

**UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ALABAMA
Southern Division**

In re:)	
)	
)	Master File No.
SILICONE GEL BREAST IMPLANTS)	CV 92-P-10000-S
PRODUCTS LIABILITY LITIGATION)	
(MDL 926))	This document relates
)	to all cases
)	
)	

**OPINION No. 25
Koken Motion to Dismiss**

Koken Co., Ltd., a Japanese company, has moved under Fed. R. Civ. P. 12(b)(2) to dismiss for lack of personal jurisdiction. Koken contends that it is not subject to personal jurisdiction anywhere in the United States and should therefore be dismissed from all actions and be relieved from further responsibilities to respond to discovery directed to it as a party. Plaintiffs assert that Koken is subject to personal jurisdiction for these product-liability claims, at least in Georgia which has a broad long-arm statute and where the bulk of Koken's contacts with the United States has occurred.

Koken argues that plaintiffs' focus on jurisdiction in Georgia is improper, or at least premature, inasmuch as it has not been properly served in any case filed in Georgia. Cases have, however, been filed against Koken in Georgia, in which service will doubtless be effected in due course; and, in any event, Koken has been served in cases brought in other states which could be transferred to Georgia under 28 U.S.C. § 1406(a) if jurisdiction would exist in Georgia. It is appropriate to decide this motion on the basis of Georgia jurisdiction, and, for the reasons stated below, the court concludes that Koken is subject to jurisdiction in Georgia and accordingly not entitled to total dismissal.

STANDARD OF REVIEW

On a motion to dismiss for lack of personal jurisdiction decided without an evidentiary hearing, the plaintiff bears the burden of establishing a prima facie case of jurisdiction over the non-resident defendant. *Morris v. SSE, Inc.*, 843 F.2d 489, 492 (11th Cir. 1988) (citations omitted). The court "must construe the allegations in the complaint as true, to the extent they are uncontroverted by defendant's

affidavits or deposition testimony." *Id.* Where the evidence conflicts, "the court must construe all reasonable inferences in favor of the non-movant plaintiff." *Id.*

FACTS

The following facts either are undisputed or should be treated as established under the prescribed standard of review:

Koken is a Japanese company incorporated under the laws of Japan and maintaining its principal place of business in Tokyo, Japan. It manufactures many different types of medical products, including breast implants. Koken is not licensed to do business and does not maintain a place of business in the United States. Koken does not own any property, does not maintain any office, employees, or accounts, and does not have a subsidiary in the United States. Prior to entering into certain arrangements with Porex Technologies Corp., a Georgia corporation, in the mid-80's, Koken sold a small number of breast implants to customers or non-exclusive distributors in the United States; these activities, conducted by Koken in Japan, did not involve sales in the United States.

In December 1985, Koken and Porex began negotiating for the distribution of Koken products in the United States and Porex products in Japan. Koken and Porex entered into a series of agreements relating to the distribution of their products in the respective countries. Koken sent a letter to Porex dated April 14, 1986, certifying Porex as "the sole and exclusive distributor of Koken . . . for the United States" and giving Porex the "authority to represent Koken in all matters relating to sales and marketing of Koken products and act as Koken's agent in matters before the Food and Drug Administration of the United States."

On April 16, 1986, Koken and Porex entered into an Agreement of Cooperation providing that Porex would "represent Koken surgical products in the United States," "register with the FDA as Koken's exclusive distributor for surgical products and represent Koken's interests with the FDA," "assist Koken on obtaining FDA approval on items Porex chooses not to market and . . . in finding an appropriate United States partner for those products," and "advise Koken in all the requirements of the GMP standards established by the [FDA]." It provided that Koken would "provide Porex with all of the necessary documentation to process Koken products through the FDA regulatory process," "manufacture products according to the [FDA's] GMP standards," and "develop products for Porex based on market needs in the United States."

Finally, in December 1988, Koken and Porex executed an Agreement designating Porex as Koken's sole distributor in the United States and as an "independent contractor not subject to the direct control of Koken and not authorized to bind Koken," setting forth terms for indemnification, stating that the Agreement would be governed by the laws of Japan, and containing a standard merger clause. This Agreement retrospectively applied to all sales of Koken products by Porex in the United States. Koken negotiated and executed this Agreement in Japan.

From 1985 through 1990, Koken and Porex regularly communicated via telephone, mail, telex, and facsimile. Porex consulted Koken regarding the form and content of product inserts, and Koken responded with its recommendations and manufactured the packages and product inserts.

Koken officials traveled to the United States, and more particularly, to Georgia, on several occasions. One of these visits occurred during an ASPRS Convention in Atlanta, Georgia, at which \$20,000 of Koken breast implants were ordered. Koken officials attended this convention and the Porex

booth. Koken employees also visited Porex's production facilities.

Koken altered its breast implants to comply with the American Standards for Testing Materials (ASTM) Regulation F701-81. After receiving complaints from doctors in the United States about the hardness of the new implants, Koken designed a softer implant. In addition, Koken retained counsel based in Georgia who received complaints and negotiated settlements with breast implant recipients.

Koken sold and tendered the implants to Porex FOB Tokyo, Japan. Koken accepted returned products from Porex under certain conditions. Koken also investigated all complaints from the United States and provided Porex with responses to submit to the FDA. Neither Koken nor Porex ever filed a Pre-Market Approval Application with the FDA regarding Koken implants.

Porex sold Koken implants from March of 1988 to December of 1990. Koken's sales of breast implants to Porex constitute approximately 3.9% of Koken's total breast implant sales and .6% of Koken's total income for that period.

ANALYSIS

Personal jurisdiction over a non-resident defendant involves two inquiries.¹ First the court must determine whether the applicable state long-arm statute provides jurisdiction. If so, the court then determines whether the due process requirements of the Constitution are met. Because the Georgia long-arm statute provides jurisdiction to the extent permitted by the Due Process Clause of the Fourteenth Amendment, *Allstate Insurance Co. v. Klein*, 262 Ga. 599, 600 n.1 (1992), the only question here is whether the exercise of jurisdiction by Georgia over Koken in these product-liability cases would be consonant with the requirements of due process.

The Due Process Clause limits the power of a court to render a valid judgment against a non-resident defendant. *World-Wide Volkswagen Corp. v. Woodson*, 444 U.S. 286, 291 (1980). For jurisdiction to exist, the defendant must have "purposefully established 'minimum contacts'" in the forum state." *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 474 (1985), quoting *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945).² The contacts are sufficient if the defendant "should reasonably anticipate being haled into court there." *World-Wide Volkswagen*, 444 U.S. at 297. In addition,

1 Plaintiffs argue that Porex is Koken's agent because of the April 14, 1986, letter and therefore Koken is subject to Georgia's jurisdiction. The parole evidence rule and the merger clause bar evidence of the earlier agreements. *Schlange-Schoeningen v. Parrish*, 767 F.2d 788, 792 (11th Cir. 1985). The April 14, 1986, letter is therefore inapplicable to the present minimum contacts analysis. Porex acted as an independent contractor when it sold breast implants.

2 Two types of personal jurisdiction exist, general and specific. Specific jurisdiction, as alleged in this case, exists when the non-resident defendant has allegedly caused injuries arising out of or relating to activities purposefully directed at residents of the forum state. *Burger King*, 471 U.S. at 472 (citations omitted).

maintenance of the suit must not "offend 'traditional notions of fair play and substantial justice.'"

International Shoe, 326 U.S. at 316, quoting *Milliken v. Meyer*, 311 U.S. 457, 463 (1940).

Foreseeability, though alone an insufficient basis for jurisdiction, is not "wholly irrelevant" to a due process analysis. *Asahi Metal Industry Co. v. Superior Court of California*, 480 U.S. 102, 109 (1987), citing *World-Wide Volkswagen*, 444 U.S. 286 at 295-298. the Court in *World-Wide Volkswagen* reasoned: [I]f the sale of a product of a manufacturer or distributor such as Audi or Volkswagen is not simply an isolated occurrence, but arises from the efforts of the manufacturer or distributor to serve, directly or indirectly, the market for its product in other States, it is not unreasonable to subject it to suit in one of those States if its allegedly defective merchandise has there been the source of injury to its owner or to others.

World-Wide Volkswagen, 444 U.S. at 297. The Court concluded that "[t]he forum State does not exceed its powers under the Due Process Clause if it asserts personal jurisdiction over a corporation that delivers its products into the stream of commerce with the expectation that they will be purchased by consumers in the forum state." *Id.* at 297-298 (citation omitted).

In *Asahi*, the Court held that an exercise of personal jurisdiction would, in the circumstances of that case,³ offend "traditional notions of fair play and substantial justice." 480 U.S. at 116, quoting *International Shoe*, 326 U.S. at 316. Justice O'Connor, writing for the plurality, also stated that the mere placement of a product in the stream of commerce is not an act purposefully directed at the forum state, and that some additional act directed toward the forum state would be required. 480 U.S. at 112. This language has created confusion regarding the standard to apply in personal jurisdiction cases.

These breast-implant product-liability cases are quite different from *Asahi*. The plaintiffs in these cases are United States citizens who seek relief for harm allegedly suffered as a result of implants sold in the United States. Plaintiffs have a manifest interest in obtaining relief. Georgia also has an interest in ensuring that products sold within or from its borders are safe. If Koken is not subject to suit in Georgia, the plaintiffs would likely be required to bring their suits in Japan. The burden on them to bring suits in Japan would be much more significant than Koken's burden in defending cases in the United States. The court concludes that the exercise of jurisdiction by Georgia would not violate traditional notions of fair play and substantial justice.

³ The only remaining claim was for indemnification between the Japanese and Taiwanese companies.

The court must now determine whether minimum contacts exist. When presented with the issue of what test should be applied to determine minimum contacts after *Asahi*, the Eleventh Circuit, noting the disagreement among the Circuits, concluded that, because the facts of that case met the more stringent requirements of Justice O'Connor's "stream of commerce plus" test, it would not decide which standard controls in this Circuit. *Vermeulen v. Renault, U.S.A., Inc.*, 985 F.2d 1534, 1548 (11th Cir. 1993).⁴ The court stated that the fact that the title to the automobiles changed hands in France "in no way determin[e] the degree of contacts between the United States and RNUR," and that *International Shoe* stands for the proposition that a truly international business may not "shield itself from suit by a careful but formalistic structuring of its business dealings." *Id.* (citations omitted). Because "RNUR intended its LeCars to be brought to the United States and took numerous affirmative steps to bring that result about," jurisdiction would not violate RNUR's due process rights. *Id.* at 1550 (emphasis supplied).

On facts very similar to these cases, the Northern District of Georgia found that jurisdiction existed in Georgia over a Japanese automobile manufacturer in an automobile accident case. *Burton v. Subaru of America, Inc.*, 646 F.Supp. 78 (N.D. Ga. 1986).⁵ The court reasoned that "[b]y introducing Subaru automobiles into the stream of commerce in the United States through an exclusive distributorship with defendant [Subaru], defendant Fuji purposely availed itself of the resulting economic benefits of the sale of the automobiles in the various states, including Georgia" and that "its system of distribution provided ample warning that use of Subaru automobiles in a state such as Georgia might result in litigation over the design and manufacture of the product." *Id.* at 80 citing *World-Wide Volkswagen*, 444 U.S. at 297.

In determining whether Koken has had sufficient contacts with the state of Georgia to be subject to its personal jurisdiction, the court considers the quantity, nature, and quality of the contacts. Koken argues that the only potentially relevant contacts are those related to drafting the Agreement. Because

⁴ *Vermeulen* involved an automobile accident in a LeCar sold by American Motors Corporation which was the exclusive distributor of automobiles manufactured by Regie Nationale Des Usines Renault, a corporation wholly owned by the French government.

⁵ Fuji Heavy Industries, Ltd. manufactured the automobile and sold it to Subaru of America pursuant to an exclusive distributorship agreement. Subaru took delivery and title to the automobiles in Japan.

these cases involve personal injury claims by implant recipients and not a breach of contract claim by Porex, it is appropriate to consider the sale of implants by Koken and the use of implants by plaintiffs which have resulted in this litigation. All contacts related to the sale of implants by Koken, including investigations into complaints, are therefore relevant to the determination of personal jurisdiction.

Clearly, Koken delivered its implants to Porex with the expectation that they would be purchased by consumers in the United States and, specifically, in and from Georgia. Although Koken did not engage in as much additional conduct as RNUR in *Vermeulen*, Koken had more contacts with Georgia than Fuji had in *Burton*. Whether the jurisdictional contacts are evaluated using the O'Connor opinion or the concurrence, it is clear that more contacts exist in these cases than the mere placement of breast implants into the stream of commerce.

Koken has used Georgia as the focal point for the distribution and modification of breast implants. Koken redesigned its implants to comply with ASTM standards. Although this change may have been made in all implants Koken manufactured, it was undertaken because of requirements for sale in the United States. The product was then redesigned because of complaints of hardness generated in the United States and delivered through Georgia. Although Porex was not Koken's agent, Koken did execute an exclusive distributorship agreement with Porex, a Georgia corporation. This resulted in the distribution of a not insignificant volume of its products in the United States and, specifically, in Georgia. The fact that Koken did not control Porex's distribution of implants to doctors does not negate the fact that Koken distributed the implants to Porex for redistribution in the United States. Koken intended its implants to be brought to Georgia and took affirmative steps to effect this result. Koken also had other contacts with Georgia that must be considered, such as the numerous faxes and other correspondence as well as several visits by Koken principals to Georgia regarding breast implants. Exercise of jurisdiction by Georgia does not violate Koken's due process rights. *Id.* at 1550.

CONCLUSION

By separate order, Koken's motion to wholly dismiss it from all breast-implant actions for lack of personal jurisdiction will be denied. This ruling does not preclude motions by Koken in individual actions that such cases should be transferred to Georgia district courts under 28 U.S.C. § 1406.

This the 9th day of August, 1995.

/s/ Sam C. Pointer, Jr.
United States District Judge

Service:
Plaintiffs' Liaison Counsel
Defendants' Liaison Counsel

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**ORDER No. 25
Koken Motion to Dismiss**

For the reasons stated in the accompanying opinion, defendant Koken's Motion to dismiss for lack of personal jurisdiction is hereby DENIED, without prejudice to refiling in a particular case in which, in lieu of dismissal, the case should be transferred to a United States District Court in the State of Georgia under 28 U.S.C. § 1406.

This the 9th day of August, 1995.

/s/ Sam C. Pointer, Jr.
United States District Judge

Service:
Plaintiffs' Liaison Counsel
Defendants' Liaison Counsel