SUPREME COURT OF THE STATE OF NEW YORK
COUNTY OF NEW YORK, PART 11

----------X INDEX NO.: 158570/17

ZAYRE PRESTON,

Plaintiff,

-against-

JANSSEN PHARMACEUTICALS, INC, JANSSEN ORTHO, LLC, JANSSEN PHRMS, GLENMARK PHARMACEUTICALS, INC., GLENMARK PHARMACEUTICALS, USA INC., GLEMARK GENERICS INC., USA, GLENMARK GENERICS and DR. RAIHANA KHORASANEE, M.D.,

Defendants.

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JOAN A. MADDEN, J.

In this action asserting claims for medical malpractice, negligence and products liability, defendants Glenmark Pharmaceuticals, Inc., Glenmark Pharmaceuticals Inc., USA, and Glenmark Generics (together "Glenmark") move to dismiss the claims against them on the grounds that they are preempted by federal law and for failure to state a cause of action (motion seq no. 002). Defendants Janssen Pharmaceuticals, Inc., Janssen Ortho, LLC and Janssen Phrms (together "Janssen") separately move to dismiss the claims against them, asserting that they cannot be held liable to plaintiff as its product was not responsible for plaintiff's alleged injuries (motion seq. no. 003).[1] Plaintiff opposes both motions.

[1]Motion sequence nos. 002 and 003 are consolidated for disposition.

Background[2]

In this action, plaintiff alleges that she lost most of the vision in both eyes as a result of being prescribed "Topamax and/or Topiramate" by defendant Dr. Raihana Khorasannee ("Dr. Khorasannee"), on or about April 16, 2014,[3] while being treated for a psychiatric condition (Complaint ¶ 11, Plaintiff's Aff. ¶ 1). Plaintiff alleges that "from about April 28, 2015 to May 1, 2015, she began experiencing pain to the left eye... [and thereafter] was diagnosed with uveitis and other eye disorders directly caused by consumption of Topamax and/or Topiramate" (Complaint ¶'s 12, 13). Plaintiff did not know that the uveitis and other eye disorders were caused by the medication until May 24, 2017, after she consulted with her attorney (Plaintiff's Aff ¶ 4). The pharmacy records submitted by plaintiff show that she was prescribed Topiramate between April 16, 2014 and March 22, 2017.

The complaint asserts claims for strict product liability, breach of implied warranty, breach of express warranty, negligence, and violation of General Business Law § 349 and § 350,

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[2]Unless otherwise noted, the facts in the background section are based on the allegations in the verified complaint, which must be accepted as true for the purposes of this motion, plaintiff's affidavit, and Federal Drug Administration's public records available on its website, which are cited by the parties in their papers, and may be judicially noticed. See Bertini. v. Smith & Nephew, Inc., 8 FSupp3d 246, 250 n. 1 (ED NY 2014) (taking judicial notice of FDA approval documents); Gale v. Smith & Nephew, Inc., 989 FSupp. 2d 243, 246 n. 2 (SDNY 2013) (taking judicial notice of FDA public records available on FDA's website); See also Kingsbrook Jewish Medical Center v. Allstate Ins Co., 61 AD3d 13, 20 (2d Dept 2009)(noting that judicial notice, as provided for under CPLR 4511(b) "has never been strictly limited to the constitutions, resolutions, ordinances, and regulations of government, but has been applied by case law to other public documents that are generated in a manner which assures their reliability...including ...material derived from official government websites...")(internal citation omitted).

[3]While the complaint alleges that plaintiff was first prescribed Topamax and/or Topiramate on or about April 25, 2015, in plaintiff's affidavit which is submitted in connection with these motions, plaintiff states that her treatment began on or about April 16, 2014.

against Janssen and Glenmark, and for medical malpractice and lack of informed consent against Dr. Khorasanee, who has separately moved to dismiss the claims against her.

Topamax is a brand name topiramate drug manufactured by Janssen that is indicated for the treatment of certain types of seizures, as well as for migraine prevention. The Food and Drug Administration ("FDA") approved Topamax for sale by Janssen on December 24, 1996, and granted Janssen market exclusivity for thirteen years. In 2001, Janssen issued a letter to consumers stating that it had strengthened the drug's warnings and precautions regarding an ocular syndrome reportedly experienced by users-namely cases of secondary angle closure glaucoma characterized by ocular pain, acute myopia, and increased intraocular pressure. The strengthened warning included a warning that if left untreated, serious injury including permanent vision loss could occur. This warning has been displayed by Janssen since 2001.

In 2009, after Janssen's patent protection expired, the FDA approved the sale of generic versions of Topamax marketed as Topiramate. Of relevance here, on March 27, 2009, the FDA approved the sale of the generic Topiramate by Glenmark. Topiramate has the same active ingredients, strength, dosage form, and route of administration as the brand-name FDA-approved Topamax.

Janssen's Motion

Janssen moves to dismiss the complaint against it, arguing that it has never manufactured, marketed or sold generic Topiramate, nor does plaintiff allege that Janssen ever did, and thus it cannot be held liable to plaintiff for any injuries she sustained as a result ingesting generic Topiramate. Janssen further argues that applicable New York statutes mandate that absent an explicit instruction from the prescribing physician, of which there is no allegation or evidence here, plaintiff's pharmacy was required to dispense plaintiff a generic form of Topiramate, citing

Education Law § 6810(6)(a)[4]; Public Health Law § 206(1)(o).[5]

In opposition, plaintiff argues that Janssen's motion should be denied without prejudice to renewal since, although it is "reasonably believed" that plaintiff received the Glenmark's generic version of Topamax, discovery is needed to confirm this fact. Moreover, plaintiff asserts that while it has been diligent in attempting to obtain plaintiff's medical and pharmacy records, such records are not conclusive. However, the court notes that the records submitted by plaintiff show that plaintiff was prescribed Topiramate, and not Topamax.

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[4]Section 6810(6)(a) of the New York State Education Law provides, in part, that:

> a) Every prescription written in this state by a person authorized to issue such prescription shall be on prescription forms containing one line for the prescriber's signature. The prescriber's signature shall validate the prescription. Every electronic prescription shall provide for the prescriber's electronic signature, which shall validate the electronic prescription Imprinted conspicuously on every prescription written in this state in eight point upper case type immediately below the signature line shall be the words: "THIS PRESCRIPTION WILL BE FILLED GENERICALLY UNLESS PRESCRIBER WRITES 'd a w' IN THE BOX BELOW". Unless the prescriber writes d a w in such box in the prescriber's own handwriting or, in the case of electronic prescriptions, inserts an electronic direction to dispense the drug as written, the prescriber's signature or electronic signature shall designate approval of substitution by a pharmacist of a drug product pursuant to paragraph (o) of subdivision one of section two hundred six of the public health law. No other letters or marks in such box shall prohibit substitution. No prescription forms used or intended to be used by a person authorized to issue a prescription shall have 'd a w' preprinted in such box. Such box shall be placed directly under the signature line and shall be three-quarters inch in length and one-half inch in height, or in comparable form for an electronic prescription as may be specified by regulation of the commissioner. Immediately below such box shall be imprinted in six point type the words "Dispense As Written."

[5]Public Health Law § 206(1)(o) mandates that the commissioner of the Department of Health "establish and publish a list of drug products" which are FDA approved and medically equivalent generic drug products.

"A CPLR 3211(a)(7) motion ...may be used to dispose of an action in which the plaintiff identifie[s] a cognizable cause of action but fail[s] to assert a material allegation necessary to support the cause of action." Basis Yield Alpha Fund v. Goldman Sachs, Group, Inc., 115 AD3d 128, 134 (1st Dept 2014). In support of such a motion, "a defendant can submit evidence in support of the motion attacking a well-pleaded cognizable claim...[and] if the defendant's evidence establishes that the plaintiff has no cause of action (i.e., that a well-pleaded cognizable claim is flatly rejected by the documentary evidence), dismissal would be appropriate." Id at 135 (internal citations omitted).

The courts have held that named-brand drug manufacturers, like Janssen, cannot be held liable to the user of the generic form of their drug, since the manufacturer of the brand named drug owes no duty to the user of the drug's generic form. See Weese v. Pfizer, 2013 WL 5691993, *2 (Sup Ct NY Co. 2013)(dismissing product liability claims against Pfizer, the named brand manufacturer of the drug Zoloft, when the injuries were allegedly caused by ingestion of the Zoloft's generic form, noting that Pfizer's "duty should not extend to products and labeling over which it has no control, even if those products and labels mirror its own, because it has done nothing toward putting them in the hands of consumers"); Coleson v. Janssen Pharmaceutical, Inc., 251 F. Supp3d 716 (SD NY 2017)("[T]he New York authorities are consistent with the majority of other courts around the country in rejecting liability for a company that itself did not manufacture, sell, or distribute generic versions of its name-brand drug."); Goldych v. Eli Lilly & Co., 2006 WL 2038436, at *6 (N.D.N.Y. July 19, 2006) (holding that name-brand manufacturer had "no duty to the users of other manufacturers' products").

Here, assuming *arguendo* that the complaint adequately asserts claims against Janssen,

based on allegations that plaintiff was injured in connection with the use of its product, Topamax, the documentary and other evidence flatly contradicts these allegations. Specifically, the pharmacy records submitted by plaintiff show that plaintiff was prescribed Topiramate from April 16, 2014 through March 22, 2017. In addition, as noted by Janssen, New York law requires that, absent an explicit instruction from the prescribing physician, which plaintiff has not alleged or argued is the case here, plaintiff's pharmacy was required to dispense plaintiff a generic form of Topiramate. See Education Law § 6810(6)(a); Public Health Law § 206(1)(o).

Accordingly, as the documentary evidence establishes that plaintiff did not use Janssen's Topamax, and as Janssen cannot be held liable for any injuries sustained by plaintiff based on her use of Topiramate, the action must be dismissed as against Janssen.

Glenmark's Motion

Glenmark moves to dismiss the claims against it arguing that they are based on New York tort law regarding failure to warn and design defects and are thus preempted by federal law regarding requirements for generic drug manufacturers, citing PLIVA, Inc. v. Mensing, 564 US 604 (2011)(holding that federal law requiring generic drug manufacturers to use the same label as the brand named drug pre-empted state laws imposing duty to change a drug's label upon generic drug manufacturers); Mutual Pharmaceutical Co., Inc. v Bartlett, 570 US 472 (2013)(holding that federal law requiring generic drug manufacturers to be chemically equivalent to the approved brand-name drug preempted states law regarding design defects). Alternatively, Glenmark moves to dismiss the claims against it on the grounds that they are not adequately pleaded.

In opposition, plaintiff does not dispute that her failure to warn claims would be preempted to the extent that Glenmark's generic Topiramate label are the same as the Janssen's

label for the brand-name Topamax. Nor does plaintiff deny that any claims for design defects would be preempted by federal law requiring that Topiramate be chemically equivalent to Topamax under the holding in Barlett supra.

Plaintiff, however, argues that preemption does not apply to her allegations of failure to warn as the warning label for Glenmark's generic Topiramate, is not the same as name brand Topamax, citing In re Fosamax Products Liability Ligation, 965 FSupp2d 413 (SD NY 2013)(holding that the claims that manufacturers of generic drug allegedly failed to update labels to match the name brand drug are not preempted by federal law). In support of her opposition, plaintiff submits a patient insert for Janssen's Topamax, as revised in December 2014 (Plaintiff's Opp, Exh F), and a patient insert and product label for Glenmark's generic Topiramate as revised in July 2017 (Id, Exhs. H, I), which contain different warnings with respect to the effect of the use of the drug on the user's vision. In particular, plaintiff notes that Topiramate label and insert do not include the phrases in the Topamax insert regarding "untreated elevated intraocular pressure" and "these have been reported independent of elevated intraocular pressure." Plaintiff argues therefore that the Topiramate label is "confusing, ambiguous and significantly different from the FDA approved Janssen warnings."

In reply, Glenmark asserts that plaintiff's argument that preemption does not apply to the failure to warn claims as the warning label on Topiramate is not identical to that of Topamax is without merit since the labels and inserts relied on by plaintiff are from different time frames, that is Glenmark's Topiramate label and insert is the version based on a revision in July 2017, while Janssen's Topamax label is the version revised in December 2014. Moreover, Glenmark argues that the record shows that during the time period between December 2014 and July 2017,

both Janssen and Glenmark updated their labels. In support of its position, Glenmark submits the label for Glenmark's generic Topiramate, as revised in December 2014, and Janssen's Topamax label as revised in December 2014, and notes that the relevant warning language with respect to possible effects of the drug on the user's vision is the same in each of the labels.[6] Glenmark also

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[6]The Topamax and Topiramate December 2014 labels contain the following language within the "highlights" section:

> • Acute myopia and secondary angle closure glaucoma: Untreated elevated intraocular pressure can lead to permanent visual loss. The primary treatment to reverse symptoms is discontinuation of [Topamax or Topiramate] as rapidly as possible (5.1)
> • Visual field defects: These have been reported independent of elevated intraocular pressure. Consider discontinuation of [Topamax or Topiramate](5.2)

The label also provides that:

> **5.1 Acute Myopia and Secondary Angle Closure Glaucoma**
> A syndrome consisting of acute myopia associated with secondary angle closure glaucoma has been reported in patients receiving [Topamax or Topiramate]. Symptoms include acute onset of decreased visual acuity and/or ocular pain. Ophthalmologic findings can include myopia, anterior chamber shallowing, ocular hyperemia (redness), and increased intraocular pressure. Mydriasis may or may not be present. This syndrome may be associated with supraciliary effusion resulting in anterior displacement of the lens and iris, with secondary angle closure glaucoma. Symptoms typically occur within 1 month of initiating [Topamax or Topiramate] therapy. In contrast to primary narrow angle glaucoma, which is rare under 40 years of age, secondary angle closure glaucoma associated with topiramate has been reported in pediatric patients as well as adults. The primary treatment to reverse symptoms is discontinuation of [Topamax or Topiramate] as rapidly as possible, according to the judgment of the treating physician. Other measures, in conjunction with discontinuation of [Topamax or Topiramate], may be helpful. Elevated intraocular pressure of any. etiology, if left untreated, can lead to serious sequelae including permanent vision loss.
>
> **5.2 Visual Field Defects**
> Visual field defects (independent of elevated intraocular pressure) have

points out that the complaint alleges that plaintiff used Topiramate during the period when the December 2014 label would have been in effect.[7]

The Supremacy Clause of the United States Constitution establishes that federal law "shall be the supreme Law of the Land ... any Thing in the Constitution or Laws of any State to the Contrary notwithstanding." U.S. Const., Art. VI, cl. 2. " Mensing, 564 US at 617. Thus, "where state and federal law directly conflict, state law must give way [and].. [s]uch a conflict exists where it is impossible for a private party to comply with both state and federal requirements." Id. (internal citations and quotations omitted); see also, Freightliner Corp. v. Myrick, 514 U.S. 280, 287 (1995)(noting that the "impossibility" preemption, occurs when it is "impossible for a private party to comply with both state and federal requirements").

In Mensing, United States Supreme Court held that state law failure-to-warn claims were preempted by federal law requiring that a generic drug's labeling must be the same as the brand name drug, which is the basis for the generic drug's approval.[8] Specifically, the Court held that

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> been reported in clinical trials and in postmarketing experience in patients receiving topiramate. In clinical trials, most of these events were reversible after topiramate discontinuation. If visual problems occur at any time during topiramate treatment, consideration should be given to discontinuing the drug.

[7]Glenmark also submits a Topiramate label that was revised in February 2015 (Glenmark's motion, Exh. 2). To the extent plaintiff's counsel asserted at oral argument that the February 2015 label is evidence that Glenmark failed to timely update Topiramate label to match the Topamax label revised in December 2014, such argument is belied by the fact that the record contains a Topiramate label revised in December 2014 which, as noted above, has the same relevant warning language as the December 2014 Topamax label.

[8]Under federal law, a generic drug manufacturer may obtain approval of a drug from the FDA simply by showing equivalence to a reference-listed drug that has already undergone clinical trials and gained approval from the FDA. 21 U.S.C. § 355(j)(2)(A). A generic drug

"impossibility preemption" applied since it would be impossible for generic drug manufacturers "to comply with both with their state-law duty to change the label and their federal law duty to keep the label the same." Mensing, 564 US at 618.

Under the holding in Mensing, to the extent that Glenmark's generic Topiramate has the same labeling as Janssen's name-brand drug, Topamax, the label would be in compliance with federal law and preempt any state law claims based on allegations of failure to warn. Here, the record establishes that the relevant warning on the Topiramate label as revised in December 2014 is the same as that on the Topamax label as revised in December 2014. In reaching this conclusion, the court notes the labels for Topiramate and Topamax submitted by plaintiff in opposition are from different time periods. As Glenmark has shown that its Topiramate label, as revised in December 2014, was the same as the Topamax label for the same time period, the Topiramate label is in compliance with the sameness requirement under federal law, and plaintiff's failure to warn claims relating to her use of Topiramate beginning in December 2014 are preempted by federal law.[9]

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manufacturer has the responsibility to ensure that the labeling for the generic drug is the same as the labeling approved for the listed drug. 21 U.S.C. § 355(j)(2)(A)(v) & (j)(4)(G); 21 C.F.R. §§ 314.94(a)(8) & 314.127(a)(7). The FDA interprets these regulations as imposing an ongoing duty for generic manufacturers to update their product labels to ensure the sameness of the generic and name-brand drug labels. See Mensing, 564 US at 612-613; 57 Fed.Reg. 17961 (1992) ("Abbreviated New Drug Application (ANDA) product's labeling must be the same as the listed drug product's labeling because the listed drug product is the basis for ANDA approval").

[9] The documents submitted by Glenmark in reply indicate that while Janssen revised its Topamax label in May 2017 (Glenmark's reply, Exh. 4), Glenmark did not revise its label to match Janssen's updated label until July 2017 (Id, Exh. 3). Even assuming *arguendo* this delay in updating the label would provide a basis for failure update claim, which type of claim is not preempted by federal law (In re Fosamax Products Liability Litigation, 906 FSupp2d at 417), here the complaint does not contain any allegations to make out such a claim, nor does plaintiff argue in opposition to the motion that she should be permitted to assert such a claim based on

Based on this holding, plaintiff's claims for strict liability, negligence, breach of express warranty and violations of the GBL, which are grounded in part on an alleged failure to warn, are preempted to the extent such claims relate to plaintiff's use of Topiramate beginning in December 2014. However, as discussed below, based on the record before the court, which does not include any evidence as to labeling of Topiramate (or Topamax) before December 2014, it cannot be established that the failure to warn claims based on plaintiff's alleged Topiramate use during the earlier period, that is from April 2014 to December 2014, are preempted by federal law.

With regard to design defect claims, such claims relate to the chemical composition of Topiramate. As it is undisputed that generic Topiramate is chemically equivalent to the approved brand name drug Topamax, to the extent plaintiff's claims for strict liability, negligence, breach of implied warranty, are grounded in allegations of design defects, they are preempted by federal law. See Bartlett, 570 US at 487. Moreover, unlike the failure to warn claim, the finding of preemption applies throughout the period of plaintiff's alleged use of Topiramate.

The court now turns to the remaining issue, which is whether during the period for which the record does not establish preemption applies, that is from April 2014 to December 2014, the

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Glenmark's failure to timely update its label in 2017. In addition, plaintiff does not allege in her complaint or state in her affidavit, that she used, or obtained a prescription for, Topiramate during the time that she would have been affected by any failure by Glenmark to update its label in May 2017. In this connection, as noted herein, the pharmaceutical records show that plaintiff's last prescription for Topiramate was obtained in March 2017. Moreover, while the record contains a letter from plaintiff's counsel dated March 28, 2018, submitted in response to the court's inquiry at oral argument on motion sequence no. 004, which advised the court that plaintiff stopped taking the medication in June 2017, such unsupported statement is insufficient to provide a basis for finding a claim for failure to update the label, where the complaint alleges no such claim and the evidence shows that plaintiff's last prescription was filled in March 2017.

the claims against Glenmark grounded in a failure to warn are sufficient to state a cause of action.

On a motion to dismiss for failure to state a cause of action under CPLR 3211(a)(7), the court "accept[s] 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 NY2d 83, 87–88 (1994). "Dismissal of the complaint is warranted [however] if the plaintiff fails to assert facts in support of an element of the claim, or if the factual allegations and inferences to be drawn from them do not allow for an enforceable right of recovery." Connaughton v. Chiptole Mexican Grill, Inc., 29 NY3d 137, 142 (2017).[10]

As for the claims of strict liability and negligence based on the failure to warn, "negligence and strict liability claims [are viewed] as equivalent. " Estrada v. Berkel Inc., 14 AD3d 529, 530 (2d Dept 2005) (internal citation omitted). To state a claim for failure to warn, a plaintiff must prove that "(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." State Farm Fire & Cas. Co. v. Nutone, Inc., 426 Fed.Appx. 8, 10 (2d Cir.2011), citing Liriano v. Hobart Corp., 92 NY2d 232, 237 (1998)

It has been held that "a failure to warn cause of action is appropriately dismissed if a

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[10]"In a products liability action, identification of the exact defendant whose product injured the plaintiff is...generally required." Hymowitz v. Eli Lilly & Co., 73 NY2d 487, 504 (1989). Here, while plaintiff does not specify whether Janssen's product or Glenmark's product injured the plaintiff, as it has been found that the plaintiff used Glenmark's product, this pleading defect is not dispositive here.

plaintiff does not plead facts indicating how the provided warnings were inadequate." Reid v. Pfizer, Inc., 839 FSupp2d 571, 575 (ED NY 2012). Here, the complaint alleges that the Topiramate warning is defective "because of the lack of adequate warnings regarding the propensity to cause [the] loss of vision as caused in plaintiff..by Topiramate [and that] the warnings violate both federal and state law" (Complaint ¶'s 24, 25). The court finds that under liberal pleading requirements, such allegations are sufficient at this juncture to state a claim for a defective warning. See Nagel v. Brothers Intern. Food, Inc., 34 AD3d 545, 548 (2d Dept 2006)(noting that "in all but the most unusual circumstances, the adequacy of a warning is a question of fact"); but see, Goldin v. Smith & Nephew, Inc., 2013 WL 1759575, *5 (SD NY 2013)(granting motion to dismiss failure to warn claim where plaintiff failed to "identify the allegedly defective warnings, nor does she allege facts in support of her claim that these warnings were, in fact, defective"). Accordingly, the complaint states a claim for strict liability and negligence based on the failure to warn to the extent such claims have not been shown to be preempted by federal law during plaintiff's alleged use of Topiramate between April 2014 and before December 2014.

As for the claim for breach of express warranty, such claim alleges, *inter alia*, that Glenmark expressly warranted that Topiramate "was safe and effective for those patients requiring psychiatric treatment and would not cause uveitis and plaintiff's other eye problems that develop directly from its use...[and that]... Topiramate...[as]...labeled, sold and distributed did not conform with those express representations...[and that] as a proximate result of [such] breach of warranty plaintiff has suffered serious injury." (Complaint ¶'s 36, 37). To state a claim for breach of express warranty, it must be shown that there was an "affirmation of fact or promise

by the seller, the natural tendency of which [was] to induce the buyer to purchase, and that the warranty was relied upon." Schimmenti v. Ply Gem Indus., Inc., 156 AD2d 658, 659 (2d Dept 1989). Here, absent from the complaint is any allegation that plaintiff or her doctor relied on the alleged express warranties prior to plaintiff using Topiramate, or that such reliance induced their purchase of drug. Accordingly, the claim for breach of express warranties is insufficient to state a claim.

The next claim alleges violations of GBL §§ 349 and 350 based on allegations that Glenmark engaged in "unfair competition or unfair or deceptive acts or practices when [it] failed to disclose to the FDA, to plaintiff and/or plaintiff's physician known dangers of... Topiramate causing certain eye sensitivities and uveitis" (Complaint ¶ 44). It is further alleges that the conduct included "false and misleading representations and omissions of material facts regarding safety and potential risks of ...Topiramate [and]...concealment, suppression or omission of material facts in connection with the sale of merchandise" and that "[t]he FDA, plaintiff and/or plaintiff's physicians relied upon [Glenmark's] misrepresentations and omissions" (Id ¶'s 47, 48), and plaintiff was harmed as a proximate cause of the alleged conduct.

To state a claim under GBL § 349, a plaintiff must allege that the defendant engaged "in an act or practice that is deceptive or misleading in a material way and that plaintiff has been injured by reason thereof." Small v. Lorillard Tobacco Co., 94 NY2d 43, 55 (1999)(internal citations and quotations omitted). Deceptive or misleading representations or omissions are defined as those "likely to mislead a reasonable consumer acting reasonably under the [plaintiff's] circumstances." Solomon v. Bell Atlantic Corp., 9 AD3d 49, 52 (1st Dept 2004)(internal citations and quotations omitted). The deceptive act or practice must be "the

actual misrepresentation or omission to a consumer," Goshen v. Mutual Life Ins. Co. of New York, 98 NY2d 314, 325 (2002), by which the consumer is "caused actual, although not necessarily pecuniary, harm. " Oswego Laborers' Local 214 Pension Fund v. Marine Midland Bank, N.A., 85 NY2d 20, 26 (1995). To qualify for protection under the statute, it must be shown that "the acts or practices have a broader impact on consumers at large [and] [p]rivate contract disputes, unique to the parties, ... would not fall within the ambit of the statute." Id at 25.

Here, plaintiff has adequately alleged a material deceptive act in the form of the failure to disclose the known dangers of Topiramate. Moreover, as Topiramate was made available to the public at large, there is no dispute that the alleged acts are "consumer oriented" for the purpose of the statute. Accordingly, to the extent that the claim for failure to warn has not been shown to be preempted, that is for the period between April 24, 2014 and before December 2014, the complaint states a claim for violation of GBL § 349.

As for GBL § 350, to state a claim under this section, which proscribes "[f]alse advertising in the conduct of any business, trade or commerce," a plaintiff must allege that the advertisement "(1) had an impact on consumers at large, (2) was deceptive or misleading in a material way, and (3) resulted in injury." Andre Strishak & Assocs., P.C. v. Hewlett Packard Co., 300 AD2d 608, 609 (2d Dept 2002). Moreover, a plaintiff must show that she relied "upon or [was] aware of the allegedly false advertisement when purchasing the [product]." Id at 610. Here, as the complaint contains no allegations that plaintiff (or her physician) relied on any false advertisement of Topiramate before purchasing the drug, thee GBL § 350 claim fails to state a cause of action.

Conclusion

In view of the above, it is

ORDERED that the motion by defendants Glenmark Pharmaceuticals, Inc., Glenmark Pharmaceuticals Inc., USA, and Glenmark Generics (motion sequence 002) is granted to the extent of dismissing the claims against them as preempted by federal law except insofar as the claims for strict liability, negligence, and violation of the General Business Law § 349 are based on a failure to warn for the period between April 24, 2014 and before December 2014; and it is further

ORDERED that the claims against defendants Glenmark Pharmaceuticals, Inc., Glenmark Pharmaceuticals Inc., USA, and Glenmark Generics for breach of implied breach of warranty is dismissed in its entirety as preempted by federal law; and it is further

ORDERED that plaintiff's claims for breach of express warranty and violation of General Business Law § 350 are dismissed for failure to state a cause of action; and it is further

ORDERED that within 20 days of efiling of this order, plaintiff shall efile an amended complaint consistent with this order; and it is further

ORDERED that defendants Glenmark Pharmaceuticals, Inc., Glenmark Pharmaceuticals Inc., USA, and Glenmark Generics shall answer the amended complaint within 30 days of the efiling of the amended complaint; and it is further

ORDERED that the motion to dismiss by defendants Janssen Pharmaceuticals, Inc., Janssen Ortho, LLC and Janssen Phrms (motion sequence 003) is granted; and it is further

ORDERED that the Clerk shall enter judgment dismissing the complaint as against defendants Janssen Pharmaceuticals, Inc., Janssen Ortho, LLC and Janssen Phrms; and it is

further

ORDERED that the remaining parties shall appear for a preliminary conference on January 3, 2019, at 11:00 am, in Part 11, room 351, 60 Centre Street, New York, NY.

DATED: October 2, 2018

J.S.C.

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HON. JOAN A. MADDEN
J.S.C.