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May 16, 2005

BY ELECTRONIC FILING
The Honorable Gregory M. Sleet
United States District Court
844 North King Street
Wilmington, DE 19801

Re: Allergan, Inc., *et al.* v. Alcon, Inc., *et al.*, C.A. No. 04-968 GMS

Dear Judge Sleet:

Defendants Alcon Inc., Alcon Laboratories, Inc. and Alcon Research, Ltd. (collectively, "Alcon") submit this letter in response to Plaintiffs' Allergan, Inc. and Allergan Sales, LLC (collectively, "Allergan") May 9, 2005 letter to the Court. In the Scheduling Order, this Court requested the parties to brief "the issue of whether or such a claim [for willful infringement] may be asserted by [Allergan] (and, consequently, whether discovery into that defense is necessary). . . ." (D.I. 30 ¶3). Since Allergan has failed to establish its right to pursue a charge of willful infringement, no discovery on that defense is warranted.

I. PRELIMINARY STATEMENT

Allergan accused Alcon of willful infringement of the '834 patent in paragraph 19 of the Complaint.[1] There, Allergan alleged that "Alcon acted without a reasonable basis for believing that

[1] Allergan does not now accuse Alcon of any impropriety with respect to the '337 patent-in-suit. It has apparently abandoned its allegation in paragraph 23 of the Complaint that Alcon's infringement of that patent is willful because it recently learned that Alcon scientist Ramon Espino conducted experimental studies in 2003 and 2004 that conclusively demonstrate that povidone does

it would not be liable for infringement of the '834 patent, and, as such, its infringement of the '834 patent is willful." Allergan's conclusory allegation – standing alone – cannot support a charge of willful infringement.[2] As the Federal Circuit made clear in Glaxo Group. Ltd. v. Apotex, Inc., 376 F.3d 1339, 1349 (Fed. Cir. 2004) "the mere filing of an ANDA cannot constitute grounds for a willful infringement determination." (emphasis added). Recognizing that more is needed than what it pleaded, Allergan desperately attempts to create an impression of litigation misconduct by accusing Alcon of "abandon[ing]" its original claims construction and "switch[ing]" its written description defense. D.I. 64 ("Allergan Let. Br."). Even if true, "changing" a summary judgment argument would not be "litigation misconduct" in any sense; thus, Allergan's predicate is entirely insufficient. More importantly, it is entirely wrong: Alcon's written description defense remains as first asserted; there is no support in the specification and original claims for dose-related claims added during prosecution of the '834 patent, i.e., the 0.15% limitation on the amount of active ingredient required to achieve the claimed therapeutically effective composition. Alcon has not moved away in the slightest from its consistent position that the disclosure of the '834 patent does not suggest that the inventors considered their invention to be about reducing the dose of the active ingredient in the product from the 0.2% concentration disclosed in the prior art.

II. ARGUMENT

A. Applicable Law On Willful Infringement In Hatch-Waxman Actions.

The Federal Circuit first addressed the present issue in Yamanouchi Phar. Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339 (Fed. Cir. 2000). There, the defendant Danbury filed a paragraph IV certification asserting that the patent-in-suit was invalid. Since their position at trial, which was based upon their paragraph IV certification, contained "largely hindsight, speculation, and argument without an adequate foundation," the district court held that Danbury willfully infringed the patent, that the case was therefore "exceptional," and that an award of attorneys fees was warranted. Id. at 1343. The Federal Circuit affirmed the award, but not solely on the basis of the lower court's finding of willful infringement. Rather, the court stated that "[a]n ANDA filing by its very nature is a highly artificial act of infringement," therefore, the trial court need not have elevated the ANDA certification into a finding of willful infringement." Id. at 1347. Thus, it was "Danbury's misconduct in filing a wholly unjustified ANDA certification **and** misconduct during the litigation that followed [that] warranted the district court's finding that the case was exceptional." Id. (emphasis added). Alcon again submits that Allergan cannot satisfy either such requirement, let alone both.[3]

More recently, the Federal Circuit addressed this same issue in Glaxo v. Apotex, supra. There, the district court held that Apotex had willfully infringed Glaxo's patent. The case was

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not increase the solubility of brimonidine tartrate in Alcon's proposed drug product, as the asserted claims of the '337 patent require. See Espino Dep. Tr. 211-13 (attached as Exhibit 1).

[2] It is noteworthy that Alcon, in its paragraph IV certification, alleged that the five Allergan patents listed in the Orange Book were invalid and/or non-infringed. As to three of the five, Allergan presumably agreed, as Allergan has not accused Alcon of infringing those listed patents.

[3] Allergan argues that in Glaxo Group. Ltd. v. Apotex, Inc., 376 F.3d 1339 (Fed. Cir. 2004) the court "left open the possibility of willfulness in cases involving litigation misconduct and/**or** baseless accusations in a Paragraph IV certification." Allergan Let. Br. at 4 (emphasis added; footnote omitted). As shown herein, Allergan's characterization of the applicable law on this issue is erroneous.

therefore "exceptional," and an award of attorneys fees was warranted. Glaxo Group Ltd. v. Apotex, Inc., 268 F. Supp.2d 1013, 1035 (N.D. Ill. 2003). The Federal Circuit reversed because "the mere filing of an ANDA cannot constitute grounds for a willful infringement determination." Glaxo, 376 F.3d at 1349 (emphasis added). In reaching its decision, the Glaxo court noted that its earlier Yamanouchi decision was premised on the baseless ANDA certification and litigation misconduct. Thus, "as suggested by Yamanouchi, we now hold that the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4)." Id. at 1350-51. In summarizing the rationale for its holding, the Federal Circuit stated:

> Because 35 U.S.C. § 271(e)(2) is designed to create an artificial act of infringement for purposes of establishing jurisdiction in the federal courts, we hold 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 such as that filed in Yamanouchi.

Id. at 1351. (first emphasis in original). Apparently, only one district court has addressed this issue since Glaxo. In Aventis Pharma Deutschland GmbH v. Cobalt Pharmaceuticals, Inc., 355 F. Supp. 2d 586 (D. Mass. 2005), the court granted the defendant's motion for judgment on the pleadings on the patentee's charge of willful infringement. In its complaint, plaintiff Aventis had alleged that defendant Cobalt had willfully infringed the patents-in-suit by filing an "utterly baseless" paragraph IV certification. In rejecting this allegation as a basis for pursuing a charge of willful infringement, the court held:

> The only act of infringement alleged in Plaintiffs' amended complaint is Cobalt's filing of an ANDA and a paragraph IV certification with the FDA. Because this artificial act of infringement cannot be considered willful, Plaintiffs have averred no facts that can support a finding of willful patent infringement. For the foregoing reasons, Cobalt's motion for judgment on the pleadings is ALLOWED with respect to Plaintiffs' claim of willful infringement.

Id. at 592. (emphasis added). In rendering its decision, the court recognized that "the Federal Circuit [in Glaxo] has limited the types of conduct that may give rise to an award of attorney's fees under the Hatch-Waxman Act." Id. at 591 (footnote omitted). The court then quoted the Federal Circuit's admonition in Glaxo that, "'the mere fact that a company has filed an ANDA application or certification cannot support a finding of willful infringement for purposes of awarding attorney's fees pursuant to 35 U.S.C. § 271(e)(4).'" Id. at 592 (emphasis in original). Here, Allergan's allegations do not come close to meeting the strict requirements established by the Federal Circuit in Yamanouchi and Glaxo.

B. Allergan's Accusations Regarding Alcon's Purported "Switch" In Its Position Are Wrong.

Allergan's accusation that Alcon "switched its written description defense" is more than hyper-technical; it is mistaken. All claims of the '834 patent (all of which were added during prosecution) require a "therapeutically effective" aqueous ophthalmic composition comprising, inter alia, "up to about 0.15% (w/v)" brimonidine tartrate. This is in contrast to Allergan's own prior art

product, which used 0.2% brimonidine tartrate. The basis for Alcon's summary judgment motion on the '834 patent is that neither the specification nor the original claims contain an adequate written description of a lower dose (0.15% (w/v)) invention. In addition, the 0.15% numerical limitation does not stand alone or in isolation, as Allergan argues. It is an integral part of the claimed "therapeutically effective" ophthalmic composition and must be viewed in the context of the surrounding claim language. As Judge (now Chief Judge) Robinson stated succinctly in BOC Health Care, Inc. v. Nellcor, Inc., 892 F. Supp. 598, 613 (D. Del. 1995), aff'd, 98 F.3d 1357 (Fed. Cir. 1996) (non-precedential decision), "in reality, claim language must be construed as a whole and it is something of an intellectual fiction to separate the phrase of a claim as if they stood in isolation."

All 22 claims in the '834 patent have the same preamble – "A therapeutically effective aqueous ophthalmic composition comprising . . . " – which Allergan admits is a claim limitation. Allergan construes this limitation as "requir[ing] a therapeutically effective ophthalmic composition" having the additional limitations recited in the body of the claims.[4] Accordingly, Allergan has already conceded that language serves to "'give meaning to [the] claim and properly define the invention.'" Apple Computer, Inc. v. Articulate Systems, Inc., 234 F.3d 14, 22 (Fed. Cir. 2000) quoting In re Paulsen, 30 F.3d 1475, 1479 (Fed. Cir. 1994) (quoting DeGeorge v. Bernier, 768 F.2d 1318, 1322 n.3 (Fed. Cir. 1985)). It cannot be ignored.

Critically, there is no claim construction dispute relevant to Alcon's summary judgment motion on the '834 patent – the issue is whether the specification and original claims contain an adequate written description of the 0.15% limitation, first introduced during prosecution. The 0.15% (w/v) limitation on the concentration of active ingredient in the claimed compositions cannot be viewed in isolation nor can it be divorced from the remainder of the claims. See Hockerson-Halberstadt, Inc. v. Converse, Inc., 183 F.3d 1369, 1374 (Fed. Cir. 1999) ("Proper claim construction, however, demands interpretation of the entire claim in context, not a single element in isolation." (emphasis added)); Middleton, Inc. v. Minnesota Mining and Manufacturing Co., 311 F.3d 1384, 1387 (Fed. Cir. 2002) ("As usual, the most important indicator of the meaning of [the disputed term] is its usage and context within the claim itself."). Accordingly, disputed terms find "context" in the surrounding claim language. Thus, while the specific 0.15% (w/v) limitation is at the center of the present debate, "the context of the surrounding words of the claim" (e.g., "therapeutically effective") also "must be considered." Brookhill-Wilk 1 LLC v. Intuitive Surgical, Inc., 334 F.3d 1294, 1299 (Fed. Cir. 2003). Thus, Allergan's argument that some "shift" has occurred in Alcon's position mischaracterizes how claims are understood and, ultimately, Alcon's § 112 defense itself.

It appears, however, that Allergan understood these principles at one time. During prosecution of the '834 patent, Allergan itself recognized that the 0.15% limitation could not be read in isolation, but was one facet of the claimed invention: "The current claims are directed to therapeutically effective aqueous ophthalmic compositions comprising brimonidine and salts and esters thereof at a pH of up to about 7.0, and in a concentration of about 0.15% or less."[5] As stated above, there is no dispute relevant to summary judgment as to what the claims are directed to – the dispute is about whether the specification contains an adequate written description, and Allergan cannot make up for the absence of such a description by unfounded attacks on Alcon.

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[4] See Joint Claim Chart at 5 (emphasis added), a copy of which is annexed hereto as Exhibit 2.

[5] Prosecution History of the '834 patent, Reply to Office Action mailed on March 17, 2003 at 4, a copy of which is annexed hereto as Exhibit 3. (emphasis added).

C. The Range Of Values Afforded To The Phase "About 0.15%" Has No Relevance To Alcon's Summary Judgment Argument.

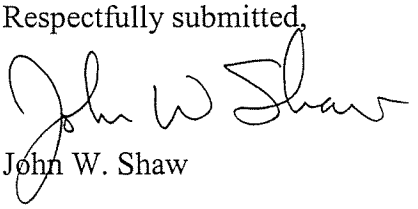
Allergan argues that Alcon originally proffered a claim construction for limiting the "about 0.15%" to "0.1499-0.1501," and submitted interrogatory responses that claimed this particular concentration was not disclosed in the patent. Allergan Let. Br. at 3. Alcon's interrogatory response, id. Exh. B, however, did not refer to any numerical range for the 0.15% limitation to support its written description defense. During preparation of the Joint Claim Chart, Alcon preliminarily proposed a more limited range for the term "about 0.15%" (i.e., 0.15% ∀ 0.0001%), id. Exh. A, but after exchanging preliminary positions with Allergan's counsel, Alcon expanded its proposed scope of the concentration limitation to use the same scientific basis as used to limit the pH range of "about 7.0" and the temperature range of "about 21°C." In the Joint Claim Chart that followed, Alcon asserted that "[t]he claimed composition [of the '834 patent] must contain up to 0.155% (w/v) (the upper limit of 0.15 ± 0.005% (w/v)) of brimonidine tartrate."[6] As Alcon argued in its summary judgment motion, the precise numerical range used to construct the term "about 0.15%" is entirely irrelevant to Alcon's written description defense because the specification and original claims supply no teaching or support to suggest that any particular concentration of active ingredient was the inventors' invention at the time the original claims were filed. Alcon's difficulty in attempting to construe the term "about 0.15% (w/v)" in the '834 patent serves only to further demonstrate that the specification lacks an adequate written description of that limitation.

In summary, Alcon's position has never wavered. It has consistently maintained that the claims of the '834 patent, which all require "a therapeutically effective" composition, are invalid because the critical limitation on the concentration of active ingredient – "about 0.15% (w/v)" – is not supported in the specification or original claims of that patent. Accordingly, the factual basis for Allergan's position is simply wrong. Certainly, nothing about Alcon's argument suggests any "misconduct," and Allergan's accusation of the same is unwarranted.

III. CONCLUSION

Because the allegations in Allergan's Complaint fail to justify a charge of willful infringement, and further, because Allergan's misguided attempts to bolster these allegations also fail, Allergan's request to pursue a charge of willful infringement against Alcon should be denied.

Respectfully submitted,



John W. Shaw

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6 Joint Claim Chart (Exhibit 2) at 5 (emphasis added).