

**ASTRAZENECA AB, et al., Plaintiffs, v. MYLAN LABORATORIES, INC. and MYLAN PHARMACEUTICALS, INC., Defendants.
ASTRA AKTIEBOLAG, et al., Plaintiffs, v. EON LABS MANUFACTURING, INC., Defendant. In re OMEPRAZOLE PATENT LITIGATION**

00 Civ. 6749 (BSJ), 00 Civ. 7598 (BSJ), M-21-81, MDL Docket No. 1291

UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

265 F. Supp. 2d 213; 2003 U.S. Dist. LEXIS 8600

May 20, 2003, Decided

May 21, 2003, Filed

PRIOR HISTORY: *Astra Aktiebolag v. Andrx Pharms., Inc. (In re Omeprazole Patent Litig.)*, 222 F. Supp. 2d 423, 2002 U.S. Dist. LEXIS 19960 (S.D.N.Y., 2002)

DISPOSITION: **[**1]** Plaintiffs' motion to amend complaints to add defendants denied.

COUNSEL: For Astrazeneca AB, Aktiebolaget Hassle, KBI-E Inc, KBI Inc, Astrazenaca, LP, Astrazeneca LP, PLAINTIFFS: Robert L Baechtold, Fitzpatrick, Cella, Harper & Scinto, New York, NY USA.

For Mylan Laboratories Inc, Mylan Pharmaceuticals Incorporated, DEFENDANTS: Elliot Lauer, Curtis Mallet-Prevost Colt & Mosle, Edward M Spiro, Morvillo, Abramowitz, Grand, Iason & Silberberg, New York, NY USA.

For Mylan Laboratories Inc, Mylan Pharmaceuticals Incorporated, DEFENDANTS: Roberta R Wilson, DKW Law Group, PC, Pittsburgh, PA USA.

For Eon Labs Manufacturing, Inc, DEFENDANT: Thomas C Pontani, Martin B

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For **[**2]** Astrazeneca AB, Aktiebolaget Hassle, KBI-E Inc, KBI Inc, Astrazenaca, LP, Astrazeneca LP, COUNTER-DEFENDANTS: Robert L Baechtold, Fitzpatrick, Cella, Harper & Scinto, New York, NY USA.

JUDGES: BARBARA S. JONES, UNITED STATES DISTRICT JUDGE.

OPINION BY: BARBARA S. JONES

OPINION

[*213] OPINION AND ORDER

Plaintiffs, AstraZeneca AB, Aktiebolaget Hassle, KBI-E-Inc., KBI Inc., and AstraZeneca, LP, (collectively “Astra”), seek leave to amend their complaint against defendants Mylan Laboratories Inc., and Mylan Pharmaceuticals, Inc. (collectively “Mylan”) to add Esteve Quimica S.A. (“Esteve Quimica”) and Laboratorios Dr. Esteve S.A (“Laboratorios Dr. Esteve”), (collectively “Esteve”) as defendants accused of inducing infringement of *U.S. Patent No. 4,786,505* (“the ‘505 patent’”) and *U.S. Patent No. 4,853,230* (“the ‘230 patent’”). Likewise, Astra seeks to amend its complaint against defendant Eon Labs Manufacturing Inc. (“Eon”) to add Hexal AG (“Hexal”) and A/S GEA Farmaceutisk Fabrik (“GEA”) as defendants accused of infringement of the ‘505 and ‘230 patents. For the reasons to follow, Astra’s motion [*214] to amend with respect to the Mylan and Eon complaints is denied.

BACKGROUND

These actions relate to Astra’s [**3] patents for PRILOSEC(R), a pharmaceutical product that inhibits the production of acid in the stomach. The present controversies began when defendants notified Astra that they had submitted to the FDA Abbreviated New Drug Applications (“ANDAs”) seeking approval to manufacture a generic version of Astra’s PRILOSEC(R). In response to the notices, Astra filed a complaint against Eon on May 15, 2000 and a complaint against Mylan on September 8, 2000. Those complaints contend that Eon and Mylan’s ANDA filings constituted infringement of Astra’s ‘505 and ‘230 patents.¹ Discovery in these cases was consolidated before the Special Master on December 2, 2002 providing approximately six months for completion of fact discovery from the five defendants.

¹ In addition to the complaints at issue in this motion, Astra filed several other

complaints against numerous other ANDA filers with respect to PRILOSEC(R). The defendants were grouped as “first-wave defendants” and “second-wave defendants”. Astra’s claims against the first-wave defendants were tried to the court sitting without a jury for fifty-two trial days between December 6, 2001 through June 13, 2002, and an opinion was issued on October 11, 2002. Three other groups of pharmaceutical companies are considered second-wave defendants, however Astra has not moved to amend the complaints with respect to any of these other second-wave defendants.

[**4] Astra served document requests on Mylan and Eon on December 13, 2002 in addition to a request that Mylan produce documents from the files of Esteve Quimica and Laboratorios Dr. Esteve, and a request that Eon produce documents from the files of Hexal and GEA. Mylan denied custody and control over the Esteve documents and informed Astra that it would provide some documents related to Mylan’s ANDA products. Eon likewise denied custody and control over the Hexal and GEA documents and stated that it would not assist Astra in obtaining discovery from either Hexal or GEA.²

² The Special Master found that neither Mylan nor Eon had custody and control of the documents at issue, and this Court affirmed the Special Master’s ruling on May 12, 2003.

On January 10, 2003, Astra requested that Mylan and Eon consent to an amendment to the complaints against them to add Esteve Quimica and Laboratorios Dr. Esteve, and Hexal and GEA, respectively, as defendants. Both Mylan and Eon responded that they would not consent. This [**5] motion for leave to amend followed.

DISCUSSION

A. Legal Standard for Motion to Amend

Pursuant to *Rule 15(a) of the Federal Rules of Civil Procedure*, “leave [to amend] shall be freely given when justice so requires.” The Second Circuit has stated that leave to amend should “generally not be denied” unless such amendment would be futile, or “there is evidence of undue delay, bad faith, [or] undue prejudice to the non-movant” *Milanese v. Rust-Oleum Corp.*, 244 F.3d 104, 110 (2d Cir. 2001) (citing *Foman v. Davis*, 371 U.S. 178, 182, 9 L. Ed. 2d 222, 83 S. Ct. 227 (1962)).

Further, *Rule 20(a)* and *Rule 21 of the Federal Rules of Civil Procedure* provide for the addition of parties. Under *Rule 20(a)*, the movant must aver a right to relief “against each defendant relating to or arising out of the same transaction, occurrence, or series of transactions or occurrences” and that some “question of law or fact common to all defendants will [*215] arise in the action.” *Deleo v. Zconnexx Corp.*, 00 CV 0319, 2000 U.S. Dist. LEXIS 18765, at *4 (W.D.N.Y. Dec. 18, 2000) (internal quotations and citation omitted). *Rule 21* provides that a party may be [**6] added to an action “at any stage of the action and on such terms as are just.” *Fed. R. Civ. P. 21*.

Mylan and Eon both contend that Astra’s motion to amend the respective complaints against them should be denied because Astra’s claims against the four proposed defendants are defective as a matter of law and thus are futile. Additionally, Mylan and Eon argue that Astra’s motion should be denied because it is untimely, improperly motivated, and unduly prejudicial to them. Finally, Mylan contends that even if Astra does have a cause of action against the Esteve companies, those claims should be pursued in a separate action. Because the Court finds that Astra’s claims against the four proposed defendants are futile, Astra’s motion to amend the respective complaints is denied.

B. The Claims for Inducement Against Esteve Quimica, Dr. Laboratorios Esteve, GEA, and Hexal are Futile

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat 1585 (1984) (codified at 21 U.S.C. §§ 355 and 260cc and 35 U.S.C. §§ 156 and 271) (the “Hatch-Waxman Act”) provides that “whoever actively induces infringement of a patent [**7] shall be liable as an infringer.” 35 U.S.C. § 271(b). The Federal Circuit has said that to succeed on a theory of inducement under § 271(b) “a plaintiff must prove that the defendants’ actions induced infringing acts and that they knew or should have known their actions would induce actual infringement.” *Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1363 (Fed. Cir. 2003) (internal quotations and citation omitted). Moreover, to prove inducement, a plaintiff must show “actual intent to cause the acts which constitute the infringement” and “that the accused infringer knowingly aided and abetted another’s direct infringement of the patent”. *Warner-Lambert*, 316 F.3d at 1363 (internal quotations and citation omitted).

Two other district courts have reasoned that because the filing of the ANDA is an act of infringement, the active inducement of an ANDA submission is a remediable act of infringement. See *SmithKline Beecham Corp. v. Geneva Pharms., Inc.*, 99 CV 2926, 2002 U.S. Dist. LEXIS 19411, at *31 (E.D. Pa. Oct. 1, 2002) (stating that “where neither the terms of [Hatch-Waxman] nor its legislative history [**8] contain any express language precluding inducement liability under § 271(b) for the act of infringement defined in § 271(e)(2), we will not write such a provision into the law.”); *SmithKline Beecham Corp. v. Pentech Pharms., Inc.*, 00 C 2855, 2001 U.S. Dist. LEXIS 1935 (N.D. Ill Feb. 20, 2001). In Geneva, plaintiff SmithKline, who was the owner of a series of patents relating to its drug Paxil(R), alleged that Sumika, a manufacturer

and seller of chemicals including bulk pharmaceutical compounds, provided information and technical assistance that formed the basis of Geneva and Zenith's ANDAs for a generic version of Paxil(R). In further support of its inducement claim, SmithKline alleged that Sumika filed its Drug Master File ("DMF") with the PDA and authorized the FDA to rely on it for purposes of evaluating Geneva and Zenith's ANDAs.³ SmithKline further alleged that Sumika would [*216] make and sell the active ingredient of Geneva and Zenith's generic product if the ANDAs were approved. The court permitted SmithKline to amend its complaint to add Sumika as a party, finding that the allegations "that Sumika collaborated as a partner with Geneva and Zenith, and actively [**9] and knowingly induced the act of infringement committed with the submission of their ANDAs" were sufficient to state a claim for inducement. 2002 U.S. Dist. LEXIS 19411, at *26.

3 A DMF is a document filed in the FDA which provides confidential detailed information about the facilities, processes, and equipment used in the manufacturing, processing, packaging, and storing of a drug.

Likewise, in Pentech, a case also involving SmithKline's drug Paxil(R), the court permitted SmithKline to amend its complaint to add a claim for inducement against Asahi, a manufacturer and marketer of pharmaceutical compounds. In its proposed amended complaint, SmithKline alleged that Asahi actively induced the filing of Pentech's ANDA for a generic form of Paxil(R) when it collaborated with Pentech with respect to the research and development of Pentech's ANDA, provided material for use in Pentech's clinical studies, and permitted Pentech and the FDA to rely on its DMF in support of Pentech's ANDA. Pentech, 2001 U.S. Dist. LEXIS 1935, [**10] at *11-12. The court held that the amendment would not be futile and that SmithKline satisfied the "re-

quirements of permissive joinder." Pentech, 2001 U.S. Dist. LEXIS 1935, at *12-13.

There is no doubt that Astra's proposed complaints sufficiently allege that each of the four proposed new parties significantly and intentionally aided Mylan and Eon in the preparation of their ANDAs and would likely participate in the manufacture of the proposed product if approved. In its proposed amended complaint against Mylan, Astra alleges that beginning in 1994, Esteve Quimica, a supplier of bulk active ingredients for pharmaceuticals, developed an omeprazole pellet formulation. (Astra Ex. 1). In August, 1994, Esteve Quimica approached Mylan to propose a partnership based on Esteve Quimica's omeprazole technology. Mylan subsequently licensed Esteve Quimica's omeprazole technology and agreed to submit an ANDA for an omeprazole product based on it. Pursuant to this agreement, Esteve Quimica and Laboratorios Dr. Esteve provided raw materials, including bulk omeprazole and formulations of omeprazole, technical information and assistance to Mylan to develop an ANDA omeprazole product [**11] and to assist in the preparation of Mylan's ANDA. (Astra Ex. 13). Astra contends that omeprazole, made by Esteve Quimica, and pellets, manufactured by Laboratorios Dr. Esteve, were used to make Mylan's ANDA product batches and were relied on in Mylan's ANDA. (Astra Ex. 14). Moreover, Mylan's ANDA references and includes certificates of analysis for Esteve Quimica's raw omeprazole and Laboratorios Dr. Esteve's omeprazole pellet batches used in Mylan's ANDA batches, and authorizes the FDA to rely on Esteve Quimica's DMF for omeprazole. Astra alleges that batch records executed by employees of Laboratorios Dr. Esteve are included in Mylan's ANDA, and, if Mylan's ANDA is sold, Esteve Quimica will supply bulk omeprazole and Laboratorios Dr. Esteve will manufacture omeprazole pellets that Mylan will encapsulate and sell as Mylan's ANDA products. (Astra Exs. 14, 15).

As to GEA and Hexal, Astra alleges that GEA, a wholly-owned subsidiary of Hexal, developed Eon's ANDA product. (Astra Exs. 17, 18, 19, 20). Astra further contends that GEA provided bulk omeprazole, technical assistance, and information to Eon to enable Eon to manufacture and use GEA's omeprazole formulation. (Astra Ex. 21). **[**12]** Moreover, Eon's ANDA states that GEA will supply bulk omeprazole for **[*217]** Eon's products. (Astra Ex. 22). Hexal, which Astra alleges is the pharmaceutical sister company of Eon, initiated the transfer of technology from GEA to Eon, provided assistance to develop Eon's ANDA product, and provided information to Eon regarding availability and specifications of omeprazole. (Astra Exs. 23, 51, 71). Astra further contends that Eon, in its prospectus, has admitted that there is a strategic partnership between Eon and Hexal with respect to omeprazole and that documents filed with the S.E.C. state that Hexal has a technology agreement with Eon. Moreover, Astra alleges that Hexal has received a percentage of sales from certain products sold by Eon, and that Hexal and Eon have entered into a strategic alliance with respect to omeprazole. (Astra Ex. 23, Prospectus at 6, 32, 50, 51, 69, 71, 93, 116).

Despite these allegations, however, Mylan and Eon contend that Astra's motion to amend is futile because whether the submission of an ANDA was induced is not the proper subject of a Hatch-Waxman action. The Court agrees. While there is no doubt that the Federal Circuit has held that inducement actions **[**13]** are available under § 271(e)(2), the inquiry is properly focused on the ANDA product, not the ANDA filing. ⁴ In *Allergan v. Alcon Labs.*, the Federal Circuit stated that "the language of *section 271(e)(2)* does not limit the reach of the statute to direct infringement actions to the exclusion of actions for induced infringement ... therefore, *section 271(e)(2)* may support an action for induced infringement." *324 F.3d 1322, 1330 (Fed. Cir. 2003)*. However, as the Federal Circuit noted in *Glaxo, Inc. v. Novopharm,*

Ltd., the "infringement inquiry focuses on what is likely to be sold following FDA approval." *110 F.3d 1562, 1568 (Fed. Cir. 1997)*. Moreover, as explained by the Federal Circuit in *Warner-Lambert Co. v. Apotex Corp.*, "35 U.S.C. § 271(e)(2)(A) simply provides 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 ... [and] *once jurisdiction is established ... the substantive determination whether actual infringement or inducement will take place is determined [**14]* by traditional patent infringement analysis, just the same as it is in other infringement suits." *316 F.3d 1348, 1365 (Fed. Cir. 2003)* (emphasis added). ⁵ Consequently, the appropriate question in an inducement inquiry brought under § 271(b) with respect to an ANDA filing is whether the drug, if approved, will induce infringement of the plaintiff's patents. Therefore, the Court finds that an action for inducement for **[*218]** aiding and abetting the filing of an ANDA is unavailable.

4 Section 271(e)(2) of the Hatch-Waxman Act provides that: "It shall be an act of infringement to submit (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act [known as an ANDA] ... for a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. § 271(e)(2). The Federal Circuit has stated that the purpose of this provision is to "allow a brand name drug manufacturer to challenge the ANDA application and a generic drug manufacturer to challenge the validity and infringement of an asserted patent before the patent expires." *Allergan v. Alcon Labs.*, *324 F.3d 1322, 1326 (Fed. Cir. 2003)*.

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5 It is also worth noting that in *Allergan and Warner-Lambert*, the Federal Circuit

analyzed the inducement claims based on whether the ANDA product would induce infringement of the patents. Thus, while those cases clearly hold that inducement of infringement is a cause of action under Hatch-Waxman, they provide no support for the notion that inducement of the filing of the ANDA can be a cause of action. See *Allergan*, 324 F.3d at 1330-31; *Warner-Lambert*, 316 F.3d at 1365-66.

The Court has considered Astra's argument that Esteve Quimica, Dr. Esteve Laboratorios, GEA and Hexal should be added as parties because "even if Astra succeeds on its claims against Mylan and Eon, Esteve, Hexal and GEA may be free to approach other generic pharmaceutical companies with the products not materially changed from those developed for Mylan and Eon, [and] an injunction solely against Eon and Mylan would not prevent that." ⁶ (Astra's Reply at 9). This argument is without merit. Section 271 (e)(3) specifically states: "In any action for patent infringement brought under **[**16]** this section;, no injunctive or other relief may be granted which would prohibit the making, using, offering to sell, or selling within the United States or importing into the United States of a patented invention under [271(e)(1)]." 35 U.S.C. § 271(e)(3). Section 271(e)(1) provides that "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.*" 35 U.S.C. § 271(e)(1) (emphasis added). Consequently, Hatch-Waxman does not permit the Court to enjoin the proposed additional defendants from acts in furtherance of filing a future ANDA. ⁷

⁶ If Astra is successful in its suits for patent infringement against Mylan and

Eon, neither party will be permitted to sell the omeprazole product described in its ANDA until Astra's patents expire. See 35 U.S.C. § 271(e)(4)(A) (stating that if the drug described in the ANDA is found to infringe, "the court shall order the effective date of any approval of the drug [by the FDA] ... to be a date which is not earlier than the date of the expiration of the patent which has been infringed.").

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⁷ Astra's only argument that its claims against the proposed defendants fall outside of the activities that § 271(e)(1) exempts from liability is that "the statutory basis for its claims of induced infringement against the new defendants ... [is] 35 U.S.C. § 271(b)" and not § 271(e). (Astra's Reply at 2). The Court rejects this argument, as Astra's claims for inducement cannot be considered without reference to § 271(e), which creates the artificial act of infringement in the first place. Without referring to § 271(e), there would be no infringement to induce and no claim for inducement under § 271(b) would be possible.

The Court notes that any other interpretation of the statute would be inconsistent not only with the clear language of the statutory exemption from liability, but also the policies underlying the Hatch-Waxman Act. If this Court accepted Astra's theory of liability in this action, active ingredient suppliers would be discouraged from contributing to an ANDA for fear of liability for inducement. This result is contrary to one of the primary purposes **[**18]** of Hatch-Waxman's statutory exemption from liability for making, using, or selling a patented invention for the purpose of submitting an ANDA, namely, to "enable[] generic manufacturers to test and seek approval to market during the patent term." *Warner-Lambert*, 316 F.3d at 1358 (discussing the purposes of 35 U.S.C. § 271(e)(1)).

CONCLUSION

Astra's motion to amend the Mylan complaint to add Esteve Quimica and Laboratorios Dr. Esteve and to amend the Eon complaint to add GEA and Hexal is denied.

SO ORDERED:

BARBARA S. JONES

UNITED STATES DISTRICT JUDGE

Dated: May 20, 2003