREST OLEJNIK, Ph.D.

Dear Sir,

I, Orest Olejnik, Ph.D., hereby declare as follows:

1. I received a B.Sc. degree in Pharmacy, with honors, from the Sunderland School of Pharmacy, England in 1977. In 1981 I was awarded a Ph.D. in Pharmaceutics by the University of Nottingham, Nottingham, England.

2. I have worked in the pharmaceutical development field as a pharmacist and in various managerial capacities since 1977. From 1991-1999 I was Director of Pharmaceutical Development at Allergan, Inc., in Irvine, California. I presently hold the position of Vice President of Pharmaceutical Sciences at Allergan.

3. I am a co-inventor of the present patent application 09/904,018, entitled "Compositions Containing Alpha-2-Adrenergic Agonist Components". I understand that the formerly pending claims were rejected under 35 USC 103 as obvious over US Patent 5,215,991 (the "Burke" patent) in view of Remington's Pharmaceutical Sciences, cited in the Form PTO-892 as part of Paper No. 7. I have reviewed each of these references.

4. The Burke patent references the presently claimed alpha-2-agonist 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline ("brimonidine"). The Burke patent discloses a multitude of different ingredients that may be contained in formulations containing brimonidine; among these are mentioned optional "vehicles" which may include, without limitation, polyvinyl alcohol, povidone (polyvinylpyrrolidone), hydroxypropylcellulose, poloxamers, carboxymethylcellulose (CMC), and

hydroxyethylcellulose. See Burke, column 5, line 28-34. Burke is silent concerning the purpose of these prospective vehicles.

5. Remington discloses that these listed polymers, including CMC, may be used as viscosity-increasing agents.

6. Neither Burke nor Remington discloses that CMC would have any characteristics that would motivate a person of ordinary skill in the art to choose it over other polymers in formulating a brimonidine solution.

7. Unlike the other listed polymers (polyvinyl alcohol, povidone (polyvinylpyrrolidone), hydroxypropylcellulose, poloxamers, and hydroxyethylcellulose), CMC is anionic at pH 7 or greater. The other listed polymers are non-ionic polymers. I have discovered as a result of work done and/or directed by me at Allergan that CMC possesses the surprising advantages of both increasing the solubility of brimonidine in solution, as shown in Table 1, and causing such solutions to have superior adherence to cell surfaces, including ocular surfaces such as the cornea. Polyvinyl alcohol was found not to possess both of these properties. Increased adherence of the CMC solution is particularly surprising given the fact that the corneal surface is negatively charged; one would expect less adherence in such a solution due to electrostatic repulsion, rather than increased adherence. This surprising result may be due to repulsive forces between the polymer and the cornea orienting the hydrophilic portions of the molecule away from the cornea, thus permitting the hydrophobic domains of these polymers to form an interaction with the lipid portion of the cell surface. With such increased adherence, the active ingredient in solution is placed in contact with the cell surface longer than would otherwise be the case.

8. 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.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under §1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Sincerely yours,

Orest Olejnik, Ph.D.

CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire hereby certify that on January 31, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

William J. Marsden, Jr., Esquire
Fish & Richardson, P.A.
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Wilmington, DE 19801

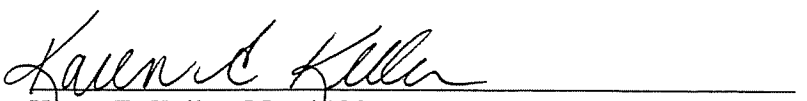
I further certify that on January 31, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above captioned individual and upon the following non-registered participants in the manner indicated:

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CERTIFICATE OF SERVICE

I, Karen E. Keller, Esquire hereby certify that on February 2, 2006, I caused to be electronically filed a true and correct copy of the foregoing document with the Clerk of the Court using CM/ECF, which will send notification that such filing is available for viewing and downloading to the following counsel of record:

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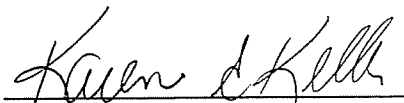
I further certify that on February 2, 2006, I caused a copy of the foregoing document to be served by hand delivery on the above captioned individual and upon the following non-registered participants in the manner indicated:

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