

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PFIZER INC., PFIZER IRELAND :
PHARMACEUTICALS, WARNER- :
LAMBERT COMPANY, WARNER- :
LAMBERT COMPANY, LLC, and :
WARNER-LAMBERT EXPORT, LTD., :
 :
Plaintiffs, :
 :
v. : Civil Action No. 03-209-JJF
 : (Consolidated)
RANBAXY LABORATORIES LIMITED :
and RANBAXY PHARMACEUTICALS, :
INC., :
 :
Defendants. :

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OPINION

June 18, 2004

Wilmington, Delaware

Farnan, District Judge.

Pending before me are two related motions, Defendants' Motion For Partial Judgment On The Pleadings Pursuant To Fed. R. Civ. P. 12(c) (D.I. 79) and Plaintiffs' Motion Pursuant To Fed. R. Civ. P. 56(f) To Obtain Discovery And Evidence Necessary To Respond To Ranbaxy's Motion For Partial Judgment On The Pleadings (D.I. 92). For the reasons set forth below, I will grant Defendants' Motion For Partial Judgment On The Pleadings Pursuant To Fed. R. Civ. P. 12(c) and dismiss Plaintiffs' inducement of infringement claims in each of the complaints comprising this consolidated action. In addition, I will deny Plaintiffs' Motion Pursuant To Fed. R. Civ. P. 56(f) To Obtain Discovery And Evidence Necessary To Respond To Ranbaxy's Motion For Partial Judgment On The Pleadings.

BACKGROUND

Plaintiffs have brought four actions against Defendants which have been consolidated. By its complaints, Plaintiffs allege that Defendants infringed U.S. Patent Nos. 4,681,893 ("893 patent") and 5,273,995 ("the '995 patent") under 35 U.S.C. § 271(e)(2) and induced infringement of those patents under 35 U.S.C. § 271(b). Plaintiffs are the owners of both patents, and the United States Food and Drug Administration has identified both patents pursuant to 21 U.S.C. § 335(b)(1) as covering Plaintiffs' Lipitor® product, a cholesterol inhibitor. Although the '893 patent was to expire on May 30, 2006, and the '995

patent was to expire on December 28, 2010, both patents have been granted extensions.

By their complaints, Plaintiffs allege that Defendants submitted an Abbreviated New Drug Application, ANDA 76-477, requesting FDA approval to commercially manufacture, use or sell a drug product containing atorvastatin calcium salt and referencing Plaintiffs' Lipitor® product. Pursuant to 21 U.S.C. § 355(j)(2)(B), Defendants notified Plaintiffs of their ANDA filing and asserted that neither the '893 patent nor the '995 patent would be infringed by their manufacture, use or sale of the atorvastatin product.

Plaintiffs' complaints assert claims of infringement and inducement of infringement of the '893 and '995 patents. For purposes of the instant motion, the claims of inducement of infringement are relevant. The three complaints pertaining to the '893 patent make the following allegations regarding inducement of infringement:

30. Ranbaxy Laboratories has infringed the '893 patent under 35 U.S.C. 271(b) by actively inducing Ranbaxy Pharmaceuticals to infringe the '893 patent.
31. Alternatively, Ranbaxy Pharmaceuticals has infringed the '893 patent under 35 U.S.C. 271(b) by actively inducing Ranbaxy Laboratories to infringe the '893 patent.

(See e.g. D.I. 97, Exh. 2 at 5). The complaint pertaining to the '995 patent makes substantially identical allegations, except that the '995 patent is inserted in place of the '893 patent.

(D.I. 97, Exh. 1 at 5). Plaintiffs contend that their claims were pled in the alternative against each Defendant, because the ANDA notice provided to Plaintiffs by Defendants was ambiguous as to the roles played by the two Defendant entities. Plaintiffs further allege in their complaints that Defendant Ranbaxy Pharmaceuticals, Inc. ("Ranbaxy Pharmaceuticals") is a wholly-owned subsidiary of Defendant Ranbaxy Laboratories Limited ("Ranbaxy Laboratories"), each ANDA letter was received from Ranbaxy Pharmaceuticals, Ranbaxy Laboratories filed the ANDA, Ranbaxy Pharmaceuticals is Ranbaxy Laboratories' agent for service of process under the ANDA, and Ranbaxy Pharmaceuticals was responsible for and controlled the filing of the ANDA.

Defendants have moved for partial judgment on the pleadings contending that the claims for inducing infringement alleged by Plaintiffs in the complaints are not legally cognizable as pled. Specifically, Defendants contend that neither the act of filing an ANDA nor the act of aiding in the filing of an ANDA will support a claim for inducing infringement under 35 U.S.C. § 271(b).

Plaintiffs filed an Answer Brief to Defendants' Motion For Partial Judgment On The Pleadings and also filed a separate motion for additional discovery pursuant to Federal Rule of Civil Procedure 56(f). Both motions have been fully briefed and are ripe for review.

STANDARD OF REVIEW

Pursuant to Federal Rule of Civil Procedure 12(c), any party may move for judgment on the pleadings after the pleadings are closed, but within such time as not to delay the trial. A motion under Rule 12(c) is reviewed under the same standard as a motion to dismiss under Rule 12(b)(6). Turbe v. Government of the Virgin Islands, 938 F.2d 427, 428 (3d Cir. 1991). Thus, a court must accept as true the factual allegations of the complaint and draw all reasonable factual inferences in the light most favorable to the non-moving party. Id. However, a court is "not required to accept legal conclusions either alleged or inferred from the pleaded facts." Kost v. Kozakiewicz, 1 F.3d 176, 183 (3d Cir. 1993). Judgment on the pleadings should be granted only if "it appears beyond doubt that the plaintiff can prove no set of facts in support of his claims which would entitle him to relief." Conley v. Gibson, 355 U.S. 41, 45 (1957). The burden of establishing that judgment on the pleadings is appropriate rests on the moving party. Institute for Scientific Information, Inc. v. Gordon & Breach, Sci. Publishers, Inc., 931 F.2d 1002, 1005 (3d Cir. 1991); Jablonski v. Pan Am. World Airways, Inc., 863 F.2d 289, 290-91 (3d Cir.1988).¹

¹ Plaintiffs urge me to convert the instant motion to a motion for summary judgment by considering facts referenced outside of the pleadings. Fed. R. Civ. P. 12(c) (recognizing that Rule 12(c) motion may be treated as one for summary judgment and disposed of as provided in Rule 56 if matters outside the

DISCUSSION

I. Defendants' Motion For Partial Judgment On The Pleadings

Defendants move for partial judgment on the pleadings with respect to Plaintiffs' inducement of infringement claims. Defendants contend that Plaintiffs' inducement of infringement claims are based solely on Plaintiffs' allegations of infringement under 35 U.S.C. § 271(e)(2), pertaining to the filing of the ANDA. Defendants contend that, according to Federal Circuit precedent in Warner-Lambert Company v. Apotex Corp., 316 F.3d 1348 (Fed. Cir. 2003) and Allergan, Inc. v. Alcon Laboratories, Inc., 324 F.3d 1322 (Fed. Cir. 2003), there can be no cause of action for induced infringement based on alleged aiding and abetting the filing of an ANDA.

Plaintiffs distinguish the circumstances in Warner-Lambert and Allergen and contend that, in this case, infringement occurred when Defendants filed the ANDA, because the ANDA product sought by Defendants infringes the '893 and '995 patents. Thus, Defendants contend that inducement of infringement occurred when one Defendant induced the other to file the ANDA. Plaintiffs contend that their position is consistent with the application of

pleadings are presented and not excluded by the court). I conclude that such a conversion is not necessary, because Defendants' motion presents a purely legal question. Therefore, I will not consider factual information beyond the pleadings to resolve the issue presented. See infra Section II of the Discussion resolving Plaintiffs' discovery motion.

statutory construction principles to the statutes at issue.

Pursuant to 35 U.S.C. § 271(b), "whoever actively induces infringement of a patent shall be liable as an infringer." Interpreting this section, the Court of Appeals for the Federal Circuit requires the plaintiff to prove that the defendants' "actions induced infringing acts and that [they] knew or should have known [their] actions would induce actual infringement." Warner, 316 F.3d at 1362 (citing Manville Sales Corp. v. Paramount Sys., Inc., 917 F.2d 544, 553 (Fed. Cir. 1990)). However, the Federal Circuit has also concluded that "knowledge of the acts alleged to constitute infringement is not enough." Id. Rather, a finding of active inducement requires proof of actual intent to cause the acts which constitute the infringement. Id. Thus, "[i]nducement requires proof that the accused infringer knowingly aided and abetted another's direct infringement of the patent." Id. (citing Rodime PLC v. Seagate Tech., Inc., 174 F.3d 1294, 1306 (Fed. Cir. 1999)). Inducement of infringement also requires the commission of an act that constitutes inducement, and not merely the power to act or the failure to act. See Beverly Hills Fan Co. v. Royal Sovereign Corp., 21 F.3d 1558, 1569 (Fed. Cir. 1994).

In this case, Plaintiffs' claims for inducement of infringement are based on allegations of direct infringement under 35 U.S.C. § 271(e)(2). In pertinent part, Section

271(e) (2) provides:

It shall be an act of infringement to submit--(A) an application under section 505(j) of the Federal Food, Drug and Cosmetic Act or described in section 505(b) (2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent . . . if the purpose of such submission is to obtain approval under such Act to engage in the commercial manufacture, use, or sale of a drug . . . claimed in a patent or the use of which is claimed in a patent before the expiration of such patent.

The Federal Circuit has recognized that a claim for inducement of infringement may be premised on Section 271(e) (2); however, the question presented by Defendants is whether such a claim may be premised only upon allegations that the alleged inducer aided and abetted the filing of an ANDA. The Federal Circuit has not squarely addressed this issue, but three district courts have including the United States District Court for the Southern District of New York in Astrazeneca v. Mylan Laboratories, Inc., 265 F. Supp. 2d 213 (S.D.N.Y. 2003), the United States District Court for the Northern District of Illinois in Smithkline Beecham Corp v. Pentech Pharmaceuticals, Inc., 2001 WL 184804 (N.D. Ill. Feb. 20, 2001) and the United States District Court for the Eastern District of Pennsylvania in Smithkline Beecham Corp. v. Geneva Pharmaceuticals, Inc., 287 F. Supp. 2d 576 (E.D. Pa. 2002).

Although I am not bound by any of these decisions, I am persuaded by the reasoning espoused by the court in Astrazeneca and conclude that a claim for inducement of infringement cannot

be based solely upon allegations that a defendant aided and abetted the filing of an ANDA. A claim for inducement of infringement is based on an act of direct infringement, and thus, requires proof of direct infringement. Epcon Gas Systems, Inc. v. Bauer Compressors, Inc., 279 F.3d 1022, 1033 (Fed. Cir. 2002). As the Federal Circuit has explained, the act of filing an ANDA is "an 'artificial' act of infringement that creates case-or-controversy jurisdiction to enable the resolution of an infringement dispute before the ANDA applicant has actually made or marketed the proposed product." Warner-Lambert, 316 F.3d at 1365 (citing Glaxo, Inc. v. Novopharm, Ltd., 110 F.3d 1562, 1569 (Fed. Cir. 1997)). Once jurisdiction is established; however, "the substantive determination whether actual infringement or inducement will take place is determined by traditional patent infringement analysis, just the same as it is in other infringement suits . . . the only difference being that the inquiries now are hypothetical because the allegedly infringing product has not yet been marketed." Id. at 1366. Stated another way, the inquiry for a claim of direct infringement under Section 271(e) (2) (A) is "'whether, if a particular drug were put on the market, it would infringe the relevant patent.'" Id. (citing Bristol-Myers Squibb Co. v. Royce Labs., Inc., 69 F.3d 1130, 1135 (Fed. Cir. 1995)). Thus, as the Astrazeneca court explained, the appropriate inquiry in an inducement action brought under Section

271(b) and premised on an ANDA filing under Section 271(e) is “whether the drug, if approved, will induce infringement of the plaintiff’s patent.” Astrazeneca, 265 F. Supp. 2d at 217.

Because the time frame for the direct infringement claim forming the basis of the inducement claim is post-FDA approval, I conclude that allegations of activities done in preparation for filing an ANDA cannot state a claim for inducement of infringement.

Plaintiffs contend that it is inappropriate to rely upon the Federal Circuit’s formulation of the proof required for infringement under Section 271(e) (2) to determine whether a claim for inducement of infringement can exist. But, Plaintiffs’ claim for inducement of infringement cannot be considered without referring to Section 271(e), because without infringement under Section 271(e) there would be no claim for inducement under Section 271(b) in this case. Id. at 218 n.7; see also Epcon, 279 F.3d at 1033 (“Upon a failure of proof of direct infringement, any claim of inducement of infringement also fails.”).

Plaintiffs next contend that precluding an action for inducement of infringement based on aiding and abetting the filing of an ANDA conflicts with the plain language of the relevant statutes, because nothing in the statutory framework evidences an intent to exclude claims for inducement under Section 271(b) where the act of direct infringement arises under

Section 271(e) (2) and nothing in Section 271 negates liability for inducing the filing of the ANDA. The Federal Circuit has recognized that claims for inducement of infringement under Section 271(b) may be based on Section 271(e) (2), and nothing in my decision is contrary to that principle. Indeed, my decision is directed only to the manner in which an inducement claim premised upon Section 271(e) (2) must be pled to be cognizable. As such, my decision represents an integration of inducement under Section 271(b) with its predicate under Section 271(e) (2) and not an exclusion of Section 271(b) from Section 271(e) (2).

Plaintiffs' argument regarding the statutory scheme is akin to the position taken by the court in Geneva. However, the Geneva court did not consider the Federal Circuit's guidance with respect to the appropriate time frame to consider when analyzing claims premised upon Section 271(e) (2). Because infringement under Section 271(e) (2) is premised upon whether the drug, if approved and placed on the market, would infringe, an inducement claim premised on Section 271(e) (2) must also be considered in this light.

Further, the Geneva court referenced, in support of its holding, the decision of the court in Pentech. However, I am not persuaded by the rationale of the Pentech court, because the Pentech court did not consider whether a claim for aiding and abetting the filing of an ANDA is substantively permitted under

the patent law. In my view, the Pentech court presumed the legal existence of such a claim, and proceeded to consider the issue only under the federal notice pleading standards as construed by the Seventh Circuit and not under substantive patent law.

Moreover, I am persuaded that my conclusion is consistent with the statutory framework as a whole, because a contrary construction would conflict with the purposes of the Hatch-Waxman Act to make low-cost generic drugs more available and create new incentives for research and development of certain products which are subject to premarket approval. Glaxo, 110 F.3d at 1568 (citing H.R. Rep. No. 98-857(I) at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2647-48). These purposes are effectuated, in part, by the statutory exemption to infringement provided under Section 271(e)(1). Specifically, Section 271(e)(1) provides:

It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use or sale of drugs or veterinary biological products.

The activities described in Section 271(e)(1) are activities involved in the preparation of an ANDA filing. As the Federal Circuit recognized in considering this section, "a generic drug manufacturer is free from liability for patent infringement based solely upon acts necessary to prepare the ANDA." Glaxo, 110 F.3d

at 1568. To allow one to be liable for inducement of infringement based solely on activities related to the preparation of the ANDA filing would undercut Section 271(e)(1) and discourage entities from participating in the research and other activities needed to submit an ANDA application, a result which is clearly at odds with the purposes of the Hatch-Waxman Act, and therefore, I decline to adopt such an interpretation.

In the alternative, Plaintiffs contend that under the liberal pleading standard, their allegations are sufficient to state a claim. I disagree with Plaintiffs' position. Plaintiffs' allegations related to inducement appear to be related solely to the filing of the ANDA, and therefore, I conclude that Plaintiffs have not stated a cognizable claim for inducement of infringement.²

In sum, I conclude that Plaintiffs cannot maintain a claim for inducement of infringement based upon Section 271(e)(2) for aiding and abetting the filing of an ANDA. I believe my

² Plaintiffs contend that "it is clear that [Ranbaxy Pharmaceuticals] and [Ranbaxy Laboratories] intend to be active in the importation, sales and marketing of Ranbaxy's ANDA product," and "the relief requested by [Plaintiffs] makes this clear." (D.I. 97 at 34). In their Complaint, Plaintiffs do seek to enjoin active inducement of infringement until after the expiration of the patent, which suggests a time frame following any FDA approval of the ANDA, but Plaintiffs make no factual allegations pertaining to inducement following FDA approval to support their claim for relief. Accordingly, I am not persuaded that the Complaint sufficiently states a cognizable claim for inducement of infringement.

conclusion is consistent with the approach to infringement under Section 271(e) (2) taken by the Federal Circuit and with the statutory scheme, taken as a whole, including its protection of generic drug manufacturers from liability based upon acts taken in preparation of an ANDA filing.³ Accordingly, I will grant Defendants' motion for judgment on the pleadings and dismiss Plaintiffs' inducement claims in each of the complaints comprising this consolidated action.

II. Plaintiffs' Motion Pursuant To Fed. R. Civ. P. 56(f) To Obtain Discovery And Evidence Necessary To Respond To Ranbaxy's Motion For Partial Judgment On The Pleadings

By their Motion, Plaintiffs request additional discovery which they contend will assist them in responding to Defendants' motion for partial judgment on the pleadings. Plaintiffs contend that this discovery would provide evidence regarding the roles played by Ranbaxy Laboratories and Ranbaxy Pharmaceuticals with regard to their filing of the ANDA. Plaintiffs also contend that this discovery is relevant to any inducement of infringement that will occur following the FDA's approval of the ANDA. Defendants contend that additional discovery is not necessary, because their motion presents the purely legal question of whether aiding and

³ Having concluded that Plaintiffs cannot maintain their claims for inducement of infringement, I decline to consider Defendants' alternative argument that Plaintiffs' claims for inducement should be dismissed because Plaintiffs seek a remedy for inducement which is unavailable under Section 271(e) (4).

abetting the filing of an ANDA states a cognizable claim for inducement of infringement. Defendants also contend that Plaintiffs have not pled a claim for inducement of infringement based on anything other than the filing of the ANDA.

In adjudicating Defendants' motion for judgment on the pleadings, I have concluded that Plaintiffs' cannot maintain a claim based upon aiding and abetting the filing of the ANDA. I approached this issue as a purely legal question, and because I believe this approach is correct, additional factual discovery is not relevant. In addition, I have concluded that Plaintiffs have failed to sufficiently plead an inducement claim based upon activities other than the filing and preparation of the ANDA. Accordingly, I conclude, in this context, that additional discovery is not required, and therefore, I will deny Plaintiffs' Motion Pursuant To Fed. R. Civ. P. 56(f) To Obtain Discovery And Evidence Necessary To Respond To Ranbaxy's Motion For Partial Judgment On The Pleadings.⁴

CONCLUSION

For the reasons discussed, I will grant Defendants' Motion

⁴ Plaintiffs have also alleged that the discovery they seek is necessary to respond to Defendants' counterclaim that their patents are invalid due to obviousness. Defendants do not address this issue in their response to Plaintiffs' motion, and Plaintiffs have filed a second motion seeking the same discovery on grounds unrelated to the inducement claims. (D.I. 93). Accordingly, I will address the discovery sought as it relates to obviousness in the context of Plaintiffs' second motion by separate Order.

For Partial Judgment On The Pleadings Pursuant To Fed. R. Civ. P. 12(c) and dismiss Plaintiffs' inducement of infringement claims. In addition, I will deny Plaintiffs' Motion Pursuant To Fed. R. Civ. P. 56(f) To Obtain Discovery And Evidence Necessary To Respond To Ranbaxy's Motion For Partial Judgment On The Pleadings.

An appropriate Order will be entered.

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RANBAXY LABORATORIES LIMITED :
and RANBAXY PHARMACEUTICALS, :
INC., :
 :
Defendants. :

ORDER

At Wilmington, this 18th day of June 2004, for the reasons set forth in the Opinion issued this date;

IT IS HEREBY ORDERED that:

1. Defendants' Motion For Partial Judgment On The Pleadings Pursuant To Fed. R. Civ. P. 12(c) (D.I. 79) is GRANTED. Plaintiffs' claims for inducement of infringement in each of the complaints comprising Civil Action No. 03-209-JJF (consolidated) are hereby dismissed.

2. Plaintiff's Motion Pursuant To Fed. R. Civ. P. 56(f) To Obtain Discovery And Evidence Necessary To Respond To Ranbaxy's Motion For Partial Judgment On The Pleadings (D.I. 92) is DENIED.

JOSEPH J. FARNAN, JR.
UNITED STATES DISTRICT JUDGE