Exhibit B

ORRICK

ORRICK, HERRINGTON & SUTCLIFF LLP
666 FIFTH AVENUE
NEW YORK, NY 10103-0001
tel 212-506-5000
fax 212-506-5151
WWW.ORRICK.COM

December 1, 2004

212-506-5106
vmullally@orrick.com

VIA FACSIMILE

Michael Kane
Fish & Richardson P.C.
3300 Dane Rauscher Plaza
60 South Sixth Street
Minneapolis, Minnesota 55402

Re: ***Allergan Inc. v. Alcon Inc.*, 04-968-GMS**

Dear Michael:

Thank you for you letter of this date. We can confirm our availability to participate in a conference call on December 3, 2004 at 2.00 p.m. (EST). We can also confirm that the summary judgment motion that Alcon intends to file be limited to two arguments: (1) the claims of the '834 patent are invalid for lack of written description under 35 U.S.C. §112 because there is no support for the limitation "up to about 0.15%," and (2) the '337 patent will not be infringed by Alcon's proposed product because it does not contain the anionic solubility enhancing component required by the claims.

Given the narrow focus of our intended "early" summary judgment motion, we expect that Allergan will be able to narrow the discovery needed to oppose the motion and that you will be ready to specify exactly what that discovery is when we talk on Friday.

Sincerely,

Veronica Mullally

M. Veronica Mullally

cc: John Shaw

DOCSNY1:1086868.1
11716-2004 VM2

ORRICK

ORRICK, HERRINGTON & SUTCLIFFE LLP
666 FIFTH AVENUE
NEW YORK, NY 10103-0001
tel 212-506-5000
fax 212-506-5151
WWW.ORRICK.COM

FAX TRANSMISSION

DATE 12/1/04

NO. OF PAGES (INCLUDING COVER SHEET) 2

FROM

name	tel
M. Veronica Mullally, Esq.	(212) 506-5106

TO

name	company/firm	tel	fax
Michael Kane, Esq.	Fish & Richardson, P.C.	612-337-2502	612-288-9696

RE Allergan v. Alcon

MESSAGE

C-M-A 11716.2004 6459 Originals Will Not Follow

IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL ANOUCHE MARDIROSSIAN AT 212-506-5067 AS SOON AS POSSIBLE.

notice to recipient

THE INFORMATION CONTAINED IN THIS FACSIMILE TRANSMISSION IS INTENDED TO BE SENT ONLY TO THE STATED ADDRESSEE OF THE TRANSMISSION. IT MAY BE PROTECTED FROM UNAUTHORIZED USE OR DISSEMINATION BY THE ATTORNEY-CLIENT PRIVILEGE, THE ATTORNEY WORK-PRODUCT DOCTRINE, OR ANY OTHER APPLICABLE PRIVILEGE. IF YOU ARE NOT THE STATED ADDRESSEE, YOUR RECEIPT OF THIS TRANSMISSION WAS UNINTENDED AND INADVERTENT, AND YOU ARE HEREBY NOTIFIED THAT ANY REVIEW, USE, DISSEMINATION, DISTRIBUTION, OR COPYING OF THIS COMMUNICATION IS STRICTLY PROHIBITED. YOU ARE ALSO ASKED TO NOTIFY US IMMEDIATELY BY TELEPHONE AND TO RETURN THE ORIGINAL DOCUMENT TO US IMMEDIATELY BY MAIL AT THE ADDRESS ABOVE. THANK YOU IN ADVANCE FOR YOUR COOPERATION.

DOCSNY1:1086596.1

11716-2004 VM2

Exhibit C

IN THE UNITED STATES DISTRICT COURT
IN AND FOR THE DISTRICT OF DELAWARE

- - -

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

- - -

Wilmington, Delaware
Wednesday, December 15, 2004
3:00 p.m.
In Chambers

- - -

BEFORE: HONORABLE GREGORY M. SLEET, U.S.D.C.J.

APPEARANCES:

WILLIAM J. MARSDEN, JR., ESQ.
Fish & Richardson P.C.
-and-
JUANITA R. BROOKS, ESQ. (San Diego, California),
JONATHAN E. SINGER, ESQ., and
MICHAEL J. KANE, ESQ.
Fish & Richardson, P.C., P.A.
(Minneapolis, Minnesota)

Counsel for Plaintiffs

JOHN W. SHAW, ESQ.
Young Conaway Stargatt & Taylor, LLP
-and-
DANIEL J. THOMASCH, ESQ.,
M. VERONICA MULLALLY, ESQ., and
BRIAN D. COGGIO, ESQ.
Orrick, Herrington & Sutcliffe LLP
(New York, New York)

Counsel for Defendants

MR. MARSDEN: Your Honor, William Marsden. I apologize for the delay. We had a little mixup with the operator. This is William Marsden from Fish & Richardson for Allergan. I have with me on the line other lead trial counsel, Juanita Brooks, John Singer and Michael Kane.

THE COURT: Good afternoon, all.

(Counsel respond "Good afternoon.")

MR. SHAW: Your Honor, John Shaw for defendants at Young Conaway. In New York is Daniel Thomasch and Veronica Mullaley, who you met at the scheduling conference, and Brian Coggio.

THE COURT: Good afternoon.

I understand there is a small difference regarding the positioning of an item on the schedule.

MR. THOMASCH: Yes, Your Honor. It relates to our request, and that is the defendant Alcon's request for permission to file a summary judgment motion, specifically two summary judgment motions on the two patents at issue. There was discussion at the conference on November 22nd about the possibility that we would attempt to accelerate the timing of those two summary judgment motions, in return for which we voluntarily agreed that if we could do so we would agree not to bring any further summary judgment motions in the course of the litigations if we did not prevail on the two that we would bring on a more expedited basis.

To very briefly refresh Your Honor, one of the two summary judgment motions dealt with the claim construction to be given to one term in the patent, and the entire body of evidence that will be used to base that argument will be the intrinsic evidence itself of the file wrapper and the specification and the claims. And that is the entirety of the evidence we will rely on to define that. That will be evidence coming from the patent in suit and the parent patent.

The second motion relates to an allegation of lack of written description about the term .15 percent. That is obviously a mathematical term. Everyone knows what .15 percent is. The question is whether or not the claimed limitations that use .15 percent are supported by the specification.

We think both motions are very straightforward. We understand that plaintiffs think neither is well-founded and will oppose on both.

That's what the summary judgment process would be about. We would seek permission to make that motion on the 24th of January. We believe that we could provide plaintiff with a one-month period to oppose that motion, which I believe would be the 21st of February. If we took a month to reply, that would be the 21st of March, then have a hearing on the first convenient date for the Court in the month of

April.

That would be the schedule we would propose. Our product is slated to be approved by the FDA or otherwise approvable by the FDA in late February of this year. And that is the reason why we believe it is essential for us to try to present these crisp legal issues as early as possible, so that if we are correct and if we are properly approvable, that we could get on the market without further prejudice.

THE COURT: When you say a hearing, are you talking about a Markman hearing?

MR. THOMASCH: It would be a summary judgment argument. Imbedded in that argument would be a construction of one term, the term solubility enhancing component as used in that patent. And it's really a binary consideration, Your Honor. There are anionic and ionic solubility enhancing components. We say that, as used in the patent, the requirement is that it be an anionic solubility enhancing component. If we are right, we don't use that, we don't infringe and there will be no disputed fact. If we are wrong, then there will be disputed facts that would require going to trial, and we would proceed in that direction without further summary judgment motion.

THE COURT: So the disagreement, then, is over the timing, over the schedule you have presented. And I take it plaintiff has a different schedule in mind?

MR. THOMASCH: The plaintiff has a different schedule in mind. It has, in our discussions to date, indicated that there is additional discovery that they would wish out of our files that would relate to --

THE COURT: Let's hear from plaintiff. Go ahead.

MR. MARSDEN: I believe Juanita Brooks will address this issue for us.

MS. BROOKS: Yes, Your Honor. I believe it was addressed before Your Honor at the original case management conference. Your Honor has already set a date for this summary judgment motion.

THE COURT: Did we? I don't have that.

MR. THOMASCH: Your Honor, it is Pages 37 and 38 of the transcript.

THE COURT: Okay.

MR. THOMASCH: After discussion about dates, we asked whether there was an opportunity to try to work between ourselves to decide if we could reach a date agreement and if not could we submit letters to the Court. And you responded at the bottom of Page 37: I don't want letters back. You can contact chambers by phone if you can't agree and we will set a teleconference.

And you repeated that on Page 38. We have had discussions between us. We have not reached an agreement

and, we are availing ourselves of the relief, the procedure that you laid out at Page 37 and 38 of the transcript.

THE COURT: If that's what I said, that's what I said.

Plaintiff, let's hear from you.

MS. BROOKS: Yes, Your Honor.

I was going to say that there has already been a date set.

Mr. Kane, perhaps you can give the specific date.

MR. KANE: Yes, Your Honor. As you may recall, again, on Page --

THE COURT: Counsel, I don't recall any of this. I do recall the expedited process that we discussed.

MR. KANE: Let me read. We did have a discussion. I think we had proposed, the plaintiff had proposed an original Markman date of June 6. You said you had an available date on June 7. After this discussion of a potential early summary judgment, it was proposed that June 7th be a date. Mr. Shaw, in fact -- there was further discussion as to whether it could happen even earlier. Mr. Shaw said could we put June 7 on our calendar so we don't lose that. You said, it's on the calendar, June 7th, at 9:30.

THE COURT: I remember that.

MS. BROOKS: That is the date I was talking

about. I apologize I didn't quite get to finish. The issue now, Your Honor, is whether to have a hearing prior to the June 7th date on the two issues that defendants have laid out.

Our position is that, especially as to the written description, it is by no means simply a straightforward legal issue. Written description is always taken in the context of and from the viewpoint of one of skill in the art. And the most recent case from the Fed Circuit, the Metabolite case, at 370 F.3rd, 1354, discussed this very issue, that the record had established, quote, from the viewpoint of one of skill in the art that physicians in Homeless 15 research, that is people of ordinary skill in the art understood from the specification that the inventors possessed -- in this case the issue was correlating steps at the time they filed the patent application. The bottom line is what the Court found extremely persuasive in that case was that the defendant's own expert and employees understood the meaning of the term. And therefore, the Court found there was substantial evidence to support in this case the jury's finding that the claim was adequately supported by the written description.

What we are asking for is an opportunity to establish that very same evidence. We have already propounded discovery. We propounded it three and a half

weeks ago. Our position is that if defendants are interested in expediting this, then answer the discovery, give us an opportunity to take the depositions of the, quote, defendants' own employees to determine whether or not one of skill in the art believes that the claim is supported by the specification. It can't be done without the taking of testimony. And we can't get that done within the time frame that the defendants have asked for.

MR. THOMASCH: Your Honor --

THE COURT: I don't need to hear from you, counsel. I doubt very seriously I can accommodate your request for an April hearing. You just have to wait a second.

(Pause.)

THE COURT: Counsel, you were about to say?

MR. THOMASCH: I was only going to briefly say, Your Honor, whether or not our motion could be argued that way is a matter for the Court ultimately to decide. We believe that what is different about this case is that the term being interpreted is .15 percent, that there isn't a dispute about how to interpret 15 one-hundredths of a percent. It is a mathematical term. The question is whether that mathematical term in the claim --

THE COURT: You know, counsel, let me interrupt. I don't think the Court should be put to the task at this

point of trying to determine the merits of whether you should be permitted to bring a dispute, given that we are just trying to work out a schedule.

The plaintiff puts the proposition thusly: that it is not as straightforward as you make it sound. Consequently, I am not going to invest a lot of my energy and time at this point trying to figure out whether you are right or whether she is wrong. What I am going to do is what we originally said we would do, that is, have a hearing on June 7th.

Why would you feel that it would be appropriate for me to put the plaintiff at a disadvantage, an evidentiary disadvantage, at this early stage of these proceedings? Could you tell me why?

MR. THOMASCH: Because --

THE COURT: Other than the fact you want to get to market.

MR. THOMASCH: No, Your Honor. I believe in our position, Rule 56(f) provides the procedure under the Federal Rules to oppose summary judgment in the absence of sufficient discovery. We run a substantial risk by making the motion without giving them the discovery because we could lose this procedurally without you ever reaching the merits if we are wrong. All they have to establish at the time that you agree to hear the motion is that they had a right to the discovery

and didn't get it, in which case we lose, and we understand we lose.

THE COURT: What do you say about that, counsel in opposition?

MS. BROOKS: Your Honor, why are we going to go through an exercise in futility? Indeed, if they file this motion prematurely, we will, indeed, argue that under 56(f) the Court should deny the motion. Then we will be back on June 7 to argue it.

THE COURT: It puts the Court in a position of spinning its wheels and utilizing its limited resources, much more limited than counsel on the phone on either side, inefficiently.

MR. THOMASCH: Your Honor, may we make it clear that on June 7th we will have, in advance of that, fully briefed the summary judgment motions and have that as the return date for the combined Markman hearing and summary judgment motion argument.

THE COURT: Counsel, I am not going to revisit the scheduling conference. What did we decide upon at the time of the scheduling conference?

MR. THOMASCH: Your Honor, on the scheduling conference --

THE COURT: I would like to hear from someone else, counsel.

MR. SHAW: Your Honor, at the scheduling conference, you had set June 7th as the Markman hearing. Mr. Kane had suggested perhaps we could do the combined summary judgment motion/Markman hearing on that date. There is some discussion about that. And we left the scheduling conference with the issue of the parties go back and see if the June 7 date would work for the combined hearing or something earlier could be worked out. But we didn't establish the June 7 date for anything more than the Markman hearing at that time.

THE COURT: That is what we agreed upon. We would have a Markman hearing on this one disputed term. Is that correct?

MR. THOMASCH: I understood it to be we would have both, unless the parties could agree to an earlier summary judgment or the Court ordered one in response to a teleconference.

THE COURT: I don't normally hold summary judgment hearings, counsel.

MR. THOMASCH: I understand, Your Honor.

THE COURT: I don't combine summary judgment with Markman.

MR. THOMASCH: Right. On June 7th.

THE COURT: I don't combine as a matter of practice, unlike the Chief Judge --

MR. THOMASCH: I actually thought at the

conference on November 22nd you specifically thought about utilizing the procedure that Judge Robinson uses.

THE COURT: I may have said that. I am explaining to you what my normal practice is. You need to convince me why I should deviate from that.

MR. THOMASCH: I think that the discussion from November 22nd was that this was, these were straightforward motions and if we could do them early, it would expedite the case --

THE COURT: If I had an agreement -- you know, counsel, the reporter is only taking down my voice. You can't talk over me. You won't get on the record.

MR. THOMASCH: I am sorry, Your Honor.

THE COURT: Open your ears.

What I am sure -- perhaps I said it inartfully. I would have wished that counsel had been able to agree before I agreed to engage a process that I am uncomfortable with. Counsel do not agree that the summary judgment process should be combined with the Markman process. Do I understand that correctly? Am I misstating plaintiffs' position?

MS. BROOKS: No, Your Honor. I will let Mr. Kane and Mr. Singer address that, since they were at the hearing.

THE COURT: Whoever wants to speak up here.

MR. SINGER: Your Honor, we would be able to do it on the June 7th date.

THE COURT: That's when we will do it. And that's when it seems to me it makes sense to do it. Plaintiff can't then complain, counsel for defense, that they have been unfairly positioned from the standpoint of discovery. And more to the point, the Court will have not needlessly expended resources that it shouldn't have expended in the first place.

What you need to do is repair back to the conference table and agree upon a round of briefing or whatever you must do, including discovery, to tee the matter up for June 7th. Okay?

(Counsel respond "Thank you.")

- - -

(Court recessed at 3:25 p.m.)

Reporter: Kevin Maurer

Exhibit D

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED
No. 7001 0360 0000 3739 2601 (Allergan, Inc.)
No. 7001 0360 0000 3739 2595 (Allergan Sales, Inc.)

6201 South Freeway
Fort Worth, Texas 76134-2099
(817) 293-0450

Direct Line: (817) 551-3066
Telefax No: (817) 551-4610

July 6, 2004

Allergan, Inc.
2525 Dupont Drive
Irvine, CA 92612

Allergan Sales, Inc.
2525 Dupont Drive
Irvine, CA 92612

Re: U.S. Patent Nos. 5,424,078; 6,562,873; 6,627,210; 6,641,834; and 6,673,337

Dear Sirs:

The above-referenced patents are identified in the Orange Book as covering Allergan's Alphagan®P (brimonidine tartrate ophthalmic solution) 0.15%. Pursuant to Section 505(b)(3)(B) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. §355(b)(3)(B)), the purpose of this letter is to notify Allergan, Inc. as holder of the approved application and the owner of record of U.S. Patent Nos. 5,424,078; 6,627,210; 6,641,834 and 6,673,337, and Allergan Sales, Inc. as owner of record of U.S. Patent No. 6,562,873 (collectively, "Allergan") that Alcon, Inc. ("Alcon") has filed a certification under 21 CFR 314.50(i)(1)(i)(A)(4) ("Paragraph IV certification") with the United States Food and Drug Administration (FDA) regarding the above-referenced patents.

A 505(b)(2) application directed to a brimonidine tartrate ophthalmic solution 0.15% has been submitted by Alcon and has been filed by the FDA.

The FDA has acknowledged receipt of Alcon's 505(b)(2) application. The number assigned to Alcon's application by the FDA is NDA 21-764.

The established name of the proposed drug product is Brimonidine Tartrate Ophthalmic Solution 0.15% (hereinafter referred to as "Alcon's Proposed Product").

The active ingredient in Alcon's Proposed Product is brimonidine tartrate, present at a concentration of 0.15% by weight. Alcon's Proposed Product is formulated as a topically administrable aqueous solution.

The only indication for which Alcon seeks FDA approval concerning Alcon's Proposed Product is "the lowering of intraocular pressure in patients with open-angle glaucoma or ocular hypertension."

Alcon has certified that the following patents are invalid and/or will not be infringed by Alcon's Proposed Product: U.S. Patent Nos. 5,424,078; 6,562,873; 6,627,210; 6,641,834; and 6,673,337, which, according to the Orange Book, will expire on June 13, 2012; July 10, 2021; July 18, 2021; July 28, 2021; and July 26, 2021, respectively. The Orange Book also indicates that each of these expiration dates is extended by six months due to a pediatric exclusivity extension award.

The factual and legal grounds for Alcon's certification of invalidity and/or noninfringement under 35 U.S.C. § 271(e)(2) of the subject patents are as follows.

1. **U.S. Patent No. 5,424,078**

The '078 patent contains a total of eighteen claims. Four of the eighteen claims are independent claims: Claims 1, 7, 8, and 18. Claims 1 and 7 recite, in part, methods of preserving an aqueous ophthalmic formulation comprising incorporating into the formulation stabilized chlorine dioxide in an amount effective to act as the sole preservative in the formulation, provided that no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers are incorporated into the formulation. Claims 8 and 18 recite, in part, preserved ophthalmic formulations comprising stabilized chlorine dioxide in an amount effective to act as the sole preservative in the formulation, provided that no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers are incorporated into the formulation.

The file history of the '078 patent makes it unmistakably clear that the claims of the '078 patent cannot be construed to cover any composition that contains a germicidally effective amount of a positively charged, nitrogen-containing cationic polymer. See, for example, Allergan's remarks submitted to the PTO with Amendment A dated Feb. 27. 1992, in which Allergan added to Claim 1 the express limitation that the claimed composition is free of germicidally effective amounts of any positively charged, nitrogen containing cationic polymers. ("...The present invention is based on the discovery that stabilized chlorine dioxide is effective as the sole preservative...These preserved formulations include no germicidally effective amounts of any positively charged, nitrogen-containing cationic polymers, such as those disclosed as being required in the cited Stockel et al. patents. The preserved formulations of the present invention are free of germicidally effective amounts of such positively charged, nitrogen-containing cationic polymers, which can result in eye irritation or discomfort" (page 4). "...Stockel et al. U.S. Patent 4,499,077 teaches a solution of Onamer M (a positively charged, nitrogen-containing cationic polymer) and stabilized chlorine dioxide....The Stockel et al. patents teach that germicidally effective amounts of positively charged, nitrogen-containing cationic polymers are required and, therefore, actually teach away from the present invention which involves methods and formulations in which no germicidally effective amounts of such polymers are used or are present" (pages 6 – 7)). See also Allergan's Amendment B dated July 13, 1992 at page 3; Allergan's Appellant's Brief dated September 18, 1992, at pages 2 and 6; and Allergan's Reply Brief dated December 23, 1992, at page 3. Alcon's Proposed Product contains a germicidally effective amount of polyquaternium-1 (Onamer M), which Allergan has

characterized as a positively charged, nitrogen-containing cationic polymer – the very type that Allergan expressly excluded from the claims of the '078 patent. Consequently, Alcon's Proposed Product cannot literally infringe the claims of the '078 patent.

Moreover, every claim of the '078 patent requires a stabilized chlorine dioxide component and Alcon's Proposed Product does not contain stabilized chlorine dioxide. Thus, for this independent reason as well, there is no literal infringement.

In addition, there is no infringement under the doctrine of equivalents because Allergan cannot recapture as an equivalent what it has expressly disclaimed during the prosecution history. See Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 978 (Fed. Cir. 1999). Therefore, because Alcon's Proposed Product does not contain stabilized chlorine dioxide and does contain a germicidally effective amount of a positively charged, nitrogen-containing cationic polymer, it does not infringe the '078 patent either literally or by equivalents.

Moreover, if any claim of the '078 patent were construed to cover a formulation, such as Alcon's Proposed Product, that lacks stabilized chlorine dioxide and contains a germicidally effective amount of a positively charged, nitrogen-containing cationic polymer, such claim would be invalid as anticipated by prior art, including, but not limited to, U.S. Patent No. 4,407,791. The '791 patent, issued October 4, 1983, discloses the use of "Onamer M" (i.e., polyquaternium-1), a positively charged, nitrogen-containing cationic polymer, as a preservative for ophthalmic compositions used for treatment of glaucoma.

2. U.S. Patent No. 6,562,873

The '873 patent contains forty-nine claims, four of which are independent: Claims 1, 28, 32, and 35. Claims 1, 28 and 32 recite compositions that require, in addition to a specified drug and a solubility enhancing component ("SEC"), either an oxy-chloro component or a chlorite component in an effective amount to at least aid in preserving the composition. Claim 35 recites a composition that requires, in addition to a drug and a liquid carrier that is substantially free of cyclodextrins, an oxy-chloro component in an effective amount to at least aid in preserving the composition.

All claims of the '873 patent expressly require an oxy-chloro or a chlorite preservative component. During prosecution of the application that lead to the '873 patent, Allergan argued that "[a]n important aspect of the invention is that the compositions comprise a therapeutically active component and both a solubility enhancing component and an oxy-chloro component to render the therapeutically active component more effective." See Response to Restriction Requirement dated January 25, 2002 (page 2, third paragraph, second sentence) (emphasis added). In the same paper at page 3, first full paragraph, Allergan argued that "[o]ne important feature of the invention is that a solubility enhancing component and an oxy-chloro component is [sic] used together in a composition to enhance the therapeutic effects of a therapeutically active component." (emphasis in original). Allergan concluded that: "[t]he main point ... is that compositions comprising a combination of solubility enhancing components (other than cyclodextrin) and an oxy-chloro components are effective to enhance the therapeutic effects of a therapeutically active component." (emphasis in original).

In responding to a rejection of some of the claims in the application that led to the '873 patent, Allergan attempted to distinguish U.S. Patent No. 5,719,197 (Kanios et al.) from the

pending claims by arguing that "Kanios et al. fails to teach or even suggest an oxy-chloro component in a composition in an amount to aid in preserving the composition." See Response to May 8, 2002 Office Action dated August 5, 2002, at page 11, second paragraph. Thus, according to the file history of the '873 patent, a critical element of the claimed invention is an oxy-chloro component.

Because Alcon's Proposed Product does not contain an oxy-chloro or a chlorite component, it does not literally infringe any claim of the '873 patent. Furthermore, Alcon's Proposed Product contains polyquaternium-1, a polymeric quaternary ammonium compound, as a preservative. The '873 patent teaches that polyquaternium-1 is not equivalent to the required oxy-chloro component. According to the '873 patent, oxy-chloro components are a type of oxidative preservative component. At Col. 11, lines 47 – 57, the '873 patent discusses preservative ingredients that are "additional preservatives other than oxidative preservative components" that may be included in the compositions of the invention (emphasis added). One of the types of 'additional' preservatives listed in the '873 patent is quaternary ammonium compounds. Thus, because Alcon's Proposed Product does not contain an oxy-chloro component and because the specification expressly distinguishes Alcon's preservative from an oxy-chloro preservative, Alcon's Proposed Product does not infringe the '873 patent either literally or under the doctrine of equivalents.

In addition, because the prosecution history of the '873 patents makes it clear that the presence of a solubility enhancing component is critical to the invention in combination with the oxy-chloro component, Claim 35 (which does not require a solubility enhancing component) is invalid for lack of enablement under 35 U.S.C. §112.

3. U.S. Patent No. 6,627,210

The '210 patent contains thirty-four claims, three of which are independent: Claims 1, 16, and 20. Each of these independent claims recites an aqueous composition that requires, in addition to a specified drug, an anionic solubility enhancing component. In Claim 1, the required solubility enhancing component is "a polyanionic solubility enhancing component in an amount effective to increase the solubility of the [drug] in the composition relative to the solubility of an identical [drug] in a similar composition without the solubility enhancing component." In Claim 16, the required SEC is "an anionic cellulose derivative in an amount effective to increase the solubility of the [drug]." In Claim 20, the required anionic solubility enhancing component is "an anionic solubility enhancing component in an amount effective to increase the solubility of the [drug]."

In the prosecution history of the '210 patent, Allergan elected to prosecute initial Claims 1 – 30 in response to a restriction requirement made against the original forty-six claims. The Examiner rejected all thirty claims under 35 U.S.C. §103(a) as unpatentable over Burke (US 5,215,991) in view of Remington's Pharmaceutical Sciences. According to the Examiner, Burke discloses compositions of the same quinoxaline drugs that are recited in Allergan's claims and Burke discloses that those compositions contain solubility enhancing components such as polyvinyl alcohol, polyvinylpyrrolidone, hydroxypropylcellulose, poloxamers, carboxymethylcellulose and hydroxyethylcellulose. In response to this rejection, Allergan obtained an interview with the Examiner on February 25, 2003, and argued that the instant invention was "an invention of selection." In the Amendment submitted by Allergan dated March 11, 2003, Allergan amended independent Claims 1 and 20 so that all of the pending

claims would be limited to compositions comprising an anionic SEC. According to Allergan, "[t]he current claims are directed to compositions comprising brimonidine and salts and esters thereof in combination with an anionic polymeric solubility enhancing component." Allergan also argued as follows:

> 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.

Response to Office Action dated March 11, 2003 at 6.

In connection with this argument, Allergan submitted a Declaration of Orest Olejnik, Ph.D., one of the inventors, asserting that "anionic solubility enhancing components such as CMC have surprising and beneficial properties in the solubilization of brimonidine as compared to non-ionic or cationic polymers." Although completely lacking any supporting data, Allergan argued to the Examiner that the Declaration stated that "the use of an anionic polymer solubility enhancing component such as CMC (as compared to the nonionic polymer hydroxypropyl methyl cellulose) has the advantage of adsorbing to cellular surfaces ...in a manner that retains any drug in solution with the CMC to be retained at the ocular surface far longer (and in larger volume) than viscous formulations made with other, non-anionic polymers, while simultaneously increasing solubility." Allergan concluded its argument by emphasizing that the art cited by the Examiner "would not direct or motivate the person of ordinary skill in the art to select or want to select an anionic polymeric solubility enhancing component such as CMC from the list of optional viscous 'vehicles' contained in the [Burke] patent."

According to the prosecution history of the '210 patent, the anionic nature of the solubility enhancing component is critical. Although Allergan initially presented broad claims that required any "solubility enhancing component," the Examiner did not allow any claims until Allergan amended the claims to limit the solubility enhancing component to an anionic solubility enhancing component. Allergan secured issuance of the patent only after emphasizing that its invention was a selection invention and that anionic polymeric solubility enhancing components were surprisingly and unexpectedly different than nonionic or cationic polymeric solubility enhancing components. Accordingly, it is unquestionably clear, in view of the prosecution history of the '210 patent, that Allergan is estopped from asserting that the '210 patent's claims cover any compositions that do not contain an anionic solubility enhancing component. Futhermore, Allergan cannot expand the scope of the claims of the '210 patent to recapture subject matter that was expressly surrendered during prosecution. See Elkay, 192 F.3d at 978.

Thus, because Alcon's Proposed Product contains a nonionic polymer, povidone, but does not contain any anionic solubility enhancing component, it does not infringe the '210 patent literally or under the doctrine of equivalents.[1]

---

[1] The povidone in Alcon's Proposed Product (formulated like Alphagan®P at pH 7.2) is not acting as an SEC because 0.15% brimonidine tartrate is fully soluble up to at least pH 7.3 (based on Allergan's own solubility data provided in Table IV and Figure 1 in the specification). This argument is also applicable to the '337 patent (see discussion set forth infra under section 7).

Furthermore, the claims of the '210 patent are invalid under 35 U. S. C. §112 for lack of written description because the claims do not identify the formula or chemical name of the required SEC, claiming instead through a functional definition. "A written description of "an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559,1568 (Fed. Cir. 1997). This reasoning is also applicable to the claims of the '337 patent, see discussion infra at section 7.

4. U.S. Patent No. 6,641,834

The '834 patent contains twenty-two claims, two of which are independent: Claims 1 and 10. Each independent claims recites an aqueous composition that contains a maximum of 0.15% brimonidine and has a pH of about 7.0 or greater. Claim 10 differs from Claim 1 in that Claim 10 recites 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline, salts, esters and mixtures thereof, instead of just 5-bromo-6-(2-imidozolin-2-ylamino) quinoxaline tartrate. Both independent claims also require that the brimonidine is soluble in the composition at about 21°C. Dependent claims 2, 3, 4, 11, 12, and 13 address the concentration of the drug in the composition. Dependent claims 5 and 14 recite a pH of 7.0 or greater for the composition instead of a pH of about 7.0 or greater. Dependent claims 6, 7, 15, 16, and 19 – 22 require a preservative ingredient for the compositions. Dependent claims 8, 9, 17 and 18 specify that the compositions are substantially free of anionic cellulose derivatives or of carboxymethyl cellulose.

The '834 patent was filed as application USSN 10/236,566 on September 6, 2002, which was a continuation of application USSN 09/904,018, filed on July 10, 2001, which claims the benefit of provisional application serial number 60/218,200, which was filed on July 14, 2000. The claims that issued in the '834 patent were added by a preliminary amendment submitted with the application on September 6, 2002. This preliminary amendment cancelled all the claims originally contained in the parent application (USSN 09/904,018) and replaced them with a set of claims containing only two independent claims: one similar to issued Claim 1 that was directed toward compositions containing up to 0.15% brimonidine tartrate and that had a pH of about 7.0 or greater, where the drug was soluble in the composition at 21°C; and the other with the same limitations but where the drug could take different forms (brimonidine, salts, esters and mixtures thereof). The specifications of USSN 10/236,566 and USSN 09/904,018 are identical and nowhere in the specifications is there support for the claim limitations "up to about 0.15%" or "0.15%" of brimonidine tartrate or brimonidine salts, esters and mixtures thereof, which are part of each issued claim. The 0.15% concentration limitation does not appear anywhere in the specifications or in the originally filed claims; it first appeared in the new claims submitted by preliminary amendment on September 6, 2002.

The claims of the '834 patent are invalid under 35 U.S.C. § 112 for lack of written description because there is no support in the specification or the claims originally filed in the parent application for the claim term "up to about 0.15% (w/v)" or "0.15%." See, e.g., Tronzo v. Biomet, Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998). Allergan did not cite to any disclosure to support the term when it was introduced by preliminary amendment upon filing of the continuation application. Furthermore, the specification teaches away from a 0.15% limitation

in that all concentrations of the drug referred to in the specification are 0.2% and higher. Moreover, Figure 1 and Table IV in the specification indicate that in the absence of an SEC component the drug is fully soluble at the required pH limitation (around pH 7) up to a concentration of around 0.25%. A patent may be held invalid for failure to meet the written description requirements, based solely on the specification. See, PIN/NIP, Inc. v. Platte Chemical Co., 304 F.3d 1235, 1247-48 (Fed. Cir. 2002); TurboCare Division of Demag Delaval Turbomachinery Corp. v. General Electric Co., 264 F.3d 1111, (Fed. Cir. 2001) (summary judgment of invalidity where original disclosure not sufficiently detailed to enable one skilled in the art to recognize that appellant had invented what was claimed).

Thus, all of the claims of the '834 patent are invalid under 35 U.S.C. §112 first and second paragraphs because there is no support for the 0.15% limitation in the specification or in the claims originally filed with the parent application. Also, the claims that do not require an SEC or a preservative (claims 1-5, 8-14, 17-18), are not supported by the specification and are invalid for lack of written description under 35 U.S.C. § 112 as well.

Most of the claims of the '834 patent are also invalid for anticipation by prior art under 35 U. S. C. § 102(b). The 0.15% concentration limitation that the inventors argued was a critical component of their invention while prosecuting its application is not supported in the specification. All of the claims recite a concentration limitation that is simply not found anywhere in the specification. Thus, through the preliminary amendment filed in the continuation application, Allergan added new matter and claimed a new invention that was not disclosed in the parent application. Therefore, the claims of the '834 patent are not entitled to the priority date of the parent application. See, AK Steel Corp. v. Sollac, 344 F.3d 1234 (2003) (summary judgment of invalidity where claims unsupported by the specification were not enabled and claims were also anticipated by prior art when new matter improperly added was not entitled to the priority date of the parent application); see also, Purdue Pharma L.P. v. Faulding Inc., 230 F.3d 1320, 1323-1327 (Fed. Cir. 2000).

The specification of the '834 patent is replete with descriptions of the invention as a composition of the drug with an SEC at higher pHs than had previously been in use. Indeed, the prosecution history of the '834 patent reveals that in prosecuting the USSN 10/236,566 application filed on September 6, 2002, the inventors characterized their invention as "drawn to surprising new therapeutic compositions comprising at least a 25% lower concentration of brimonidine than previous ophthalmic formulations, at pH closer both to the solubility limits of brimonidine, and to the pKa of the compound." This is not the same "invention" that was characterized in the parent application (USSN 09/904,018). In that parent application, the "invention" was characterized as a selection invention that selected anionic solubility enhancing agents from the vehicles disclosed in the cited prior art. See the Interview Summary record dated February 25, 2003, for USSN 09/904,018.

An invention requiring the 0.15% limitation is new matter unsupported by the disclosure of the parent application USSN 09/904,018. The claims of the '834 patent are thus only entitled to the filing date of application USSN 10/236,566, September 6, 2002. Allergan's Alphagan®P product was approved by the FDA on March 16, 2001 and the product label for Alphagan®P was posted on the FDA's website on August 21, 2001, as the "Approved Labeling" for NDA 21-262. That labeling bears a copyright notice dated 2000 and describes the Alphagan®P product as containing 0.15% brimonidine tartrate, with the brimonidine tartrate soluble in the product

vehicle at pH 7.2. It also indicates that Alphagan®P product has a pH of 6.6 – 7.4. This posted labeling is prior art under 35 U.S.C. §102 (b) because it was published in August 2001, more than one year prior to the September 6, 2002, filing date of USSN 10/236,566 to which the claims of the '834 patent are entitled.

Thus, claims 1-7, 10-16, 20 and 22 of the '834 patent are invalid as anticipated over the Alphagan®P product label as prior art under 35 U. S. C. § 102(b). The only claims of the '834 patent that are not anticipated by Allergan's Alphagan®P product label are Claims 8, 9, 17-19 and 21 (i.e., claims that specify that the composition is substantially free of an anionic cellulosic derivative or that the composition comprises benzalkonium chloride as a preservative), but these claims are invalid under 35 U.S.C. §103 as obvious over a combination of the posted labeling and Burke U.S. Patent No. 5,215,991. Burke discloses a composition containing an alpha 2 agonist and benzalkonium chloride that is free of an anionic cellulose derivative (see, for example, Table II of Burke).

Furthermore, the claims of the '834 patent are invalid because the best mode of practicing the claimed invention was not disclosed. See United States Gypsum Co. v. National Gypsum Co., 74 F.3d 1209 (Fed. Cir. 1996).. Nothing in the specification of the '834 patent discloses the claimed compositions as preferred formulations, indeed, the specification does not disclose any formulations with concentrations of up to 0.15% of active ingredient. Yet, Allergan's inventor employees must have known of the preferred method of practicing the invention when the application that led to the '210 parent patent was filed on July 14, 2000 because Allergan had already selected a 0.15% formulation for its Alphagan® P product. See Chemcast Corp. v. Arco Industries Corp., 913 F.2d 923, 928 (Fed. Cir. 1990).

5. U.S. Patent No. 6,673,337

The '337 patent contains ten claims of which only claim 1 is independent. Claim 1 recites an ophthalmic composition comprising an alpha-2-adrenergic agonist and a solubility enhancing component other than a cyclodextrin. The SEC is present in an amount effective to increase the solubility of the drug in the composition relative to the solubility of an identical drug in a similar composition without the SEC. Dependent claims 2 – 4 further specify the alpha-2-adrenergic agonist. Dependent claim 5 specifies that the SEC comprises an anionic polymer. Dependent claim 6 specifies that the SEC is effective to increase the solubility in a biological environment relative to the solubility in a biological environment of an identical alpha-2-adrenergic agonist component in a similar composition without the SEC. Dependent claims 7 and 8 specify that the SEC in the compositions of claims 6 and 3, respectively, comprises an anionic polymer. Dependent claims 9 and 10 specify that the compositions of claims 1 and 6, respectively, further comprises an effective amount of a preservative.

The '337 patent issued from USSN 10/299,386, filed Nov. 19, 2002, which was a divisional application from USSN 09/904,018 (now U.S. Patent No. 6,627,210), filed on July 10, 2001. The '210 patent is discussed above. When the application that led to the '210 patent was filed, the Patent Office restricted the claims into four groups: I. Claims 1 – 30 drawn to a composition; II. Claims 31 – 33, drawn to a complex; III. Claims 34 – 39, drawn to an oligomer; and IV. Claims 40 – 46, drawn to a composition comprising an oxychloro component. In response, the applicants elected to pursue the invention of Group I in the application that led to

the '210 patent. Allergan filed USSN 10/299,386 to pursue the invention of Group IV (original Claims 40 – 46, drawn to a composition comprising an oxychloro component).

In the first Office Action (mailed March 13, 2003) issued for USSN 10/299,386, the Examiner rejected Claims 40 – 43 under the doctrine of obviousness-type double patenting as unpatentable over Claims 47 – 77 of USSN 10/236,566 (which issued as US 6,641,834) and over Claims 1 – 52 of USSN 09/903,962 (which issued as US 6,562,873). The Examiner concluded that the present application and both cited applications claimed an alpha-2-adrenergic agonist with an oxy-chloro component. The Examiner also rejected Claims 40 – 46 as obvious over Burke, US 5,215,991, in view of Beck et al., US 6,358,935. According to the Examiner, Burke discloses compositions that contain brimonidine from about 0.001 – about 1.0% w/v. The Examiner also noted that Burke disclosed that benzalkonium chloride may be used as a preservative and that suitable vehicles included carboxymethyl cellulose. The only limitation that the Examiner did not find expressly disclosed in Burke is the requirement that the preservative be a "chlorite component." The Examiner cited Beck et al. for this disclosure.

In response to the March 13, 2003, Office Action, Allergan amended the pending claims to eliminate the requirement for an oxychloro component despite the fact that this was the very basis for the restriction requirement imposed in USSN 09/904,018 and the characterization of USSN 10/299,386 as a "divisional" patent application. As a result, the amended claims, in effect, were the same claims that the Examiner refused to allow in USSN 09/904,018 (the parent application and now the '210 patent). In that parent application, the Examiner only allowed claims that limited the SEC to polyanionic/anionic SECs after Allergan argued that anionic polymers were different than the other polymers disclosed in the prior art (i.e., polyvinyl alcohol, polyvinylpyrrolidone, hydroxypropylcellulose, poloxamers, and hydroxyethylcellulose) and only after Allergan presented a Declaration of Orest Olejnik, Ph.D., asserting that "anionic solubility enhancing components such as CMC have surprising and beneficial properties in the solubilization of brimonidine as compared to non-ionic or cationic polymers."

As discussed above, while prosecuting USSN 09/904,018, Allergan distinguished CMC from the other vehicles disclosed in the Burke reference (US 5,215,991) cited by the Examiner. Allergan argued to the Examiner that CMC was special among vehicles, specifically the vehicles disclosed in the Burke '991 patent. See, for example, Allergan's March 11, 2003 Response to the Office Action dated January 15, 2003, at page 6, 5th paragraph:

> Of the "vehicles" specifically disclosed by the Burke patent, all will function to increase 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.

With its March 11, 2003, Response, Allergan also submitted a Declaration of Orest Olejnik, Ph.D., the first-named inventor of the '873, '210, '834, and '337 patents. In Dr. Olejnik's Declaration, he describes the cited Burke patent as disclosing "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." Dr. Olejnik asserts that neither Burke nor a Remington reference cited

by the Examiner for disclosing that the polymers in Burke may be used as viscosity-increasing agents 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. Dr. Olejnik then states that CMC, unlike the other polymers disclosed in Burke, 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." Dr. Olejnik then concludes that the other polymers disclosed in Burke would not be suitable for use in the invention:

> 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.

Declaration of Orest Olejnik, Ph.D. (not dated) at paragraph 8 submitted with Allergan's March 11, 2003 Response (emphasis added).

Statements in the prosecution history of one patent apply to the interpretation of terms in a related patent. Elkay, 192 F.3d at 980 (Fed. Cir. 1999). Thus, because the prosecution history of the '210 patent defines the scope of the invention and limits the SEC component to an "anionic" SEC , that same SEC component in the claims of the `337 should be similarly limited. See, e.g., Microsoft Corp. v. Multi-Tech Systems, Inc., 357 F.3d 1340, 1349-1350 (Fed. Cir. 2004). This is especially true in light of Dr. Olejnik's, one of the inventors, statement that anything other than an anionic SEC would not work in the invention. Also, the examiner made the same rejection over the same references (Burke and Beck et al.) as in the '210 patent. The same limitation to the claims should have been required to overcome that same rejection. Properly construed, the claims of '337 patent will be not infringed by Alcon's Proposed Product because the SEC component must be limited to an anionic SEC, and Alcon's Proposed Product does not contain any anionic SEC component.

Moreover, Alcon's Proposed Product does not infringe the claims of the `337 patent because it does not contain an SEC. Although Alcon's product contains povidone, which the `337 patent identifies as a potential SEC, Figure 1 makes it clear that no SEC is required at a 0.15% concentration of the drug at pH 7.2. This is because all of the brimonidine tartrate at 0.15% is soluble at pH 7.2 and the addition of an SEC could not act to increase solubility at that pH. As Figure 1 shows, brimonidine tartrate is fully soluble at a concentration of 0.15% up to around pH 7.3. At pHs of around 7.3 and below, addition of any "SEC" cannot increase solubility of brimonidine tartrate in solution at a concentration of 0.15%, because solubility is at 100% and thus no increase in solubility is physically possible. In Alcon's Proposed Product which is formulated at pH 7.2, povidone is acting as a viscosity enhancer or a "suspending agent" (see col. 11, lns. 56-60) but not as an SEC. Furthermore, as described above, the inventors have specifically stated that povidone is not an SEC that will work in the invention.

All claims of the '337 patent are also invalid for lack of written description under 35 U.S.C. § 112 because the claims do not identify the formula or chemical name of the required SEC, claiming instead through a functional definition. "A written description of "an invention involving a chemical genus, like a description of a chemical species, 'requires a precise

definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Regents of the University of California v. Eli Lilly, 119 F.3d 1559,1568 (Fed. Cir. 1997). The claims of the '337 patent attempt to claim the genus of SECs by function alone and impermissibly requires one to make and test a particular composition in order to determine whether it falls within the scope of the claims. This plainly violates the written description requirement. See New Railhead Mfg. L.L.C. v. Vermeer Mfg. Co., 298 F.3d 1290, 1296-1297 (Fed. Cir. 2002). A chemical genus may not be defined by its function. See Enzo Biochem, Inc. v. Gen-probe, Inc., 296 F.3d 1316, 1324 (Fed. Cir. 2002).

All claims of the '337 patent are invalid under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 5,834,470. The '470 patent discloses alpha-2-adrenergic agonist compositions that comprise quinoxaline alpha-2-agonists and pharmaceutically acceptable carriers. The compositions are useful for treating ocular disorders associated with intraocular pressure and are administered either perorally or topically to the surface of the eye. The pharmaceutically acceptable carriers include "cellulose and its derivatives, such as sodium carboxymethyl cellulose." The '470 patent discusses topical ocular compositions:

> Preferred compositions of the subject invention include aqueous solutions comprising a safe and effective amount of a subject compound intended for topical intraocular administration. Such compositions preferably comprise from about 0.0001% to about 5% of a subject compound, more preferably from about 0.01% to about 0.5%. Such compositions also typically include one or more preservatives, such as benzalkonium chloride, thimerosal, phenylmercuric acetate; vehicles, such as poloxamers, modified celluloses, povidone and purified water; tonicity adjustors, ...; acids and bases may be used to adjust the pH of these formulations as needed.

col. 10, lns. 38—52 (emphasis added).

All claims of the '337 are also invalid under 35 U.S.C. §102(b) as anticipated by U.S. 5,091,528. The '528 patent contains a disclosure of preferred vehicles similar to that contained in the Burke '991 patent (cited by the Examiner). The '528 patent, however, also discloses that the reference compositions may be used for the treatment of ocular bleeding. For such use, the compounds are administered to the eye in a pharmaceutical composition. Ophthalmic solutions are one type of preferred carrier, which may contain a thickening agent "such as carboxymethylcellulose or carbopol" to enhance delivery. Carpobol is a polyacrylic acid polymer. Both carboxymethylcellulose and polyacrylic acid polymers are listed as SECs in the '337 patent. Allergan's failure to disclose this Allergan patent as prior art during the prosecution of the '337 patent constitutes inequitable conduct before the PTO. To the extent that the '528 patent does not expressly disclose preservatives for use in the compositions useful for treating ocular bleeding, Claims 9 and 10 of the '337 patent are invalid under 35 U.S.C. 103 as obvious over a combination of the '528 patent and the Burke '991 patent or Beck et al. '933 patent.

All claims of the '337 patent are also invalid under 35 U.S.C. §102(b) as anticipated by U.S. 5,776,445. The '445 patent discloses vehicles for ophthalmic delivery. The vehicles include alginates having a particular proportion of guluronic acid. Specific alginates disclosed in the '445 patent are commercially available sodium alginates. Although the '337 patent does not define SEC's except by example, homopolymers and copolymers of alginic acid and metal

alginates are listed as representative SECs (see col. 6, lns. 18 – 61). The '445 patent identifies therapeutic agents suitable for use in the formulations containing the alginates glaucoma agents such as the alpha-2-adrenergic agonist apraclonidine and related 2-substituted amino imidazolines.

To the extent that Claims 3 and 4 of the '337 patent are not anticipated by the '445 patent because it does not expressly disclose quinoxaline alpha-2-adrenergic agonists as suitable drugs for the reference vehicles, those claims are invalid under 35 U.S.C §103 as obvious over a combination of the '445 patent and the Burke '991 patent. The Burke '991 patent equates clonidine, apraclonidine and brimonidine as "most preferred" imidazolidine-derived alpha-2 agonist compounds.

Offer of Confidential Access to Alcon's NDA

Pursuant to 21 U.S.C. §355(c)(3)(D)(i)(III), Alcon, Inc. hereby offers Allergan confidential access to its 505(b)(2) application on the following terms: Alcon's NDA will be disclosed only to Allergan's outside litigation counsel and one in-house attorney, provided that the in-house attorney has first been identified to Alcon. Additionally, Allergan's designated in-house attorney may disclose the NDA to one previously identified in-house scientist or non-attorney employee, who may assist the designated in-house attorney. Allergan and its outside litigation counsel must agree to keep the entire contents of Alcon's NDA ("Alcon's Confidential Information") confidential and not disclose it or any portion thereof to any other party for any purpose. Allergan and its outside litigation counsel may use Alcon's Confidential Information solely for purposes of determining whether to initiate litigation under 35 U.S.C. §271(e)(2) against Alcon within 45 days of its receipt of this notice letter and for the purposes of such action if one is initiated within the aforementioned 45-day period. Upon termination of any such action under 35 U.S.C. §271(e)(2), or at the end of the 45-day period if no suit is filed, all tangible forms of Alcon's Confidential Information shall be returned to Alcon and all other documents bearing notes or references or any form of attorney work product concerning Alcon's Confidential Information shall be destroyed at that time. Allergan shall certify to Alcon in writing that it has complied with these provisions within 30 days of the termination of such action or the expiration of the aforementioned 45-day period. In the event that Allergan wishes to obtain confidential access to Alcon's NDA on the terms set forth herein, Allergan shall make a request for such access in writng and expressly indicate its agreement to the terms set forth herein and shall at that time identify the designated in-house counsel and scientist or non-attorney employee, if any, to be provided access to Alcon's Confidential Information.

On behalf of Alcon, Inc.,



Patrick M. Ryan
Assistant General Counsel