ORIGINAL

NO. S233898

IN THE SUPREME COURT OF CALIFORNIA

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

v.

NOVARTIS PHARMACEUTICALS CORP.,
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.)

BRIEF OF *AMICI CURIAE* GENENTECH, INC. AND CALIFORNIA LIFE SCIENCES ASSOCIATION IN SUPPORT OF DEFENDANT AND RESPONDENT NOVARTIS PHARMACEUTICALS CORP.

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SUMMARY OF ARGUMENT

Amici — one of California's leading biotechnology companies and California's largest life sciences advocacy organization — write to highlight the perverse consequences that affirming the Court of Appeal's decision would have for companies that develop innovative products and consumers who rely on their innovations. By re-casting the foundational tort principle of foreseeability in a manner that is limited only by the imagination of a skilled advocate, the Court of Appeal's decision positions innovator companies to face potential liability whenever consumers are injured from third-party copies of their innovations. This unprecedented expansion of liability would not only raise significant questions of fundamental fairness, but it would also meaningfully disincentivize innovation and drive up the prices of innovative products. Any well-designed tort system should reject the notion of innovator liability.

ARGUMENT

In determining the existence of a duty of care, this Court has consistently looked to foreseeability of the harm as the principal determinant. (See, e.g., *Ann M. v. Pacific Plaza Shopping Center* (1993) 6 Cal.4th 666, 676 [863 P.2d 207] ["[F]oreseeability is a crucial factor in determining the existence of duty."]; *Tarasoff v. Regents of the University of California* (1976) 17 Cal.3d 425, 434 [551 P.2d 334, 342] ["The most important of these considerations in establishing duty is foreseeability."].)

But in holding that a pharmaceutical manufacturer could be liable for injuries allegedly sustained by a plaintiff who ingested a generic copy of one of its formerly marketed medicines, the Court of Appeal stretched the concept of foreseeability too far. The court's reasoning — that Novartis could have foreseen that a user of a generic version of its medicine might have relied on the warnings developed when Novartis owned the branded product years earlier — creates a regime of uncabined liability for pharmaceutical and non-pharmaceutical innovator companies alike, because third parties will always have a financial incentive to copy a successful innovation while changing as little of the innovation as they can.[1] Although

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[1] Scholars and jurists have recognized the lack of a principled basis to cabin innovator liability to the pharmaceutical industry. (See, e.g., *Huck v. Wyeth, Inc.* (Iowa 2014) 850 N.W.2d 353, 380 (plur. opn.) ["[W]e decline Huck's invitation to step onto the slippery slope of imposing a form of innovator liability on manufacturers for harm caused by a competitor's product. Where would such liability stop?"]; Strong, *"But He Told Me It Was Safe!": The Expanding Tort of Negligent Misrepresentation* (2009) 40 U. Mem. L. Rev. 105, 142 ["It is not unreasonable to assume that the California Court of Appeal's decision in *Conte v. Wyeth* could be used to support the application of Section 311 liability in entirely new areas of the law."]; Comment, *Resolving Drug Manufacturer Liability for Generic Drug Warning Labeling Defects* (2015) 47 St. Mary's L.J. 219, 236 ["[T]here is little to stop this emerging application of limitless vicarious liability on innovators from spreading to every other industry."].) As one judge put it,

> [M]ost troubling, I see no principled barrier to the extension of the "foreseeability" doctrine to deficient representations . . . made by developers of other types of popular products copied by competitors. [citation] . . . There may be differences in the degree of foreseeability, but if foreseeability without relationship is to be the test, the line

examples abound, *amici* focus on three contexts beyond generic pharmaceuticals in which innovator companies can expect to face liability for injuries sustained while using a competitor's product: technological innovations, counterfeit products, and household goods.

1. Technological Innovations

That every successful manufacturer of an innovative product has potential exposure under the liability theory endorsed by the Court of Appeal is particularly true in the technology sector, where innovative new technologies rapidly become "genericized."

Consider the following hypothetical: A smartphone manufacturer develops and incorporates into its newest device an antenna that is far superior to any antenna on the market in its ability to pick up a signal. Recognizing the new antenna's superiority, other smartphone manufacturers imitate the design and incorporate it into their own devices. Studies subsequently demonstrate that the innovative antenna technology reflects significant radiation into the user's head, causing brain cancer.

Because it is foreseeable that innovative products (here, the antenna) will be replicated and that those who replicate such products will rely on

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> between the prescription-drug industry and other industry is arbitrary, and there is no principle to which this or other courts may anchor themselves in an effort to hold that line.

(*Wyeth, Inc. v. Weeks* (Ala. 2014) 159 So.3d 649, 684 (dis. opn. of Murdock, J.).)

the innovator to develop the appropriate warnings and instructions to accompany the product, the Court of Appeal's logic potentially exposes the innovator to liability for failing to warn of the risk (here, cancer) not only by users of its own products, but also by users of its competitors' products that imitate its innovation.

Such an outcome would weigh heavily on the pace of innovation. Innovative technology companies may be reluctant to invest in the research and development necessary to develop innovative technologies if they know they will be rendered the *de facto* insurer of every product in the marketplace that imitates their innovations.

2. Counterfeit Products

Innovator liability is particularly troubling in the context of counterfeit goods. By their very nature, counterfeit goods endeavor to resemble authentic products in all material respects. Indeed, it has become a distressing reality in today's marketplace that innovators face the ubiquitous specter of illicit copying of their successful products. Today, counterfeit products are not merely foreseeable but virtually guaranteed. In 2015, the Department of Homeland Security seized nearly $1.4 trillion worth of counterfeit goods across a variety of industries, including pharmaceuticals/personal care ($75 million), consumer electronics ($132 million), computers ($38 million), jewelry ($581 million), and apparel ($157 million). (U.S. Dept. of Homeland Sec., *Intellectual Property Rights*

Fiscal Year 2015 Seizure Statistics (2016) p. 19 <https://www.cbp.gov/sites/default/files/assets/documents/2016-Nov/ipr_annual_report_FY%202015_final1.pdf>.)

The counterfeiting industry has become extraordinarily sophisticated, with fake products becoming almost indistinguishable from the legitimate products they copy, down to the packaging and labeling. (See Organisation for Economic Co-Operation and Development, *The Economic Impact of Counterfeiting and Piracy* (2007) p. 29 <http://www.oecd.org/industry/ind/38707619.pdf> ["It has become easier for counterfeiters and pirates to deceive consumers through high quality packaging and/or through fake products that are virtually impossible to distinguish from authentic merchandise."].) It is certainly foreseeable for innovators that some consumers will unfortunately receive counterfeit products — products that include the verbatim labeling and warnings copied from the authentic product. Under the Court of Appeal's expansive definition of foreseeability, there is no limiting principal that would allow even the victim of the crime of counterfeiting from avoiding potential liability for some alleged misstatement on the counterfeit product's labeling. The absurdity of that result exposes the folly of the Court of Appeal's holding. Allowing a manufacturer to face liability for injuries suffered in connection with a third-party's counterfeit good, sold in

violation of the manufacturer's intellectual property rights, is antithetical to the American tort system.

Such a holding would also have perverse consequences in the marketplace. U.S. manufacturers of authentic goods lose up to $250 billion annually from the sale of counterfeit goods. (U.S. Dept. of Commerce, Internat. Trade Admin., *Are Counterfeiting and Piracy Serious Problems?* (2016) <https://www.stopfakes.gov/article?id=Are-Counterfeiting-and-Piracy-Serious-Problems>.) They already face substantial hurdles to enforcing their intellectual property rights against counterfeiters, including difficulties exercising personal jurisdiction over foreign-based counterfeiters and enforcing American judgments in foreign courts. (See, e.g., *China's Alibaba Spent $160m Fighting Fake Goods*, BBC News (Dec. 24, 2014) <http://www.bbc.com/news/business-30595150> [reporting that e-commerce giant Alibaba spent more than $160 million combatting counterfeit goods over a two-year period].) If manufacturers had to add to those enforcement expenditures the costs of personal injury litigation arising from those counterfeit products — costs that they would have no prospect of recovering from the counterfeiters — the prices of their innovative products would be driven up even further.

3. Household Goods

The concerns posed by innovator liability extend well beyond companies that develop sophisticated technological or biopharmaceutical

products, even to companies that develop and market basic consumer and household goods.

Private-label, or store-brand, imitations of brand-name products are ubiquitous. In 2015, retailers sold $118.4 billion worth of private-label products, capturing 17.7% of the U.S. retail market. (See Private Label Manufacturers Assn., *PLMA's 2016 Private Label Yearbook* (2016) p. 27 http://plma.com/share/press/resources/PLMA2016YB_COMB_RPT.pdf.) Given the extensive market share captured by manufacturers of private-label goods, brand-name manufacturers — particularly in certain industries (*e.g.*, groceries, household goods) — can easily foresee that their products will be imitated. It is equally foreseeable that imitation products will copy the brand-name representations and warnings directed at consumers, as private-label products mimic the overall appearance of brand-name products by "copying the[ir] sizes, shapes, colors, *and labeling*." (Finch, *When Imitation Is the Sincerest Form of Flattery: Private Label Products and the Role of Intention in Determining Trade Dress Infringement* (1996) 63 U. Chi. L. Rev. 1243, 1243, italics added.)

The rationale underlying the Court of Appeal's decision below would expose brand-name manufacturers of countless goods to liability for injuries allegedly suffered at the hands of their competitors' products. (See Noah, *Adding Insult to Injury: Paying for Harms Caused by a Competitor's Copycat Product* (2010) 45 Tort Trial & Ins. Prac. L.J. 673, 694

[recognizing that innovator liability implicates "any market served by brand-name companies that actively promote their wares but face competition from largely identical but lower-priced store brands"].) Such a result is inherently unfair. (See, e.g., *Foster v. American Home Products Corp.* (4th Cir. 1994) 29 F.3d 165, 170 [holding that it would be "especially unfair" to "us[e] a name brand manufacturer's statements about its own product as a basis for liability for injuries caused by other manufacturers' products" when another manufacturer "reaps the benefits of the name brand manufacturer's statements by copying its labels and riding on the coattails of its advertising"].)

Brand-name manufacturers may not willingly pay liabilities incurred from sales they never made, especially when they have a ready alternative: vigorously enforce their trademark rights. Because private-label imitations are designed to resemble the trade dress of the brand-name product, they may infringe upon the brand's trademark. (See, e.g., *Tommy Hilfiger Licensing, Inc. v. Goody's Family Clothing, Inc.* (N.D. Ga., May 9, 2003, No. 100-CV-1934-BBM) 2003 WL 22331254, at *39 [holding that private-label denim products infringed on Tommy Hilfiger's flag design trademark].) Although manufacturers today sue retailers for private-label imitations infrequently (Goldman, *Brand Spillovers* (2009) 22 Harv. J.L. & Tech. 381, 393), if brand-name manufacturers are made liable in tort for

injuries sustained while using private-label competitors' products, actions for trademark infringement may become the norm.

This alteration of the current equilibrium would harm consumers and stifle competition. More aggressive intellectual property enforcement not only would increase brand holders' costs, but it would also result in fewer private-label alternatives, both of which would ultimately lead to higher prices for these consumer goods. Private-label manufacturers piggyback off of the advertising and promotional efforts of the brand-name manufacturers whose products they imitate. (See, e.g., *Smithkline Beckman Corp. v. Pennex Prods. Co.* (E.D. Pa. 1985) 605 F.Supp. 746, 748 ["Private label brands owe their existence to the advertising and promotion efforts of the national brand. The national brand will expend tremendous sources of funds to build consumer recognition of both its product and tradename .... The store brand plays upon increased consumer awareness ...."].) By avoiding the enormous marketing costs that brand-name manufacturers build into their prices, private-label manufacturers can pass substantial price savings onto consumers, which in turn serves as a competitive check on the prices of the brand products themselves. (See Karp, *Store Brands Step Up Their Game, and Prices*, Wall Street Journal (Jan. 31, 2012) <http://www.wsj.com/articles/SB10001424052970204624204577179193540556620> [stating that private-label products cost an average of 29% less than comparable brand-name products].) Fewer available private-label

goods and the increased costs for the brand holder both translate into higher prices for consumers.

CONCLUSION

The American tort system carefully balances two interests: (1) "creat[ing] a climate in which trade and business innovation can flourish," and (2) "justly allocat[ing] risks that are a function of that free trade and innovation." (*Huck v. Wyeth, Inc.*, *supra*, 850 N.W.2d at p. 379 [quoting *Wyeth, Inc. v. Weeks*, *supra*, 159 So.3d at p. 684 (dis. opn. of Murdock, J.)].) "These dual needs have resulted in an economic and legal system that always has coupled the rewards from the sale of a good or service with the costs of tortious injury resulting from the same. Indeed, this and the corollary notion that parties are responsible for their own products, not those of others, are so organic to western economic and legal thought that they rarely find need of expression." (*Id.* at 380 [quoting *Wyeth, Inc. v. Weeks*, *supra*, 159 So.3d at pp. 684-685 (dis. opn. of Murdock, J.)].) The Court of Appeal's decision disregarded these bedrock principles of American jurisprudence, exposing to severe consequences both innovator companies and the consumers who benefit from their innovations. The Court of Appeal's decision should be reversed.

Respectfully submitted,

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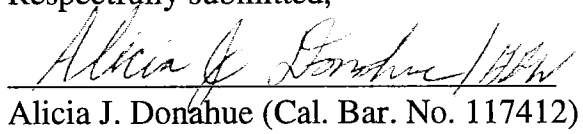
CERTIFICATE OF WORD COUNT

I, Alicia J. Donahue, 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 (2,460 words) as measured using the word count function of "Word 2010."

Respectfully submitted,



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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, Genentech, Inc. and California Life Sciences 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:

BRIEF OF *AMICI CURIAE* GENENTECH, INC. AND CALIFORNIA LIFE SCIENCES ASSOCIATION IN SUPPORT OF DEFENDANT AND RESPONDENT NOVARTIS PHARMACEUTICALS CORP.

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

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