# FIRST DIVISION DOYLE, C. J., PHIPPS, P. J., and BOGGS, J.

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November 20, 2015

### In the Court of Appeals of Georgia

A15A1157. PLIVA, INC. v. DEMENT.

A15A1158. GOLD STANDARD, INC. v. DEMENT.

A15A1159. WOLTERS KLUWER HEALTH, INC. v. DEMENT.

A15A1160. TEVA PHARMACEUTICALS USA, INC. v. DEMENT.

A15A1161. DEMENT v. PLIVA, INC. et al.

A15A1162. DEMENT v. ALAVEN PHARMACEUTICAL, LLC et al.

A15A1163. PLIVA, INC. v. TANNER.

A15A1164. TANNER v. WYETH LLC et al.

A15A1165. TANNER v. PLIVA, INC. et al.

A15A1349. WOLTERS KLUWER HEALTH, INC. v. TANNER.

A15A1404. GENERICS BIDCO I, LLC v. DEMENT.

PHIPPS, Presiding Judge.

These cases, which we have consolidated for the purposes of deciding the appeals, concern claims related to the prescription drug metoclopramide (brand name

"Reglan"). Angela Dement and Dorothy Tanner allegedly developed a neurological condition, tardive dyskinesia, after taking generic versions of the drug; Dement used the drug from February 2008 to June 2009, and Tanner used it from August 2004 to December 2004.

Each of the plaintiffs filed an action against multiple defendants, including three companies that manufactured a generic version of the drug (PLIVA, Inc., Generics Bidco I, LLC, and Teva Pharmaceuticals USA, Inc., hereinafter collectively referred to as the "generic drug manufacturers"), four companies that manufactured the name brand version of the drug (Alaven Pharmaceutical, LLC, Wyeth LLC, Wyeth Pharmaceuticals, Inc., and Schwarz Pharma, Inc., hereinafter collectively referred to as the "name brand drug manufacturers"), and two companies that authored patient education materials pertaining to the drug (Wolters Kluwer Health, Inc. and Gold Standard, Inc.).

In the complaints, the plaintiffs asserted claims against the defendants in connection with allegedly inadequate warnings based on, inter alia, negligence, misrepresentation, and breach of warranty. The plaintiffs sought damages for injuries resulting from alleged violations of federal law and breaches of common law duties; the plaintiffs' allegations included the following: the generic drug manufacturers

failed to include in their package labeling warnings that the drug should not be taken for more than 12 weeks, failed to timely update the labeling to include such warnings, and failed to communicate warning label change information to the healthcare community; the name brand drug manufacturers distributed the drug without disclosing warnings or accurate information about the risks of long-term use; and the authors of patient education materials provided misleading drug information to the plaintiffs' pharmacies (for patient use). Various defendants filed motions to dismiss, for summary judgment, and for judgment on the pleadings, which, as detailed below, the trial court granted in part and denied in part. These appeals are from the trial court's rulings on those motions.<sup>1</sup>

<sup>&</sup>lt;sup>1</sup> We granted the applications for interlocutory review in Case Nos. A15A1157 and A15A1158. We accepted the remaining appeals as permissible cross-appeals. See generally *Executive Jet Sales v. Jet America*, 242 Ga. 307 (248 SE2d 676) (1978).

In Case Nos. A15A1161 and A15A1165, the plaintiffs appeal the grant of the generic drug manufacturers' joint motion to dismiss their claims that were based on Georgia law. In Case Nos. A15A1157, A15A1160, A15A1163 and A15A1404, the generic drug manufacturers appeal the denial of their joint motion to dismiss the plaintiffs' claims for failure to warn based on their alleged failure to update their labels. In Case Nos. A15A1162 and A15A1164, the plaintiffs appeal the grant of summary judgment to the name brand drug manufacturers. In Case Nos. A15A1159 and A15A1349, Wolters Kluwer Health, Inc. appeals the denial of its motion to dismiss as to each plaintiff. In Case No. A15A1158, Gold Standard, Inc. appeals the denial of its motion for judgment on the pleadings as to Dement.

## A. GRANT OF GENERIC DRUG MANUFACTURERS' MOTIONS TO DISMISS

#### Case No. A15A1161. DEMENT v. PLIVA et al.

1. The generic drug manufacturers moved to dismiss the plaintiffs' claims against them, asserting that all of the claims were barred by the principle of federal preemption, as stated by the United States Supreme Court in *PLIVA v. Mensing*.<sup>2</sup> The trial court agreed in part, and granted the motions to dismiss (as preempted by federal law) those claims that were based on a "failure to warn arising under Georgia law," failure to withdraw or suspend sales, and failure to communicate warning label change information to the healthcare community. (The court denied the motions to dismiss as to the claims for "failure to update" the labels.<sup>3</sup>) Dement appeals the ruling to the extent the motions to dismiss were granted, contending that *Mensing* is distinguishable and does not require dismissal.

It is well established that a motion to dismiss for failure to state a claim upon which relief may be granted should not be sustained unless (1) the allegations of the complaint disclose with certainty that the claimant would not be entitled to relief under any state of provable facts asserted

<sup>&</sup>lt;sup>2</sup> \_ U. S. \_ (131 SCt 2567, 180 LE2d 580) (2011).

<sup>&</sup>lt;sup>3</sup> This ruling is discussed in Division 3, infra.

in support thereof; and (2) the movant establishes that the claimant could not possibly introduce evidence within the framework of the complaint sufficient to warrant a grant of the relief sought. In deciding a motion to dismiss, all pleadings are to be construed most favorably to the party who filed them, and all doubts regarding such pleadings must be resolved in the filing party's favor.

[A] plaintiff is not required to plead in the complaint facts sufficient to set out each element of a cause of action so long as it puts the opposing party on reasonable notice of the issues that must be defended against. If within the framework of the complaint, evidence may be introduced which will sustain a grant of relief to the plaintiff, the complaint is sufficient. We review the trial court's ruling on a motion to dismiss for failure to state a claim upon which relief can be granted under the de novo standard of review.<sup>4</sup>

In *Mensing*, the plaintiffs brought actions asserting against generic drug manufacturers state-law tort claims based on the defendants' alleged failure to provide adequate warning labels for the generic drug metoclopramide. Under state laws applicable to the actions brought in *Mensing*, all drug manufacturers had a duty

<sup>&</sup>lt;sup>4</sup> *TechBios, Inc. v. Champagne*, 301 Ga. App. 592-593 (688 SE2d 378) (2009) (footnote omitted).

<sup>&</sup>lt;sup>5</sup> *Mensing*, 131 SCt at 2572.

to adequately warn consumers and safely label their products.<sup>6</sup> It was undisputed in *Mensing* that, accepting the plaintiffs' allegations as true, state law required generic drug manufacturers to use a "different, safer" label than the brand-name manufacturers' label.<sup>7</sup> But, the Court pointed out, federal regulations require that the labels on generic drugs match the label on the brand-name counterparts, thus preventing generic drug manufacturers from independently changing their drugs' safety labels.<sup>8</sup> "[F]ederal law would permit the [generic drug manufacturers] to comply with the state labeling requirements if, and only if, the FDA and the brand-name manufacturer changed the brand-name label to do so." Thus, the *Mensing* Court held, the state-law claims were barred because it was impossible for generic drug manufacturers to comply with both state-law duties to adequately warn consumers and safely label their products and federal requirements that generic drug

<sup>&</sup>lt;sup>6</sup> Id. at 2577 (II) (C).

<sup>&</sup>lt;sup>7</sup> Id. at 2573-2574 (II) (A).

<sup>&</sup>lt;sup>8</sup> Id. at 2474 (II) (B).

<sup>&</sup>lt;sup>9</sup> Id. at 2578 (III) (B).

labels be the same as federally-approved labels for the brand-name drug (the federal "sameness" requirement). 10

The generic drug manufacturers, as defendants, bear the burden of establishing a preemption defense.<sup>11</sup>

(a) Contrary to the assertion of the generic drug manufacturers in their motions to dismiss, the *Mensing* Court did not "[find] *unequivocally* that claims against generic drug companies are preempted under the Supremacy Clause of the United States Constitution." The *Mensing* decision is not so broad. As the Supreme Court explained in *Mutual Pharmaceutical Co. v. Bartlett*, under *Mensing*, state-law failure to warn claims were preempted by federal law because "it was impossible for the [generic drug manufacturers] to comply with both their state-law duty to change the label and their federal law duty to keep the label the same" as the federally-approved label. Thus, under *Mensing*, the impossibility preemption applies to those

<sup>&</sup>lt;sup>10</sup> Id. at 2574-2575 (II) (B), 2577 (II) (C); 2577-2578 (III) (A).

<sup>&</sup>lt;sup>11</sup> Wyeth v. Levine, 555 U. S. 555, 569 (III) (129 SCt 1187, 173 LE2d 51) (2009).

<sup>&</sup>lt;sup>12</sup> (Emphasis supplied.)

<sup>&</sup>lt;sup>13</sup> \_ U. S. \_ (133 SCt 2466, 186 LE2d 607) (2013).

<sup>&</sup>lt;sup>14</sup> Id. at 133 S. Ct. 2478-2479 (IV-V).

claims involving a generic drug manufacturer's failure to unilaterally alter its labeling to comply with state-law warning duties; *Mensing* does not provide generic drug manufacturers with blanket immunity against all state-law warning claims.

Dement asserted claims other than those regarding the generic drug manufacturers' federal "sameness" duties. She alleged that the generic drug defendants also had duties under Georgia law, including the following duties: "the manufacturer of a product which, to its actual or constructive knowledge, involves danger to users, has a duty to give warning of such danger"; and "[a] manufacturer's failure to warn of the dangers in using a product may constitute a defect in the product for purposes of strict liability." Dement alleged that the generic drug manufacturers violated those duties, inter alia, by failing to provide adequate warnings (which, she added, the generic drug manufacturers could have provided after the name-brand manufacturers changed their label, without violating federal "sameness" rules). Thus, the impossibility principle was not implicated as to

<sup>&</sup>lt;sup>15</sup> Chrysler Corp. v. Batten, 264 Ga. 723, 724 (1) (450 SE2d 208) (1994) (citations and punctuation omitted).

<sup>&</sup>lt;sup>16</sup> Pepper v. Selig Chemical Inds., 161 Ga. App. 548, 550 (3) (288 SE2d 693) (1982); OCGA § 51-1-11 (b) (1) (pertinently providing that a manufacturer is strictly liable when a consumer suffers injuries due to a product that was not merchantable and reasonably suited to the use intended).

Dement's claims, and preemption, as set out in *Mensing*, does not apply. Accordingly, the trial court erred by dismissing the claims as preempted. Notably, although Georgia's appellate courts have not decided whether state-law failure to warn claims such as those asserted by Dement are precluded under *Mensing*, several courts in other jurisdictions have (as we do here) declined to dismiss state-law failure to warn claims asserted against generic drug manufacturers.<sup>17</sup>

(b) Similarly, *Mensing* does not require dismissal of Dement's claims based on the generic drug manufacturers' failure to suspend or withdraw sales of a misbranded drug. In her complaint as amended, Dement included allegations that the generic

<sup>&</sup>lt;sup>17</sup> See, e.g., *Couick v. Wyeth, Inc.*, 2012 U. S. Dist. LEXIS 3699, \*6, 11, 14 (A); 16-19 (B) (WDNC 2012) (denying motion to dismiss state law failure to warn and breach of warranty claims against generic drug manufacturers; holding that a state law claim for failure to include warnings was not preempted by federal law where the federal Food, Drug & Cosmetic Act ("FDCA") would have permitted or even required such changes); Franzman v. Wyeth, Inc., 451 SW3d 676, 688-689 (c) (Mo. App. 2014) (while the alleged failure to update generic drug labels may also constitute a violation of federal law, the plaintiff's claim was based on an independent state law duty and was not preempted). See also Fisher v. Pelstring, 817 FSupp2d 791, 832 (a) (DSC 2012) (breach of implied warranty of merchantability under state law is not created by labeling content, and claims alleging its breach by generic drug manufacturers remain viable post-Mensing); Metz v. Wyeth, 872 FSupp2d 1335, 1341-1342 (MD Fla. 2012) (implied warranty claim against generic drug manufacturers may survive preemption based on a showing that defendant knew the drug was likely to be used more than 12 weeks and implicitly warranted that it was safe and effective for such use).

drug manufacturers had: placed misleading labels on their drug; failed to update the drug's labels with the mandated 2004 label revisions; failed to disclose all known risks regarding the drug; made misleading warranties regarding the drug's safety; concealed the drug's defects; allowed the drug to leave their control when it was defective or unreasonably dangerous; and, despite having knowledge that the drug was unsafe, continued to sell the drug. Notably, Dement asserted in her trial brief in response to the motion to dismiss that the generic drug was misbranded because the generic drug manufacturers had failed to, inter alia, include information that they were required to include, namely the 2004 update; that Georgia law prohibits drug manufacturers from selling misbranded drugs;<sup>18</sup> and that state law parallels federal law in that regard.<sup>19</sup>

Although Dement did not in her complaint use the terms "misbranded" or "failure to suspend or withdraw sales," a court deciding a motion to dismiss a complaint must resolve all doubts in favor of the party that filed the complaint.<sup>20</sup> Here, the allegations of the complaint put the generic drug manufacturers on

<sup>&</sup>lt;sup>18</sup> See OCGA §§ 26-3-3, 26-3-8.

<sup>&</sup>lt;sup>19</sup> See 21 USC §§ 331 (a), 352 (a) (c) (f).

<sup>&</sup>lt;sup>20</sup> See *TechBios*, supra.

reasonable notice of the claims at issue here.<sup>21</sup> Further, as Dement contends, it was not impossible for the generic drug manufacturers to simultaneously comply with both state and federal law. Accordingly, these state-law claims asserted by Dement do not run afoul of *Mensing* or the cases cited in the trial court's order (*Mutual Pharmaceutical v. Bartlett*<sup>22</sup> and *Morris v. PLIVA*),<sup>23</sup> and dismissal was not warranted.

<sup>&</sup>lt;sup>21</sup> Id.

<sup>&</sup>lt;sup>22</sup> 133 SCt at 2476 (explaining that "preemption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability"; rejecting argument that state law claims are protected from preemption because a defendant faced with a conflict between federal and state law could have opted to suspend sales of its product; a "failure to stop selling" theory of liability is incompatible with *preemption* jurisprudence).

<sup>&</sup>lt;sup>23</sup> 713 F3d 774, 778 (II) ("failure to stop selling claim" was preempted by federal law because "[a]ny state law-based holding that the generic [drug] manufacturers should have acted differently with respect to warnings or should have ceased manufacturing these products because of insufficient warnings not only violates the duty of sameness but conflicts with FDA's exclusive authority to approve drugs and drug labels"). See *Lyman v. Pfizer, Inc.*, 2012 U. S. Dist. LEXIS 13185, \*18-19 (D. Vt. 2012) ("[T]he *Mensing* holding does not prevent plaintiffs from asserting liability against the [defendants] for distributing a drug that is misbranded"; "[f]ederal law prohibits a manufacturer from introducing into commerce a misbranded drug.").

(c) However, the trial court properly dismissed Dement's claims based on "failure to communicate" warning label change information to the healthcare community, as those claims are preempted by federal law.<sup>24</sup>

Construing the pleadings most favorably to Dement, we hold that the generic drug manufacturers failed to establish that Dement could not possibly introduce evidence within the framework of the complaint sufficient to warrant a grant of the relief sought as to her claims for failure to warn and failure to suspend or withdraw sales.<sup>25</sup> The trial court's judgment is reversed to the extent it holds otherwise. With regard to the claim based on an alleged failure to communicate warning label change information to the healthcare community, the judgment is affirmed.

Case No. A15A1165. TANNER v. PLIVA et al.

2. Tanner appeals the grant of the generic drug manufacturers' motion to dismiss, making substantively the same contentions Dement makes in Case No.

<sup>&</sup>lt;sup>24</sup> *Mensing*, supra at 131 SCt 2576 (federal law did not permit manufacturers to issue additional warnings through letters to physicians); *Guarino v. Wyeth*, *LLC*, 719 F3d 1245, 1249 (11th Cir. 2013) (generic drug manufacturers could not be compelled by state law to mail warnings directly to physicians); *Morris*, 713 F3d at 776-777 (I) (citing *Mensing*, holding that "duty of sameness" prohibits generic drug manufacturers from sending warning letters communicating a label change if name brand manufacturers did not also send such a warning).

<sup>&</sup>lt;sup>25</sup> See *TechBios, Inc.*, supra.

A15A1161. Tanner's complaint set forth similar allegations. For the reasons set out in Division 1 above, the trial court erred by granting the generic drug manufacturers' motion to dismiss Tanner's failure to warn and failure to suspend or withdraw sales claims, but properly granted the motion as to the failure to communicate claim. The judgment is reversed as to the two former claims, and affirmed as to the latter claim.

B. DENIAL OF GENERIC DRUG MANUFACTURERS' MOTIONS TO DISMISS

#### Case No. A15A1157. PLIVA v. DEMENT

3. In denying the generic drug manufacturers' motions to dismiss claims based on alleged failure to *update* labeling to include the 2004 warning that the drug should not be taken for more than 12 weeks, the trial court found that Dement's complaint had set forth sufficient allegations to state a claim for relief. PLIVA appeals the ruling. We affirm.

As stated above, Dement alleged that in 2004 the name brand drug manufacturers updated the labeling of their drug to include a warning that the drug should not be used for longer than 12 weeks. PLIVA concedes that federal law requires generic drug manufacturers to duplicate verbatim the brand-name drug's label, that PLIVA was obligated to update its packaging in 2004 to include the new

warning when the name brand drug manufacturers did, and that PLIVA failed to do so.

Nonetheless, PLIVA moved to dismiss Dement's "failure to *update*" claim, arguing that it is an impermissible attempt to enforce the FDCA's "sameness" requirement, and that the federal duty of sameness is not enforceable by private litigants.<sup>26</sup> The trial court properly denied PLIVA's motions to dismiss.

(a) First, Dement alleged in her complaint that PLIVA had a duty under Georgia common law to provide adequate warnings about its product, which PLIVA could have done by updating its labeling in 2004 (to conform to the FDA-approved and mandated revisions). Such an update was not rendered impossible by federal law.<sup>27</sup> Accordingly, federal law does not preempt the claim.<sup>28</sup>

<sup>&</sup>lt;sup>26</sup> See *Friedlander v. Hms-Pep Prods.*, 226 Ga. App. 123, 125-126 (2) (485 SE2d 240) (1997) (the FDCA does not provide a private right of enforcement).

<sup>&</sup>lt;sup>27</sup> Compare *Mensing*, supra.

<sup>&</sup>lt;sup>28</sup> See, e.g., *Fulgenzi v. PLIVA*, *Inc.*, 711 F3d 578, 584 (III) (A) (6th Cir. 2013) (plaintiffs were not preempted under *Mensing* from bringing state tort claims against generic drug manufacturer for failing to *update* its metoclopramide label to include the 2004 warning; plaintiff could base her claim on argument that drug manufacturer's warning was inadequate to the extent that it did not include language contained in the name-brand manufacturer's updated label); *Phelps v. Wyeth, Inc.*, 938 FSupp2d 1055, 23 (D. Ore. 2013) (allowing claims arising from PLIVA's alleged failure to update warning label, as not arising from violations of FDCA

(b) Second, Dement does not seek to enforce the FDCA or recover for a violation thereunder, but seeks to recover damages based on Georgia law.<sup>29</sup> Thus, PLIVA's contention presents no basis for reversal.

The trial court did not err by refusing to dismiss Dement's failure to update claims.

Case No. A15A1160. TEVA PHARMACEUTICALS USA, INC. v. DEMENT

4. To the extent Teva raises the same arguments here that PLIVA raised in Case No. A15A1157, its arguments are likewise without merit.<sup>30</sup> Insofar as Teva contends that Dement's claim should have been dismissed because Dement took Teva's drug only after its label had been updated, the contention presents no basis for reversal.

requirements).

<sup>&</sup>lt;sup>29</sup> See generally *Chrysler Corp.*, supra at 724 (1) (under Georgia negligence law, a product manufacturer has a duty to exercise reasonable care in manufacturing its products so as to make products that are reasonably safe for intended or foreseeable uses); *Banks v. ICI Americas*, 264 Ga. 732, 733 (1) (450 SE2d 671) (1994) (with respect to product manufacturers, Georgia law recognizes causes of action based on three general categories of product defect: manufacturing defects, design defects, and warning defects); *McLain v. Mariner Health Care*, 279 Ga. App. 410, (2) n.10 (631 SE2d 435) (2006) (considering federal laws and regulations when determining the appropriate standard of care for purposes of a common law negligence claim).

<sup>&</sup>lt;sup>30</sup> Division 3, supra.

On a motion to dismiss for failure to state a claim, the court must accept the plaintiff's claims as true and determine whether the complaint states a cause of action.<sup>31</sup> If, within the framework of the complaint, evidence may be introduced which will sustain a grant of relief to the plaintiff, the complaint is sufficient.<sup>32</sup> Because it cannot be said with certainty that within the framework of the complaint no evidence could be introduced that would support Dement's claims for relief, the motion to dismiss was properly denied.<sup>33</sup>

#### Case No. A15A1163. PLIVA, INC. v. TANNER

5. PLIVA appeals the denial of its motion to dismiss Tanner's claim based on failure to update. The order appealed is substantively the same as the one PLIVA appeals in Case No. A15A1157,<sup>34</sup> and PLIVA makes substantively the same arguments. This appeal is without merit for the reasons described in Division 3.<sup>35</sup>

Case No. A15A1404. GENERICS BIDCO I, LLC. v. DEMENT

<sup>&</sup>lt;sup>31</sup> Simmons v. Brady, 251 Ga. App. 717, 718 (1) (555 SE2d 94) (2001); see *Ikomoni v. Bank of America*, 330 Ga. App. 776 (769 SE2d 527) (2015).

<sup>&</sup>lt;sup>32</sup> *Ikomoni*, supra.

<sup>&</sup>lt;sup>33</sup> See id. at 778.

<sup>&</sup>lt;sup>34</sup> Division 3, supra.

<sup>35</sup> Supra.

6. Generics Bidco I, LLC appeals the trial court's denial of its motion to dismiss, asserting the same contentions PLIVA makes in Case No. A15A1157. Those contentions are without merit, for the reasons discussed in Division 3.<sup>36</sup>

Generics Bidco I asserts additionally that Dement's claim that the generic drug manufacturers failed to timely update their labels must be dismissed as to Generics Bidco I because it did not exist as an entity until 2007, and when it entered the market its drug had updated labeling. However, that assertion goes beyond the framework of the complaint. Because it cannot be said with certainty that, within the framework of the complaint, no evidence could be introduced that would support Dement's claims for relief, the motion to dismiss was properly denied.<sup>37</sup>

C. GRANT OF SUMMARY JUDGMENT IN FAVOR OF NAME BRAND
DRUG MANUFACTURERS

Case No. A15A1162. DEMENT v. ALAVEN PHARMACEUTICAL, LLC et al.

7. This court reviews the grant of summary judgment de novo, viewing the evidence in the light most favorable to the nonmovant.<sup>38</sup> "The judgment sought shall

<sup>&</sup>lt;sup>36</sup> Supra.

<sup>&</sup>lt;sup>37</sup> See generally id.

<sup>&</sup>lt;sup>38</sup> Godwin v. Mizpah Farms, LLLP, 330 Ga. App. 31 (766 SE2d 497) (2014).

be rendered forthwith if the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law."<sup>39</sup>

In granting summary judgment to the name brand drug manufacturers, the trial court held that those defendants could not be held liable because the plaintiffs had not been exposed to their products. In her challenge to the ruling, Dement contends that the name brand drug manufacturers are strictly liable because they controlled the design and labeling of the generic drugs, or, alternatively, common law negligence claims are available; further, public policy supports such claims. There was no error.

Under Georgia law, Dement, proceeding under a theory of negligence or strict liability, must prove that the defendants manufactured or distributed the product that caused her harm, or that she was exposed to the defendants' product.<sup>40</sup> Regarding

<sup>&</sup>lt;sup>39</sup> OCGA § 9-11-56 (C).

<sup>&</sup>lt;sup>40</sup> See *Hoffman v. AC&S*, 248 Ga. App. 608, 610-611 (548 SE2d 379) (2001); *Chapman v. American Cyanamid Co.*, 861 F2d 1515, 1519-1520 (I) (11th Cir. 1988); *Germain v. Teva Pharmaceuticals, USA*, 756 F3d 917, 943 (4) (6th Cir. 2014) (noting that federal courts in Georgia have rejected misrepresentation claims against name brand drug manufacturers where the plaintiffs had ingested only generic drugs, and that name brand drug manufacturers do not owe generic drug consumers a duty that could give rise to liability under Georgia law for alleged misrepresentations);

liability of a name brand drug manufacturer to a consumer who used only a generic drug, "the overwhelming national consensus . . . is that a brand-name manufacturer cannot be liable for injuries caused by the ingestion of the generic form of a product." Because the name brand drug manufacturers owed no duty of care to Dement, 42 who never used their product, those defendants were entitled to judgment as a matter of law. 43 There was no error.

Case No. A15A1164. TANNER v. WYETH LLC et al.

8. Tanner makes the same challenges as Dement to the grant of the name brand drug manufacturers' summary judgment motion. Tanner's challenge fails for the reasons set out in Division 7.

*Guarino*, supra at 1252-1253; *Smith v. Wyeth, Inc.*, 657 F3d 420, 423-424 (6th Cir. 2011) ("As have the majority of courts to address the question, we reject the argument that a name brand drug manufacturer owes a duty of care to individuals who have never taken the drug actually manufactured by that company.").

<sup>&</sup>lt;sup>41</sup> *Guarino*, supra at 1252.

<sup>&</sup>lt;sup>42</sup> See generally *Marquis Towers v. Highland Group*, 265 Ga. App. 343, 345-346 (593 SE2d 903) (2004); *Chrysler Corp.*, supra (manufacturer had the duty to warn consumers of the risks of *its* products).

<sup>&</sup>lt;sup>43</sup> See generally *Godwin*, supra.

D. DENIAL OF PATIENT EDUCATION MATERIALS AUTHOR'S MOTION TO DISMISS

Case No. A15A1159. WOLTERS KLUWER HEALTH, INC. v. DEMENT

9. Wolters Kluwer Health, Inc., contends that the trial court erred by denying its amended motion to dismiss claims asserted against it. In its motion to dismiss, Wolters Kluwer Health asserted that it owed Dement no legal duty, that the First Amendment to the Constitution barred her claim, and that no privity existed between Dement and Wolters Kluwer Health. The court found the motion to be premature, stating that the motion required the court to consider matters outside the parties' pleadings, and noted that it would consider the issues upon completion of discovery pursuant to a properly filed motion for summary judgment. There was no error.

Our Supreme Court has recently reiterated that a motion to dismiss should not be granted unless the allegations of the complaint disclose with certainty that the claimant would not be entitled to relief under any state of provable facts asserted in support thereof.<sup>44</sup> "Therefore, the movant must establish that the plaintiff cannot

<sup>&</sup>lt;sup>44</sup> Austin v. Clark, 294 Ga. 773, 774-775 (755 SE2d 796) (2014).

possibly introduce evidence within the allegations of the complaint entitling him to the relief sought."<sup>45</sup>

Dement's complaint includes the following pertinent allegations: Wolters Kluwer Health authored patient education materials, which pharmacists then provided to their patients; the materials included information about prescription drugs, including the drug at issue here; the drug information was typically given to patients (stapled to their prescription package) when the prescription was picked up, as it was here; Wolters Kluwer Health undertook to provide accurate drug information in the materials it authored and made available to pharmacies for their customers; Wolters Kluwer Health had knowledge that those using the drug would rely upon the information in the materials; Dement read and relied upon misstatements about the drug in the materials; and, as a result of Wolters Kluwer Health's wrongful conduct, Dement was injured.

<sup>&</sup>lt;sup>45</sup> *Thomas v. Gregory*, 332 Ga. App. 286, 290 (3) (772 SE2d 382) (2015) (citation omitted).

Inasmuch as Wolters Kluwer Health has not established that Dement cannot possibly introduce evidence within the allegations of the complaint entitling her to any of the relief sought, 46 the court properly denied its motion to dismiss.

Case No. A15A1349. WOLTERS KLUWER HEALTH, INC. v. TANNER

10. Wolters Kluwer Health makes substantively the same contentions as to Tanner in this case that it made in Case No. A15A1159 as to Dement.<sup>47</sup> The contentions made herein likewise present no basis for reversal.

<sup>&</sup>lt;sup>46</sup> See, e.g., Lyons v. Wyeth, Inc., 2011 U. S. Dist. LEXIS 64377, \*13-14 (ED Mo. 2011) (claims against patient education material authors were colorable under common law theory that a defendant who undertakes to act owes a duty to act carefully); Nicely v. Wyeth, Inc., 2011 U. S. Dist. LEXIS 64380, \*9 (ED Mo. 2011) (same); Bailey v. Pfizer, Inc., 2014 U. S. Dist. LEXIS 73671,\*14 (ED Pa. 2014) ("[This] Court agrees with other courts that have held that the question of the applicability of the First Amendment as a defense to Plaintiffs' claims [against Wolters Kluwer Health as authors of patient education materials plaintiffs received from their pharmacists with their prescriptions] cannot be appropriately determined in the context of a motion to remand, in the absence of any developed factual record.") (footnote omitted, emphasis supplied); Neelev v. Wolters Kluwer Health, Inc., 2013 U. S. Dist. LEXIS 106191, \*44 (ED Mo. 2013) (First Amendment case law does not require dismissal of claims against authors of patient education materials); see generally Atlanta Affordable Housing Fund, L.P. v. Brown, 253 Ga. App. 286, 292 (3) (558 SE2d 827) (2002) ("It is ancient learning that one who assumes to act, even though gratuitously, may thereby become subject to the duty of acting carefully, if he acts at all.").

<sup>&</sup>lt;sup>47</sup> Division 9, supra.

## E. DENIAL OF PATIENT EDUCATION MATERIALS AUTHOR'S MOTION FOR JUDGMENT ON THE PLEADINGS

Case No. A15A1158. GOLD STANDARD, INC. v. DEMENT

11. Gold Standard, Inc., contends that the trial court erred by denying its motion for judgment on the pleadings when Dement failed to state a claim upon which relief could be granted. Specifically, Gold Standard asserts that it owed Dement no duty of care, that there was no privity between Dement and Gold Standard, and that its right to distribute the information was protected by the First Amendment. There was no error.

A motion for judgment on the pleadings is proper where the undisputed facts that appear from the pleadings establish that the movant is entitled to judgment as a matter of law. All well-pleaded facts are to be accepted as true. . . .[T]he granting of a motion for judgment on the pleadings under OCGA § 9-11-12 (c) is proper only where there is a complete failure to state a cause of action[.]<sup>48</sup>

Our review of the trial court's ruling is de novo.<sup>49</sup>

<sup>&</sup>lt;sup>48</sup> Holland Ins. Group, LLC v. Senior Life Ins. Co., 329 Ga. App. 834, 836 (1) (766 SE2d 187) (2014); see Frady v. Irwin, 245 Ga. 307 (264 SE2d 866) (1980).

<sup>&</sup>lt;sup>49</sup> See *Ga. Farm Bureau Mut. Ins. Co. v. Croft*, 322 Ga. App. 816, 817 (746 SE2d 285) (2013).

Accepting Dement's well-pleaded facts as true,<sup>50</sup> the complaint shows the following pertinent facts: Gold Standard authored patient education materials, which pharmacists provided to their patients; the materials included information about prescription drugs, including the drug at issue here; the drug information was typically given to patients (stapled to their prescription package) when the prescription was picked up, as it was here; Gold Standard undertook to provide accurate drug information in the materials it authored and made available to pharmacies for their customers; Gold Standard had knowledge that those using the drug would rely upon the information in the materials; Dement read and relied upon misstatements about the drug in the materials; and, as a result of Gold Standard's wrongful conduct, Dement was injured. There is no "complete failure to state a cause of action,"<sup>51</sup> and the court did not err in denying the motion.

Judgments affirmed in Case Nos. A15A1157, A15A1158, A15A1159, A15A1160, A15A1162, A15A1163, A15A1164, A15A1349 and A15A1404. Judgments in Case Nos. A15A1161 and A15A1165 affirmed in part and reversed in part. Doyle, C. J., and Boggs, J., concur.

<sup>&</sup>lt;sup>50</sup> See id.

<sup>&</sup>lt;sup>51</sup> See *Holland Ins. Group*, supra. See also authority set forth in n. 46, supra, of this opinion.