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May 16, 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.*, No. 04-968 GMS
Our Ref.: 13351-012LL1

Dear Judge Sleet:

FR

AUSTIN
BOSTON
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DELAWARE
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SILICON VALLEY
TWIN CITIES
WASHINGTON, DC

Pursuant to paragraph 13 of the Scheduling Order [D.I. 30], plaintiffs Allergan, Inc. and Allergan Sales, Inc. (collectively, "Allergan") submit this letter brief in support of their jury demand and in opposition to defendants' May 9, 2005 letter brief [D.I. 63] seeking to strike that jury demand.

On August 24, 2004, Allergan brought this suit against Alcon under 35 U.S.C. § 271(e)(2), alleging that Alcon has infringed two of Allergan's patents, U.S. Patent Nos. 6,641,834 and 6,673,337 and requesting a trial by jury. Alcon filed its answer on September 3, 2004, along with counterclaims seeking a declaratory judgment of noninfringement and invalidity. Contrary to Alcon's assertions, the passage of the Hatch-Waxman Act did not take away Allergan's long-established right to a jury trial on its patent infringement claims. Moreover, under binding Federal Circuit precedent, Allergan has the right to have Alcon's declaratory judgment counterclaims for invalidity and noninfringement heard by a jury.

I. Prior to the Passage of § 271(e), Allergan Would Have Had a Right to a Jury Trial, and Nothing in § 271(e) Takes Away that Right.

A. The Hatch-Waxman Act Did Not Take Away the Right to a Jury Trial.

Before passage of the Hatch-Waxman Act in 1984, Allergan would have had an undeniable right to a jury trial on its claims because they would have been treated exactly like any other type of patent infringement for which Allergan could have sought damages and injunctive relief. With the passage of the Hatch-Waxman Act, including 35 U.S.C. § 271(e), the legal framework for dealing with infringement by generic drugs still in the FDA approval stage was altered, however.

Congress enacted § 271(e) as a direct response to the Federal Circuit's decision in *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984). In that case, the Federal Circuit held that work done in connection with seeking FDA approval for a generic drug to be sold upon expiration of a patent does not fall within the experimental use exception to patent infringement. After an outcry from the generic drug industry, Congress overturned the decision through the creation of 35

U.S.C. § 271(e). On the one hand, 35 U.S.C. § 271(e)(1) creates a special exemption that immunizes FDA-related actions from creating infringement liability. On the other hand, as a replacement of the right of patentees to sue in the circumstances presented in *Roche*, 35 U.S.C. § 271(e)(2) creates an infringement cause of action for the patentee based on the generic manufacturer's filing of an application for approval of a generic drug at the FDA. Section 271(e)(4) specifies that the patentee may only sue for injunctive relief prior to the generic product being approved and sold, as Allergan has done here. Notably, in passing this statute, there is no mention whatsoever of Congress's intent to limit the patentee or the generic manufacturer to only a bench trial.

B. Alcon's Analysis in Seeking to Deny a Jury Trial is Faulty.

In *Tull v. United States*, 481 U.S. 412 (1987), the Supreme Court set forth a two-part test for determining if a statutorily-created cause of action implicates the Seventh Amendment right to a jury trial. First, to determine the nature of the statutory action, the action is compared with eighteenth century actions brought in England prior to the merger of the courts of law and equity. *Id.* at 417. Second, the remedy sought is analyzed to determine whether it is legal or equitable in nature. *Id.*

Misapplying this test, Alcon collapses these two prongs into one, first wrongly concluding that the nature of the action is equitable because it involves injunctive relief and using the exact same reason to conclude that the nature of the remedy is also equitable. [Alcon Letter Br. at 3, D.I. 63] An analysis that turns the Supreme Court's two-prong test into a single prong test cannot be correct.

On the first prong, the nature of Allergan's § 271(e)(2) action is certainly legal rather than equitable. It is analogous to a patent infringement action that would have been brought in 18th century England. Prior to Congress's enactment of § 271(e)(1) and (2), it would have been treated as a typical patent infringement action, one in which Allergan would have been entitled to seek damages. *See Roche*, 733 F.2d at 863. Congress's passage of § 271(e) does not change the nature of Allergan's action.

On the second prong, Allergan has not chosen only to seek equitable relief. Instead, Allergan has chosen those statutory remedies available to it at the current time. *See* 35 U.S.C. § 271(e)(4)(a) and (b). Before the enactment of § 271(e), Allergan would have been entitled to seek damages for Alcon's activity. And while Congress took away that specific right, it provided instead the remedies Allergan is seeking currently.[1] Accordingly, under the Supreme Court's analysis, Allergan is simply

[1] Indeed, if this proceeding continues past the time the 30-month stay on approval expires, Alcon would have the statutory right to launch its product, and Allergan could seek damages for that activity. *See* 35 U.S.C. § 271(e)(4)(c).

seeking to vindicate the same rights as any patentee would have been at common law and the right to jury trial is preserved.

II. Allergan Is Entitled to a Trial By Jury on Alcon's Declaratory Judgment Counterclaims for Invalidity and Noninfringement.

Alcon's letter falsely implies that it is settled law that jury trials are not available in the Hatch-Waxman context. In reality, the law is far from settled. The Federal Circuit has not yet addressed the issue in a precedential opinion. And while Alcon cites two Federal Circuit orders that arose in the § 271(e)(2) context, Alcon fails to note that both are non-precedential and therefore cannot be cited as binding.

As to district court proceedings, relatively few districts have spoken on the issue in the Hatch-Waxman context, and those that have reached varying results. The District of New Jersey found a jury trial right based on the filing of declaratory judgment counterclaims on invalidity and noninfringement. *Warner-Lambert Co. v. Purepac Pharm. Co.*, No. 98-2749, 2001 WL 883232 (D.N.J. Mar. 30, 2001). The Southern District of New York, Northern District of Illinois, and District of Minnesota have all found no right to a jury trial. *See Sanofi-Synthelabo v. Apotex, Inc.*, No. 02-2255, 2002 WL 1917871 (S.D.N.Y. Aug. 20, 2002); *Glaxo Group Ltd. v. Apotex, Inc.*, No. 00-5791, 2001 WL 1246628 (N.D. Ill. Oct. 16, 2001); *Minn. Mining & Mfg. Co v. Alphapharm Pty. Ltd.*, 99-13 MJDJGL, 2002 WL 1352426 (D. Minn. Mar. 20, 2002). Taking a middle ground position, the District of Massachusetts recognized the uncertainty and concluded that it was safer to have a jury trial later deemed unnecessary than to go through a bench trial and later learn that a jury trial was required. *Zeneca Ltd. v. Pharmachemie B.V.*, No. 96-12413-RCL, 1998 WL 1013126 (D. Mass. Oct. 8, 1998).

In the non-Hatch-Waxman context, the law as to when a jury trial is available is clearer, and these cases are instructive. The Federal Circuit addressed the issue of availability of jury trials in *In re Lockwood*, 50 F.3d 966 (Fed. Cir. 1995), *vacated*, 515 U.S. 1182, albeit not specifically in the Hatch-Waxman context. Although *Lockwood* was later vacated, the Federal Circuit has approved the reasoning on jury trial issues in subsequent cases. In *Lockwood*, the plaintiff filed an infringement suit requesting both damages and an injunction, and the defendant filed a counterclaim for a declaratory judgment on noninfringement and invalidity. The district court granted summary judgment of noninfringement, leaving only the invalidity counterclaims for trial. The Federal Circuit concluded that the plaintiff had a right to a jury trial on the counterclaim, reasoning that "the historical nature of the Seventh Amendment takes as its object the nature of the underlying controversy." *Id.* at 973. The underlying controversy in *Lockwood* was legal rather than equitable because "a suit for a declaratory judgment of invalidity is more comparable to a lawsuit for patent infringement than to any historical equitable action," and the patentee was therefore

entitled to a jury trial because of the declaratory action that placed the validity of its patents at issue. *Id.* at 980.

In a later non-precedential opinion, *In re SGS-Thomson Microelectronics, Inc.*, Misc. No. 428, 1995 WL 258370 (Fed. Cir. Apr. 25, 1995), the Federal Circuit relied on *Lockwood* to hold that a defendant had a right to a jury trial on counterclaims for invalidity and noninfringement, even though the plaintiff was seeking only an injunction. In explaining why the invalidity and noninfringement counterclaims entitled the defendant to a jury, the Federal Circuit explained that "[t]he presence of [the plaintiff's] request for injunctive relief does not take those facts or issues away from the jury." *Id.* at *2. Similarly, in the present case, that Allergan may not seek damages at this stage of the proceedings does not take away its right to have a jury adjudicate the counterclaims of invalidity and noninfringement.

Because the facts are markedly different, Alcon's reliance on *Tegal Corp. v. Tokyo Electron Am., Inc.*, 257 F.3d 1331 (Fed. Cir. 2001), to support its request to strike Allergan's jury trial demand is misplaced. In *Tegal*, the patentee filed an infringement action under § 271(a), choosing to seek only an injunction. *Id.* at 1339. The defendant asserted affirmative defenses of noninfringement and invalidity, but no declaratory judgment counterclaims were involved. *Id.* at 1341. In that situation, the Federal Circuit held that the defendant had no right to a jury trial. *Id.*

The facts of the present case are markedly different from *Tegal*, and much closer to the facts of *Lockwood*, because Alcon has asserted declaratory judgment counterclaims for both noninfringement and invalidity. Alcon also relies on *Kao Corp. v. Unilever U.S., Inc.*, No. 01-680-SLR, 2003 WL 1905635 (D. Del. Apr. 17, 2003), a non-Hatch-Waxman case which found that a defendant had no right to a jury trial on declaratory judgment counterclaims when the plaintiff sought only an injunction. *Kao*, however, takes an overly limited view of *Lockwood*, which made plain the need to preserve the right to a jury trial where factual questions relating to validity are raised by a declaratory judgment claim. *See Lockwood*, 50 F.3d at 976. Furthermore, *Kao* places great emphasis on the availability of a jury trial being based on the patentee's choice of remedy (damages and/or injunctive relief) – a choice that was not available to Allergan in this case. The reasoning of *Kao* should not remove Allergan's right to a jury trial in this case.

As stated above, the District of New Jersey has recognized a right to a jury trial in actions brought under § 271(e)(2) if there are declaratory judgment counterclaims for invalidity and noninfringement. In *Warner-Lambert Co. v Purepac Pharmaceutical Co.*, No. 98-2749(JCL), 2001 WL 883232 (D.N.J. Mar. 30, 2001), the court concluded that Purepac had a right to a jury trial on its counterclaims even though Warner-Lambert brought suit under § 271(e)(2) and therefore was only entitled to seek equitable relief. The court cited *Lockwood* for the proposition that "there is a

right to a jury trial in an action for a declaratory judgment of patent invalidity." *Id.* at *2. The District of New Jersey earlier reached the same result in *Hoechst Marion Roussel, Inc. v. Par Pharm., Inc.*, No. 95-3673, 1996 WL 468593 (D.N.J. Mar. 14, 1996), where the plaintiff brought an action under § 271(e)(2) and the defendant asserted invalidity and noninfringement counterclaims. The court granted a jury trial, explaining as follows:

> Notwithstanding the fact that Hoechst brought this action pursuant to § 271(e)(2) rather than § 271(a), the counterclaim seeks declaratory judgment of noninfringement and invalidity. Par could have sought such relief under § 271(a) had it initiated a declaratory judgment action rather than filing a counterclaim. Under the ruling of *Lockwood* and *SGS-Thomson* it cannot be deprived of a jury trial.

Id. at *3.

Allergan recognizes that there is uncertainty in the law concerning the availability of jury trials in situations such as this one. Although Allergan maintains that it does have a right to a jury trial in this case, especially given that Alcon has raised invalidity and noninfringement counterclaims, the Court could choose to follow the example of the District of Massachusetts. In *Zeneca*, the District of Massachusetts recognized the uncertainty in the law and recommended a jury trial as a precaution so that the entire case would not have to be retried if a jury trial right was found on appeal. *Zeneca*, No. 96-12413-RCL, 1998 WL 1013126, at *1 (D. Mass. Oct. 8, 1998). The court explained that "striking the jury trial demand and proceeding with a protracted non-jury trial runs the considerable risk that if the right to a jury trial is sustained on appeal, the whole case would have to be retried." *Id.*

III. Conclusion

For the reasons stated above, Allergan respectfully requests that the Court deny Alcon's request to strike Allergan's jury trial demand.

Respectfully submitted,

William J. Marsden, Jr.

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