NO. S233898

IN THE SUPREME COURT OF CALIFORNIA



**T.H., A MINOR, ETC., ET AL.,**
Plaintiffs and Appellants,

v.

**NOVARTIS PHARMACEUTICALS CORPORATION,**
Defendant and Respondent.

AFTER A DECISION OF THE COURT OF APPEAL, FOURTH APPELLATE DISTRICT, DIVISION ONE, CASE NO. D067839 (MCCONNELL, P.J.)

FROM A DECISION OF THE SUPERIOR COURT SAN DIEGO COUNTY, CASE NO. 37-2013-00070440-CU-MM-CTL (LEWIS, J.)

# *AMICI CURIAE* BRIEF OF NATIONAL ASSOCIATION OF MANUFACTURERS AND AMERICAN TORT REFORM ASSOCIATION IN SUPPORT OF DEFENDANT/RESPONDENT

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## ISSUES PRESENTED

May the brand name manufacturer of a pharmaceutical drug that divested all ownership interest in the drug be held liable for injuries caused years later by another manufacturer's generic version of that drug?

## STATEMENT OF INTEREST

The National Association of Manufacturers (NAM) is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs over 12 million men and women, contributes $2.17 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters of private-sector research and development in the nation. The NAM is the powerful voice of the manufacturing community and leading advocate for policies that help manufacturers compete in the global economy and create jobs across the United States.

The American Tort Reform Association (ATRA) is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote the integrity of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For more than two decades, ATRA has filed *amicus curiae* briefs in cases before state and federal courts that have addressed important liability issues.

*Amici* have an interest in this case because they and their members are concerned with the predictability and fairness of California's civil justice system. *Amici* have an interest in ensuring that the civil litigation and liability laws affecting manufacturers in California are balanced, reflect sound public policy, and respect due process. Allowing claims against a product manufacturer for a product it did not sell, including years after it stopped producing any product in the category, violates these principles and would contribute to the growth of opportunistic lawsuits. The result would adversely impact *Amici's* members and the State's manufacturing climate.

## STATEMENT OF THE CASE

*Amici curiae* adopt Novartis Pharmaceuticals Corporation's Statement of the Case to the extent relevant to the issues raised in this brief.

## INTRODUCTION AND SUMMARY OF THE ARGUMENT

This case seeks to subject a manufacturer that invents a product to perpetual liability for harms caused, not by its own product, but for comparable products made and sold by entirely different businesses. This theory for liability, dubbed "innovator liability," has been widely rejected in federal and state courts around the country, even when the defendant is still manufacturing its own version of the product. The California Court of Appeal ruling in *Conte v. Wyeth Inc.* (2008) 168 Cal.App.4th 89, which allowed this form of innovator liability, remains an extreme outlier. Here, innovator liability was extended to a manufacturer that divested the product

line in question years before Plaintiff alleges the generic product was made, purchased, or caused injury. This extension of innovator liability is a bridge too far built on an already shaky foundation. It should be struck down.

The Supreme Court of Iowa captured the essence of innovator liability, calling it "deep-pocket jurisprudence [which] is law without principle." (*Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, 380 [internal citation omitted].) Innovator liability violates the basic tenet of American tort law. In order to be subject to liability, there must be a legal relationship between a plaintiff and a defendant. A product manufacturer may have a duty to its own customers to make lawful, non-defective products. But, as this Court held in *O'Neil v. Crane Co.* (2012) 53 Cal.4th 335, "a product manufacturer may not be held liable in strict liability or negligence for harm caused by another manufacturer's product." (*Id.* at p. 342.) Such manufacturers are not at-fault for the plaintiffs' harms and should not be subject to liability for them. Companies are not their competitors' keepers, nor are they insurers against harm from products they designed but did not sell and no longer sell.

Of particular concern to *Amici* is the impact of this new liability, not just on pharmaceutical manufacturers and the nation's healthcare, but to the broader manufacturing community. Future plaintiffs will undoubtedly argue that there is no principle limiting the Court of Appeal's assertion that, when an innovator makes, markets and sells its own products, it is

"foreseeable" that years later someone will be harmed by a comparable product made by someone else. As the Iowa Supreme Court asked, "Where would such liability stop? If a car seat manufacturer recognized as an industry leader designed a popular car seat, could it be sued for injuries sustained by a consumer using a competitor's seat that copied the design?" (*Huck, supra*, 850 N.W.2d at p. 380.) Going a step further, as here, what if the industry leader sells this car seat line? Is it still responsible for the older line of seats it no longer sells and for which it has no control over designs and warnings? Also, what if the manufacturer now makes a different car seat that competes against the older line it sold off? Does the obligation to warn against dangers with the older seat raise conflicts of interest?

The practical complications of requiring a manufacturer to retain liability over the design and warnings of products it no longer sells are vast. The net result would be to punish innovation and interfere with the common practice of manufacturers of divesting and purchasing product lines, which are essential to enhancing efficiencies to the benefit of consumers, investors, and employees. It would also invite multiple, potentially conflicting warnings, likely adding to consumer confusion, disregard, and contempt for warnings. *Amici* urge the Court to reverse the Court of Appeal ruling below. It makes no legal or economic sense for an innovator to own the liability for products sold by others, particularly after it is no longer in the business of selling that product at all.

## ARGUMENT

### I. THE COURT SHOULD REJECT THE INNOVATOR LIABILITY THEORY IN THIS CASE AS UNPRINCIPLED "DEEP POCKET JURISPRUDENCE"

Innovator liability theories surfaced in the prescription drug market in the 1990s. Some creative plaintiffs' lawyers tried to subject brand-name manufacturers, who were perceived to have deep pockets, to liability even when, as here, plaintiffs acknowledge they took only the generic forms of the drugs made by other companies. Attempts to extend traditional tort or product liability duties regardless of how remote a company's connection to an alleged injury are common. In asbestos litigation, legendary plaintiffs' attorney Dickie Scruggs called this tactic "the endless search for the solvent bystander." (See *Medical Monitoring and Asbestos Litigation – A discussion with Richard Scruggs and Victor Schwartz* (Feb. 2002) 1-7:21 MEALEY'S ASBESTOS BANKR. REP. 5 [quoting Scruggs].)

In *Conte*, the California Court of Appeal became the first court in the nation to accept any form of innovator liability. *Conte*, which formed the foundation for the case at bar, has been overwhelmingly rebuffed. In all, innovator liability has been rejected by more than 100 courts, including U.S. Courts of Appeals for six different circuits. (See Beck & Hermann, *Scorecard: Innovator Liability in Generic Drug Cases,* Drug and Device

Law (Nov. 12, 2009) [1] (last updated June 16, 2016).) In the only other state where state courts adopted a comparable innovator liability the theory,[2] the Legislature swiftly and in bi-partisan fashion overrode that decision. (See Goldberg, *Showdown in Alabama: Litigators vs. Innovators* (Sept. 24, 2015) Progressive Policy Inst. Policy Brief [The Alabama Senate voted 32-0, and the Alabama House voted 86-14 for legislation that a manufacturer cannot be subject to liability for products of others, even when its "design is copied or otherwise used by [another] manufacturer."].) The decisive, widespread nature of this rebuke is important because it underscores the tort-law, healthcare, and manufacturing concerns with innovator liability.

Yet, this case goes even further than *Conte*; no court has extended innovator liability to a manufacturer who is no longer in the business of making or selling the product in question. Extending liability here requires further undermining fundamental product liability and tort law principles. Foreseeability would be endless, tort theories would circumvent basic product liability concepts, and finding pockets to pay claims would take

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1 https://www.druganddevicelawblog.com/2009/11/scorecard-non-manufacturer-name-brand.html

2 Two federal district courts have also allowed innovator liability. (See *Kellogg v. Wyeth* (D. Vt. 2010) 762 F.Supp.2d 694 [interpreting Vermont law]; *Dolin v. SmithKlineBeecham* Corp. (N.D. Ill. 2014) 62 F.Supp.3d 705, 718 [interpreting Illinois law]; but see *In re Darvocet* (6th Cir. 2014) 756 F.3d 917 [rejecting *Dolin* and holding that Illinois would not allow innovator liability claims].)

priority over adhering to core liability principles. This Court has rejected attempts at deep pocket jurisprudence in the past and should do so here.

### A. The Innovator Liability Ruling Here Requires Courts To Be Able To "Foresee Forever"

In an effort to bridge what should be an insurmountable gap between a consumer of one product and the former manufacturer of another, the lower court hinged its duty ruling on the concept of "foreseeability." The court held that when a brand-name drug manufacturer markets and sells its own drugs, including during patent exclusivity, it is "foreseeable" the company might make statements that will result in a patient taking and being harmed by someone else's generic drug, even years into the future regardless of whether it continues selling the product itself. The innovator has a perpetual duty to future consumers of anyone's comparable drug.

The fallacy with this foreseeability ruling, the U.S. Court of Appeal for the Sixth Circuit explained, is that "generic consumers' injuries are not the foreseeable result of the brand manufacturer's conduct, but of laws over which the brand manufacturers have no control." (*In re Darvocet* (6th Cir. 2014) 756 F.3d 917, 944.) Congress made the public policy decision to lower barriers of entry for generic drugs by allowing generic drug manufacturers to copy the design and labeling of their brand-name counterparts. State legislatures facilitated this public policy by enacting "generic substitution" laws to require that certain prescriptions be filled

with available generics. Using federal and state drug laws as a basis for tort liability, courts have explained, stretches foreseeability too far.[3]

It is hornbook tort law that in misrepresentation cases, as with the case at bar, "the defendant is not liable if the plaintiff relies on the information in a type of transaction the defendant does not intend to influence." (Dobbs, The Law of Torts (2000) p. 1372.) Brand-name drug companies are not making representations or omissions about generic versions of a drug or versions of a drug that a successor company may sell. They are solely informing physicians about their own products, often years before generic drugs enter the market or they sell the product line to another company. When a patient takes generics, he or she severs any foreseeable connection with the brand-name drug's current and former manufacturers.

Since Judge Cardozo's famous opinion in *Palsgraf v. Long Island R. Co.* (1928) 162 N.E. 999, courts, including this one, have strayed away from over-extensions of foreseeability. In the high-profile case *Thing v. La Chusa* (1989) 48 Cal.3d 644, this Court cautioned that on clear days "a court can foresee forever." (*Id.* at p. 668.) The context for this statement is important. *Thing* was a response to *Dillon v. Legg* (1968) 68 Cal.2d 728, where the Court expanded elements of duty to allow an award for

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[3] See, e.g., *Dietrich v. Wyeth, Inc.* (Fla. Cir. Ct. Dec. 21, 2009) No. 50-2009-CA-021586, 2009 WL 4924722 ("[n]o federal statute or FDA regulation imposes a duty or suggests that a name brand manufacturer is
(Footnote continued on next page)

emotional harm damages to a mother and sister of a girl killed by a motorist because the driver should have foreseen that hitting the girl would cause them emotional distress. (*Thing*, *supra*, 48 Cal.3d at p. 668.)

In retrenching on this expansive view of foreseeability, the Court in *Thing* emphasized "the importance of avoiding the limitless exposure of liability for negligence" that over-reliance on foreseeability creates. (*Id.* at p. 664.) "[F]oreseeability, like light, travels indefinitely in a vacuum," and "there are circumstances in which although a foreseeable risk exists, there is no duty to avoid creation of that risk." (*Id.* at pp. 659, 652 [internal quotation omitted].) Cutting off such unreasonable liability "establish[es] meaningful rules." (*Id. at* p. 666.) In *O'Neil*, the Court reined in such a view of foreseeability against product manufacturers on point with the case at bar. It held that the foreseeability a person may be harmed by a product made by another is "not sufficient to create an independent tort duty" and that "strong policy considerations" counseled against doing so. (*O'Neil*, *supra*, 53 Cal.4th at pp. 365 [internal quotation omitted].)

These cautions against the over-reliance on foreseeability to create a duty between unconnected individuals should be heeded in the case at bar, where Plaintiff is suing a former manufacturer of someone else's product. The scores of courts rejecting *Conte's* version of innovator liability have

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responsible for the labeling of competing generic product."

expressed significant reservations with creating such a duty even on current brand-name drug manufacturers. In addition to the foreseeability fallacy, they have warned against the legal and health public policy ramifications with establishing any such duty. (See *Foster v. Am. Home Prods. Corp.* (4th Cir. 1994) 29 F.3d 165, 170.) For example, the innovator obtains no benefit from the sale of the generics and has no control over their manufacture or labeling. (*Id.*) Manufacturers of generic drugs reap enormous benefits from the innovator's work "by copying its labels and riding on the coattails of its advertising." (*Id.*) Also, innovator liability would dramatically increase the cost of branded drugs and impede on new innovations, thereby hindering access to beneficial medications. (*Id.*)

Here, the Court should hold that there is no duty requiring a former manufacturer to warn future consumers of generic versions of its previous product that are made, sold, and marketed by other companies. Saddling a brand-name drug manufacturer with the entire category's liability into perpetuity even after it divests the drug line in question stretches foreseeability too far and undermines important public policy concerns.

### B. Tort Theories Do Not Allow Courts To Circumvent Fundamental Principles of Liability Law Against Product Manufacturers

The Court should also overturn the lower court's ruling because it improperly found that tort liability theories, including negligence, can be used to circumvent the bedrock liability principle that a company is not

subject to liability for harms caused by products it did not make or sell. Here, as in *Conte*, the lower courts acknowledged that the innovator "would not be liable in strict products liability because it did not manufacture or sell the product." (*Conte, supra*, 85 Cal.Rptr.3d at p. 310.) However, as this Court stated clearly and unambiguously in *O'Neil*, "a product manufacturer may not be held liable in *strict liability or negligence* for harm caused by another manufacturer's product." (*O'Neil, supra*, 53 Cal.4th at p. 342 [emphasis added].) The Court continued that imposing such an obligation "would exceed the boundaries established over decades of product liability law," and that "[t]he same policy considerations that militate against imposing strict liability in this situation apply with equal force in the context of negligence." (*Id.* at pp. 365-66.)

These statements, along with the near-universal rejection of innovator liability in other states, are testaments to the core principles of liability against product manufacturers that were first born in this Court. (See *Greenman v. Yuba Power Products, Inc.* (1963) 59 Cal.2d 57.) The value of *Greenman* was the casting aside of the doctrinal mix of warranty and contract law that had existed to that point in order to create a direct, tort-based cause of action against a product manufacturer for harms caused by its products. In *Greenman* and its progeny, the Court did not and has not changed the fact that product identification is the bedrock element of tort liability against a product manufacturer, regardless of whether the

liability sounded in negligence or strict liability. (See *O'Neil, supra*, 53 Cal.4th at p. 348 [quoting *Greenman* that costs of injuries are to be "borne by the manufacturers that put such products on the market" or who are in chain of commerce of that product]; *Webb v. Special Elec. Co., Inc.* (2016) 63 Cal.4th 167, 177 [affirming "there is little functional difference between the two theories in the failure to warn context"].)

Dean John Wade, reporter of the Restatement (Second) that adopted *Greenman* in § 402A, explained the reasons product identification remains necessary for liability. (See Wade, *On the Nature of Strict Tort Liability for Products* (1973) 44 Miss. L.J. 825, 828.) He wrote that manufacturers do not have any responsibility to those who use another's product, have no moral or legal obligation to stand behind another's goods, and are not in a position to incorporate costs of liability into their prices when liability is associated with products they did not make or sell. (*Id.*) The innovator liability theories here are also at odds with Wade's caution against turning product manufacturers into insurers of their products. (See *id.* at p. 828.) Here, Plaintiff is seeking to make the innovator an insurer, not only of its products, but of all products in the category made by anyone.

Courts rejecting innovator liability have rightly explained that product identification cannot be circumvented. (See *Huck, supra*, at p. 379 ["limiting liability to the defendant that made the drug used by the plaintiff is consistent with 'bedrock principles of tort law and of economic realities

underlying those principles.'"] [quoting *Wyeth, Inc.* v. *Weeks* (2014) 159 So.3d 649, 684 (Murdock, J., dissenting)]; *Foster, supra*, 29 F.3d at p. 168 [calling this theory out as nothing more than "an effort to recover for injuries caused by a product without meeting the requirements the law imposes in products liability actions"].) Whether for pharmaceuticals, lawn mowers, or cars, the foundation of product identification is missing when the plaintiff sues a manufacturer of a product he or she never used, regardless if under negligence or product liability.

### C. The Court Should Not Condone "Deep Pocket Jurisprudence"

An underpinning for the Court of Appeal's ruling in this case is the U.S. Supreme Court's holding in *PLIVA, Inc. v. Mensing* (2011) 131 S.Ct. 2567, which preempted certain failure-to-warn claims against manufacturers of generic drugs. (Op. at *16, n.2.) The lower court cited the Alabama Supreme Court's assertion that *Mensing* "undermines" cases rejecting innovator liability because consumers of generic drugs can no longer obtain awards in many circumstances from manufacturers of the generic drugs they took. (*Id.*) Abandoning fundamental liability principles, including those discussed above, to make one manufacturer pay for the liability of another is the essence of deep pocket jurisprudence.

The reaction of all other courts, including several federal courts of appeal, to *Mensing* has been to faithfully apply traditional state product

liability and tort law, even if doing so leads to unfortunate results for some plaintiffs. (See Schwartz, et al., *Warning: Shifting Liability to Manufacturers of Brand-Name Medicines When the Harm was Allegedly Caused by Generic Drugs has Severe Side Effects* (2013) 80 Fordham L. Rev. 1835.) As those courts have recognized, *Mensing* did not change tort law in any state and does not provide an invitation to do so. (See *Huck*, *supra*, 850 N.W.2d at p. 380 [refusing to "contort Iowa's tort law" to create liability for brand manufacturers].[4]) Thus, regardless of federal preemption, innovator liability is still not supported by California law.

To the contrary, the U.S. Supreme Court issued its preemption ruling in *Mensing* in full light of an earlier denial of innovator liability. Before the case reached the Supreme Court, the U.S. Court of Appeals for the Eighth Circuit had dismissed innovator liability claims. The Supreme Court did not disturb this determination. Rather, it "acknowledge[d] the unfortunate hand that federal drug regulation has dealt" these plaintiffs. The dissenters highlighted this point, stating that now, "whether a consumer harmed by inadequate warnings can obtain relief turns" on whether he or she took a brand-name or generic drug. (*Id.* at p. 2592 [Sotomayor, J., joined by Ginsburg, Breyer, and Kagan, dissenting].) If only generics were

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[4] As one federal judge explained, "I cannot find that a decision to hold a manufacturer liable for injury caused by its competitor's product is rooted in common sense." (*Phelps v. Wyeth, Inc.* (D. Or. May 28, 2010) No. 09-
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taken, "she now has no right to sue." (*Id.*)[5] Thus, *Mensing* did not lay the groundwork for innovator liability, including against a manufacturer, as here, which divested itself of the brand-name drug.

The importance of *Mensing* to the case at bar is that it actually requires dismissal of Plaintiff's claims. In *Mensing* the Court held that state-law claims, such as those here, are preempted by federal law when the manufacturer does not have the ability to unilaterally change the labeling of a drug. (*Mensing*, *supra*, at pp. 2577-78.) If state law were to impose such a duty of care on a manufacturer, as this suit would do, and the company would not be able to make that change, as this Defendant cannot, then federal law preempts the claim. For the purpose of impossibility preemption, therefore, a former brand-name manufacturer that no longer owns the rights to a drug is in the same position as a generic drug manufacturer. Neither can change the product or its labeling because doing so requires a supplemental new drug application and only the current applicant, here aaiPharma, is authorized to submit this application. (21 C.F.R. § 314.70, 314.71; see *In re Darvocet* (E.D. Ky. July 31, 2012) MDL

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6168-TC, 2010 WL 2553619, *2.)

[5] On remand, the Eighth Circuit reiterated that the Supreme Court did not alter its rejection of innovator liability. (See Order Reinstating Opinion in Part, *Mensing*, No. 08-3850 (Sept. 29, 2011).)