

IN THE UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

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MYLAN PHARMACEUTICALS, INC., and	)	
ESTEVE QUIMICA, S.A.,	)	
	)	
Plaintiffs	)	
	)	
v.	)	
	)	Civil Action No. 02-1628 GMS
KREMERS URBAN DEVELOPMENT	)	
COMPANY, SCHWARZ PHARMA, INC.,	)	
SCHWARZ PHARMA AG,	)	
SCHWARZ PHARMA MANUFACTURING,	)	
INC., and SCHWARZ PHARMA-GROUP USA,	)	
	)	
Defendants.	)	

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**MEMORANDUM AND ORDER**

**I. INTRODUCTION**

The plaintiff, Mylan Pharmaceuticals, Inc. (“Mylan”), filed the above-captioned suit against multiple defendants, alleging infringement of U.S. Patent No. 5,626,875 (“the ‘875 patent”). The alleged patent owner, Esteve Quimica, S.A. (“Esteve”), was added as a plaintiff on January 22, 2003. Presently before the court is a motion by the defendant Schwarz Pharma AG (“SPAG”) to dismiss the Amended Complaint for lack of personal jurisdiction (D.I. 22). For the reasons that follow, the court will grant the motion.

**II. BACKGROUND**

The patent-in-suit allegedly is owned by Esteve and exclusively licensed to Mylan. The patented invention is a formulation of the drug omeprazole, sold by AstraZeneca under the brand name Prilosec. It is alleged that the defendants’ manufacture and sale of a generic formulation of omeprazole constitutes patent infringement. The defendant SPAG is accused of inducing its agents in the United

States, namely, the four co-defendants, to infringe the '875 patent. The complaint also alleges tortious interference with a prospective business advantage.

There are five defendants in this action: SPAG; Schwarz Pharma, Inc. ("SPI"); Schwarz Pharma Manufacturing ("SP Manufacturing"); Schwarz Pharma Group USA, incorporated under the name Schwarz Pharma USA Holdings, Inc. ("SP Holdings"); and Kremers Urban Development Co. ("KUDCo"). SPAG is a German corporation which produces and distributes pharmaceutical drugs. SP Holdings is a wholly-owned subsidiary of SPAG. In turn, SPI and SP Manufacturing are wholly-owned subsidiaries of SP Holdings. KUDCo is a wholly-owned subsidiary of SPI. KUDCo, SPI, and SP Holdings are Delaware corporations. SP Manufacturing is an Indiana corporation.

KUDCo filed Abbreviated New Drug Applications ("ANDA's") with the United States Food and Drug Administration ("FDA") in July of 1998 and July of 1999, seeking approval to market and sell a generic formulation of omeprazole. At some point, SPI also filed an ANDA for the same purpose. SPAG paid for certain of the clinical studies related to KUDCo's applications to the FDA, and made payments to the inventors of KUDCo's omeprazole formulation. This funding ended by December of 1999. Otherwise, KUDCo and SPI assumed all of the costs and responsibility for preparing, filing, and proceeding with the ANDA's, as well as all clinical studies occurring after December, 1999.

KUDCo's ANDA for omeprazole was approved on November 1, 2002. Thereafter, SP Manufacturing began producing the drug. On December 9, 2002, KUDCo's affiliate, Kremers Urban, Inc. ("KUI"), a wholly-owned subsidiary of SP Holdings and a non-party to the present suit, began to market and sell KUDCo's omeprazole product throughout the United States. SP Manufacturing has borne all manufacturing costs associated with the product, and KUI has paid for all distribution and sales costs. KUI receives all of the revenue derived from the U.S. sales of its omeprazole product. KUI keeps a portion of this revenue, and distributes the remainder to SP Manufacturing and KUDCo.

KUDCo keeps a portion of this revenue, and also uses it to provide loans and dividends to SPI. No revenue from the sale of omeprazole is directly provided to SPAG or SP Holdings. Nevertheless, SP Holdings receives a dividend from the general revenue pool of SPI, SP Manufacturing, KUI, and KUDCo. In turn, SP Holdings may then pay a dividend to SPAG. Apparently, exact figures for any such dividends are unavailable at this time.

### III. STANDARD OF REVIEW

SPAG moves to dismiss the Amended Complaint for lack of personal jurisdiction over the defendant. “Rule 12(b)(2) of the Federal Rules of Civil Procedure requires a court to dismiss a case when the court lacks personal jurisdiction over the defendant[.]” *E.I. DuPont de Nemours & Co. v. Rhodia Fiber & Resin Intermediates*, 197 F.R.D. 112, 119 (D. Del. 2000). In determining whether personal jurisdiction exists, courts engage in a two step analysis. First, the court must decide whether jurisdiction is authorized by the long arm statute of the state in which the court sits. *Transportes Aeros de Angola v. Ronair, Inc.*, 544 F. Supp. 864-65 (D. Del. 1982). If jurisdiction is proper per the long arm statute, the court must then determine whether exercising jurisdiction comports with the requirements of the Due Process Clause of the Fourteenth Amendment. *Id.* (noting, however, “intent of the legislature to exercise jurisdiction over non-residents whenever feasible”); *Compaq Computer Corp. v. Packard Bell Elec., Inc.*, 948 F. Supp 338, 342 (D. Del. 1996) (citation omitted). To satisfy the second prong of this analysis, the court must find the existence of “minimum contacts” between the defendant and the forum state, “such that the maintenance of the suit does not offend ‘traditional notions of fair play and substantial justice.’” *International Shoe Co. v. Washington*, 326 U.S. 310, 316 (1945) (citation omitted). Specifically, the plaintiffs must show that SPAG “purposefully avail[ed] itself of the privilege of conducting activities within the forum State.” *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 475 (1985) (quoting *Hanson v. Denckla*, 357 U.S. 235, 253 (1958)); *see also Asahi Metal*

*Industry Co. v. Superior Court*, 480 U.S. 102, 108-09 (1987). Unless the contacts are continuous and systematic, they must be related to the present cause of action. *Helicopteros Nacionales de Columbia, S.A. v. Hall*, 466 U.S. 408, 414-15 (1984).

In determining the jurisdictional question, the court must accept as true the allegations in the complaint, *Altech Industries, Inc. v. Al Tech Specialty Steel Corp.*, 542 F.Supp. 53, 55 (D. Del. 1982), but the plaintiffs bear the burden of alleging facts sufficient to make a *prima facie* showing of personal jurisdiction over SPAG. *ICT Pharmaceuticals, Inc. v. Boehringer Ingelheim Pharmaceuticals, Inc.*, 147 F. Supp. 2d 268, 270-71 (D. Del. 2001). To meet this burden, the plaintiffs must adduce facts which ‘establish with reasonable particularity’ that jurisdiction over the movant exists. *Id.* (quoting *Joint Stock Soc’y v. Heublein, Inc.*, 936 F. Supp. 177, 193 (D. Del. 1996)).

#### **IV. DISCUSSION**

The plaintiffs argue that jurisdiction is proper on three grounds. First, the plaintiffs maintain that specific jurisdiction is appropriate pursuant to the long arm statute because of the activities of SPAG’s agents in Delaware. Second, they argue that general jurisdiction exists pursuant to the long arm statute based on the alter ego doctrine. Third, the plaintiffs contend that jurisdiction over SPAG is appropriate pursuant to Federal Rule of Civil Procedure 4(k)(2). The court need not definitively decide these issues, however, as compliance with the Constitution is required in each of these contexts, and the court concludes that the exercise of jurisdiction over SPAG would offend the Due Process Clause.

As stated above, to satisfy the constitutional requirements of due process, the court must determine whether the defendant has “minimum contacts” with the state of Delaware such that the exercise of jurisdiction over it would be fair and just. Minimum contacts are not determined according

to a fixed formula. *Transportes Aeros de Angola*, 544 F. Supp. at 865. Nevertheless, as previously stated, minimum contacts usually are found where the defendant has purposefully availed itself of the privileges of the forum state such that it would be reasonably foreseeable that the defendant might be “haled before a court” in the forum as a result of its conduct. *Asahi Metal Indus. Co., Ltd. v. Super. Ct. of California*, 480 U.S. 102, 109 (1987). Furthermore, the defendant’s contacts with the forum state must create a ‘substantial connection’ with the forum, *Burger King Corp. v. Rukzewicz*, 471 U.S. 462, 475 (1985) (quoting *McGee v. International Life Insurance Co.*, 355 U.S. 220, 223 (1957)), and the claims must arise out of or relate to those contacts. *HollyAnne Corp. v. TFT, Inc.*, 199 F.3d 1304, 1307-08 (Fed. Cir. 1999).

The plaintiffs argue that SPAG, through its agents, including the four co-defendants, has sold and offered for sale the allegedly infringing product in Delaware. They have produced no evidence to support this theory, however. Indeed, according to state-by-state sales data for omeprazole, as of February of 2003, KUDCo had not sold any omeprazole in Delaware, nor shipped any of the product to this state. SPAG’s Reply Brief at 2. The court recognizes, and SPAG concedes, that “presumably KUDCo’s generic omeprazole product is available for purchase in Delaware.” *Id.* In the absence of any affirmative evidence to that effect, however, such a presumption is insufficient to establish a *prima facie* case for jurisdiction over SPAG. The plaintiffs have not adduced any evidence that SPAG, or any of its alleged agents, have availed themselves of the benefits or privileges of Delaware in any way, much less created a ‘substantial connection’ with the state.

In support of the court’s conclusion that the exercise of jurisdiction over SPAG, on the present record, would not comport with due process requirements, the court notes the following additional facts:

- 1) SPAG does not have any employees, sales representatives, distributors, brokers, or wholesalers in the United States;
- 2) does not own or lease any real or personal property in the United States;
- 3) does not maintain any inventory of products in the United States;
- 4) does not conduct any research or development in the United States;
- 5) does not maintain any bank accounts in the United States;
- 6) has not paid taxes or franchise fees in the United States;
- 7) does not maintain any office or telephone listing in the United States; and
- 8) has never designated anyone in the United States to accept legal service of process on its behalf.

Thus, although it is conceivable that SPAG, through its agents, is doing business in the United States generally, there is no evidence that SPAG or its agents have done so in Delaware. In the absence of such evidence, the court cannot find that the exercise of jurisdiction over SPAG, a German corporation with its principal place of business in that country, would be fair and just. Therefore, the court must grant the defendant's motion to dismiss.

## **V. CONCLUSION**

For the aforementioned reasons,

IT IS HEREBY ORDERED that:

1. Schwarz Pharma AG's Motion to Dismiss for Lack of Personal Jurisdiction (D.I. 22) is GRANTED.

Dated: April 7, 2003

Gregory M. Sleet  
UNITED STATES DISTRICT JUDGE