2025 IL App (1st) 241292-U
Order filed: June 27, 2025

FIRST DISTRICT
FOURTH DIVISION

No. 1-24-1292

IN THE
APPELLATE COURT OF ILLINOIS
FIRST JUDICIAL DISTRICT

ANGELA VALADEZ, Plaintiff-Appellant, v. GLAXOSMITHKLINE LLC, GLAXOSMITHKLINE HOLDINGS (AMERICAS) INC., GLAXOSMITHKLINE PLC, BOEHRINGER INGELHEIM PHARMACEUTICALS, INC., BOEHRINGER INGELHEIM INTERNATIONAL GMBH, BOEHRINGER INGELHEIM PROMECO, S.A. DE C.V., APOTEX CORPORATION, APOTEX INC., DR. REDDY'S LABORATORIES, INC., DR. REDDY'S LABORATORIES, LTD., DR. REDDY'S LABORATORIES LOUISIANA LLC, DR. REDDY'S LABORATORIES SA, L. PERRIGO CO., PERRIGO COMPANY, PERRIGO RESEARCH & DEVELOPMENT COMPANY, STRIDES PHARMA, INC., SUN PHARMACEUTICAL INDUSTRIES, INC., F/K/A RANBAXY PHARMACEUTICALS, INC., RANBAXY INC., SUN PHARMACEUTICAL INDUSTRIES LTD., ACTAVIS MID ATLANTIC LLC, TEVA PHARMACEUTICALS U.S.A., INC., WOCKHARDT USA LLC, WOCKHARDT USA, INC., WOCKHARDT LTD, WALGREEN CO., DUANE READ, INC., WALGREENS BOOTS ALLIANCE, INC., Defendants-Appellees.	)	Appeal from the Circuit Court of Cook County No. 2023 L 000483 Honorable Daniel A. Trevino, Judge, presiding.

PRESIDING JUSTICE ROCHFORD delivered the judgment of the court.
Justices Hoffman and Lyle concurred in the judgment.

ORDER

¶ 1 *Held*: We affirmed the order dismissing plaintiff's strict liability and negligence claims against defendants.

¶ 2 Plaintiff, Angela Valadez, developed colorectal cancer after taking Zantac and its generic equivalent, ranitidine, to treat her heartburn from 1996 to 2014. Plaintiff filed suit against the brand-name manufacturers of Zantac[1] ("brand defendants"), the generic manufacturers[2] ("generic defendants"), and retailers Walgreens and Duane Read ("retailer defendants" and together with the generic defendants, "non-brand defendants"). Count I alleged a strict liability, failure to warn claim against all the manufacturer defendants. Count II alleged a strict liability, design defect claim against all defendants (manufacturers and retailers). Count III alleged general negligence against all defendants. Count IV alleged negligent misrepresentation against the brand defendants.

¶ 3 Defendants filed motions to dismiss. The court dismissed all claims against the non-brand defendants, finding those claims preempted by federal law. The court also dismissed the design defect claim against the brand defendants on federal preemption grounds. The cause proceeded to a jury trial on the remaining counts against the brand defendants, and the jury returned a verdict in their favor.

[1] The brand defendants were GlaxoSmithKline LLC, GlaxoSmithKline Holdings (Americas) Inc., GlaxoSmithKline PLC, Pfizer, Inc., and Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GMBH, and Boehringer Ingelheim Promeco, S.A. DE C.V.

[2] The generic defendants were Apotex Corporation, Apotex Inc., Dr. Reddy's Laboratories, Inc., Dr. Reddy's Laboratories, Ltd., Dr. Reddy's Laboratories Louisiana LLC, Dr. Reddy's Laboratories SA, L. Perrigo Co., Perrigo Company, Perrigo Research & Development Company, Strides Pharma, Inc., Sun Pharmaceutical Industries, Inc., F/K/A Ranbaxy Pharmaceuticals, Inc., Ranbaxy Inc., Sun Pharmaceutical Industries Ltd., Actavis Mid Atlantic LLC, Teva Pharmaceuticals U.S.A., Inc., Wockhardt USA LLC, Wockhardt USA, Inc., Wockhardt Ltd.

¶ 4 On appeal, plaintiff argues that the trial court erred by dismissing her claims against the non-brand defendants. For the reasons that follow, we affirm.

¶ 5 We begin by giving pertinent background information regarding how new drugs are brought to market. Under the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 *et seq.*, drug manufacturers must receive approval from the United States Food and Drug Administration (FDA) before marketing any drugs in interstate commerce. *Id.* § 355(a). For a new brand-name drug, the manufacturer must submit a new drug application (NDA). The NDA must include reports of all clinical investigations (*id.* § 355 (b)(1)(A)) and relevant nonclinical studies and any other data relevant to the evaluation of the safety of the drug. 21 C.F.R. §§ 314.50(d)(2) and (5)(iv) (2012). The NDA also must include the proposed labeling of the drug. *Id.* § 314.50(c)(2)(i). The FDA may approve an NDA only after it determines that the drug is safe for use under the conditions prescribed in the proposed labeling. 21 U.S.C. § 355(d).

¶ 6 A typical NDA contains thousands of pages and is based on clinical trials conducted over many years. See Report to Congressional Requesters, Government Accountability Office, Nov. 2006, New Drug Development, 26 Biotechnology L. Rep. 82, 94 (2007). To provide a quicker route for approval of generic drugs, Congress passed the Drug Price Competition and Patent Term Restoration Act of 1984, 98 Stat. 1585, commonly known as the "Hatch-Waxman Act." Under this law, a generic drug may be approved without the same level of clinical testing required to approve a new brand-name drug, as long as the generic drug is identical to the already-approved brand-name drug in several respects.

¶ 7 First, the proposed generic drug must be chemically equivalent to the approved brand-name drug, meaning it must have the same active ingredients, route of administration, dosage form, and

strength. 21 U.S.C. §§ 355(j)(2)(A)(ii) and (iii). Second, the proposed generic drug must have the same rate and absorption as the brand-name drug. *Id.* § 355(j)(8)(B). Third, the generic drug manufacturer must show that the labeling for the new generic drug is the same as the labeling approved for the brand-name drug. *Id.* § 355(j)(2)(A)(v).

¶ 8 Once a generic or brand-name drug is approved, federal law prohibits the manufacturer from making any changes to the qualitative or quantitative formulation of the drug product, including its active ingredients. 21 C.F.R. § 314.70(b)(2)(i). Also, generic manufacturers are prohibited from unilaterally changing their generic drug's label. *Id.* §§ 314.94(a)(8)(iii), 314.150(b)(10). As a result, "brand-name and generic drug manufacturers have different federal drug labeling duties. A brand-name manufacturer seeking new drug approval is responsible for the accuracy and adequacy of its label. [Citation.] A manufacturer seeking generic drug approval, on the other hand, is responsible for ensuring that its warning label is the same as the brand name's." *Pliva, Inc. v. Mensing*, 564 U.S. 604, 613 (2011). Thus, generic drug manufacturers have "an ongoing federal duty of 'sameness'", meaning that the generic drug's labeling must be the same as the brand-name drug's labeling, because the brand-name drug was the basis for the generic drug approval. *Id.*

¶ 9 This case concerns the pharmaceutical product Zantac and its generic forms, which are widely sold as treatments for heartburn. In 1983, the FDA granted GlaxoSmithKline's NDA to sell Zantac, which became the first prescription drug to reach $1 billion in sales. In 1997, GlaxoSmithKline's patent on the original prescription Zantac expired, allowing generic manufacturers to enter the market.

¶ 10 The molecule ranitidine is the active ingredient in both Zantac and its generic forms. Scientific studies have shown that ranitidine degrades into a cancer-causing molecule called N-

nitrosodimethylamine (NDMA), which is part of a carcinogenic group of compounds called N-nitrosamines. Studies have shown that these compounds increase the risk of cancer in humans and animals.

¶ 11 Valisure LLC and ValisureRX LLC, a pharmacy and testing laboratory, filed a citizen petition on September 9, 2019, seeking the recall of all ranitidine products due to their NDMA levels. On April 1, 2020, the FDA requested the voluntary withdrawal of all ranitidine products from the market.

¶ 12 Plaintiff is one of many individuals in Illinois and nationwide suing the brand manufacturers, generic manufacturers and retailers of ranitidine. The Illinois proceedings are consolidated in Cook County by order of the Illinois Supreme Court. To streamline pretrial motion practice, the plaintiffs filed a master complaint with facts that were broadly shared across the cases. Plaintiff also filed an individual complaint alleging facts specific to her case.

¶ 13 In her individual complaint, plaintiff alleged she used Zantac and its generic ranitidine from approximately 1995 until 2014 when she developed colorectal cancer. During this time-period, plaintiff was unaware that ingesting ranitidine exposed her to NDMA, increasing her chances of contracting cancer.

¶ 14 Count I of plaintiff's complaint against all manufacturer defendants alleged that they were strictly liable for failing to warn her of the dangerous risk of cancer associated with the use and exposure to ranitidine-containing products. Count II against all defendants (manufacturers and retailers) alleged they were strictly liable for the defective design of the ranitidine-containing products, which were unreasonably dangerous because of their "inherent susceptibility to form NDMA." Count III against all defendants alleged that they acted negligently in their transportation

and storage of ranitidine-containing products. Count IV against the brand defendants alleged that they negligently misrepresented the safety and efficacy of the ranitidine-containing products.

¶ 15 On August 25, 2023, the circuit court of Cook County dismissed counts I-III of plaintiff's individual complaint against the non-brand defendants on federal preemption grounds (which we will discuss in more detail later in this order), as well as count II against the brand defendants.

¶ 16 A jury trial was subsequently held on counts I, III and IV against the brand defendants. At trial, plaintiff testified that she was 89 years old. She has type 2 diabetes, gastroesophageal reflux disease, and frequent heart burn, and she took Zantac or its generic equivalent every day from 1996 to 2014. Plaintiff was diagnosed with colorectal cancer at the age of 80. For several years prior to turning 80, plaintiff's personal physician had encouraged her to have a colonoscopy, but she always refused.

¶ 17 Plaintiff presented testimony from Richard Tanner, a scientist who formerly worked for GlaxoSmithKline. Tanner testified that a scientific study in the early 1980s showed that NDMA formed from ranitidine. Plaintiff also presented evidence that the NDMA in the Zantac and generic versions increased because they were subjected to high temperatures and humidity during storage and transport.

¶ 18 Doctor Roberta Ness, a physician and epidemiologist, testified that NDMA is a probable human carcinogen that can cause colorectal cancer.

¶ 19 Doctor Steven Bird, a physician and professor of emergency medicine and toxicology, testified that NDMA from ranitidine causes colorectal cancer and that plaintiff ingested a sufficient amount of ranitidine from Zantac to be a substantial cause of her colorectal cancer.

¶ 20 The brand defendants called plaintiff's primary care physician, Doctor George Tomecki, who testified that plaintiff was 5'1½" and weighed 199.4 pounds, with a body mass index (BMI)

of 37.2, meaning that she was classified as "very obese." She is a former smoker, has type 2 diabetes, high blood pressure and high cholesterol. For several years, Dr. Tomecki had encouraged plaintiff to undergo screening for colon cancer, including a colonoscopy, but she always refused.

¶ 21 Doctor Ryan Merkow, a GI surgical oncologist, testified that plaintiff had multiple risk factors for colorectal cancer, including her advanced age, obesity, diabetes, and history of smoking. Further, plaintiff's refusal to undergo a colonoscopy affected the nature and severity of her tumor. Doctor Merkow noted that plaintiff's tumor was large and had been present for a "long time." Doctor Merkow opined that had plaintiff followed Dr. Tomecki's advice to get a colonoscopy, the polyps would have been observed and removed before they turned into cancer.

¶ 22 Doctor Michael Vaezi, a gastroenterologist, similarly testified that plaintiff had various risk factors for colorectal cancer, including her age, obesity, diabetes, history of smoking, inactivity and refusal to follow Dr. Tomecki's recommendation that she undergo a colonoscopy. Doctor Vaezi opined that had plaintiff undergone the recommended colonoscopy in 2010, 2011, 2012, or 2013, her polyps would have been removed, thereby preventing the cancer from developing. Doctor Vaezi concluded that plaintiff's ingestion of Zantac did not cause her colon cancer.

¶ 23 Following all the evidence, the trial court instructed the jury on the three counts against the brand defendants for strict liability, negligence, and negligent misrepresentation. The court also instructed the jury on the defense claim that plaintiff was contributorily negligent "by not undergoing a colonoscopy before her cancer diagnosis, and that this failure contributed to and/or caused the plaintiff's claimed injury." The court informed the jury that "[i]f the plaintiff's contributory negligence is more than 50% of the total proximate cause of the injury or damage for which recovery is sought, the defendants shall be found not liable."

¶ 24 The jury returned a general verdict for the brand defendants on all counts and the court entered judgment on the jury's verdict on May 23, 2024.

¶ 25 Plaintiff filed a notice of appeal from the May 23, 2024, judgment entered on the jury's verdict in favor of the brand defendants seeking reversal and/or a new trial. In her appellate briefs, though, plaintiff makes no argument for reversal of the jury verdict in favor of the brand defendants and the judgment entered thereon. Instead, plaintiff argues for reversal of the August 25, 2023, order dismissing counts I-III against the non-brand defendants on federal preemption grounds. In turn, the non-brand defendants have filed a motion to dismiss plaintiff's appeal, contending that we lack jurisdiction to consider the August 25, 2023, dismissal order as it was not listed in the notice of appeal. On October 28, 2024, we entered an order taking this motion with the case.

¶ 26 Illinois Supreme Court Rule 303(b)(2) (eff. July 1, 2017) provides that a notice of appeal "shall specify the judgment or part thereof or other orders appealed from and the relief sought from the reviewing court." The notice of appeal confers jurisdiction on the appellate court "to consider only the judgments or parts of judgments specified in the notice of appeal." *General Motors Corp. v. Pappas*, 242 Ill. 2d 163, 176 (2011). However, "[a]n appeal from a final judgment draws into issue all previous interlocutory orders that produced the final judgment." *Knapp v. Bulun*, 392 Ill. App. 3d 1018, 1023 (2009). A notice of appeal is deemed to include an unspecified interlocutory order if that order was a step in the procedural progression leading to the judgment specified in the notice of appeal. *CitiMortgage, Inc. v. Hoeft*, 2015 IL App (1st) 150459, ¶ 8. We construe notices of appeal liberally. *Id.*

¶ 27 Here, the court's August 25, 2023 dismissal order streamlined the parties and issues for trial by eliminating from the jury's consideration any alleged liability by the non-brand defendants. As such, the August 25, 2023 order was a step in the procedural progression toward the jury trial

and toward the court's May 23, 2024 order specified in the notice of appeal, which entered judgment on the jury's verdict. Therefore, we have jurisdiction to review the August 25 order.

¶ 28 The non-brand defendants also argue we lack jurisdiction because the notice of appeal's caption fails to identify them as appellees as required by Illinois Supreme Court Rule 303(b)(1)(ii) (eff. July 1, 2017). Rule 303(b)(1)(ii) provides that the notice of appeal must, in the caption, bear the title of the case, "naming and designating the parties in the same manner as in the circuit court and adding the further designation 'appellant' or 'appellee.' " *Id.* We find no jurisdictional defect under the unique facts of this case. Plaintiff filed her notice of appeal from the final order dated May 23, 2024, which entered judgment on the jury's verdict in favor of the brand defendants. As discussed, the notice of appeal included the unspecified August 25, 2023 dismissal order as a step in the procedural progression leading to the May 23, 2024 final judgment. The non-brand defendants were not listed in the circuit court's caption on the May 23, 2024 judgment order because they were not parties to that judgment as the claims against them had been dismissed on August 25, 2023. Instead, the circuit court listed only the brand defendants, captioning the judgment order as "Angela Valadez, Plaintiff, v. GlaxoSmithKline LLC, et. al, Defendants." The caption on plaintiff's notice of appeal from the May 23, 2024 judgment mirrored the caption of the circuit court's judgment order and designated herself as the appellant and GlaxoSmithKline as the appellee. Plaintiff therefore complied with Rule 303(b)(1)(ii)'s requirement that the notice of appeal name the parties *in the same manner* as the circuit court and designate the parties as appellant or appellee.

¶ 29 This case is similar to *Short v. Pye*, 2018 IL App (2d) 160405. In *Short*, defendants cross-appealed the trial court's ruling determining that their sanctions motions against plaintiff's attorneys were untimely. *Id.* ¶ 1. The plaintiff's attorneys argued for dismissal of the appeal

because they were not named as cross-appellees in the notice of cross-appeal. *Id.* ¶ 28. We denied the motion to dismiss, finding that the notice of appeal complied with Rule 303(b)(1)(ii) because it named the parties as they appeared in the caption in the trial court. *Id.* ¶ 33. Because the plaintiff's attorneys were not named in the caption below, they were not required to be listed in the notice of cross-appeal. *Id.* Similarly, here, the non-brand defendants were not named in the caption of the May 23, 2024 judgment, and thus they were not required to be listed in the notice of appeal from that judgment.

¶ 30 We further note that where a deficiency in a notice of appeal is one of form rather than substance, such that there is no prejudice to the appellee, the failure to strictly comply with the form of notice does not deprive us of jurisdiction. *Nussbaum v. Kennedy*, 267 Ill. App. 3d 325, 328 (1994). Here, the non-brand defendants make no claim of any prejudice by plaintiff's failure to specifically list them as appellees in the notice of appeal. We conclude that we possess jurisdiction to consider plaintiff's appeal. Therefore, the non-brand defendants' motion to dismiss plaintiff's appeal for lack of jurisdiction is denied.

¶ 31 The non-brand defendants next ask us to strike plaintiff's opening brief and appendix and dismiss her appeal based on her failure to make appropriate citations to the record in violation of Illinois Supreme Court Rule 341(h)(7) (eff. Oct. 1, 2020) or to file an appendix with a table of contents referencing the record on appeal in violation of Illinois Supreme Court Rule 342 (eff. Oct. 1, 2019). Striking a brief and dismissing the appeal is a harsh sanction and is only appropriate where a violation of the procedural rules hinders our review. *Litwin v. County of LaSalle*, 2021 IL App. (3d) 200410, ¶ 11. Plaintiff's rules violations here have not hindered our review of the issues raised on appeal and therefore we elect to address them.

¶ 32 On appeal, plaintiff argues that the trial court erred by dismissing counts I-III of her complaint against the non-brand defendants on federal preemption grounds. The dismissal motion was brought pursuant to section 2-615 of the Code of Civil Procedure (735 ILCS 5/2-615 (West 2022)). The preemption of Illinois law by federal law is generally considered "affirmative matter" properly raised under section 2-619. *Illinois Graphics Co. v. Nickum*, 159 Ill. 2d 469, 487 (1994). Because plaintiff has shown no prejudice by the improper designation, we will treat the motion as if it had been brought pursuant to section 2-619. See *e.g.*, *Wallace v. Smyth*, 203 Ill. 2d 441, 447 (2003). Our review is *de novo*. *Id.*

¶ 33 The preemption doctrine is derived from article VI of the supremacy clause of the United States Constitution, which provides 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. Under the supremacy clause, federal law preempts state law under any one of the following three circumstances: (1) express preemption—where Congress expressly preempts state law; (2) implied field preemption—where Congress implements a comprehensive regulatory scheme in an area, thereby removing the entire field from the state realm; or (3) implied conflict preemption, where state law actually conflicts with federal law, making compliance with both federal and state law impossible (sometimes referred to as impossibility preemption). *Carter v. SSC Odin Operating Co.*, 237 Ill. 2d 30, 39-40 (2010); *Resource Technology Corp. v. Illinois Commerce Comm'n*, 354 Ill. App. 3d 895, 901 (2004).

¶ 34 The trial court here dismissed counts I-III based on impossibility preemption. First, we address the court's decision dismissing counts I and II, the strict liability counts. Then we address the dismissal of count III, the negligence count.

¶ 35 The Illinois Supreme Court has adopted strict liability as set forth in the Restatement (Second) of Torts, section 402A (1965). *Suvada v. White Motor Co.*, 32 Ill. 2d 612, 622-23 (1965). Strict liability is imposed on a seller of "any product in a defective condition unreasonably dangerous to the user or consumer or to his property." Restatement (Second) of Torts § 402A (1965). To prevail in a strict liability action, plaintiff must plead and prove: (1) the injury complained of resulted from a condition of the product; (2) the condition was unreasonably dangerous; and (3) the condition existed when the product left the manufacturer's control. *Baley v. Federal Signal Corp.*, 2012 IL App (1st) 093312, ¶ 55. A product may be found unreasonably dangerous based on proof of: (1) a manufacturing defect; (2) a design defect; or (3) inadequate warnings. *Id.* Plaintiff here brought her strict liability claims based on design defect and inadequate warnings. The trial court, though, dismissed those counts because it found that the state-law duty to strengthen the warnings and improve the design of the ranitidine-containing products conflicted with federal law, making compliance with *both* federal and state law impossible.

¶ 36 In so ruling, the trial court relied on *Pliva, Inc. v. Mensing*, 564 U.S. 604 (2011) and *Mutual Pharmaceutical Co. v. Bartlett*, 570 U.S. 472 (2013). In *Mensing*, 564 U.S. at 609-10, the plaintiffs consumed the generic drug metoclopramide to treat their digestive tract problems. After taking the drug as prescribed for several years, the plaintiffs developed tardive dyskinesia, a severe neurological disorder. *Id.* The plaintiffs brought suit under state tort law (Minnesota and Louisiana) against the generic manufacturers for failing to provide adequate warnings regarding the risk of tardive dyskinesia. *Id.* at 610. In both suits, the generic manufacturers of the drug urged that federal law preempted the state tort claims. *Id.* The Courts of Appeals held that the claims were not preempted. *Id.* at 610-11. The Supreme Court reversed, holding that under the federal duty of sameness (which we discussed earlier in this order) the generic drug's labeling/warning must be

the same as that of the name-brand drug; in other words, federal law prohibited the generic manufacturers from taking the remedial action (changing the warnings/labels) required to avoid liability under Minnesota and Louisiana law. *Id.* at 613-15. Because it was impossible for the generic manufacturers to comply with both the state law requiring more detailed warnings of tardive dyskinesia, and federal law requiring that the warnings/labels be the same as the name-brand drug, the plaintiffs' cause of action was preempted. *Id.* at 624.

¶ 37 In *Bartlett*, 570 U.S. at 478, the plaintiff took the generic drug sulindac, a nonsteroid anti-inflammatory pain reliever, for her shoulder pain. Soon after, she developed an acute case of toxic epidermal necrolysis, pursuant to which about 65% of the surface of her body deteriorated, burned off, or turned into an open wound. *Id.* The plaintiff brought a design defect claim against the generic drug manufacturer under New Hampshire law. *Id.* at 479. The cause proceeded to trial and the jury awarded her $21 million in damages. *Id.* The Court of Appeals affirmed. *Id.* The Supreme Court reversed, noting that New Hampshire has adopted the doctrine of strict liability in tort, pursuant to which manufacturers must ensure that their products are not unreasonably dangerous. *Id.* at 480-82. This duty can be satisfied either by changing a drug's design or changing its labeling to warn of its dangers. *Id.* at 482. Under the federal duty of sameness, though, the design of the generic drug and the warning labels thereon were required to be the same as the brand drug. *Id.* at 483-486. Because it was impossible for the generic manufacturers to comply with the state law requiring a safer design, and with the federal law requiring that the design be the same as the name-brand drug, the plaintiff's cause of action was preempted. *Id.* at 484-87.

¶ 38 In so holding, the Supreme Court rejected the Court of Appeals' reasoning that the generic manufacturer could escape the impossibility of complying with both federal and state law by choosing not to make the drug at all. *Id.* at 488. The Supreme Court stated:

> "We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence. Our pre-emption 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. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.'" Id.

¶ 39 In the instant case, we agree with the trial court that *Mensing* and *Bartlett* compel the conclusion that counts I and II of plaintiff's complaint against the non-brand defendants are preempted. Count I alleged strict liability under Illinois law for the inadequacy of the ranitidine's labeling/warnings regarding its cancer risks. Count II alleged strict liability under a design-defect theory because the "ranitidine-containing products were unreasonably dangerous in that they were hazardous and posed a grave risk of cancer when used in a reasonably anticipated manner." Plaintiff alleged that the non-brand defendants "could have employed safer alternative designs and formulations." As explained in *Mensing* and *Bartlett*, though, under the federal duty of sameness the design of the generic ranitidine and the warning labels thereon were required to be the same as the brand-name Zantac. Because it was impossible for the non-brand defendants to comply with the state-law requirements under Rule 402A to provide a safer design and more complete warnings about the cancer risks, *and* with the federal law requiring that the design and warnings be the same as Zantac's, counts I and II of plaintiff's complaint were preempted.

¶ 40 Plaintiff argues, though, that counts I and II are not preempted because they alleged a state-law duty not to sell unreasonably dangerous products, which is *parallel* to (and thus not in conflict with) federal law prohibiting the selling of misbranded drugs that are "dangerous to health when used in the dosage or manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 352(j) (2022). Plaintiff argues that because federal

law and Illinois law prohibit the same action, the sale of ranitidine that is misbranded and unreasonably dangerous, there is no conflict between federal and Illinois law and therefore there is no impossibility preemption.

¶ 41 This same argument was rejected in *In re Zantac (Ranitidine) Products Liability Litigation*, 510 F. Supp. 3d 1141 (S.D. Fla. 2020), which noted that no court has adopted plaintiffs' theory that impossibility pre-emption can be avoided by showing that a drug is both misbranded under federal law and unreasonably dangerous under state tort law. *Id.* at 1160. The court stated:

> "A claim based on an allegation that a generic drug's labeling renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change FDA-approved labeling. [Citation.] Likewise, a claim based on an allegation that a generic drug's formulation renders the drug misbranded is a pre-empted claim because the drug's manufacturer cannot independently and lawfully change a drug formulation that the FDA has approved." *Id.* at 1160.

¶ 42 The court further noted that "[a] finding that Plaintiffs can avoid pre-emption by alleging that defects in ranitidine products made the products misbranded under 21 U.S.C § 352 would render the vast body of pre-emption caselaw in the drug context, including binding Supreme Court decisions, meaningless." *Id.* at 1160-61. The court stated that it "cannot adopt a position that would render pre-emption caselaw meaningless." *Id.* at 1161.

¶ 43 We agree with *In re Zantac*. Plaintiff cannot avoid preemption here merely by arguing that the generic ranitidine was misbranded under federal law and unreasonably dangerous under state law. As discussed, counts I and II of plaintiff's complaint assert strict liability claims against the non-brand defendants under Illinois law based on the allegedly inadequate labeling and design of their generic ranitidine. However, it was impossible for the non-brand defendants to change the

labels and designs of the product because to do so would conflict with federal law requiring that the design and labels of the brand-name and generic drugs be the same. Therefore, the trial court correctly dismissed counts I and II as preempted.

¶ 44 Plaintiff also argues that *Guvenoz v. Target Corp.*, 2015 IL App (1st) 133940, compels a different result. In *Guvenoz*, the decedent took a generic form of Darvocet, an opioid analgesic prescription drug for treatment of mild to moderate pain. Id. at ¶ 10, ¶ 13. After ingesting the recommended doses, he suffered a cardiac arrest that caused serious brain injuries. *Id*. 10. He subsequently died. *Id*.

¶ 45 The plaintiff, decedent's widow, filed a complaint against the generic manufacturer of the drug and the retailer Target, alleging strict product liability and design defect. *Id.* ¶ 12. The plaintiff alleged that the defendants should have known of the correlation between the use of the drug and the increased risk of developing potentially fatal heart arrhythmias. *Id.* ¶ 14. The trial court denied the defendants' combined motion to dismiss and certified for immediate appellate review the question of whether *Bartlett* and *Mensing* required the dismissal of the complaint on federal preemption grounds. Id. ¶¶ 28-31.

¶ 46 The appellate court held that *Bartlett* and *Mensing* did not preempt the state law claims, stating:

> "In the case at bar, plaintiff alleges that there was no group of patients for whom the drug's benefits outweighed its risks. By contrast, in both *Bartlett* and *Mensing*, the drug was safe for the vast majority of patients taking it, and only a 'very small number of patients' suffered an adverse and severe reaction. [Citations.] In the case at bar, plaintiff alleged that the drug was simply unsafe and should not have been sold at all, and there was no warning that could have cured the problem." Id. ¶ 72.

¶ 47 The appellate court concluded that "[s]ince plaintiffs do not suggest that there was an improved design or label that could have cured the problem, there was no 'direct and positive conflict' with the generic manufacturer's federal duty to use the same design and label as the lead manufacturer." *Id.* ¶ 73.

¶ 48 In contrast to *Guvenoz*, plaintiff here did not plead that generic ranitidine was so inherently dangerous that no improved design or label could have cured the problem. Rather, plaintiff pleaded that alternative labeling and designs were available as remedial measures. Accordingly, *Guvenoz* is inapposite. As discussed, we affirm the dismissal of counts I and II of plaintiff's complaint on federal preemption grounds as it was impossible for the non-brand defendants to change the labels and design of the product without conflicting with federal law.

¶ 49 Next, we address the trial court's dismissal of count III against the non-brand defendants, which alleged that they negligently transported and stored the ranitidine-containing products. Unlike counts I and II, count III for negligent transportation and storage did not seek to change the labels and design of the ranitidine-containing products and thus did not conflict with federal law. Accordingly, the court erred in finding that count III was preempted.

¶ 50 The non-brand defendants argue, though, that plaintiff is collaterally estopped from litigating the issue of their alleged negligence because that same issue was decided in their favor in the jury trial. Collateral estoppel precludes a previously-litigated matter from being relitigated if the following three elements are met: (1) the issue decided in the prior adjudication is identical to the one presented in the current action; (2) a final judgment on the merits was entered in the prior adjudication; and (3) the party against whom estoppel is asserted was a party to or was in privity with a party to the prior adjudication. *Dearborn Maple Venture, LLC v. SCI Illinois Services, Inc.*, 2012 IL App (1st) 103513, ¶ 24.

¶ 51 Plaintiff contends that technically, the non-brand defendants are actually asserting a claim of direct estoppel, not collateral estoppel. Direct estoppel arises if the proceeding in which the defendant raises an estoppel claim is merely a continuation of a prior proceeding. *People v. Daniels*, 187 Ill. 2d 301, 320 n.3 (1999). We have held that "[t]he difference in nomenclature has no practical effect because the same rules that apply to collateral estoppel also apply to direct estoppel." *People v. Wharton*, 334 Ill. App. 3d 1066, 1078 (2002). Therefore, the analysis is the same regardless of whether the estoppel claim is labeled as collateral estoppel or direct estoppel.

¶ 52 Addressing the merits of the estoppel argument, there is no dispute that the second and third elements are met, as the trial court entered a final judgment on the merits following the jury trial and plaintiff (the party to be estopped) was a party to that trial. The parties dispute whether the first element was met, specifically, whether the issue of the non-brand defendants' negligence raised in the current appeal was the same issue decided in their favor in the jury trial. We conclude that there is an identity of issues sufficient to invoke collateral/direct estoppel.

¶ 53 Plaintiff's complaint made the same allegations of negligence against the brand defendants and non-brand defendants: that the ranitidine-containing products were not stored and transported at appropriate temperature and humidity levels. During plaintiff's jury trial against the brand defendants, the court instructed the jury pursuant to section 2-1116 of the Code of Civil Procedure (735 ILCS 5/2-1116 (West 2022)) that it should return a verdict against plaintiff on her negligence count if it found that she was more than 50% contributorily negligent for refusing her personal physician's request that she undergo a colonoscopy in 2010-2013. The jury returned a general verdict in the brand defendants' favor. Under the "general verdict rule," when a jury returns a general verdict, we must presume that the jury found against plaintiff on every issue (*Obermeier v. Northwestern Memorial Hospital*, 2019 IL App (1st) 170553, ¶ 51), meaning here that we

presume the jury found plaintiff was more than 50% contributorily negligent for refusing to undergo a colonoscopy in 2010, 2011, 2012, 2013, thereby barring her negligence claim. See 735 ILCS 5/2-1116 (West 2022). Plaintiff's contributory negligence not only defeats her negligence claim against the brand defendants, but it also defeats her identical negligence claim against the non-brand defendants. Accordingly, pursuant to our authority under Illinois Supreme Court Rule 366(a)(5) (eff. Feb. 1, 1994) to make any orders that the case may require, we affirm the dismissal of count III of the complaint against the non-brand defendants on estoppel grounds. See also *BMO Bank N.A. v. Zbroszcyk*, 2025 IL App (1st) 241333, ¶ 26 (we can affirm a dismissal order on any basis in the record, regardless of the circuit court's reasoning).

¶ 54 Plaintiff argues that we should not apply the general verdict rule here because the jury answered two special interrogatories that are dispositive. Plaintiff's contention is without merit. The special interrogatories merely asked whether plaintiff proved she ingested Zantac manufactured by GlaxoSmithKline and Boehringer Ingelheim Pharmaceuticals. The jury answered yes to both interrogatories. Neither interrogatory addressed plaintiff's contributory negligence and thus they have no bearing on that issue. In the absence of any special interrogatory regarding plaintiff's contributory negligence, we apply the general verdict rule and presume that the jury's finding in favor of the defense included a finding that plaintiff was more than 50% contributorily negligent, which estops her from relitigating that issue.

¶ 55 We note that our supreme court has held that even where the threshold elements of collateral/direct estoppel have been met, estoppel must not be applied unless it is clear that no unfairness results to the party being estopped. *Talarico v. Dunlap*, 177 Ill. 2d 185, 191-92 (1997). Fairness requires that the party being estopped from relitigating an issue "had a full and fair opportunity to litigate" that issue. *Id.* at 192. Here, the pertinent issue was whether plaintiff was

more than 50% contributorily negligent. Plaintiff was given the full and fair opportunity to litigate that issue at trial. As such, we find no unfairness in applying collateral/direct estoppel here.

¶ 56 For all the foregoing reasons, we affirm the circuit court.

¶ 57 Affirmed.