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May 9, 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:

The Scheduling Order, ¶ 13, entered February 11, 2005, authorizes defendants, Alcon Inc., Alcon Laboratories, Inc., and Alcon Research, Ltd. (collectively "Alcon"), to submit this letter brief supporting its request to strike the jury trial demand interposed by plaintiffs, Allergan, Inc. and Allergan Sales, LLC (collectively "Allergan").

Allergan instituted this action under 35 U.S.C. § 271(e)(2), part of the Hatch-Waxman Act, alleging that Alcon's submission of an abbreviated generic application to the Food and Drug Administration ("FDA"), seeking approval of its proposed brimonidine tartrate ophthalmic drug product, infringed Allergan's U.S. Patent Nos. 6,641,834 and 6,673,337.

The Hatch-Waxman Act created a cause of action ("a § 271(e)(2) action") that permits manufacturers of generic drugs to challenge patents listed in the so-called "Orange Book" without incurring the risk of monetary damages for actual infringement. Thus, under § 271(e)(2), the act of submitting an Abbreviated New Drug Application (an "ANDA") or, as here, a § 505(b)(2) application (often called a "paper NDA") to the FDA is a "technical act of infringement" that

permits a patentee to file suit against the generic applicant. However, the patentee (here, Allergan) cannot recover monetary damages because the FDA has not approved the generic product and thus no actual infringement could occur. *See* 35 U.S.C. § 271(e)(4)(C). Accordingly, in its Complaint, Allergan only seeks injunctive relief preventing FDA approval of Alcon's generic application and an award of attorneys fees. Alcon answered the Complaint and interposed declaratory judgment counterclaims that its proposed brimonidine product would not infringe the patents-in-suit and that both patents are invalid. Although no damages were sought, Allergan requested a jury trial.

I. ARGUMENT

A. There Is No Statutorily-Created Right To A Jury Trial In Section 271(e)(2) Actions

Section 271(e)(2) does not provide for a right to a jury trial. Absent commercialization, only equitable – not legal – remedies are available to a patentee and these available remedies are expressly limited by § 271(e)(4) and may only be granted by a "court." Therefore, under the statute, no right to a jury trial exists. *See Sanofi-Synthelabo v. Apotex Inc.*, 64 U.S.P.Q.2d 1684, 1686 (S.D.N.Y. 2002) ("There is no question that Sanofi has no right to a jury trial on its claims pursuant to § 271(e)(2) . . . ."); *Pfizer, Inc. v. Novopharm Ltd.*, No. 00 C 1475, 2001 WL 477163 at *5 (N.D. Ill. May 3, 2001) ("Pfizer admittedly has no right to a jury trial on its equitable claims for relief under § 271(e)(2).").

B. There Is No Seventh Amendment Right To A Jury Trial In Section 271(e)(2) Actions

Absent specific authorization in a statute, the right to a jury trial in civil actions is governed by the Seventh Amendment, which provides: "In Suits at common law, where the value in controversy shall exceed twenty dollars, the right of trial by jury shall be preserved, and no fact tried by a jury, shall be otherwise reexamined in any Court of the United States, than according to the rules of common law." U.S. Const. amend. VII. Limiting its application to "suits at common law," the amendment preserves the right to a jury trial for those actions that in 1791 created legal rights and remedies enforceable in a court of law. *See* Fed. R. Civ. P. 39(a)(2). No such right exists for suits in equity.

In *Tull v. United States*, 481 U.S. 412 (1987), the Supreme Court established a two-part test to assess whether the Seventh Amendment right to a jury trial attaches to newly-created statutory actions (such as § 271(e)(2) actions). Under the test, "those actions that are analogous to 18th-century cases tried in courts of equity or admiralty do not require a jury trial. . . . To determine whether a statutory action is more similar to cases that were tried in courts of law than to suits tried in courts of equity or admiralty, the Court must examine *both* the nature of the action *and* of the remedy sought." *Id.* at 417 (emphasis added). The nature of the requested relief is the "more important" of the two factors. *Id.* at 421; *Chauffeurs, Teamsters & Helpers, Local No. 391 v. Terry*, 494 U.S. 558, 565 (1990). Because the underlying action and the available remedies in § 271(e)(2) actions are both equitable, no Seventh Amendment right to a jury trial exists.

1. The Nature Of A Section 271(e)(2) Action Is Equitable

Federal Circuit precedent supports the conclusion that § 271(e)(2) actions are equitable. In *Tegal Corp. v. Tokyo Electron Am., Inc.*, 257 F.3d 1331, 1340 (Fed. Cir. 2001), the Federal Circuit found that a patentee in 18th-century England could have brought an infringement suit either at law or at equity. If the patentee sought damages, it would have brought the action at law; if it sought an injunction, the suit would have been filed in equity. *Id.* Thus, "given Tegal's interest only in an injunction, it is clear that Tegal would have needed, in eighteenth century England, to bring its case in a court of equity." *Id.* Accordingly, in a § 271(e)(2) action, where the patentee (like Allergan) seeks (and can only seek) prospective injunctive relief, the action could have been brought only in equity. Such actions are, therefore, inherently equitable, and a right to a jury trial does not exist. *See, e.g., Sanofi-Synthelabo,* 64 U.S.P.Q.2d at 1686; *Glaxo Group Ltd. v. Apotex, Inc.,* No. 00 C 5791, 2001 WL 1246628 at *5 (N.D. Ill. Oct. 16, 2001) ("[A]n action brought pursuant to § 271(e)(2) is inherently equitable in nature . . . ."), *aff'd, In re Apotex, Inc.*, No. 690, 49 Fed. Appx. 902, 2002 U.S. App. LEXIS 23101 (Fed. Cir. Oct. 9, 2002).

2. The Remedies Available In A Section 271(e)(2) Actions Are Equitable

The second and more important prong of the Seventh Amendment analysis focuses on the nature of the requested relief. The plain language of 35 U.S.C. § 271(e)(4) precludes patentees from obtaining damages based on the statutorily-created, artificial act of infringement resulting from the filing of a generic application. Damages are available only if the defendant markets the infringing drug without FDA approval. *Pfizer,* 2001 WL 477163 at *3 ("[T]he statute expressly precludes the plaintiff from recovering damages except in the rare situation where the defendant has already engaged in the commercial manufacture, use, or sale of the drug without FDA approval."); *Glaxo Group Ltd.*, 2001 WL 1246628 at *4 ("The statute expressly precludes a plaintiff from recovering damages unless the defendant has already engaged in the commercial manufacture, use or sale of the drug without FDA approval.").[1] Here, Allergan does not allege any acts of infringement other than Alcon's FDA-filing for which only prospective injunctive relief is available. Thus, since the nature of the action is equitable and, further, the requested relief is equitable, a right to a jury trial under the Seventh Amendment does not exist in this action. *Accord, Bayer AG v. Schein Pharm., Inc.*, No. 99-2181, 2000 U.S. Dist. LEXIS 20718 at *7 (D.N.J. Feb. 23, 2000) (striking plaintiffs' jury demand because "[i]n cases seeking to enjoin future infringement, . . . the patentee has no right to a jury trial"); *Abbott Labs. v. Torpharm, Inc.,* 309 F. Supp.2d 1043, 1044 (N.D. Ill. 2004) (A bench trial

[1] That a defendant might engage in actual infringing activity at some future date does not entitle either party to a jury trial. *See Biovail Labs., Inc. v. Torpharm, Inc.*, No. 01 C 9008, 2002 U.S. Dist. LEXIS 13502 at *8-*9 (N.D. Ill. July 23, 2002) (refusing to grant a jury trial despite the "small chance" that the generic application would be approved prior to trial or that defendant would begin marketing the generic drug before trial, and noting that "at this point in the proceedings, none of this has occurred"); *Sanofi-Synthelabo,* 64 U.S.P.Q.2d at 1689 (refusing to grant a jury trial despite the possibility that the defendant might engage in actual infringing activities prior to the resolution of the case).

was conducted "because Abbott is seeking only equitable relief. Indeed, it could not seek damages, because TorPharm has not yet begun to market its generic substitute for Abbott's product.").

C. Alcon's Declaratory Judgment Counterclaims Do Not Create A Right To A Jury Trial

Declaratory judgment actions have no legal or equitable character independent of the underlying action. Therefore, counterclaims seeking declaratory relief do not alter the Seventh Amendment's two-pronged analysis. *See Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 284 (1988) ("Actions for declaratory judgments are neither legal nor equitable. . . ."); *In re Lockwood,* 50 F.3d 966, 973 (Fed. Cir. 1995), *vacated*, 515 U.S. 1182 (1995) ("[D]eclaratory judgment actions are, for Seventh Amendment purposes, only as legal or equitable in nature as the controversies on which they are founded.").[2]

In *Kao Corp. v. Unilever U.S., Inc.*, No. Civ.A. 01-680-SLR, 2003 WL 1905635 at *3 (D. Del. Apr. 17, 2003), Chief Judge Robinson ruled that the declaratory judgment counterclaims for invalidity and non-infringement do not entitle a defendant in a patent infringement suit to a jury trial. In so doing, the court stated: "[A]n alleged infringer has no entitlement to a trial by jury by virtue of pleading counterclaims asserting noninfringement and invalidity, claims which are equitable in nature with no attendant right to damages." *Id.* In her decision, Judge Robinson interpreted the Federal Circuit precedents in *Tegal* and *Lockwood* as holding that "the patentee's infringement case is the linchpin of the Federal Circuit's Seventh Amendment analyses." *Id.* The *Lockwood* court, 50 F.3d at 976, had stressed that "[u]nder both English and American practice, then, it was the patentee who decided in the first instance whether a jury trial on the factual questions relating to validity would be compelled." Similarly, the *Tegal* court, 257 F.3d at 1340, stressed that in 18th-century England, it was the patentee's choice whether to bring an infringement action at law or at equity and that the choice depended on the remedy sought. Thus, Alcon's counterclaims do not provide either party with a right to a jury trial.

The Federal Circuit addressed this same issue in the context of a § 271(e)(2) action. In *Glaxo Group Ltd.*, 2001 WL 1246628 at *1, the district court granted plaintiffs' motion to strike the jury demand in an action where defendant had asserted counterclaims seeking declarations of invalidity and non-infringement. The *Glaxo* court relied on *Lockwood* and stated that "in 18th Century England, the validity of a patent where there was no claim for damages was equitable in nature and decided by the court." *Id.* at *5. In conclusion, the district court held that :

> [A]n action brought pursuant to § 271(e)(2) is inherently equitable in nature, and . . . the remedies are limited accordingly. Therefore, as in *Tegal,* both prongs of the *Tull* test point to equity, and neither plaintiff nor defendant is entitled to a jury trial on any of the issues raised in this case. *The mere fact that invalidity has been raised in a*

[2] Although the *Lockwood* decision was vacated after the patentee withdrew its jury demand, the opinion is still instructive as an indication of the Federal Circuit's views on this issue. *See Pfizer*, 2001 WL 477163 at *3.

> *counterclaim rather than in an affirmative defense does nothing to change this characterization.*

Id. (emphasis added).

The defendant in *Glaxo* petitioned the Federal Circuit for a writ of mandamus directing the lower court to vacate its order granting plaintiffs' motion to strike defendant's jury demand. In a nonprecedential opinion, the Federal Circuit denied the writ. *In re Apotex Inc.*, No. 690, 49 Fed. Appx. 902, 2002 WL 31388364 (Fed. Cir. Oct. 9, 2002). Relying on both *Tegal* and *Lockwood,* the Federal Circuit reasoned that "the important question when deciding whether a party is entitled to a jury trial in an action involving a declaratory judgment claim is to determine what type of action would have been brought by the declaratory judgment defendant [*i.e.*, the plaintiff-patentee] concerning the dispute." *Id.* at 903. The court found that "the nature of the underlying controversy is entirely equitable, involving only a controversy whether future acts should be enjoined." *Id.* Thus, in a § 271(e)(2) action "involving only possible future infringement, and in which there can be no damages because no infringing products have been marketed, the only relief that is before the district court is equitable in nature. Because the nature of the underlying controversy is entirely equitable, there can be no right to a jury trial." *Id. Accord, Glaxo Wellcome Inc. v. Geneva Pharms., Inc.*, 45 U.S.P.Q.2d 1702, 1703 (D.N.J. 1997). (Defendants' counterclaim for non-infringement was "'analogous to a traditional equitable remedy.'. . . Such an action does not provide any Seventh Amendment right to jury trial and cannot sustain plaintiffs' jury demand.") (internal citation omitted); *Sanofi-Synthelabo,* 64 U.S.P.Q.2d at 1688-89 (no right to a jury trial on counterclaims seeking a declaration of non-infringement or invalidity in a § 271(e)(2) action in the absence of actual damages).

II. CONCLUSION

Neither section 271(e)(2), the Seventh Amendment, nor Alcon's declaratory judgment counterclaims establish a basis for a jury trial in this action. Accordingly, Alcon respectfully requests that the Court grant its motion to strike Allergan's jury demand.

Respectfully submitted,

John W. Shaw

JWS/prt
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