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May 9, 2005

**BY HAND DELIVERY**
The Honorable Gregory M. Sleet
United States District Court
844 King Street
Wilmington, DE 19801

Re: Allergan v. Alcon Laboratories, et al.
D. Del. - Civil Action No. 04-968-GMS

FR

BOSTON
DALLAS
DELAWARE
NEW YORK
SAN DIEGO
SILICON VALLEY
TWIN CITIES
WASHINGTON, DC

Dear Judge Sleet:

Plaintiffs Allergan, Inc. and Allergan Sales, LLC (together, "Allergan") submit this letter pursuant to the Court's request in the Scheduling Order for briefing on whether to require Defendants Alcon, Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (together, "Alcon") to elect either to permit discovery into their reliance on advice of counsel or waive the right to raise advice of counsel as a defense. Alcon contends that it need not make such an election because no willfulness claim is permitted in this case.

## I. Background

In July, 2004, Allergan received notice that Alcon had filed an application under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (sometimes referred to as "505(b)(2) application" or as a "paper NDA") with the United States Food and Drug Administration ("FDA") seeking approval of a generic version of Allergan's widely sold glaucoma drug, ALPHAGAN® P. ALPHAGAN® P is a 0.15% formulation of the drug brimonidine, which is used by doctors to treat the elevated intra-ocular pressure commonly found in glaucoma patients or those at risk for glaucoma. On July 6, 2004, Alcon sent to Allergan a Paragraph IV certification alleging that Alcon's proposed generic product would not infringe any Allergan patent listed in the Orange Book and/or that the Allergan patents listed in the Orange Book were invalid. The Paragraph IV certification addressed the patents-in-suit.

On August 24, 2004, Allergan brought this suit against Alcon under 35 U.S.C. § 271(e)(2), alleging infringement of Allergan's United States Patent Nos. 6,641,834 and 6,673,337. Section 271(e)(2) provides that it is an act of infringement to submit a paper NDA for a drug claimed in a patent if the purpose of the submission is to obtain approval to engage in the commercial manufacture, use, or sale of the drug before the expiration of the patent.

Allergan's complaint seeks an injunction against the commercial manufacture, use, sale, offer for sale, and importation of Alcon's proposed generic drug in the United States until after the patents-in-suit have expired. Allergan is not presently seeking damages, but will seek damages if Alcon markets its generic drug before the conclusion of this case. Allergan also seeks its attorney fees under 35 U.S.C. § 285, which provides that a court may award such fees in "exceptional cases." In support of its claim for attorney fees, Allergan alleges that Alcon has acted without a reasonable basis for believing it would not infringe the patents-in-suit, and that its infringement is willful.

As set forth in the parties' Rule 26(f) report, Allergan requests that a date be set by which Alcon must notify Allergan if it intends to rely on an advice of counsel defense, in order to allow Allergan sufficient time to engage in discovery regarding the defense. Alcon, on the other hand, contends that the decision of the Federal Circuit in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004) forecloses any possibility of a willfulness finding in this case, and that it therefore need not raise or permit discovery into any advice of counsel defense.

## II. Allergan's Willfulness Claim is Based On the Totality of The Circumstances

Section 271(e)(4) expressly permits attorney fee awards in cases such as this:

> The remedies prescribed by subparagraphs (A), (B), and (C) are the only remedies which may be granted by a court for an act of infringement described in paragraph (2), except that a court may award attorney fees under section 285.

35 U.S.C. § 271(e)(4). For example, in *Yamanouchi Pharm. Co. v. Danbury Pharm., Inc.*, 231 F.3d 1339 (Fed. Cir. 2000), the Federal Circuit affirmed the district court's award of attorney fees to the patentee based on the accused infringer's baseless invalidity assertions in its Paragraph IV certification and in the subsequent litigation. *Id.* at 1347. Under well-established precedent, willfulness can be a basis for awarding attorney fees under Section 285. *See, e.g., Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 1548 (Fed. Cir. 1984).

Willfulness is determined based on the totality of the circumstances. The totality of the circumstances comprises a number of factors, which include but are not limited to whether Alcon intentionally copied ALPHAGAN® P, whether Alcon exercised due care to avoid infringing Allergan's patents, whether Alcon relied on competent legal advice, and Alcon's behavior as a party to the litigation. *See In re Hayes Microcomputer Prods., Inc. Patent Litig.*, 982 F.2d 1527, 1543 (Fed. Cir. 1992); *Jurgens v. CBK, Ltd.*, 80 F.3d 1566, 1571 (Fed. Cir. 1996).

Here, Allergan bases its claim of willfulness on the totality of the circumstances, and not simply the paper NDA filing. Allergan contends: 1) that Alcon's Paragraph IV certification was without reasonable basis and 2) that Alcon's conduct in this litigation to date demonstrates this lack of reasonable basis.

For example, Alcon contended in its Paragraph IV certification that Allergan's '834 patent was invalid for failure to comply with the written description requirement of 35 U.S.C. § 112. The basis of this claim was that the '834 patent allegedly failed to disclose to a person of skill in the art a concentration limitation of "about 0.15%." Indeed, Alcon persuaded the Court that the Court should put aside its normal procedures and allow Alcon to make a summary judgment motion on that basis. *See* Scheduling Order, at 3-4.

In support of this defense, Alcon originally proffered a claim construction limiting the term "about 0.15%" to "0.1499-0.1501%," and submitted interrogatory responses that claimed that this concentration limit was nowhere disclosed in the patent. *See* Exs. A and B attached hereto for the Court's convenience.

Discovery has demonstrated that this defense has no basis in law or in fact, so much so that Alcon has: 1) abandoned its claim construction originally offered, and upon which its Paragraph IV certification was presumably based; and 2) switched its written description defense almost entirely to focus on a different limitation in the claim ("therapeutically effective"), which is nowhere mentioned in its discovery responses or in its Paragraph IV letter. This latter tactic, which violates the Court's Scheduling Order, will be the separate subject of Allergan's Motion to Strike. Moreover, Alcon's summary judgment motion of invalidity is unsupported by an expert declaration, and does not even bother to mention the evidentiary standard—clear and convincing evidence—to which its motion is subject.

## III. The Federal Circuit did not Hold that there Can be no Willful Infringement in ANDA cases

In *Glaxo Group Ltd. v. Apotex, Inc.,* 376 F.3d 1339 (Fed. Cir. 2004), the Federal Circuit held that a finding of willfulness could not be based solely on the filing of an ANDA with the FDA. *Id.* at 1349. *Glaxo* was not the typical ANDA case because the ANDA filer was not required to file a Paragraph IV certification. *Id.* at 1344. The district court found Apotex to be a willful infringer based on the filing of its ANDA and its failure to obtain an opinion of competent patent counsel. *Id.* at 1345. Apotex argued that (1) its only act of infringement was filing the ANDA; (2) it never certified that the patent was invalid or not infringed; and (3) the district court ignored evidence that Apotex exercised due care. *Id.* at 1349. The Federal Circuit reversed:

> Because we agree with Apotex that the mere filing of an ANDA cannot constitute grounds for a willful infringement determination, we reverse the district court's award of attorney's fees to Glaxo.

*Id.* at 1349. The Federal Circuit elaborated on its holding:

> we hold that that the district court committed clear legal error in finding that Apotex's mere filing of an ANDA could form the basis of a willful infringement finding. The district court did not find that Apotex engaged in any litigation misconduct, and Apotex did not file a Paragraph IV certification of any kind, let alone one that made baseless accusations of invalidity as that filed in *Yamanouchi.*

*Id.* at 1351. The *Glaxo* court ***did not*** hold that there could be no willfulness in ANDA cases. Indeed, the court left open the possibility of willfulness in cases involving litigation misconduct and/or baseless accusations in a Paragraph IV certification.[1]

As shown above, Allergan does not base its willfulness contentions simply on Alcon's 505(b)(2) filing, but rather points to Alcon's baseless Paragraph IV certification and litigation misconduct. Accordingly, Allergan should be allowed to proceed with discovery into the willfulness issue and Alcon should be required to make an election as to a potential advice of counsel defense.[2]

## IV. Alcon Must Either Permit Discovery into its Advice of Counsel Defense or Waive its Right to Rely on that Defense

Alcon must either permit discovery into whatever advice of counsel defense it intends to raise or waive its right to rely on that defense. Accordingly, Allergan respectfully requests the Court to order Alcon to notify Allergan no later than 10 weeks before the close of fact discovery whether it intends to rely on advice of counsel. Allergan

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[1] Alcon will likely point to the court's statement in *Glaxo* that a certification could not support a finding of willfulness. *Id.* at 1350. This statement is, of course, dicta because Apotex was not required to file and had not filed a Paragraph IV certification. In any event, this dicta does not address the situation here, which involves litigation misconduct in addition to a baseless Paragraph IV certification.

[2] Even if *Glaxo* did foreclose any possibility willfulness, however, Alcon's reliance on advice of counsel is nevertheless relevant to whether this is an "exceptional case" under 35 U.S.C. § 285. Allergan seeks judgment that it is, and has asked the Court to award attorney fees on that basis.

further requests that the Court order Alcon to produce any advice of counsel evidence it intends to rely on no later than 6 weeks before the close of fact discovery.

Respectfully,

***/s/ William J. Marsden, Jr.***

William J. Marsden, Jr.

WJM/kxk

cc: Clerk, U.S. District Court (By Hand Delivery)
Josy W. Ingersoll, Esq. (By Hand Delivery)
Brian D. Coggio, Esq. (By Federal Express)