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SUPREME COURT OF THE STATE OF NEW YORK — NEW YORK COUNTY

PRESENT: SHIRLEY WERNER KORNREICH J.S.C. PART 54

Index Number : 101572/2005

SABATINO, MARY ANN

vs

PFIZER INC

Sequence Number : 001

DISMISS ACTION

INDEX NO. _____

MOTION DATE _____

MOTION SEQ. NO. _____

MOTION CAL. NO. _____

The following papers, numbered 1 to _____ were read on this motion to/for _____

	PAPERS NUMBERED
Notice of Motion/ Order to Show Cause — Affidavits — Exhibits ...	1, 2
Answering Affidavits — Exhibits	3
Replying Affidavits	4, 5

Cross-Motion: ☐ Yes ☒ No

Upon the foregoing papers, it is ordered that this motion is decided in accordance with the annexed decision -

ENTERED
JAN - 4 2006
COUNTY CLERK'S OFFICE

FILED
JAN 10 2006
COUNTY CLERK'S OFFICE
NEW YORK

Dated: 12/27/05

SHIRLEY WERNER KORNREICH J.S.C.

J.S.C.

MOTION/CASE IS RESPECTFULLY REFERRED TO JUSTICE FOR THE FOLLOWING REASON(S):

Check one: ☐ FINAL DISPOSITION ☒ NON-FINAL DISPOSITION

Check if appropriate: ☐ DO NOT POST ☐ REFERENCE

[* 2]

SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK: PART 54

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MARY ANN SABATINO & RAYMOND SABATINO, LUCRETIA NOBILE et ux. MATTHEW A. NOBILE, ANTHONY ORIOLES et ux. GERALDINE ORIOLES, HILDA PELTZ et ux. JACK J. PELTZ, & MARGARET STEIN-HOFF et ux. MICHAEL STEINHOFF,

Plaintiffs,

-against-

INDEX NO.: 101572/05
DECISION AND JUDGMENT

PFIZER INC., PHARMACIA CORP., a wholly-owned subsidiary of PFIZER INC., PHARMACIA & UPJOHN CO., a wholly-owned subsidiary of PHARMACIA CORP. & MERCK & CO., INC.,

Defendants.

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HON. SHIRLEY WERNER KORNREICH, J.:

Plaintiffs commenced this action to recover for injury allegedly caused them by ingesting prescription drugs manufactured by defendants. The defendants, other than Merck & Co., Inc. ("Merck"), now move to dismiss the action against them.

Specifically, the complaint in this action contends that the moving parties ("Pfizer defendants") manufactured, marketed and distributed Celebrex and Bextra and promoted the products in medical journals, by using sales representatives, experts and medical education programs to encourage physicians to prescribe the products, by direct advertising and through the media to promote their use by consumers. Compl., paras. 6, 7, 9, 10. It continues by alleging that, "based on defendant's [sic] promotional activity with respect to the aforesaid products, plaintiffs were prescribed the drugs based on the belief the same was safe to use and was unlikely

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to subject each plaintiff to serious side effects as a result of use of the products." *Id.* at 11. The complaint then states that six plaintiffs, relying "on the same," ingested the drugs "for a period of time as instructed by their prescribing physicians." *Id.* at 12.

The complaint contends that "had defendants carried out proper testing on their products it [sic] would have realized the risks of using their products including cardiovascular events but not limited to heart attack, stroke and thromboembulism, and that the risk outweighed any alleged benefits from the products." *Id.* at para. 13. It also alleges that defendants intentionally hid and withheld from the public, safety concerns expressed by its researchers linking the drug to heart risks. *Id.* at 14. Finally, the complaint states that Mary Ann and Raymond Sabatino and Anthony Orioles ingested Vioxx, Bextra and Celebrex, Lucretia Nobile ingested Vioxx and Bextra, and Hilda Peltz and Margaret Steinhoff ingested Vioxx and Celebrex, "at the direction of [their] physicians and in accordance with the manufacturer's [sic] instructions" and that they sustained injuries as a "direct and proximate result," solely by reason of defendants' defective products. *Id.* at 15-24.

The following causes of action are alleged: 1) negligence and gross negligence; 2) strict products liability; 3) misrepresentation; 4) breach of express and implied warranties; and 5) violations of BCL §349. Movants argue that dismissal is in order because: 1) plaintiffs failed to plead specific facts "demonstrating how each Defendant caused injury to Plaintiffs"; 2) the doctrine of "informed intermediary" bars plaintiffs' negligence, gross negligence, negligent misrepresentation, failure to warn and breach of implied warranty causes of action; 3) plaintiffs failed to allege negligent misrepresentation with the required particularity; 4) the complaint fails to allege facts sufficient to establish the material elements of strict products liability,

manufacturing defect and breach of warranty; and 5) plaintiffs failed to adequately plead the elements of BCL §349.

Plaintiffs oppose the motion, arguing that the complaint, alleging that the defendants are jointly and severally liable, is sufficient to withstand a dismissal motion,. Moreover, they contend that defendants prematurely are moving on the learned intermediary doctrine, a defense which, as yet, has not been pled. They further deny the necessity of detailing the alleged misrepresentations made by defendants and argue that the complaint alleges ample facts to establish the elements of design defect since they need not plead a safe alternative design in pleadings. Finally, plaintiffs contend they need not allege a specific defect for breach of warranty and, given the fact that discovery has not taken place, adequate allegations have been asserted to allege a violation of GBL §349.

Conclusions of Law

The motion, here, seeks dismissal for failure to state a cause of action pursuant to CPLR 3211(a)(7). In determining a motion under this section, the Court must "accept the facts as alleged in the complaint as true, accord plaintiff the benefit of every possible favorable inference, and determine only whether the facts as alleged fit within any cognizable legal theory." *Leon v. Martinez,* 84 N.Y.2d 83, 87-88 (1994).

1. Specificity of Complaint Demonstrating Proximate Cause

Moving defendants argue that plaintiffs have failed to allege the precise tortuous conduct attributable to each defendant, specifically failing to identify a causal link between each defendant's product and each plaintiff's injuries. CPLR §3013 requires that pleadings "shall be sufficiently particular to give the court and parties notice of the transactions, occurrences, or

series of transactions or occurrences, intended to be proved and the material elements of each cause of action." The facts alleged in the instant complaint are pleaded in sufficient detail to provide adequate notice of the causal connection between defendants' conduct and plaintiffs' injuries.[1]

The complaint alleges that the Pfizer defendants manufactured, promoted, failed to properly test and improperly suppressed research results regarding Celebrex and Bextra. It further contends that the Sabatinos and Anthony Orioles ingested Bextra and Celebrex, that Lucretia Nobile ingested Bextra, and that Hilda Peltz and Margaret Steinhoff ingested Celebrex due to Pfizer's promotion of its product and that, "as a direct and proximate result," they all sustained injuries. Additionally, as noted by plaintiffs the complaint alleges joint and several liability as against Pfizer and Merck, the manufacturer of Vioxx, a drug also ingested by all of the plaintiffs. Accepting the facts as alleged in the complaint as true, as the Court must do in this pre-answer motion to dismiss, and according plaintiffs the benefit of every possible favorable inference, the facts are sufficient to allege concurrent, successive or alternative liability theories which would establish a causal link between the Pfizer defendants' products and plaintiffs' injuries. *See Hymowitz v. Eli Lilly & Co.*, 73 N.Y.2d 487, 505-7 (1989); *Ravo v. Rogatnick*, 70 N.Y.2d 305, 309-12 (1987). Nonetheless, the Court grants defendants' motion to dismiss without prejudice and with leave to replead the allegedly injured plaintiffs' six actions in separate complaints under separate index numbers.

2. Informed Intermediary Doctrine

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[1] The Court discusses the sufficiency of the pleading alleging negligent misrepresentation and express warranty, *infra*.

Movants further argue that the informed intermediary doctrine mandates dismissal of the negligence claims (negligence, gross negligence and negligent misrepresentation) and the failure to warn claims. Plaintiffs counter that the motion is premature since the learned intermediary defense must be pled and movants' have not as yet answered. They further argue that, even were this issue timely raised, dismissal should not be granted on this defense.

As explained in *Martin v. Hacker*, 83 N.Y.2d 1, 9 (1993):

> Warnings for prescription drugs are intended for the physician, whose duty it is to balance the risks against the benefits of various drugs and treatments and to prescribe them and supervise their effects. The physician acts as an "informed intermediary"...between the manufacturer and the patient; and thus, the manufacturer's duty to caution against a drug's side effects is fulfilled by giving adequate warning through the prescribing physician, not directly to the patient.... The warning must provide sufficient information to that category of prescribing physicians who may be expected to have the least knowledge and experience with the drug...

Accord McDonnell v. Chelsea Manufacturers, Inc., 259 A.D.2d 674, 676 (2d Dept. 1999).

The informed intermediary doctrine requires the warnings to be sufficient for the doctor to assess the risks associated with the drug or medical device in relation to the patient's needs. *Bukowski v. CooperVision, Inc.*, 185 A.D.2d 31, 35 (3d Dept. 1993). The adequacy of the warnings is generally a question of fact left to trial. *Id.* at 34; *Erony v. Alza Corp.*, 913 F.Supp. 195, 199 (SDNY 1995); *Figueroa, supra*. Here, where issue has not been joined and discovery has not as yet taken place, dismissal based on the informed intermediary doctrine would be inappropriate.

3. Negligent Misrepresentation

Defendants' motion, however, should be granted as to negligent misrepresentation in regard to any representations allegedly made to plaintiffs, rather than their doctors. CPLR

§3016(b) provides:

> Where a cause of action or defense is based upon misrepresentation, fraud, mistake, wilful default, breach of trust or undue influence, the circumstances constituting the wrong shall be stated in detail.

In the case of misrepresentation, this has been interpreted to require that the essential material facts supporting the allegations, be included. *Lipton v. Unumprovident Corp.*, 10 A.D.3d 703, 707 (2d Dept. 2004); *Shalmoni v. Shalmoni*, 141 A.D.2d 628, 629 (2d Dept. 1988). However, when the circumstances constituting the misrepresentation are within the knowledge of the defendant, the specificity required by CPLR §3016(b), will not be strictly enforced. *Bazak Intl. Corp. v. Mast Indus., Inc.*, 73 N.Y.2d 113, 125 (1989).

Here, plaintiffs rely on conclusory allegations, failing to specify with the requisite particularity, the misrepresentations made in any public advertisements and promotions upon which they allegedly relied. The misrepresentation cause of action in regard to the public advertisements and promotions, therefore, is dismissed. *See Hernandez v. N.Y.C. Law Dept. Corp.*, 258 A.D.2d 390 (1st Dept. 1999). However, given the fact that the details of any representations made by defendants' representatives to plaintiffs' doctors are peculiarly within the knowledge of defendants and those doctors, the Court will not dismiss the cause of action as it pertains to misrepresentations allegedly made to plaintiffs' physicians. *See Bazak Intl. Corp. v. Mast Indus., Inc., supra.*

4. Strict Products Liability and Breach of Warranty

A. Strict Products Liability

The theory of strict liability does not require a showing of negligence, but rather focuses upon whether the product was reasonably safe. *Voss v. Black & Decker Mfg. Co.*, 59 N.Y.2d 102

(1983). A product is unreasonably safe and, thus, defective when its " 'utility does not outweigh the danger inherent in its introduction into the stream of commerce. ' " *Id.* Strict liability is proved

> "..if the defect was a substantial factor in bringing about [plaintiff's] damages; provided: 1) that at the time of the occurrence the product is being used *** for the purpose and in the manner normally intended, 2) that if the person injured or damaged is himself the user of the product he would not by exercise of reasonable care have both discovered the defect and perceived its danger, and 3) that by the exercise of reasonable care the person injured or damaged would not otherwise have averted his injury or damages."

Id. at 106. A plaintiff may bring an action based on strict products liability due to a mistake in the manufacturing process, the defective design of the product or the inadequacy of warnings regarding the product's use. *Sprung v. MTR Ravensburg, Inc.*, 99 N.Y.2d 468, 472 (2002).

Here, plaintiffs base their action for strict products liability on design defect and inadequate warnings. In pleading design defect, plaintiffs allege that the Pfizer defendants manufactured Celebrex and Bextra without properly testing the products for safety and that these drugs had risks of causing cardiac events – heart attack, stroke and thromboembulism. They further allege, that each plaintiff ingested one or both of these drugs for a period of time, as prescribed by their doctors, and, as a result, suffered injury. Finally, plaintiffs allege that the risks associated with Celebrex and Bextra outweighed their benefits. Accepting these facts and according plaintiffs the benefit of every possible favorable inference, the Court determines that plaintiffs' allegations are sufficient, at the pleading stage, to establish design defect.

Similarly, the Court declines to dismiss the causes of action based on the inadequacy of the warnings given to physicians. A drug manufacturer is under a duty to warn physicians of the potential hazards of pharmaceuticals which it knew or should have known to exist, and when this

duty is breached, the drug is rendered unreasonably dangerous. *Bikowicz v. Nedco Pharmacy, Inc.*, 130 A.D.2d 89, 93 (3d Dept. 1987); *Baker v. St. Agnes Hosp.*, 70 A.D.2d 400, 405 (2d Dept. 1979). As noted by this Court in discussing the learned intermediary defense, the adequacy of warnings is generally a question of fact left to trial. *Supra* §2. Where, as here, issue has not been joined and discovery has not taken place, the warnings provided to plaintiffs' doctors have not been revealed and it would be inappropriate to dismiss the complaint for failure to specify the warnings and their inadequacies.

B. Breach of Warranty

Again, defendants contend that plaintiffs failed to allege the requisite specificity in their claims for breach of both express and implied warranty. In their complaint, plaintiffs allege that defendants, in advertisements to the public and in literature and verbal and written promotions to their physicians, stated that Celebrex and Bextra were safe and unlikely to cause serious side-effects. These allegations, clearly, were not specific and, therefore, did not allege sufficient facts to establish plaintiffs', not the public's, awareness of and reliance upon the advertisements' guarantees. Thus, a cause of action based upon express warranty made to plaintiffs, cannot stand. *See Wojcik v. Empire Forklift, Inc.*, 14 A.D.3d 63, 65 (3d Dept. 2004); *Murrin v. Ford Motor Co.*, 303 A.D.2d 475, 477 (2d Dept. 2003). However, given the fact that this is a pre-discovery dismissal motion and plaintiffs are not privy to the literature and promotions made to their physicians, the cause of action, applying to express representations made to their physicians, is not dismissed.

On the other hand, a cause of action for breach of implied warranty of merchantability and fitness does not rely on express representations, but, instead, requires the plaintiff to "show that

the product was not 'reasonably fit for [its] intended purpose,' an inquiry that 'focuses on the expectations for the performance of the product when used in the customary, usual and reasonably foreseeable manners.' " *Wojcik, supra* at 66 quoting *Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 258-9 (1995). Plaintiffs' contentions in their complaint that Celebrex and Bextra were defective in that they could cause cardiovascular events, that defendants-manufacturers failed to properly test for this and/or intentionally hid and withheld this information, that plaintiffs, relying on information provided by defendants, ingested Celebrex and/or Bextra "at the direction of [their] physicians and in accordance with the manufacturer's [sic] instructions" and that they sustained injuries as a "direct and proximate result," are sufficient to withstand a motion to dismiss their cause of action for implied warranty.

5. GBL §349

To establish a cause of action pursuant to GBL §349, a plaintiff must prove that the challenged conduct was consumer-oriented, that it was materially misleading and that he suffered injury as a result of the conduct. *Stutman v. Chemical Bk.*, 95 N.Y.2d 24, 29 (2000). Here, the challenged conduct ultimately targeted consumers using defendants' pharmaceuticals. Moreover, plaintiffs allege that the conduct – misrepresentations regarding the drugs' safety and the intentional withholding of vital safety information – was materially misleading, causing plaintiffs injury. Consequently, plaintiffs' cause of action pursuant to GBL §349 withstands dismissal. Accordingly, it is

ORDERED that the Pfizer defendants' motion to dismiss is granted to the extent of dismissing the misrepresentation, failure to warn and express warranty causes of action as they relate to the advertisements of the drugs and promotional activity aimed at the public, i.e.

plaintiffs, not their physicians; and it is further

ORDERED that the Pfizer defendants' motion to dismiss the remainder of the complaint is granted without prejudice and with leave to replead the actions separately as to each of the six plaintiffs under separate index numbers; and it is further

ORDERED that the Clerk shall enter judgment accordingly.

Date: December 27, 2005
New York, New York

SHIRLEY WERNER KORNREICH