IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

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

PLAINTIFFS' MOTION IN LIMINE TO EXCLUDE EVIDENCE OF ANY CONTINUATION APPLICATIONS OF THE '834 PATENT

Allergan hereby moves for an order ruling that evidence of the filing, contents and prosecution of any and all continuation and continuation-in-part applications filed after the '834 patent's filing date is inadmissible. As described below, such evidence is irrelevant (both factually and legally) and the introduction of these applications will only serve to confuse the issues and cause delay.

I. ALCON HAS PREVIOUSLY ATTEMPTED TO INJECT THE CONTINUATION APPLICATIONS INTO THE WRITTEN DESCRIPTION ANALYSIS

Plaintiffs expect that, in a manner similar to the defendants' prior failed attempt to inject this issue into the summary judgment briefing, Alcon will refer to certain continuation and continuation-in-part applications filed *after* the filing of the '834 patent. Alcon argued, wrongly and impermissibly (*see* D.I. 93, Order of June 13, 2005 granting Allergan's motion to strike Alcon's argument regarding the CIP application), that this later-filed application was evidence that the '834 patent fails to comply with 35 U.S.C. § 112, ¶ 1.

II. THE EXISTENCE AND CONTENT OF THE CONTINUATION APPLICATIONS ARE NOT RELEVANT TO THE ISSUE OF THE '834 PATENT'S WRITTEN DESCRIPTION

The relevance of the continuation applications to the determination of whether the application that led to the issuance of the '834 patent satisfied the requirements of 35 U.S.C. § 112 ¶ 1 is simply nil, both factually and legally.

A. The Applications Are Factually Irrelevant

Allergan's Alphagan® product line has evolved and improved over time. The first product was Alphagan®, followed by the second-generation Alphagan® P product, and now Allergan has developed a third-generation product that is formulated at a yet lower concentration of brimonidine tartrate and a higher pH; this new product was recently approved by the FDA. As part of its product development, Allergan filed a continuation-in-part application ("CIP") directed to this third generation product. As befits a CIP application, the patent adds additional examples in support of the new inventions contained therein. The CIP also names new and different inventors for at least a portion of that material. The CIP application provides a teaching of a yet higher pH range for a therapeutically effective brimonidine tartrate, "even more preferably between about 7.5 and about 8.0 or at about pH 7.7." *See* D.I. 85, Exhibit SJ9, Page 2, ¶ 0018.

The CIP was directed to the discovery by the named inventors of a precise pH range that they believed was even more effective than the "greater than about 7.0" range disclosed in the '834 patent-in-suit. Moreover, as is also disclosed in the CIP, at the same time the pH is raised, the concentration of the active ingredient is most preferably lowered well below that of Alphagan® P: "even more preferably between 0.15% (w/v) and about 0.001% (w/v), most preferably about 0.1% (w/v) or less." *See* D.I. 85, SJ9, Page 3, ¶ 32. This is another thirty-three percent reduction in the drug concentration.

All of this is being done in an effort to increase or maintain the efficacy while lowering the toxicity and improve upon Alphagan® P. Accordingly, the now-abandoned CIP was directed to a narrower invention than is at issue in the '834 patent, which disclosed for the first time the use of elevated pHs and lowered concentration of brimonidine tartrate in ophthalmic preparations. And, Allergan is certainly within its rights to seek patent protection on continued innovation.

B. The Applications Are Legally Irrelevant

Compliance with the written description requirement of 35 U.S.C. § 112, ¶ 1 "must be judged as of the filing date." *United States Steel Corp. v. Phillips Petroleum Co*., 865 F.2d 1247, 1251 (Fed. Cir. 1989). As the Federal Circuit has explained:

> The written description inquiry, therefore, focuses on a comparison between the specification and the invention referenced by the terms of the claims – not comparison between how the product was made as disclosed in the patent and future developments of this process that might alter or even improve how the same product is made.

Amgen, Inc. v. Hoechst Marion Roussel, 314 F.3d 1313, 1331-32 (Fed. Cir. 2003) (emphasis added) (citing with approval, *Amgen, Inc. v. Hoechst Marion Roussel*, 126 F.Supp.2d. 69, 150 (D. Mass. 2001)). "[T]he Patent Act and this court's case law require only sufficient description to show one of skill in the … art that the inventor possessed the claimed invention at the time of filing." *Union Oil Co. of California v. Atlantic Richfield Co*., 208 F.3d 989, 997 (Fed. Cir. 2000) (emphasis added) (noting that the applicant "does not have to describe exactly the subject matter claimed" and that describing an invention in terms of ranges "does not offend § 112, ¶ 1"). Therefore, sufficiency of the written description of the '834 patent must be judged based on the provisional application and the original claims – the later filed CIP is irrelevant. *See United States Steel Corp*., 865 F.2d at 1252 (concluding defendant's post-filing date

evidence immaterial to a § 112, ¶ 1 inquiry). This analysis is "intensely factual" and only requires a consideration of the support in the specification for the claimed invention and how one of skill in the art would have understood the specification. *Union Oil*, 208 F.3d at 1000 (limiting the applicability of *In re Ruschig*, 379 F.2d 990 (CCPA 1967), by reiterating that the rule that "the invention claimed does not have to be described *in ipsis verbis*" is not "empty verbiage").

Alcon conceded all of this in argument before the Court. In asking the Court for the right to file an early summary judgment motion on written description, Alcon counsel told the Court:

> So we have a straightforward lack of written description, invalidity based on absence of written description, requires no discovery whatsoever. The only issue is looking at the specification, does that specification support the revised claims which added the new matter of up to 0.15 percent.
>
> So in the case of the ['834] patent, it is a written description summary judgment argument. No discovery required. We simply want to look at the claim and spec and say there is no support for these claims …

D.I. 24, Transcript of the Scheduled Hearing, Nov. 22, 2004, page 7, lines 10-19 (emphasis added). As Alcon told the Court, in a written description analysis the inquiry focuses on how one of skill in the art would interpret the specification and the originally filed claims. Nothing more is proper. Indeed, the Federal Circuit has gone so far as to say that "the mere filing of a CIP with additional matter or revised claims is not itself an admission that the matter is 'new' or that the original application was legally insufficient to support the claims." *Paperless Accounting, Inc. v. Bay Area Rapid Transit Sys.*, 804 F.2d 659, 664 (Fed. Cir. 1986) (noting that there may be any number of reasons to file a CIP, including providing new technical information, disclosing recent developments or improvements, and enabling more extensive prosecution or prosecution of non-elected

claims). This is especially so, as in the case of the '834 patent and its continuation progeny, where there was no rejection in the parent application for lack of an adequate disclosure. *See, e.g., id*. at 663. In sum, there is simply nothing in the proper legal standard which requires or suggests the examination of later-filed applications.

III. WHATEVER RELEVANCE ALCON MAY ASCRIBE TO THE APPLICATIONS IS SUBSTANTIALLY OUTWEIGHED BY CONSIDERATIONS OF CONFUSION AND DELAY

As shown above, the existence and content of the continuation applications have no relevance to the written description issue, but - to the extent that Alcon may argue that they are minimally relevant - Federal Rule of Evidence 403 would still preclude admission of such evidence. In light of the minimal probative value of the evidence, the confusion potentially precipitated by the admission of this evidence will divert the Court's attention from the critical, technologically-complex issues of the case. Plaintiff will be forced to devote time to address the differences between the applications, the reasons why Allergan may have filed them, the procedural propriety of such filings, the regularity with which such filings are made industry-wide, the incorrectness of the inferences which Alcon may seek to draw from such applications, and the proper legal standard for addressing the written description issue. Given the short amount of time available for trial, the delay and disruption caused by admitting such evidence will impair Plaintiffs' ability to put on its case-in-chief.

IV. CONCLUSION

For the reasons stated above, Plaintiff Allergan respectfully requests that the Court issue an Order precluding Defendants from introducing into evidence, or making any direct or indirect references to, the existence or content of any continuing patent applications filed after the filing date of the '834 patent.

Dated: January 9, 2006

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CERTIFICATE OF SERVICE

I hereby certify that on January 9, 2006, I electronically filed with the Clerk of Court using CM/ECF, PLAINTIFF'S MOTION IN LIMINE TO EXCLUDE EVIDENCE OF ANY CONTINUATION APPLICATIONS OF THE '834 PATENT which will send notification of such filing(s) to the following:

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I hereby certify that on January 9, 2006, I have mailed by Federal Express, the document(s) to the following non-registered participants:

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