SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: PART 33

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VINOD SAMUEL,

Plaintiff,

- v -

BOEHRINGER INGELHEIM PHARMACEUTICALS, INC.,SANOFI US SERVICES INC.,CHATTEM, INC.,PFIZER INC.,GLAXOSMITHKLINE, LLC.

Defendant.

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INDEX NO. 155628/2020

MOTION DATE 04/30/2021

MOTION SEQ. NO. 003

DECISION + ORDER ON MOTION

HON. MARY V. ROSADO:

The following e-filed documents, listed by NYSCEF document number (Motion 003) 36, 37, 38, 39, 42, 44, 46, 47, 65

were read on this motion to/for DISMISSAL.

Oral argument was held on June 22, 2022 with Christopher LoPalo appearing on behalf of Vinod Samuel as the personal representative of the Estate of Mary E. Samuel and Vinod Samuel individually ("Plaintiffs") and Cole Carter and Nicholas Gallagher appearing on behalf of Defendant Glaxosmithkline, LLC ("GSK"). Upon the foregoing documents, and after oral argument, the motion to dismiss is denied.

I. Factual Background

In November of 2018, Plaintiff Mary E. Samuel ("Samuel") was diagnosed with appendiceal cancer which metastasized to her ovaries, colon and fallopian tubes (NYSCEF Doc. 2 at ¶ 83). Samuel died on July 26, 2020 (*id.* at ¶ 6). From January 2, 2003, to December 16, 2018, Samuel ingested over the counter ("OTC") Zantac, a brand-named antacid (*id.* at ¶ 82).

Zantac was developed by Defendant GlaxoSmithKline ("GSK") and approved for prescription use by the U.S. Food and Drug Administration ("FDA") in 1983 (*id.* at ¶ 16). Zantac became available over the counter in 1996 through a joint venture between GSK and Warner-

Lambert (NYSCEF Doc. 37). In 1998, the joint venture ended, with Warner-Lambert retaining control over the sale of OTC Zantac and GSK retaining control over the sale of prescription Zantac. (*id*). In 2000, Defendant Pfizer, Inc. ("Pfizer") acquired Warner-Lambert and control over the sale of OTC Zantac (*id.*) Control over OTC Zantac passed to Defendant Boehringer Ingelheim Pharmaceuticals, Inc. ("BI") in 2006 followed by Defendant Sanofi US Services Inc. ("Sanofi") in 2017 (*id.*). While the U.S. rights to OTC Zantac have transferred several times, GSK has and continues to retain the rights to the prescription version of Zantac.

On October 2, 2019, the FDA ordered all manufacturers of Zantac to conduct testing for N-Nitrosodimethylamine ("NDMA") after an independent researcher found unsafe levels of NDMA in Zantac (NYSCEF Doc. 2. at ¶ 22). NDMA is classified by the Environmental Protection Agency ("EPA") as a probable human carcinogen (*id.* at ¶ 25). Plaintiffs allege Samuel's cancer was caused by Zantac related NDMA exposure (*id.* at ¶ 6).

Plaintiffs claim Samuel did not learn about an alleged link between her cancer and Zantac until April 2020 when she saw a TV commercial about Zantac and NDMA (*id.* at ¶ 87). Plaintiffs allege Samuel would have avoided Zantac if warned about Zantac's link to NDMA (*id.* at ¶ 86).

II. Procedural History

Plaintiffs filed their Amended Complaint in this products liability action on August 4, 2020 (NYSCEF Doc. 2). GSK has not filed an Answer, but rather moved to dismiss Plaintiffs' claims against GSK (NYSCEF Doc. 36). GSK moves to dismiss on two grounds: (1) failure to state a claim and (2) personal jurisdiction (NYSCEF Doc. 37).

III. Discussion

A. Failure to State a Claim

When reviewing a pre-answer motion to dismiss for failure to state a claim, the Court must give Plaintiff the benefit of all favorable inferences which may be drawn from the pleadings and determine only whether the alleged facts fit within any cognizable legal theory (*Sassi v Mobile Life Support Services, Inc.*, 37 NY3d 236, 239 [2021]). All factual allegations must be accepted as true (*Allianz Underwriters Ins. Co. v Landmark Ins. Co.*, 13 AD3d 172, 174 [1st Dept 2004]). Conclusory allegations or claims consisting of bare legal conclusions with no factual specificity are insufficient to survive a motion to dismiss (*Godfrey v Spano*, 13 NY3d 358, 373 [2009]; *Barnes v Hodge*, 118 AD3d 633, 633-634 [1st Dept 2014]). Moreover, a motion to dismiss for failure to state a claim will be granted if the factual allegations do not allow for an enforceable right of recovery *Connaughton v Chipotle Mexican Grill, Inc.*, 29 NY3d 137, 142 [2017]).

Plaintiffs admit that Samuel "began using over-the-counter brand name Zantac from approximately June 2, 2003 and continued to use it daily through approximately December 16, 2018" (*id.* at ¶ 82). Therefore, Plaintiff began using OTC Zantac after GSK relinquished the rights to OTC Zantac (NYSCEF Doc. 37). Plaintiffs, however, argue that as the brand-name manufacturer of prescription Zantac, GSK had a continuing duty to warn Plaintiffs about dangers of taking OTC Zantac. Although GSK construes Plaintiffs' argument as an "innovator liability" argument and urges this Court to reject the minority of other states that accept "innovator liability", this Court disagrees that Plaintiffs' theory of liability comports with innovator liability at all.

Innovator liability is a theory of liability which permits plaintiffs who used a generic medication to sue the pharmaceutical company that manufactured the brand name bio-equivalent

(*Rafferty v Merck & Co., Inc.*, 479 Mass 141 [Mass. 2018]); *T.H. v Novartis Pharmaceuticals Corp.*, 4 Cal. 5th 145 [Cal. 2017]). These states have adopted innovator liability because federal law preempts failure to warn claims against generic manufactures of brand-name drugs (*PLIVA, Inc. v Mensing,* 564 US 604 [2011]). Per FDA regulations, the generic manufacturers' warning labels must be identical with the brand-name manufacturer's warning label. Therefore, based on the present landscape of federal preemption precedent and FDA regulations, a plaintiff who suffers an injury from a generic manufacturer's failure to warn has no relief except against the brand-name manufacturer, hence the rationale behind certain states adopting what has been dubbed "innovator liability".

However, what has been described above is not the facts of our case. In the case before this Court, the Plaintiff only took the brand name OTC Zantac, of which GSK was an original manufacturer. Plaintiff never took a generic version of Zantac. At issue here is that GSK was no longer a manufacturer of OTC Zantac when Plaintiff consumed OTC Zantac. Based on the facts of this case, this Court need not address any innovator liability arguments, nor divine whether the New York Court of Appeals would adopt a theory of innovator liability in the near future.

Moreover, although it appears that, based on the allegations, GSK did not manufacture or sell OTC Zantac consumed by Samuel, this alone does not let GSK off the hook since Plaintiffs have pleaded concert of action and civil conspiracy in relation to their failure to warn claim. GSK is expressly implicated in the allegation of civil conspiracy and concert of action since it is alleged that GSK utilized studies that it "rigged" to hide the risk of cancer caused by Zantac. Moreover, there are allegations that GSK, which retained the right to sell and manufacture prescription Zantac, took part in the suppression of scientific information indicating that Zantac was dangerous in order to enhance its profits related to the sale of OTC and prescription Zantac. Therefore,

because GSK is implicated, jointly and severally, in the other Defendants failure to warn Plaintiffs about the alleged dangers of Zantac, GSK is not entitled to dismissal based on failure to state a claim.

B. Personal Jurisdiction

A plaintiff bears the ultimate burden of proof on the issue of personal jurisdiction since they are the party seeking to assert it over a defendant. However, courts do not require the plaintiff to make a *prima facie* showing of personal jurisdiction, but only to demonstrate that facts "may exist" to exercise personal jurisdiction over the defendant (*see* CPLR 3211[d]; *American BankNote Corp. v.* Daniele, 45 AD3d 338, 340 [1st Dept 2007]).

Pursuant to CPLR 302(a)(1), a New York Court may exercise personal jurisdiction over a nondomiciliary if the nondomiciliary has purposefully transacted business within the state and there is "a substantial relationship between the transaction and the claim asserted" (*Coast to Coast Energy, Inc. v Gasarch*, 149 AD3d 485 [1st Dept 2017] quoting *Paterno v Laser Spine Ins.*, 24 NY3d 370, 376 [2014]). A court must engage in a two-prong inquiry to determine (1) whether the defendant transacts any business in New York and, if so, (2) whether the cause of action arises from such a business transaction (*Wilson v Danta*, 128 AD3d 176 [1st Dept 2015]). A plaintiff does not need to have been involved in the transaction; rather, a plaintiff need only demonstrate that, considering all the circumstances, there is an articulable nexus or substantial relationship between the business transaction and the claim asserted (*D & R global Selections, S.L. v Bodega Olegario Falcon Pineiro*, 29 NY3d 292, 298-299; *English v Avon Products, Inc.*, 206 AD3d 404 [1st Dept 2022]).

The Court finds personal jurisdiction over GSK is proper given the existence of concert of action and civil conspiracy claims alleging that GSK is jointly and severally liable with the other

manufacturer defendants for their failure to warn Plaintiffs about Zantac's alleged potential to cause cancer. It is alleged that at the time Plaintiff was consuming OTC Zantac, GSK was still advertising, marketing, and selling OTC Zantac's bio-equivalent prescription Zantac. Moreover, GSK conducted the initial studies so that OTC Zantac would get FDA authorization, and it is alleged that GSK purposefully suppressed certain scientific information related to the safety of OTC Zantac. GSK also has sold substantial amounts of both OTC and Prescription Zantac in the New York market, designed the original warning label for OTC Zantac which entered New York markets, and helped create the market for OTC Zantac which was exploited by GSK's predecessors who manufactured and sold the Zantac that Samuel ingested.

Indeed, "where [a] defendant knowingly sends into a state a false statement, intending that it should there be relied upon to the injury of a resident of the state, he has, for jurisdictional purposes, acted within that state" (*Philan Ins. Ltd v Frank B. Hall & Co., Inc.*, 215 AD2d 112 [1st Dept 1995]; *Travelers Indem. Co. v Inoue*, 111 AD2d 686, 687 [1st Dept 1985] quoting *Polish v Threshold Technology,* 72 Misc2d 610, 612 [Sup Ct, New York County 1972]). Since GSK allegedly designed a misbranded and inaccurate warning label and sent it into New York, which Plaintiffs have alleged caused them injury, then this Court may exercise jurisdiction over GSK.

Alternatively, since civil conspiracy is alleged, and GSK is said to have committed tortious acts through the other defendants, the co-conspirators can be deemed as agents for purposes of exercising long arm jurisdiction (*CIBC Mellon Trust Co. v Mora Hotel Corp. N.V.*, 296 AD2d 81, 98 [1st Dept 2002] [relying on co-conspirator jurisdiction, which requires a showing that defendants were part of a conspiracy, at least part of which took place within the jurisdiction, to exercise jurisdiction over non-domiciled corporate defendants]).

Therefore, there is a sufficient articulable nexus between Plaintiffs' alleged injuries and GSK's transactions related to the design, manufacture, advertisement, and sale of OTC Zantac to allow this Court to exercise personal jurisdiction over GSK (*Ford Motor Co. v Mont. Eighth Jud. Dist. Ct.*, 141 SCt 1017, 1022 [2021] [holding that specific personal jurisdiction does not depend on a strict causation-only approach that only asks where a product is sold, designed, or manufactured, and that where a nonresident corporation has continuously and deliberately exploited a state's market, it must reasonably anticipate being haled into that state's courts to defendant actions based on products causing injury there]). As GSK is alleged to have partaken in a civil conspiracy to suppress scientific information, a conspiracy at least part of which has taken place in New York, and its own contacts with New York (i.e., marketing, advertising, and selling OTC and Prescription Zantac throughout New York) contain a sufficient nexus to Plaintiff's injury, GSK's motion to dismiss for lack of personal jurisdiction fails.

Accordingly, it is hereby

ORDERED, that Defendant Glaxosmithkline, LLC's motion to dismiss is denied in its entirety; and it is further

ORDERED, that counsel for Glaxosmithkline, LLC serve a copy of this order along with notice of entry on all parties within thirty (30) days of this order.

This constitutes the decision and order of the Court.

11/21/2022
DATE

Mary V Rosado
HON. MARY V. ROSADO, J.S.C.

CHECK ONE:		CASE DISPOSED		x	NON-FINAL DISPOSITION		
		GRANTED	x DENIED		GRANTED IN PART		OTHER
APPLICATION:		SETTLE ORDER			SUBMIT ORDER		
CHECK IF APPROPRIATE:		INCLUDES TRANSFER/REASSIGN			FIDUCIARY APPOINTMENT		REFERENCE