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May 23, 2005

The Honorable Gregory M. Sleet
United States District Court
844 King Street, Room 4324
Wilmington, DE 19801

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

FR

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Dear Judge Sleet:

In the Scheduling Order (D.I. 30), the Court asked the parties to brief whether Allergan can assert a claim of willful infringement. Effectively conceding that Allergan can, [Alcon's Letter Brief, at 2, D.I. 75], and missing that Allergan is not required to prove its claim at this point, Alcon prematurely argues the merits in an attempt to justify its violation of the Court's Scheduling Order—clearly leading to the conclusion that further discovery is warranted.

As set forth in Allergan's Motion to Strike (D.I. 68), Alcon, in violation of the Court's limited permission given in the Scheduling Order, brought summary judgment on grounds not disclosed to the Court or to Allergan in either the Paragraph IV certification or in its discovery responses. In its response to Allergan's Letter Brief regarding willfulness (D.I. 75), Alcon devotes several pages to justifying its deviation from the Scheduling Order. That issue is thoroughly addressed in Allergan's Motion to Strike and will be addressed by the parties in additional briefing on the issue; accordingly, it will not be addressed any further here. Rather, this reply shall remain focused on the briefing requested by the Court, whether a claim of willful infringement is legally cognizable in an action brought under 35 U.S.C. § 271(e)(2)—and, as Alcon has already conceded, it is.

As is clear from Allergan's opening letter, Alcon's response, and the cited case law, willful infringement is legally cognizable in a § 271(e)(2) action; accordingly, discovery on the topic is appropriate. As Allergan set forth in its opening letter on willfulness, the Federal Circuit in *Glaxo* did not hold that there could be no willfulness in ANDA cases. Rather, the Court left open the possibility of willfulness in cases involving litigation misconduct and/or baseless claims in a Paragraph IV certification. [Allergan's Letter Br. at 4, D.I. 64]

In its response, Alcon accurately quotes the Federal Circuit's holding in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339, 1351 (Fed. Cir. 2004), but clearly fails to appreciate the import of the language.

> 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 (underlined emphasis added).

Notably, the Federal Circuit here is commenting on what the district court did not base its decision of willfulness. The district court found neither that Apotex had engaged in any litigation misconduct nor that Apotex had filed a baseless paragraph IV certification. The obvious implication from the Federal Circuit's language in *Glaxo* is that, if the district court had found either or both of these, the Federal Circuit would have affirmed its finding of willful infringement.

Alcon's reliance on *Aventis Pharma Deutschland GMBH v. Cobalt Pharma., Inc.*, 355 F.Supp.2d 586 (D. Mass. 2005), is misplaced. First, there was no allegation of litigation misconduct in that case. Second, the District Court's decision cannot trump the Federal Circuit's decision. As *Glaxo Group* states (and Alcon has conceded), at the very least, there can be willful infringement where the defendant has filed a baseless paragraph IV certification and there is litigation misconduct. [Alcon's Letter Brief, at 2, D.I. 75].

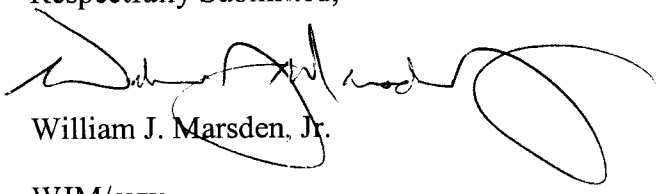
In this case, Alcon did file a baseless paragraph IV as evidenced by Alcon's constantly changing position as to what "about 0.15% (w/v)" means. Alcon's Paragraph IV letter was based on an untenable construction of "about 0.15% (w/v)" that was limited to the range of 0.1499% to 0.1501%. In light of the limited discovery taken thus far, Alcon has had to completely abandon that position and now asserts that "about 0.15%" means 0.15% ± 0.005%. Moreover, because of fatal flaws in its argument, Alcon chose to move for summary judgment, not on the grounds set forth in the Paragraph IV letter for which the Court granted permission, but instead on the ground that the '834 Patent does not disclose "therapeutically effective concentrations." This change in tactics is litigation misconduct, in that it: 1) violates the scheduling order; and 2) seeks to surprise Allergan with Alcon's true arguments, arguments that Allergan had no opportunity to test in discovery.

Moreover, with respect to the '337 patent, Alcon's claim in footnote 1 is simply unsupported by the testimony. To the extent Alcon's claims in its Paragraph IV letter were based on Mr. Espino's tests, these claims were baseless. To the extent done

properly, these tests demonstrate that povidone acts as a solubility enhancing component, exactly as the patent says it will. And, as has been demonstrated in the summary judgment and claim construction briefing, Alcon's legal arguments for excluding povidone from the claims of the '337 patent are based on a creative reconstruction of the parent file history and ignore applicable caselaw.

Accordingly, Allergan should be permitted discovery on the willful infringement issue. Alcon has conceded that willfulness is cognizable in an § 271(e)(2) action, and the enumerated circumstances for making such a claim that were not present in the *Glaxo Group* case are present here.

Respectfully Submitted,



William J. Marsden, Jr.

WJM/cyw

cc: Clerk, U.S. District Court
Josy Ingersoll, Esq. (Via ECF)
Brian Coggio, Esq. (Via Mail)

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