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-
(Footnote continued on next page)

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

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).)

No. 2226, 2012 WL 3109424, at *3 [stating that such post-divestiture claims are preempted].)

Finally, contrary to the lower court's assertion, creating liability in perpetuity against a former manufacturer of a product is not needed for, and is not an accurate measure of, deterrence. (See *Huck*, *supra*, 850 N.W.2d at p. 377 [finding no "persuasive case that public health and safety would be advanced through imposing tort liability on brand defendants for injuries caused by generic products"].) If an innovator, through labeling or marketing, overstates benefits or downplays risks of a product, it can be subject to significant liability when selling its own products, as well as substantial civil fines from the U.S. Department of Justice and state attorneys general. Finding a bystander to pay a claim is not a valid tort theory. The Court should reject this attempt at deep pocket jurisprudence.

II. ALLOWING INNOVATOR LIABILITY CLAIMS AGAINST FORMER MANUFACTURERS WILL HAVE HARMFUL IMPACTS ON CALIFORNIA CONSUMERS, BUSINESSES

Tort law history repeatedly demonstrates that once a court introduces a liability-expanding principle in litigation against one industry, it migrates to others. If the Court approves the innovator liability theory here, future plaintiffs will undoubtedly argue that innovators of other products, not just pharmaceuticals, will be subject to liability for not warning about harms caused by products they no longer make or by knock-offs of those former products. The scenarios where such allegations can be made are vast.

For example, what if a foreign company over which U.S. courts do not have jurisdiction reverse engineers an American manufacturer's product and sells it with identical packaging, instructions, and warnings? What if, instead of FDA law creating the connection between the innovator and the subsequent generic product, federal patent law is used to link the two? Should anyone who files a patent and divulges the design of a product foresee that a consumer will be injured by knock-offs of that product, including after they sell that product line to another manufacturer?

Innovator liability does not make sense in the pharmaceutical industry, nor does it make sense in other contexts.

A. Former Manufacturers Should Not Be Required To Interfere With a Current Manufacturer and Its Customers

Product line divestitures have become fundamental business strategies for manufacturers generally, "leading companies to focus on selling assets in the same rigorous way they focus on acquisitions." (Global Corporate Divestment Study, EY (2014) at i.)[6] Divesting older product lines may, for example, allow manufacturers to "sharpen their strategic focus" on their core competency of innovation, or help them manage cash flow, address underperforming sales, or take advantage of a profitable deal. (Mankins et al., *How the Best Divest*, Harvard Bus. Rev.

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[6] http://www.ey.com/Publication/vwLUAssets/EY_Global_Corporate_

(Footnote continued on next page)

(Oct. 2008) [discussing results of Bain & Company study of over 7,300 divestitures by 742 companies over a 20-year period].) Key to such a divestiture is for both sides to do their due diligence, set forth any reservations in the sales contract, and receive a "clean break" so that they can re-focus their energies on their own businesses after the transaction.

If the Court accepts this extension of innovator liability to predecessor companies, it would eliminate the certainty and finality that are necessary elements of asset transfers. (*Cf. Pacific Scene, Inc. v. Penasquitos, Inc.* (1988) 46 Cal.3d 407, 416 [noting "objectives of certainty and finality undergirding the dissolution provisions of the Corporations Code"].)[7] Businesses would hesitate to divest a product line, even when it makes business sense, because they would lose control over ongoing warnings, but still be subject to liability indefinitely for those warnings, their successors' post-sale products, and other manufacturers' comparable

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Divestment_Study/$FILE/EY-Global-Corporate-Divestment-Study.pdf.

[7] This Court has emphasized the public policy goals of certainty and finality in a broad range of civil litigation contexts. (See, e.g., *Cedars-Sinai Med. Ctr. v. Superior Court* (1998) 18 Cal.4th 1, 17 [declining to recognize spoliation tort out of concern it would "impair the fundamental interest in the finality of adjudication and the stability of judgments"] and *In re Hanley's Estate* (1943) 23 Cal.2d 120, 123-24 [expressing the "particular importance" of limitation periods to foster finality with respect to "the security of rights of contract, titles to property, and the status of persons"].

post-sale products. This result would violate the longstanding legal rules governing liability for post-sale activities.

The primary reason predecessor corporations are not subject to liability for products made and sold by successors is that the predecessor has no control over a successor's operations. (See Phillips, *Product Line Continuity and Successor Corporation Liability* (1983) 58 N.Y.U. L. Rev. 906, 927 ["control is not of the defective product but of the business that produced it"].) This Court has long found that "instrumentality under the defendant's control" is "fundamental" to the imposition of liability. (*O'Neil, supra,* 53 Cal.4th 349.)[8] "To hold otherwise, where defendant had no actual role in the manufacture or marketing of the particular product that caused plaintiff's injury, would create perpetual industrywide liability for anyone who historically manufactured or marketed a product." (Weil & Brown, Cal. Prac. Guide: Personal Injury (Rutter Group 2014) § 2:1370 [citing *Cadlo v. Owens Illinois, Inc.* (2004) 125 Cal.App.4th 513; *Taylor v. Elliott Turbomachinery, Inc.* (2009) 171 Cal.App.4th 564].)

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[8] See also *Artiglio v. General Elec. Co.* (1998) 61 Cal.App.4th 830, 840-41 [supplier of silicone owed no duty to warn recipients of breast implants of potential risks where supplier had "no control" over purchaser's manufacturing process]; *Groll v. Shell Oil Co.* (1983) 148 Cal.App.3d 444, 449 [supplier of fuel owed no duty to warn user where supplier lacked "control over the subsequent packaging and marketing" of the product]; *Walker v. Stauffer Chem. Corp.* (1971) 19 Cal.App.3d 669, 674 [supplier of sulfuric acid "not having control over the subsequent compounding, packaging or marketing" of the product owed no duty to warn].

Little moral blame can attach to a failure to warn about products one no longer makes or sells. Here, as discussed above, Novartis had not been involved in Brethine's labeling for years, and no longer had the ability to dictate or amend the prescribing information that accompanied the brand-name or generic version of the drug. It was prohibited under federal law from communicating any warnings about its former drug or making any statements contrary to the FDA-approved labeling maintained by the new drug application holder. Whether the warnings resemble those last used by Novartis is irrelevant. Further, requiring any former manufacturer to monitor and potentially override safety decisions about other companies' products would likely impose high burdens on former manufacturers, create friction in the market, and add vast new potential for litigation that may be uninsurable. (*Cf. Webb, supra,* 63 Cal.4th at p. 187 [suggesting courts should "appropriately and equitably balance[] the practical realities" of business against legal duties].)

In addition, consumers would not be presented with a single, complete set of warnings. Current manufacturers would lose the ability to control warnings over their own products, as former manufacturers would be incentivized to interfere in consumer warnings. Former manufacturers, in an effort to guard against liability, would likely over-warn about certain risks, rather than try to achieve the proper balance between benefits and risks. Such over-warnings could create consumer confusion if they differ

from those of the current manufacturers or force the current manufacturers to similarly "over-warn" to avoid liability. (See *O'Neil*, *supra*, at pp. 363-65 [warning that imposing a duty to warn for another manufacturer's product could lead to potentially conflicting warnings and undermine consumer safety].) Over-warning, just like under-warning, should be avoided because it undermines the value of warnings and deters people from trusting useful, beneficial products. Consumers benefit when duties of care are clearly defined so they know whose warnings to heed.

Earlier this year, the Court adhered to these concepts, ruling against liability laws that "invite consumer disregard and contempt for warnings." (*Webb*, *supra*, 63 Cal.4th at p. 182.) In *Webb*, the Court established the sophisticated intermediary doctrine, finding that a product manufacturer discharges any duty to warn end-users when it sells its product to a sophisticated purchaser and reasonably relies on that purchaser to convey adequate warnings to consumers. (See *id.* at p. 177.) There is no liability when a defendant manufacturer had "no effective way to convey a product warning to the ultimate consumer" and the manufacturer of the product causing the injury had its own independent duty to warn its customers. (*Id.*) That is the situation here. Ironically, though, Plaintiff seeks to subject a product manufacturer to liability after selling an *entire product line* to a sophisticated purchaser, not only for that company's products, but every other company's comparable products. The result would be absolute

perpetual liability over an entire product category.

Finally, liability here would be inconsistent with post-sale liability law against successors for acts of predecessors. (See, e.g., *Ray v. Alad Corp.* (1977) 19 Cal.3d 22, 25 [establishing "the general rule against imposition upon a successor corporation of its predecessor's liabilities."].) Courts have been historically wary of allowing successor liability to avoid, among other things, "significantly restraining corporate assets transfers." (Restatement (Third) of Torts: Products Liability (1998) § 12, cmt. b.) The Court has set forth specific criteria for when a clean break will not be recognized against successors. (See *Ray*, *supra*, 19 Cal.3d at p. 28.) None of the indicia for these rare exceptions exist in the case at bar: all indications are that Novartis liquidated, in good faith and at arms-length, assets associated with a product, just as countless companies do in the ordinary course of business.

The Court should deny the innovator liability theories in this case or risk undermining everyday business practices and consumer warnings.

B. The Innovator Liability Theories Here Would Hurt Manufacturing in California

A ruling that exposes innovators to perpetual category liability, including after they have left the relevant market, could have substantial negative consequences for manufacturing in this State. It would place tort law on a collision track with the spirit of entrepreneurship in California, a

state known as a hub for innovation. Adherence to fair legal principles is critical to California's continued economic success.

Manufacturing accounts for roughly eleven percent of California's total gross state product. (See Nat'l Ass'n of Manuf., Manufacturing Facts: California (2016).[9]) California manufacturers produce $255 billion in goods, including $144 billion in exports. (See *id.*) Manufacturing output in California rose significantly between 2002 and 2008, experienced a dip during the recession, and, since 2011, is getting back on track. (See *id.*) The manufacturing industry not only provides jobs for about 1.3 million Californians, it provides high-paying jobs. (See *id.*) The average annual compensation for a manufacturing job in California is $93,000, about 65% more than other nonfarm employees in the state. (See *id.*)

Further, California is an innovation-based manufacturing economy, more so than anywhere else in the world. Each of the top three companies viewed as the most innovative—Apple, Google, and Tesla—is headquartered in California. (See Boston Consulting Group, The Most Innovative Companies 2015 (2015).[10]) Other California companies considered among the most innovative include biotechnology companies

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[9] http://www.nam.org/Data-and-Reports/State-Manufacturing-Data/State-Manufacturing-Data/March-2016/Manufacturing-Facts--California/ (citing U.S. Bureau of Economic Analysis and U.S. Census Bureau data).

[10] https://media-publications.bcg.com/MIC/BCG-Most-Innovative-Companies-2015.pdf

Amgen and Gilead Sciences, internet heavyweights Facebook and Yahoo, technology manufacturers Hewlett-Packard and Cisco Systems, as well as Netflix and VISA. (See *id.*) Also, Silicon Valley has long been leading the "innovation economy," supporting development of technology-based startup companies, and fueling growth in the state. (See Silicon Valley Competitiveness and Innovation Project, 2016 Update 8-10.)[11]

Allowing innovator liability, including where, as here, the manufacturer no longer even sells the product at issue, will make California a magnet for novel lawsuits against manufacturers, thereby hurting California's economy and costing manufacturing jobs. Companies that create innovative products frequently are copied by competitors. It is commonplace to walk through supermarket aisles and find brand-name products side-by-side with store-brand products listing the same ingredients and packaged to resemble the original. Generic products are prevalent. (See Tuttle, *Brand Names Just Don't Mean as Much Anymore* (Nov. 1, 2012) Time [reporting that 93% of consumers changed their grocery-shopping habits to purchase more store-brand products].)[12]

Not all product-copying is legal. Chinese companies have a history of creating clones of Apple's iPhones and iPods, Chevy automobiles, Nike

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11 http://svcip.com/files/SVCIP_2016.pdf

12 http://business.time.com/2012/11/01/brand-names-just-dont-mean-as-much-anymore/

and Reebok sneakers, Callaway golf clubs, Intel processors, and Duracell batteries, among other products. (See Koeppel, *Chinas IClone*, Popular Sci. (Aug. 7, 2007)[13]; see also Bogage, *This Car Company Ripped Off Land Rover: Here's Why it Might Get Away With It* (July 19, 2016) Wash. Post.) Some of these products may be cheap knockoffs, but others are reverse-engineered to be close copies of the original designs. (See, e.g., Koeppel, *supra* [reporting that, in some instances, competitors have replicated factories from illegally obtained blueprints and precisely replicated products].) The risk of a lawsuit stemming from such replicas is not farfetched. Some manufacturers have already received complaints about products they did not produce. (See *id.*)

Future plaintiffs' lawyers could argue that given the pervasiveness of generic products, reverse engineering, and counterfeiting, it is reasonably foreseeable to manufacturers of innovative products that companies will replicate their designs, or attempt to do so. But, it would be economically absurd for this possible foreseeability to lead to liability when a product the company did not make or sell allegedly causes injury. A manufacturer that copies a product, sells it, and profits from that sale, should not be able to shift liability to the innovator. Nor should a court permit a plaintiff to shift

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[13] http://www.popsci.com/iclone

such liability because the company that made the product at issue cannot be sued because it is located in China, cannot be found, or otherwise.

As one California practice guide counsels:

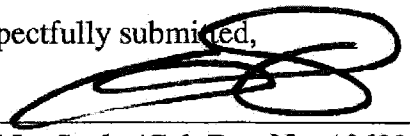
> A defendant's historic role as the original designer, manufacturer or marketer of a product cannot give rise to liability absent evidence it had an actual connection with the design, manufacturer or distribution of the particular product that caused plaintiff's injury. Thus, after a product manufacturer ceases all manufacture, sale and distribution of its product, it lacks the requisite causal connection to be held liable for injury caused by the same type of product manufactured and marketed by another company.

(Haning et al., Cal. Prac. Guide: Personal Injury (Rutter Group 2014) § 2:1370.) This statement of California law should not be changed to allow liability in this case. Innovator liability is already on a shaky foundation; extending such deep pocket jurisprudence to former manufacturers of an innovative product is a bridge too far.

CONCLUSION

For these reasons, the Court of Appeal's opinion should be reversed.

Respectfully submitted,



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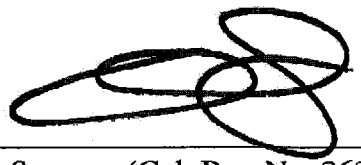
CERTIFICATE OF COMPLIANCE

I, Gabriel Spooner, an attorney duly admitted to practice before all courts of the State of California and a member of Shook, Hardy & Bacon L.L.P., counsel of record for *amici curiae*, certify that the foregoing complies with the requirements of Rules 8.520 and 8.204 of the California Rules of Court in that it was prepared in proportionally spaced type in Times Roman 13-point font, double spaced, and contains less than 14,000 words as measured using the word count function of "Word 2010."



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Dated: December 7, 2016

PROOF OF SERVICE

I, Ruby G. Darmstadt, am a resident of the State of California and over the age of 18 years. Neither I, nor my clients, National Association of Manufacturers and American Tort Reform Association, are a party to this action. My business address is One Montgomery Tower, Suite 2700, San Francisco, CA 94104.

On December 7, 2016, I caused the following document entitled:

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

to be served on the following persons by delivering a true copy thereof, in a sealed envelope, to Federal Express for overnight delivery as follows:

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I declare under the penalty of perjury under the laws of the State of California that the foregoing is true and correct.

Dated: December 7, 2016

Ruby G. Darmstadt