No. S233898

IN THE SUPREME COURT
OF THE STATE OF CALIFORNIA

T.H., a Minor, etc., et al.,

Plaintiffs and Appellants

v.

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant and Respondent

Review of a Decision of the Court of Appeal
Fourth Appellate District, Division One, Case No. D067839

APPLICATION OF ATLANTIC LEGAL FOUNDATION FOR LEAVE TO FILE AMICUS CURIAE BRIEF; AND PROPOSED BRIEF IN SUPPORT OF RESPONDENT, NOVARTIS PHARMACEUTICALS CORPORATION

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TABLE OF CONTENTS

PAGE

TABLE OF AUTHORITIES

Page(s)

Cases

Statutes and Regulations

Legislative Materials

Constitutions

Other Authorities

APPLICATION FOR LEAVE TO FILE AMICUS CURIAE BRIEF IN SUPPORT OF RESPONDENT, NOVARTIS PHARMACEUTICALS CORPORATION

To the Honorable Chief Justice Tani Gorree Cantil-Sakauye and Associate Justices of the California Supreme Court:

Atlantic Legal Foundation requests leave to file an *amicus curiae* brief in this case in support of Respondent, NOVARTIS PHARMACEUTICAL CORPORATION, on the issue regarding whether California imposes liability on a former manufacturer of a branded product for injuries allegedly caused by a competitor's generic version of that product, although the former manufacturer divested all ownership interest in the branded product years before the generic product was sold and allegedly caused injuries.

STATEMENT OF INTEREST

Atlantic Legal Foundation is a non-profit public interest law firm founded in 1976 whose mandate is to advocate and protect the principles of less intrusive and more accountable government, a market-based economic system, and individual rights. It seeks to advance this goal through litigation and other public advocacy and through education. Atlantic Legal Foundation's board of directors and legal advisory council consist of legal

scholars, corporate legal officers, private practitioners, business executives, and prominent scientists.[1]

Because of the importance of uniformity of law concerning interstate commerce and other federal questions, Atlantic Legal Foundation has frequently filed amicus briefs in cases in which the issue of preemption is prominent.

CORPORATE DISCLOSURE STATEMENT

Amicus Curiae Atlantic Legal Foundation is a 26 U.S.C. § 501(c)(3) nonprofit, nonpartisan, public interest law firm incorporated as a Pennsylvania not for profit corporation. It has no shareholders, subsidiaries, or parent corporation. It does not issue stock or other securities.

Neither the Respondent, Novartis Pharmaceuticals Corporation, nor its counsel participated in drafting this *amicus* brief, nor did they fund its preparation.[2]

DATED: December 7, 2016

Respectfully submitted,

ATLANTIC LEGAL FOUNDATION

GREENBERG TRAURIG, LLP

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[1] Joe Hollingsworth, a senior partner in Hollingsworth LLP, counsel for Respondent Novartis Pharmaceuticals Corporation, is a member of Atlantic Legal Foundation's Board of Directors, but was recused from any discussion or consideration of the Foundation's decision to file an *amicus curiae* brief in this case.

[2] GlaxoSmithKline made a monetary contribution intended to fund the preparation of the brief.

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PROPOSED AMICUS CURIAE BRIEF IN SUPPORT OF RESPONDENT, NOVARTIS PHARMACEUTICALS CORPORATION

INTRODUCTION

Products liability has long presupposed that a manufacturer cannot be held liable for injuries caused by a product that it did not manufacture or sell. *Greenman v. Yuba Power Prods., Inc.*, 59 Cal.2d 57 (1963) (Traynor, J.). The Court of Appeal dispensed with that requirement in holding that a defendant could be held liable for a defectively labeled generic drug even though the defendant never manufactured that drug, no longer manufactured the branded version of that drug, and the generic drug that caused the alleged injury was manufactured by a putative competitor. The Court of Appeal's decision is not the natural outgrowth of the evolution of common law tort doctrine. Rather, the decision is a radical distortion of established liability principles in response to recent U.S. Supreme Court decisions holding that tort claims against generic drug manufacturers are preempted by federal law.

In *Pliva v. Mensing*, the Supreme Court held that federal law preempts tort claims brought against generic manufacturers alleging that a generic drug was accompanied by inadequate warnings. 131 S.Ct. 2567 (2011). Two years later, the Supreme Court extended the scope of that decision by holding that federal law also preempts claims that generic drugs

were defectively designed. *Mutual Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). These two decisions have curtailed consumers' ability to pursue tort actions under state law against generic manufacturers, such as the manufacturer of the generic drug that allegedly harmed the Plaintiffs. In this case, seeking to circumvent the effect of the Supreme Court's preemption decisions, the Court of Appeal manipulated common law tort doctrine in order to give the Plaintiffs – along with all other consumers of generic drugs – an alternative defendant to sue.

Imposing untethered duties on unsuspecting defendants by forcing them to pay damages caused by their competitors has never been a function of tort law. As this Court has long recognized, one of the rationales for holding manufacturers strictly liable for harms caused by their products is that a manufacturer can insure against the risk of injury and distribute the cost among the consuming public. *See Escola v. Coca Cola Bottling Co.*, 150 P.2d 436, 462 (Cal. 1944) (Traynor, J., concurring) (reasoning that a manufacturer should be held liable for an injury caused by its product even if it is not negligent, because "the risk of injury can be insured by the manufacturer and distributed among the public as a cost of doing business"). Under this well-entrenched tort principle, consumers of a branded drug may sue the brand manufacturer for harms allegedly caused by its product, and consumers of a generic drug may sue a generic manufacturer for harms allegedly caused by its generic version.

It is true that the Supreme Court's preemption decisions in *Pliva v. Mensing* and *Mutual Pharm. Co. v. Bartlett* have significantly restricted consumers' ability to pursue tort actions against generic manufacturers. Congress can of course enact legislation to override these decisions if it wishes to do so. California, however, should not abandon basic common law principles in order to shift onto brand manufacturers the cost of insuring consumers of generic competitors' products.

The Court of Appeal's novel and expansive theory of liability is so antithetical to the law of torts that it collides with other fundamental principles embedded in the Constitution and in federal law, including the Food, Drug, and Cosmetic Act, the Patent Act, and the First Amendment. First, the relationship between a branded drug and its generic versions is regulated exclusively by the Drug Price Competition and Patent Term Extension Act of 1984, commonly known as Hatch-Waxman. The Court of Appeal's decision upsets the delicate compromise between branded and generic drug manufacturers established by Hatch-Waxman. Second, the decision collides with the Patent Act, which vests in the federal government the exclusive right to promulgate patent policy. The courts have consistently held that state laws that seek to diminish the economic value of a patented product, which the Court of Appeal's decision would do, impermissibly interfere with federal patent law. Third, given that the Plaintiffs aim to impose liability on a defendant for scientific speech that is

unassociated with the product that caused injury, the Court of Appeal's decision contravenes the First Amendment.

ARGUMENT

I. State Law Must Yield to Federal Law Under the Supremacy Clause of the U.S. Constitution

The Supremacy Clause of the U.S. Constitution establishes 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 this federal system, "[a]s long as it is acting within the powers granted it under the Constitution, Congress may impose its will on the States." *Gregory v. Ashcroft*, 501 U.S. 452, 460 (1991). "Accordingly, it has long been settled that state laws that conflict with federal law are 'without effect.'" *Bartlett*, 133 S. Ct. at 2473 (quoting *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981)).

Federal law impliedly preempts state law "where it is impossible for a private party to comply with both state and federal requirements." *Id.* at 2476-77 (quoting *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990)). Conflict preemption also applies "where state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995) (internal quotation marks omitted). *See also Gade v. National Solid Wastes*

Management Assn., 505 U.S. 88, 108 (1992) ("[U]nder the Supremacy Clause, from which our pre-emption doctrine is derived, any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield" (internal quotation marks omitted)).

A. The Court of Appeal's Decision Collides With the Hatch-Waxman Act

1. Innovator Liability Disrupts the Legislative Compromise Between Brand and Generic Manufacturers

The imposition of liability disrupts the federal Hatch-Waxman scheme even if Novartis had not divested its new drug application ("NDA") and had continued to sell Brethine during the time that the plaintiff took a generic version of the drug. As the United States Supreme Court has noted, the FDA drug approval process is "onerous and lengthy." *Bartlett*, 133 S. Ct. at 2471. To gain approval of a new drug, an innovative manufacturer must submit an NDA that provides "substantial evidence that the drug will have the effect it...is represented to have." 21 U.S.C. § 355(d)(5). To meet this burden, an innovative manufacturer must submit the results of "adequate and well-controlled investigations, including clinical investigations, by experts qualified by scientific training and experience to evaluate the effectiveness of the drug involved." *Id.* § 355(d)(7). Because the process of submitting an NDA is onerous and expensive, Congress

passed the Hatch-Waxman Act in 1984 to "'make available more low cost generic drugs by establishing a generic drug approval procedure.'" *Mensing,* 131 S. Ct. at 2574 (citing H.R. Rep. No. 98-857, pt. 1, p. 14 (1984)). Under Hatch-Waxman, a generic drug may be approved by a manufacturer submitting an abbreviated new drug application ("ANDA") showing that the drug is sufficiently similar to its branded counterpart and that "the [safety and efficacy] labeling proposed ... is the same as the labeling approved for the [branded] drug." 21 U.S.C. § 355(j)(2)(A)(v).

"The [Hatch-Waxman] Act emerged from Congress's efforts to balance two conflicting policy objectives: to induce brand name pharmaceutical firms to make the investments necessary to research and develop new drug products, while simultaneously enabling competitors to bring cheaper, generic copies of these drugs to market." *Abbott Labs. v. Young*, 920 F.2d 984, 991 (D.C. Cir. 1990). The Court of Appeal's decision clashes with this federal scheme, because imposing liability on brand manufacturers for harms caused by generic drugs invariably alters the *quid pro quo* underlying Hatch-Waxman and thereby undercuts Congress's policy decisions. *See Hines v. Davidowitz*, 312 U.S. 52, 67 (1941) (explaining that state law is preempted when it "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.").

Before the passage of the Hatch-Waxman Act, the FDA required manufacturers of generic copies of previously approved drugs to produce their own clinical data establishing their products' safety and efficacy. Generic manufacturers lobbied Congress to lower regulatory barriers, while innovators argued that it was only fair that regulation effectively extended their exclusivity periods, because regulation also significantly shortened their patents' effective lives. *See* Rebecca Eisenberg, *The Role of the FDA in Innovation Policy*, Mich. Telecomm. Tech. L. Rev. 345, 356-57 (2007). In passing Hatch-Waxman, Congress adopted a series of compromises between the interests of generic and innovator manufacturers. The complex federal legislative scheme streamlined FDA approval of generic drugs while simultaneously preserving sufficient incentives for innovators to invest in the research and development of new drugs.

Hatch-Waxman made several changes to patent law and the Food, Drug, and Cosmetic Act (the "FDCA"). Hatch-Waxman's most transformative provision was the creation of the ANDA application for generic manufacturers. By filing an ANDA showing that the applicant's drug is "bioequivalent" to a previously approved product, Hatch-Waxman enabled generic manufacturers to bring off-patent products to market without performing costly clinical trials. *See* FDCA § 505(j), codified at 21 U.S.C. § 355(j). As a result of this modification to the regulatory regime, generic manufacturers that utilize the ANDA pathway need only spend

about $2 million to complete the approval process, in stark contrast to the hundreds of millions of dollars that pioneers must invest to generate safety and efficacy data. *See Big Generic Pharma*, The Economist, July 30, 2005, *available at* http://www.economist.com/node/4233872 . Hatch-Waxman also exempted from patent infringement the use of patented inventions for research intended to generate information for ANDA submission. 35 U.S.C. § 271(e)(1). On the other side, Hatch-Waxman authorized patent term extensions for innovative drugs to compensate for patent life lost during premarket review by the Food and Drug Administration (FDA) and created FDA-administered data exclusivities for new products and indications. *See* 35 U.S.C. § 156(c); 21 U.S.C. § 355(j)(5)(F)(ii), (iii).

Hatch-Waxman thus prescribes a comprehensive pathway for generic manufacturers to free ride on brand manufacturers' research and development efforts and marketing expenditures. The federal scheme does not, however, force brand manufacturers to act as insurers for their generic competitors. The Hatch-Waxman scheme reflects a deliberate legislative balance between innovative and generic manufacturers. Any realignment of the Hatch-Waxman balance can only be accomplished by Congress and not by the States.

A bedrock tenet of products liability law is that manufacturers are liable for harms caused by the products that they sell to consumers, not products that are sold by their competitors. Allowing plaintiffs to

circumvent this principle destroys Hatch-Waxman's carefully structured and balanced compromise between innovative and follow-on manufacturers. The Court of Appeal's decision thus collides with federal law, because the imposition of liability against innovative manufacturers for alleged harms caused by generic products "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" in its regulation of the pharmaceutical industry. *See Hines,* 312 U.S. at 67.

2. Predecessor Liability Conflicts With Federal Labeling Requirements

The Court of Appeal's decision further collides with the Hatch-Waxman Act, because it is impossible for Novartis to avoid tort liability without violating federal law. In a series of recent cases, the Supreme Court has addressed how principles of federal preemption apply to failure to warn claims against pharmaceutical manufacturers. These cases establish that the impossibility preemption doctrine applies to claims against *all* manufacturers that did not hold the NDA for the allegedly harmful drug at the time of the plaintiff's injuries, because FDA regulations prohibit such manufacturers from altering the drug's labeling.

The general rule is that a manufacturer must obtain FDA approval for a proposed change before altering a drug's label. 21 C.F.R. § 314.70(b)(2)(v)(A). However, under the Changes Being Effected ("CBE")

regulation, *id.* § 314.70(c)(6)(iii), the current NDA holder can make certain types of changes to its label prior to securing FDA approval. The change must "reflect newly acquired information," *id.*, and must be intended to enhance the safety and effectiveness of the drug for its approved uses in certain specified ways. *See id.* (delineating the five authorized objectives of the CBE procedure).

In *Wyeth v. Levine*, a jury found a drug manufacturer liable under Vermont law for what the jurors deemed to be an inadequate warning of risks in an FDA-approved label. *Wyeth v. Levine*, 555 U.S. 555, 558 (2009). In rejecting the manufacturer's preemption defense to liability under Vermont law, the Supreme Court pointed to the CBE regulation, "which both reflects the manufacturer's ultimate responsibility for its label and provides a mechanism for adding safety information to the label prior to FDA approval." *Id.* at 571. "Thus, when the risk ... became apparent, Wyeth had a duty [under federal law] to provide a warning that adequately described that risk, and the CBE regulation permitted it to provide such a warning before receiving the FDA's approval." *Id.* Based on these observations, the Court found that state tort liability penalizing the manufacturer for not changing its label under the CBE regulation was not preempted. *Id.* at 581.

Two years later, the Supreme Court distinguished *Wyeth*, and sustained a preemption defense to the imposition of tort liability on a

generic drug manufacturer for failure to add a warning to its label. *Mensing,* 131 S.Ct. at 2581. The court observed two key aspects of the federal "drug labeling duties" that applied to generic manufacturers. *Id.* at 2574. First, a generic manufacturer "is responsible for ensuring that its warning label is the same as the brand name's." *Id.* Second, "the CBE process was not open to [generic manufacturers]." *Id.* at 2575. Therefore, the generic drug manufacturer in *Mensing* could not have changed its label without prior FDA approval, which it could only have obtained by proposing that the FDA require a change in the corresponding brand label. *Id.* at 2576. The Court found that the possibility that the FDA would have agreed to require a change to the brand label in response to such a proposal did not preclude the court from concluding that compliance with both state and federal branding requirements was impossible. The Court explained that "[t]he question for `impossibility' is whether the private party could *independently* do under federal law what state law requires of it." *Id.* at 2579 (citing *Wyeth,* 555 U.S. at 573) (emphasis added). The Court limited *Wyeth* to situations in which the drug manufacturer can, "of its own volition, ... strengthen its label in compliance with its state tort duty." *Mensing,* 131 S.Ct. at 2581.

The Supreme Court in *Wyeth* and *Mensing* thus drew a line between labeling changes that can be independently made using the CBE regulation and labeling changes that require prior FDA approval. Importantly, only

the *current* NDA holder may rely on the CBE regulation to change a drug's label. All other companies – regardless of whether they manufacture branded or generic drugs – are prohibited from altering a drug's labeling. *See In re Darvocet, Darvon, Propoxyphene Products Liab. Litig.*, 756 F.3d 917, 940 (6th Cir. 2014) (a company that is not the NDA holder cannot change a drug's label).

Federal law thus prohibited Novartis from updating Brethine's labeling after it sold its rights and interests in Brethine in 2001. Indeed, as the Court of Appeal recognized, Plaintiffs conceded that Novartis had no duty to warn after its divestiture in 2001. *See TH v. Novartis*, 245 Cal. App.4th at 601. The Court of Appeal attempted to avoid this conflict between state and federal law by constructing a novel theory of predecessor liability. But construing a pre-2001 duty, the breach of which exposes Novartis to liability for all harms to consumers who ingest terbutaline at any point after the breach, is no different from imposing a post-2001 duty to warn.

Stripped of its doctrinal machinations, the practical effect of the Court of Appeal's decision is the same. An allegation that Novartis acted negligently during the time that it sold Brethine exposes Novartis to a lawsuit not only by those who took Brethine before 2001, but also by all persons who ingested or will ingest either Brethine or generic terbutaline any time after Novartis divested its rights and interests in the NDA.

This expansive distortion of California tort doctrine creates a direct conflict with federal law. Assuming, *arguendo*, that Novartis breached a duty to warn during the time that it marketed Brethine, federal law prohibited Novartis from remedying the alleged breach after its divestiture in 2001. As the plaintiffs tacitly acknowledge, the FDCA does not allow a drug manufacturer to alter the labeling of a drug that it no longer sells. *See TH v. Novartis*, 245 Cal. App.4th at 601 (noting that the plaintiffs do not claim that Novartis had a duty to warn after it sold its rights and interests in the NDA). Imposing perpetual liability on Novartis for an alleged breach of a duty that it had in the past does not merely disregard the fundamental policies of California's statutes of limitations. The Court of Appeal's decision so distorts common law tort doctrine that defendants cannot avoid liability without violating federal law, so it impermissibly clashes with the federal regulatory scheme. *See Mensing*, 131 S.Ct. at 2579 (explaining that state tort claims are preempted where a defendant cannot "independently do under federal law what state law requires of it").

When a brand manufacturer does not hold the NDA for a drug, it has "no more power to change the label" of the drug than a generic manufacturer. *In re Darvocet, Darvon, Propoxyphene Products Liab. Litig.*, 756 F.3d 917, 940 (6th Cir. 2014). Failure to warn claims are preempted against all companies who do not hold the NDA at the time of sale to the plaintiff, because in all such cases the CBE procedure is not

available. *See In re Celexa & Lexapro Mktg. & Sales Practices Litig.*, 779 F.3d at 41-43 (explaining that the Supreme Court's opinions in *Wyeth* and *Mensing* "make[] clear that a necessary step in defeating [a brand manufacturer's] preemption defense is to establish that the complaint alleges a labeling deficiency that [the brand manufacturer] *could have corrected using the CBE regulation.*") (emphasis added); *Brazil v. Janssen Research & Development LLC*, 2016 WL 3748771 (July 11, 2016) (holding that failure to warn claims against the manufacturer of a branded drug were preempted because the defendant was not the NDA applicant); *In re Fosamax (Alendronate Sodium) Products Liab. Litig.(II)*, No. MDL 2243 JAP-LHG, 2012 WL 181411, at *4 (D.N.J. Jan. 17, 2012) ("Because [the defendant manufacturer] could not 'independently do under federal law what state law requires of it,' the state law claims brought against it are preempted.") (quoting *Mensing*, 131 S.Ct. at 2579)).

Impossibility preemption applies equally to brand and generic manufacturers. Only the NDA holder can use the CBE process, therefore the Supreme Court's holding in *Mensing* forecloses failure to warn claims against any entity that did not hold an NDA for a terbutaline product at the time of Plaintiffs' alleged injuries. Plaintiffs cannot avoid preemption by arguing that Novartis could have submitted a request to the FDA to change the labeling for terbutaline products. Since federal law prohibits Novartis from unilaterally altering the FDA approved label in a manner that

Plaintiffs allege is mandated by state law, the Court of Appeal's decision inevitably runs up against federal preemption doctrine. *See Mensing*, 131 S.Ct. at 2580-81.

B. The Court of Appeal's Decision Collides With the Patent Act

1. Congress Has Exclusive Authority to Promulgate Patent Policy

The Court of Appeal's decision also collides with the Patent Act. Brethine, like most innovative drugs, was protected by a patent. *See* "Orally active bronchospasmolytic compounds and their preparation," U.S. Patent 3,937,838. Indeed, virtually all drugs that are approved for marketing through submission of an NDA are protected by one or more patents for the limited period of time prescribed by the federal patent laws. *See* FDA, Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), *available at* http://www.fda.gov/Drugs/InformationOnDrugs/ucm129662.htm (listing patent and exclusivity information for drug products approved by FDA on the basis of safety and effectiveness). State tort liability laws that selectively target current and former NDA holders thus invariably diminish the value of federal patent rights.

The Constitution directs Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries."

U.S. CONST. art. I, § 8, cl. 8. Congress fulfilled this constitutional mandate by enacting the Patent Act, codified as amended in Title 35 of the U.S. Code. The instrumental purpose of the federal patent law is to induce inventors to incur the costs of risky research and development with the promise of a federally protected right to exclude competitors. The right to exclude is valuable because it enables patent holders to obtain above-market profits during the patent term. *Biotech. Industry Org v. District of Columbia*, 496 F.3d 1362, 1372 (Fed. Cir. 2007). As the Supreme Court has noted, "The federal patent system thus embodies a carefully crafted bargain for encouraging the creation and disclosure of new, useful, and nonobvious advances in technology and design in return for the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150-51 (1989).

Patents play a central role in federal innovation policy. *See, e.g.*, H.R. Rep. No. 98-857, at 17 (1984), U.S.C.C.A.N. pp. 2647, 2650 (1984) ("Patents...enable innovators to obtain greater profits than could have been obtained if direct competition existed. These profits act as incentives for innovative activities."). The Federal Circuit, the specialized court with exclusive appellate jurisdiction over patent cases, has repeatedly reiterated that "the encouragement of investment-based risk is the fundamental purpose of the patent grant...." *Sanofi-Synthelabo v. Apotex, Inc.*, 470 F.3d 1368, 1383 (Fed.Cir.2006) (quoting *Patlex Corp. v. Mossinghoff*, 758 F.2d

594, 599 (Fed.Cir.1985)). *See also King Instruments Corp. v. Perego*, 65 F.3d 941, 950 (Fed. Cir. 1995) ("The economic rewards during the period of exclusivity are the carrot...Upon grant of the patent, the only limitation on the size of the carrot should be the dictates of the marketplace.").

The current patent system reflects a deliberate legislative balance between the competing federal objectives of rewarding inventors and preserving consumer access to innovative products. As the Federal Circuit has recognized, Congress has sole authority to calibrate patent law's incentive structure. *See Hunter Douglas, Inc. v. Harmonic Design, Inc.*, 153 F.3d 1318, 1333 (Fed. Cir. 1998) ("[T]he objectives of the federal patent laws...are in some tension with one another, and Congress struck a balance between them."). "Congress, as the promulgator of patent policy, is charged with balancing [the patent system's] disparate goals." *Biotech. Industry Org v. District of Columbia*, 496 F.3d, at 1373. The Supreme Court has "made clear that state regulation of intellectual property must yield to the extent that it clashes with the balance struck by Congress in our patent laws." *Bonito Boats*, 489 U.S. at 152.

2. Innovator Liability Levies a "Patent Tax" on Brand Manufacturers

As the Federal Circuit has recognized, federal patent law preempts state laws that constrain the pecuniary rewards that innovators derive from a patent grant. In *Biotech. Industry Org v. District of Columbia*, the court

applied this principle to conclude that federal patent law entirely preempted a District of Columbia ("D.C.") statute setting price limits on patented drugs. 496 F.3d at 1373-74. The Federal Circuit explained that "the essential criteria for determining whether a state law is preempted are the objectives of the federal patent laws." *Id.* at 1372 (internal quotations and citations omitted). It noted that any state law, however clearly within a state's general police power, must yield if it interferes with the goals established by Congress in the patent laws. *Id.* at 1373-74. The court concluded that the D.C. statute was preempted, because "[b]y penalizing high prices – and thus limiting the full exercise of the exclusionary power that derives from a patent – the District has chosen to re-balance the statutory framework of rewards and incentives insofar as it relates to inventive new drugs." *Id.* at 1374.

The U.S. District Court for the Eastern District of Pennsylvania recently applied the Federal Circuit's reasoning in *Biotech. Industry Org v. District of Columbia* to dismiss a claim that Gilead Sciences, Inc. ("Gilead"), *inter alia*, violated the California Business & Professions Code § 17200 with its pricing scheme for the sale of its patented Hepatitis C drugs. *See Southeastern Pennsylvania Transit Authority v. Gilead Sciences, Inc.*, 102 F. Supp. 3d 688 (E.D. Pa. 2015). The district court explained that the plaintiff could not use state law to disrupt the federal patent system "by forcing Gilead to lower its prices or disgorge profits from

the sale of its patented drugs." *Id.* at 703. Such claims were preempted, because they stood as an obstacle to the federal patent law's balance of objectives. *Id.* at 702-03.

State laws that diminish the economic value of a patent by capping the revenues derived from sales of a patented drug thus impermissibly clash with the Patent Act. Innovator liability similarly clashes with federal patent law, because forcing an innovative manufacturer of a patented drug to shoulder the entire liability burden for harms caused by its generic competitors' products diminishes –perhaps very considerably – the economic value of the innovator's patents.

Imposing liability on NDA holders for alleged harms caused by generic competitors effectively constitutes the imposition of a "patent tax" on innovative manufacturers. The Court of Appeal's decision interferes with federal patent policy by manipulating common law tort doctrine to attach a liability cost on patent rights granted by the federal government solely by reason of the defendant having been the first to discover the drug. "Congress has decided that patentees' present amount of exclusionary power, the present length of patent terms, and the present conditions for patentability represent the best balance between exclusion and free use." *Biotech. Industry Org v. District of Columbia*, 496 F.3d, at 1373. Innovator liability disturbs this federal balance by altering the economic value of the time limited right to exclude.

II. The Court of Appeal's Decision Conflicts With the Free Speech Clause of the First Amendment

The Court of Appeal's decision also collides with the Free Speech Clause of the First Amendment. The Plaintiffs assert two theories of liability: (1) Novartis should be held liable for promoting Brethine's off-label use as a tocolytic during the time that it held the NDA; and (2) Novartis should be held liable for failing to communicate information about terbutaline's risks beyond what was contained in the Brethine label at the time of Novartis's divestiture. *TH v. Novartis*, 245 Cal. App.4th at 599. Neither theory is viable, because the imposition of liability under either theory infringes Novartis's free speech rights.

With respect to the first theory, manufacturers have a constitutional right to make truthful statements about off-label uses of their products. *See United States v. Caronia*, 703 F.3d 149,168 (2nd Cir. 2012) (holding that constitutional principles bar the government from penalizing "the truthful off-label promotion of FDA-approved prescription drugs"). With respect to the second theory, scientific information that is not connected to the sale of a product is fully protected noncommercial speech. *See Washington Legal Foundation v. Friedman*, 13 F.Supp.2d 51, 62 (D.D.C. 1998) ("Scientific and academic speech reside at the core of the First Amendment."). Novartis has a First Amendment right to speak – or *not* to speak – about the benefits and risks of a drug that it does not sell. *See First National Bank of*

Boston v. Bellotti, 436 U.S. 765, 784 (1978) (the expression of views on matters of public importance does not lose First Amendment protection merely because a corporation seeks to utter the speech).

A. Speech That Is Unconnected To Commercial Sale Is Fully Protected By the First Amendment

"[A]s a general matter, the First Amendment means that government has no power to restrict expression because of its message, its ideas, its subject matter or its content." *Bolger v. Youngs Drug Products Corp.*, 463 U.S. 60, 65 (1983). The Supreme Court has drawn a distinction between noncommercial and commercial speech in considering the degree of protection afforded by the First Amendment. Whether a given communication constitutes commercial speech is predicated upon "the 'commonsense' distinction between speech proposing a commercial transaction...and other varieties of speech." *Bolger,* 463 U.S. at 64 (quoting *Ohralik v. Ohio State Bar Assn.*, 436 U.S. 447, 455-56 (1978)). With respect to noncommercial speech, content-based restrictions are permissible "only in the most extraordinary circumstances." *Id.* at 65. "There is no longer any room to doubt" that commercial speech is also entitled to the protection of the First Amendment, "albeit protection somewhat less extensive than that afforded 'noncommercial speech.'" *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 37 (1985). (quoting *Bolger*, 463 U.S. at 60).

Any communication about a drug that is unconnected to the sale of a product is noncommercial speech that is fully protected by the First Amendment. This type of scientific exchange constitutes pure speech that lies at the core of First Amendment protection. *See Friedman,* 13 F.Supp.2d at 62; *Board of Trustees of Leland Stanford Junior University v. Sullivan*, 773 F.Supp. 472, 474 (D.D.C. 1991) ("[T]he First Amendment protects scientific expression and debate just as it protects political and artistic expression."). *See also Keyishian v. Board of Regents*, 385 U.S. 589, 604 (1967) ("Because First Amendment freedoms need breathing space to survive, government may regulate in the area only with narrow specificity.") (internal quotation and citation omitted). "Lawmakers may no more silence unwanted speech by burdening its utterance than by censoring its content." *Sorrell v. IMS Health Inc.*, 564 U.S. 552, 566 (2011).

B. Manufacturers Cannot Be Compelled To Speak About Products That They Do Not Sell

The Court of Appeal decision cites several articles about the risks and benefits of using terbutaline to prevent pre-term labor published in medical journals in the decades preceding plaintiffs' injuries. *See TH v. Novartis*, 245 Cal. App.4th at 596-98. Yet neither the Court of Appeal nor Plaintiffs contend that the numerous members of the medical community who published these studies breached a legal duty to the plaintiffs' to warn their mother's physician of the risks of terbutaline. Indeed, such an

assertion would be manifestly untenable. The law is clear that noncommercial speech that conveys scientific or clinical information about a drug is fully protected by the First Amendment. *See Washington Legal Foundation v. Friedman*, 13 F.Supp.2d at 62 ("It is beyond dispute that when considered outside the context of manufacturer promotion of their drug products, CME seminars, peer-reviewed medical journal articles and commercially-available medical textbooks merit the highest degree of constitutional protection.").

The Ninth Circuit Court of Appeal decision in *Vess v. Ciba-Geigy Corp.*, 317 F.3d 1097 (9th Cir. 2003), illustrates the scope and strength of the constitutional right to speak about the clinical effects and uses of lawfully marketed drugs. The plaintiffs in *Vess* alleged that the American Psychiatric Association ("APA"), publisher of the Diagnostic and Statistical Manual of Mental Disorders ("DSM"), and the nonprofit advocacy group Children and Adults with Attention Deficit/Hyperactivity Disorder ("CHADD"), conspired with the manufacturer of the drug Ritalin to increase its sales by listing ADHD as a mental disorder in the DSM. *Vess*, 317 F.3d at 1101. After affirming the district court's holding that the plaintiffs failed to state a claim, the Ninth Circuit determined that the suit constituted a "Strategic Lawsuit Against Public Participation ("SLAPP") suit within the meaning of Cal. Civ. Code § 425.16. *Id.* at 1109-10. The court granted the APA's and CHADD's motion to strike under California's

anti-SLAPP statute, concluding that the plaintiff's lawsuit violated the APA's right to publish the DSM and CHADD's right to engage in public advocacy activities in connection with the use of Ritalin. *Id.* at 1110.

Physicians, researchers, medical organizations, and patient advocacy groups thus enjoy robust First Amendment rights that allow them to freely engage in scientific exchange. The First Amendment also protects their right *not* to speak. *See Va. Pharmacy Bd. V. Va. Consumer Council*, 425 U.S., 478, 756 (1976) ("Freedom of speech presupposes a willing speaker."). "Both the right to speak and the right to refrain from speaking are 'complimentary components of the broader concept of individual freedom of mind' protected by the First Amendment." *R.J. Reynolds Tobacco Co. v. Food & Drug Admin.*, 696 F.3d 1205, 1211 (D.C. Cir. 2012) (quoting *Wooley v. Maynard*, 430 U.S. 705, 74 (1977)).

Plaintiffs seek to deprive Novartis of the free speech rights enjoyed by other members of the biomedical community. Their failure to warn claims are based on the notion that Novartis – unlike the numerous others who had published information about terbutaline's risks and benefits– was required to communicate information to plaintiffs' mother's physician because Novartis had previously sold a product that was similar to the generic drug that their mother ingested. Yet, at the time plaintiff's mother was taking terbutaline, information about the drug's risks and benefits was entirely unrelated to any commercial transaction in which Novartis was

involved. Indeed, the Brethine label was completely detached from any commercial product sold by Novartis in 2007. This information therefore comprised noncommercial speech at the time of Plaintiffs' alleged injuries.

Novartis had the same constitutional right to speak – or *not* to speak – about terbutaline as did clinicians and researchers who had previously published information about terbutaline. *See Sorrell*, 564 U.S. 566-67 (explaining that the First Amendment requires heightened scrutiny whenever the government creates a restriction on protected expression based on the content of speech and the identity of the speaker). *See also Citizens United v. Federal Election Comm'n*, 130 S. Ct. 876, 899 ("The Court has recognized that First Amendment protection extends to corporations."); *Pacific Gas & Elec. Co. v. Public Util. Comm'n of Cal.*, 475 U.S. 1, 8 (1986) (plurality opinion) ("Corporations and other associations, like individuals, contribute to the 'discussion, debate, and the dissemination of information and ideas' that the First Amendment seeks to foster.") (quoting *Bellotti*, 436 U.S. at 783).

C. Manufacturers May Make Truthful Statements About Off-Label Uses For Their Products

The imposition of tort liability conflicts with Novartis's First Amendment rights even if Novartis's statements about Brethine are deemed to permanently and perpetually constitute commercial speech. "[T]he extension of First Amendment protection to commercial speech is justified

principally by the value to consumers of the information such speech provides." *Zauderer*, 471 U.S. at 651. This principle "has great relevance in the fields of medicine and public health, where information can save lives." *Sorrell*, 564 U.S. at 566. Moreover, because "manufacturers have superior access to information about their drugs," *Levine*, 555 U.S. at 578-79, they are frequently the most well-informed speakers in the information marketplace. Restricting manufacturers' speech therefore degrades the quality of information accessible to physicians, researchers, patients, and payers.

A manufacturer's dissemination of truthful information about off-label uses of its products is fully protected by the First Amendment. *See Caronia*, 703 F.3d at 168 (holding that constitutional principles bar the government from penalizing "the truthful off-label promotion of FDA-approved prescription drugs"). "Off-label drug usage is not unlawful, and the FDA's drug approval process generally contemplates that approved drugs will be used in off-label ways." *Id.* at 166. *See also Amarin Pharm, Inc. v. FDA*, 119 F. Supp. 3d 196, 224 (S.D.N.Y. 2015) (concluding that "the FDA may *not* bring [an enforcement] action based on truthful promotional speech alone, consistent with the First Amendment.").

Congress declined, when it enacted the FDCA, to "limit or interfere with the authority of a health care practitioner to prescribe or administer any legally marketed device to a patient *for any condition or disease*." 21

U.S.C. § 396 (emphasis added). Similarly, federal regulations expressly leave unregulated "the use in the practice of medicine for an unlabeled indication of a new drug product approved" by FDA. 21 C.F.R. §312.2(d). This federal regulatory policy reflects the fact that off-label use "is an accepted and necessary corollary of the FDA's mission to regulate in this area without directly interfering with the practice of medicine." *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 350 & n.5 (2001). FDA acknowledges that off-label use "may even constitute a medically recognized standard of care" for certain conditions. FDA, Draft Guidance for Industry: Responding to Unsolicited Requests for Off-Label Information About Prescription Drugs and Medical Devices 2 (Dec. 2011); *see also* Am. Acad. of Pediatrics, Comm. on Drugs, *Uses of Drugs Not Described in the Package Insert (Off-Label Uses)*, 110 PediatricS 181, 182 (2002) (stating that, because "[t]he full and ultimate role of a drug is rarely evident at the time of its initial approval and labeling," limiting a drug to its approved uses only would drastically and artificially restrict its value).

Federal court decisions make clear that the First Amendment affords significant protection to commercial speech about off-label uses of FDA-approved products. As the District of Columbia district court explained in the seminal case *Washington Legal Foundation v. Friedman*, "[i]n choosing between the dissemination of more or less information '[i]t is precisely this kind of choice, between the dangers of suppressing information, and the

dangers of its misuse if it is freely available, that the First Amendment makes for us.'" 13 F. Supp. 2d at 73-74 (quoting *Virginia State Board of Pharmacy*, 425 U.S. 748, 770 (1976)), *order vacated as moot sub nom. Washington Legal Foundation v. Henney*, 202 F.3d 331, 336-37 (D.C. Cir. 2000). *See also Caronia*, 703 F.3d at 168; *Amarin Pharma, Inc. v. FDA*, 119 F. Sup. 3d 196, 236 (S.D.N.Y. 2015). *Cf. Thompson v. Western States Medical Center*, 535 U.S. 357 (2002); *Sorrell v. IMS Health, Inc.*, 564 U.S. 552 (2011).

In *Caronia*, the Second Circuit declined to construe the FDCA to criminalize pharmaceutical manufacturers' promotion of a drug's off-label use, "because such a construction – and a conviction obtained under the government's application of the [FDCA] – would run afoul of the First Amendment." 703 F.3d at 161. The Department of Justice ("DOJ") did not seek Supreme Court review of the Second Circuit's decision. "That tactical decision speaks volumes about DOJ's assessment of the probable outcome." Jeffrey K. Shapiro, *Does FDA's Per Se Prohibition Against Off-Label Promotion Have a Future? The Short Answer: No*, Food and Drug Law Institute's Update Magazine, March/April 2016, *available at* http://www.hpm.com/pdf/FDLI%20mar%20apr%202016%20jks%20off%20label.pdf. *See also Amarin Pharma, Inc. v. FDA*, No. 15-3588 (S.D.N.Y. Mar. 8, 2016) (litigation settlement entered into by FDA that expressly

permits continued truthful and non-misleading off-label promotion without sanction).

The Court of Appeal's decision subjects Novartis to liability for injuries allegedly caused by generic terbutaline based on promotional statements that Novartis allegedly made about an off-label use for Brethine. In its practical operation, therefore, the Court of Appeal's decision imposes a burden based on the content of Novartis's speech about terbutaline and the identity of the speaker. Since the decision creates a content-based and speaker-based burden, the imposition of such a tort duty is subject to "heightened judicial scrutiny." *See Sorrell*, 564 U.S. at 557.

In *Sorrell*, the Supreme Court instructed that "[s]peech in aid of pharmaceutical marketing...is a form of expression protected by the Free Speech Clause of the First Amendment." *Id.* Therefore, where a manufacturer makes truthful and non-misleading statements about how its approved products may be lawfully used, any restriction on that speech – whether it is a regulatory ban or a liability burden – must "directly advance[] a substantial government interest" and be carefully "drawn to achieve that interest." *Id.* at 565-66, 572.

The liability burden imposed by the Court of Appeal does not satisfy the constitutional requirement that the speech restriction advance a "substantial government interest" and be "carefully drawn." A desire to provide consumers of generic manufacturers' drugs with an alternative

defendant to sue in the wake of the Supreme Court's preemption decisions in *Mensing* and *Bartlett* is not a "substantial government interest" within the meaning of the Supreme Court's First Amendment jurisprudence. It is up Congress to decide whether to amend federal law to permit consumers of generic drugs to sue generic manufacturers for alleged harms caused by their products. States, however, may not manipulate fundamental common law principles to create tort duties that infringe on the constitutional rights of innovative brand drug manufacturers.

CONCLUSION

For the reasons stated above, Atlantic Legal Foundation respectfully requests that the decision of the Court of Appeal be reversed and the cause remanded to the trial court with directions to enter judgment for Novartis.

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CERTIFICATION OF WORD COUNT

Pursuant to rule 8.204(c)(1) of the California Rules of Court and in reliance on the word count of the computer program used to prepare this brief, counsel certifies that this *Amicus Curiae* brief was produced using 13-point type and contains 6,776 words.

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