IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

KING PHARMACEUTICALS RESEARCH AND DEVELOPMENT, INC., ASTELLAS US LLC, and ASTELLAS PHARMA US, INC., Plaintiffs,	)	
v.	)	Civil Action No.: 05-0337-SLR
SICOR INC. and SICOR PHARMACEUTICALS, INC., Defendants.	)	

PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS COUNT III OF THE COMPLAINT

Plaintiffs, King Pharmaceuticals Research and Development, Inc., Astellas US LLC, and Astellas Pharma US, Inc. (collectively "Plaintiffs"), hereby jointly oppose Defendants' Motion to Dismiss Count III of the Complaint brought by Sicor Inc. and Sicor Pharmaceuticals, Inc. (collectively "Sicor").[1]

Sicor moves to strike Count III of the Complaint alleging that the Federal Circuit's decision in *Glaxo Group Ltd. v. Apotex, Inc.*, 376 F.3d 1339 (Fed. Cir. 2004), precludes a finding of willful infringement in this case as a matter of law. But the question of whether, in a Hatch-Waxman case, a baseless Paragraph IV certification of non-infringement or invalidity can give rise to a finding of willful infringement is not as well settled as Sicor suggests, and the broad statements Sicor relies on from *Glaxo* are merely *dicta*. Striking the allegation at the initial

[1] The identical issue was raised by Sicor in the concurrently pending case, *Item Development AB, Astellas US LLC, and Astellas Pharma US, Inc. v. Sicor Inc. and Sicor Pharmaceuticals, Inc.*, Civil Action No. 05-0336-SLR. The arguments made by the plaintiffs in opposition to the motion in that action mirror those made here.

pleading stage would frustrate the development of a full and complete record on which this Court or the Federal Circuit could definitively resolve the issue. More importantly, Sicor fails to mention that the allegations of Count III are not limited to willful infringement but include an explicit allegation that this is an exceptional case, entitling Plaintiffs to recover attorney fees. The Federal Circuit's *Glaxo* opinion, as well as the additional authorities cited by Sicor, make abundantly clear that, regardless of whether the infringing party's conduct is considered to constitute "willful infringement," an allegation of an exceptional case is proper and a patentee may be entitled to recover its fees. Thus, even if the Court agrees that a finding of willful infringement is precluded here as a matter of law, the proper remedy is to strike *only* the specific statement in the Complaint alleging willful infringement, not Count III in its entirety.

Thus, as set forth below, Plaintiffs respectfully request that the Court deny Sicor's motion or, in the alternative, that only paragraph 41 of the Complaint, relating to willful infringement, be stricken. The relevant statutory authority and case law grants Plaintiffs the right to prove the remaining allegations of Count III, that Sicor's conduct in this action--including its filing of a baseless certification and its pursuit of unsupportable defenses--warrants an award of attorney fees to Plaintiffs.

ARGUMENT

A. Sicor's *Glaxo* Argument is Based on *Dicta* and Ignores the Facts of this Case

The Federal Circuit's decision in *Glaxo* did not settle the question of whether the patentee in an infringement action under 35 U.S.C. § 271(e)(2) is entitled to prove that an accused infringer's conduct amounts to willful infringement. Although the court's opinion contained various statements, cited by Sicor in its moving papers, concerning the ability to base a finding

of willful infringement on a generic company's actions in connection with the filing of an abbreviated new drug application (ANDA), the facts of *Glaxo* differ substantially from the facts here. First, the procedural posture of *Glaxo* was not a motion to dismiss under Rule 12, but rather a review of a district court's finding of willful infringement following a trial on the merits. Second, unlike the instant case, *Glaxo* involved an unusual generic filing of an ANDA for an "old antibiotic," for which the Hatch-Waxman Act *does not require a certification* under Paragraph IV.

While a typical generic filer, under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), must certify, "in the opinion of the applicant and to the best of his knowledge," that any patent covering the product or its use is either invalid or not infringed, the defendant in *Glaxo* was not required to make such a certification. *Glaxo*, 376 F.3d at 1344. As a result, the issue of the adequacy of the defendant's bases for its certification of non-infringement or invalidity were not at issue before the *Glaxo* court. Although Sicor argues (Motion at 1) that the Federal Circuit "expressly held" that merely filing an ANDA *or certification* cannot support a finding of willful infringement, the certification question was not a part of the *Glaxo* decision and is obviously *dictum*. The Federal Circuit has noted on more than one occasion that *dicta* in its opinions are not binding precedent. *See Co-Steel Raritan, Inc. v. International Trade Commission*, 357 F.3d 1294, 1307 (Fed. Cir. 2004), and cases cited therein.

In notable contrast to the absence of any certification requirement in *Glaxo*, Sicor was required here to certify that it did not infringe the '877 patent or that the patent was invalid and to provide the detailed factual and legal bases for its certification. While it purported to provide the required certification, Sicor offered little to support its positions beyond mere conclusory

statements. Such a facially deficient certification should certainly form part of the proof giving rise to a finding of willful infringement.[2]

The question of whether the provocation of litigation under the Hatch-Waxman Act by willfully filing an ANDA containing a deficient certification of invalidity, unenforceability, and/or non-infringement can constitute "willful infringement" presents important policy issues that simply were not resolved in *Glaxo*. While the ANDA filing itself does not create actual damage in the form of lost sales, it nonetheless substantially damages the patentee. The patentee must sue to protect its rights no matter how baseless the claims made in the certification are. The costs associated with prosecution of these actions can be staggering. Expenditures running into the millions of dollars in attorney fees and costs are commonplace, dwarfing actual damage awards in many cases of actual infringement. The costs are staggering because the asset placed at risk by even a baseless certification is usually tremendously valuable to the patent owner. Rational settlement of these cases reflecting even a small risk to a hugely valuable asset is largely foreclosed by present day antitrust policies.

In contrast, a generic manufacturer who challenges, for example, five patents and only wins on one probably comes out ahead economically. Indeed, there is an economic incentive to advance even an unmeritorious challenge to a valuable brand-name drug arising from the 180 days of generic exclusivity provided by the statute to a victorious generic supplier. That exclusivity is often worth a large multiple of the generic's anticipated legal expenses, interjecting an element of gambling into the decision to file an ANDA. *See, e.g., Eli Lilly & Co. v. Zenith Goldline Pharmaceuticals, Inc.*, 264 F. Supp. 2d 753, 759 (S.D. Ind. 2003) ("In light of the lack

[2] At this stage of the proceedings, Plaintiffs are obligated only to plead, not prove, an exceptional case. *See Tower Air, Inc. v. Nachtomi*, 416 F.3d 229, 237-38 (3d Cir. 2005).

of a foundation for the invalidity defense and the financial incentives for Zenith if it won, it appears that Zenith was simply taking a calculated longshot gamble.").

When it appears following trial on the merits that the generic challenger was simply rolling the dice, hoping for an aberrant trial or appellate court decision, thereby damaging the patent owner to the tune of millions of dollars, the question of whether the unmeritorious patent certification that set that ball in motion can constitute "willful infringement" deserves a closer look than the Federal Circuit gave it in *Glaxo*.

Moreover, it is readily apparent that this case cannot be neatly disposed of under the umbrella of the *Glaxo* holding. The defendant in *Glaxo* was not found to have committed litigation misconduct by, for example, needlessly complicating and prolonging the proceedings by maintaining baseless legal positions. By contrast here, even at this early stage, Sicor is advancing the completely untenable position that it does not infringe the '877 patent. Sicor's Answer filed in this Court denies infringement even though its letter providing the bases for its Paragraph IV certification did not offer non-infringement arguments for claims 1, 3-12, 17, 18, 20-26, or 43.

If following trial on the merits of this case, this Court feels that a finding of willful infringement is unwarranted, it can enter judgment to that effect. If Plaintiffs disagree, they can ask the Federal Circuit to take that closer look on the basis of a fully developed record in this case. If the allegation is struck at the initial pleading stage, as Sicor requests, neither this Court nor the Federal Circuit will have a proper record on which to answer these important policy questions.[3]

[3] Sicor also cites two district court decisions, including a recent Order in this district, to support its broad reading of *Glaxo*. Those decisions were clearly strongly influenced by the Federal Circuit's *Glaxo dicta* and are not, in any event, binding on this Court. *See Mosel*

B. Even If the Court Strikes the Allegation of Willful Infringement in Count III, the Allegations Concerning Exceptional Case and Attorney Fees Should Remain

In the final analysis, Sicor's argument that *Glaxo* precludes an allegation of willful infringement is more a matter of style than substance. A finding of willful infringement is important in a patent case primarily as part of the factual predicate for trebling of damages and awarding attorney fees. The issue of treble damages is currently irrelevant here because Sicor has not yet launched its product.[4] Furthermore, the Federal Circuit's *Glaxo* opinion and the additional authorities cited by Sicor make abundantly clear that, regardless of whether the infringing party's conduct constitutes "willful infringement," a patentee is entitled to seek an award of attorney fees based on other circumstances. *See Glaxo*, 376 F.3d at 1350; *Allergan, Inc. v. Alcon, Inc.*, C.A. No. 04-968 (July 26, 2005 Order ¶ 6); *Aventis Pharma Deutschland GMBH v. Cobalt Pharmaceuticals, Inc.*, 355 F. Supp. 2d 586, 592-93 (D. Mass. 2005). In ANDA-induced infringement actions, attorney fees for an "exceptional case" are specifically authorized under 35 U.S.C. § 271(e)(4) (in accordance with 35 U.S.C. § 285). For example, a baseless Paragraph IV certification, when combined with litigation misconduct, is sufficient to support a claim for an "exceptional case." *See Yamanouchi Pharm. Co. v. Danbury Pharmacal, Inc.*, 231 F.3d 1339, 1347 (Fed. Cir. 2000). While it reversed the award of attorney fees in *Glaxo*, the Federal Circuit distinguished *Glaxo* from *Yamanouchi*, noting that in *Glaxo* there was no litigation misconduct and the generic "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*." *Glaxo*,

---

Vitelic Corp. v. Micron Tech., Inc., 162 F. Supp. 2d 307, 311 (D. Del. 2000) ("[W]hile the opinion of one district judge may be found to be persuasive, it is not binding on another district judge (even if that judge happens to sit in the same district).") (citations omitted).

[4] Of course, Plaintiffs reserve the right to amend the Complaint and seek damages should Sicor launch an infringing product, or if other evidence of current infringement becomes available through discovery.

376 F.3d at 1350-1351 (emphasis supplied). Indeed, though not binding on this Court, the recent Delaware case relied upon by Sicor explicitly noted that the patent holder was not barred from, "at the appropriate time, seeking to prove additional facts that would support its claim of an exceptional case." *Allergan, Inc. v. Alcon, Inc*., C.A. No. 04-968 (July 26, 2005 Order ¶ 6.)

Here, Sicor is already engaging in conduct that will support an exceptional case finding. As provided above, by filing a facially deficient certification in combination with maintaining its baseless non-infringement position in this litigation, Sicor is already needlessly complicating these proceedings. Thus, under *Glaxo*, *Yamanouchi*, and the additional authorities cited by Sicor, Plaintiffs have the right to prove that Sicor's conduct in this action warrants an award of attorney fees to them.

Even if this Court finds that Plaintiffs' claims for willful infringement are improper in light of the Federal Circuit's holding in *Glaxo*, Plaintiffs' claims that this is an exceptional case should remain. Accordingly, Plaintiffs respectfully request that the Court deny Sicor's motion or, in the alternative, strike *only* that paragraph of the Complaint relating to willful infringement, paragraph 41.

Dated: August 29, 2005

By: */s/ Richard K. Herrmann*

Richard K. Herrmann (I.D. #405)
Mary B. Matterer (I.D. #2696)
MORRIS, JAMES, HITCHENS
& WILLIAMS LLP
222 Delaware Avenue, 10th Floor
Wilmington, DE 19801
302.888.6800
rherrmann@morrisjames.com
mmatterer@morrisjames.com

Charles E. Lipsey (admitted *pro hac vice*)
Michele L. Mayberry (admitted *pro hac vice*)
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
Two Freedom Square
11955 Freedom Drive
Reston, VA 20190-5675
571.203.2700

Susan H. Griffen (admitted *pro hac vice*)
David P. Frazier (admitted *pro hac vice*)
Antigone G. Kriss (admitted *pro hac vice*)
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.
901 New York Avenue, N.W.
Washington, DC 20001-4413
202.408.4000

Attorneys for Plaintiffs
Astellas US LLC and
Astellas Pharma US, Inc.

Dated: August 29, 2005

By: */s/ Paul E. Crawford*

Paul E. Crawford (I.D. #493)
Patricia Smink Rogowski (I.D. #2632)
CONNOLLY BOVE LODGE & HUTZ LLP
1107 N. Orange Street
P.O. Box 2207
Wilmington, DE 19899-2207
302.658.9141
pcrawford@cblh.com
progowski@cblh.com

Brian M. Poissant (admitted *pro hac vice*)
F. Dominic Cerrito (admitted *pro hac vice*)
Daniel L. Malone
Gasper J. LaRosa (admitted *pro hac vice*)
JONES DAY
222 East 41st Street
New York, NY 10017
212.326.3939

Attorneys for Co-Plaintiff King Pharmaceuticals Research and Development, Inc.

CERTIFICATE OF SERVICE

I hereby certify that on the 29th day of August, 2005, I electronically filed the foregoing document, **PLAINTIFFS' MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTION TO DISMISS COUNT III OF THE COMPLAINT**, with the Clerk of the Court using CM/ECF which will send notification of such filing to the following:

Paul E. Crawford
Patricia Smink Rogowski
Connolly Bove Lodge & Hutz LLP
1007 N. Orange Street
Wilmington, DE 19801

Josy W. Ingersoll
John W. Shaw
Young Conaway Stargatt & Taylor, LLP
The Brandywine Building
1000 West Street, 17th Floor
Wilmington, DE 19801

Additionally, I hereby certify that on the 29th day of August, 2005, the foregoing document was served via email and Federal Express on the following non-registered participants:

F. Dominic Cerrito
Daniel L. Malone
Gasper J. LaRosa
Jones Day
222 East 41 Street
New York, NY 10017
fdcerrito@jonesday.com
dlmalone@jonesday.com
gjlarosa@jonesday.com

David M. Hashmall, P.C.
Annemarie Hassett
Goodwin Proctor LLP
599 Lexington Avenue
New York, NY 10022
dhashmall@goodwinproctor.com
ahassett@goodwinproctor.com

/s/ Richard K. Herrmann
Richard K. Herrmann (#405)
MORRIS JAMES HITCHENS & WILLIAMS LLP
222 Delaware Avenue, 10th Floor
Wilmington, Delaware 19801
302.888.6800
rherrmann@morrisjames.com
Attorneys for Plaintiffs Astellas US LLC
and Astellas Pharma US, Inc.