Team No. 4

Index No. 10-1524

IN THE
Supreme Court of the United States
APRIL TERM, 2010

DAN COOKS, *ET AL.*,
PETITIONERS,

V.

CAROLINA LABORATORIES INC.,
RESPONDENT.

On writ of certiorari to the
United States Court of Appeals
for the Thirteenth Circuit

BRIEF FOR PETITIONERS, DAN COOKS, *ET AL.*

Counsel for Petitioners

QUESTIONS PRESENTED

I. Does the National Childhood Vaccine Injury Act of 1986 overcome the presumption of the use of state law in products liability cases and preempt Grace state law regarding the Plaintiffs' design defect claims?

II. Did the Court of Appeals err in expanding the use of the *Twombly* pleading rules to cover design defect claims in considering the Defendant's motion to dismiss pursuant to Civil Rule of Procedure 12(b)(6)?

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

AMENDMENTS and STATUTES

OTHER AUTHORITIES

STATEMENT OF THE CASE

The instant case arises from injuries sustained by the Plaintiff, twelve-year old Estella Marie Cooks, after receiving three doses of a vaccine manufactured by the Defendant, Carolina Laboratories, Inc. Between March 1996 and October 1998, Estella Marie received three doses of thimerosal-containing Diphteria and Tetanus Toxois and Pertussis ("DTP") – Haemophilus influenzae type b ("Hib") combination type vaccine, which was produced by the Defendant. (R. at 1.) Thimerosal, the preservative used in the Vaccine administered to Estella is approximately 50% mercury by weight. (R. at 1.) Plaintiffs contend that the mercury contained in the thimerosal preservative was toxic and caused Estella Marie's neurological injuries. (R. at 1.)

Estella Marie's parents, Dan and Loetta Cooks, filed a timely petition for compensation on her behalf with the National Vaccine Injury Compensation Program ("NVICP") on September 3, 2001, pursuant to 42 U.S.C. § 300aa-1. (R. at 1-2.) On November 5, 2009, the Cooks properly filed a notice of withdrawal in the NVICP, rejecting their awarded tort judgment. (R. at 2.) The Cooks then filed an election to file a civil action on January 21, 2004, pursuant to 42 U.S.C. §300aa-21(a). (R. at 2.)

On March 14, 2007, the Cooks filed a Complaint in the Wicked County Court of Common Pleas. Defendant then removed the case to the United States District Court for the District of Grace, based on diversity of citizenship. (R. at 2.) The Complaint alleges defendant negligently failed to conduct adequate safety tests to determine whether thimerosal was safe and nontoxic to humans in the doses administered. (R. at 2.) Count II of the Complaint asserts strict products liability for design defect, in that the vaccine was defectively designed and a safer alternative existed. (R. at 2.)

Defendant moved to dismiss Plaintiff's causes of action, on the grounds that Plaintiff's design defects claims were barred by section 22(b) of the Vaccine Act, as well as contending that Plaintiffs failed to allege facts sufficient to state a claim for design defect under Grace state law. (R. at 2-3.) The United States District Court for the District of Grace rejected Defendant's argument that Plaintiffs had failed to allege facts sufficient to state a claim. (R. 1-8.) However, the court granted Defendant's motion to dismiss, holding that Plaintiff's claims were in fact barred by the Vaccine Act. (R. 1-8.)

The Plaintiff's then filed a timely appeal with the United States Court of Appeals for the Thirteenth Circuit. (R. 9.) The Court of Appeals affirmed the decision of the District Court, however on different grounds. (R. 9-13.) The Court of Appeals disagreed with the District Court, and found that Plaintiff's design defect claims were not barred by the Vaccine Act. (R. 9-13.) The Court of Appeals held that the Vaccine Act lacked any "clear and manifest Congressional purpose" in achieving a result that would "have the perverse effect of granting complete tort immunity from design defect liability to an entire industry." (R. at 11.) However, the Court of Appeals also disagreed with the District Court in holding that Plaintiff's did not allege facts sufficient to state a claim. (R. 9-13.) The decisions are unpublished, but are included in the record.

This Court then granted the petition of the Plaintiff's for writ of certiorari to the United States Court of Appeals for the Thirteenth Circuit. (R. 14.)

SUMMARY OF THE ARGUMENT

The decision of the Thirteenth Circuit of the Court of Appeals should be affirmed in part and reversed in part. This Court should affirm the Court of Appeals decision that the Plaintiff's

design defect claims are not barred by the National Childhood Vaccine Act of 1986. Additionally, this Court should reverse the Court of Appeals decision that heightened pleadings standards applied to the Plaintiff's design defect claim, and granting the Defendant's motion to dismiss.

The National Childhood Vaccine Act of 1986 does not bar Plaintiff's design defect claims. Under long established Supreme Court precedent, as well as this Court's recent jurisprudence, there is a presumption against state law preemption. This presumption is especially pronounced in cases involving traditionally state regulated fields, such as products liability. The defendant fails to overcome this presumption against preemption, because the evidence surrounding the Vaccine Act fails as to the requirements of a clear and manifest showing of intent to preempt state law under the traditional tripartite analysis. Therefore owing to the lack of clear and manifest evidence of an intent to preempt state design defect claims, this Court must follow the presumption against preemption, and hold that Plaintiff's design defect claims are not barred under the Vaccine Act.

Furthermore, the Court of Appeals erred in applying heightened pleading standards and in granting Defendant's motion to dismiss. The rationale behind the heightened pleading requirements does not exist in a defective design claim. Additionally, broadening the scope of these pleading requirements would have an impact detrimental to broad public interest. However, even under those standards, the Plaintiffs' pled a claim sufficiently rooted in fact as to fulfill the requirements of the Federal Rules of Civil Procedure, and the *Twombly* doctrine.

Argument

I. PLAINTIFF'S DESIGN DEFECT CLAIMS ARE NOT PREEMPTED BY THE NATIONAL CHILDHOOD VACCINE INJURY ACT OF 1986 BECAUSE THE INTENT BEHIND THIS ACT FAILS TO CLEARLY AND MANIFESTLY REBUT THE PRESUMPTION AGAINST STATE LAW PREEMPTION

The United States Supreme Court should affirm the judgment of the Court of Appeals that the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. § 300aa-22 (2006) ("Vaccine Act") does not preempt the Plaintiffs' state product liability claims for design defect. (R. at 11).[1] The Supreme Court reviews questions of law *de novo*. *Gonzalez v. O Centro Espirita Beneficente Uniao do Vegetal*, 546 U.S. 418, 428 (2006).

The doctrine of federal preemption arises under the Supremacy Clause of the Constitution: "The Constitution and the laws of the United States which shall be made in pursuance thereof . . . shall be the supreme law of the land[.]" U.S. Const., art. VI, cl. 2. The Tenth Amendment to the Constitution further provides, "[t]he powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively . . . ." U.S. Const. amend. X. Under traditional preemption analysis, federal law will override state law under the Supremacy Clause only when (1) Congress expressly preempts state law; (2) Congressional intent to preempt may be inferred from existence of a pervasive federal regulatory scheme; or (3) state law conflicts with federal law or its purposes. *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 541 (2001); *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 713 (1985); *Bruesewitz v. Wyeth, Inc.*, 561 F.3d 233, 238-39 (3d Cir. 2009),

[1] References to the Record on Appeal are cited herein as "(R. at _.)"

cert. granted, 2010 U.S. LEXIS 2266 (U.S. March 8, 2010); *Graham v. Wyeth Lab.*, 666 F. Supp. 1483, 1488-89 (D. Kan. 1987), *subsequent proceeding*, 906 F.2d 1399 (10th Cir. 1990), *subsequent proceeding*, 906 F.2d 1419 (10th Cir. 1990).

Recently, this Court applied the traditional tripartite preemption analysis to a products liability case in *Bates v. Dow Agrosciences, L.L.C.*, 544 U.S. 431, 449 (2005). *Bates* and its progeny constitute a well-established legal principle that a court must begin its preemption analysis by applying a presumption against preemption. *Id.*; *see also Bruesewitz*, 561 F.3d at 240; *Am. Home Prods. Corp. v. Ferrari*, 668 S.E.2d 236, 242 (Ga. 2008), *subsequent proceeding*, 129 S. Ct. 2786 (2009). This is especially true in cases concerning traditionally state-regulated areas of law. *See Bruesewitz*, 561 F.3d at 240. The *Bates* doctrine establishes that when the intent to preempt state law is ambiguous, and there are two equally plausible readings of a statutory text, there is a presumption against state law preemption. *Id.* The burden of persuasion then shifts to the defendant to rebut the presumption against preemption by proving legislative intent to preempt the law. *See Ferrari*, 668 S.E.2d at 243. Thus, under the *Bates* framework, the traditional tripartite preemption analysis serves as a defendant's only vehicle to rebut the presumption against preemption.

In the present case, the intent to preempt state design defect claims under the Vaccine Act is ambiguous at best, and therefore this Court should apply the presumption disfavoring preemption which it adopted in *Bates*. There is no express preemptive language in the Vaccine Act regarding state design defect claims; there is no occupation by the federal government of the field of vaccine-related injuries; and state laws permitting design defect claims against vaccine manufacturers are not contrary to the purpose of the Vaccine Act. Therefore, Defendants are unable to rebut the presumption against preemption under the tripartite preemption analysis.

Under this presumption, a proper reading of section 22(b)(1) of the Vaccine Act requires a case-by-case determination of whether a vaccine is "unavoidably unsafe" before a vaccine manufacturer will be shielded from liability for design defect. *Ferrari*, 668 S.E.2d at 238. For this reason, this Court should affirm the judgment of the Court of Appeals finding that the Plaintiffs' design defect claims are not preempted by the Vaccine Act.

A. Under Traditional Preemption Analysis As Well As This Court's Decision In *Bates*, There Is A Presumption Against State Law Preemption, Especially In Areas Which Are Traditionally State Regulated, Which Can Only Be Rebutted By A Clear And Manifest Showing Of Intent To Preempt.

The presumption against preemption which this Court adopted in *Bates* should be the starting point of the preemption analysis in this case. When faced with two equally plausible readings of a statute, the *Bates* doctrine dictates that there exists a rebuttable presumption against preemption. *Bates*, 544 U.S. at 449; *see also Bruesewitz*, 561 F.3d at 240; *Ferrari*, 668 S.E.2d at 242. This is especially true "[i]n areas of traditional state regulation, [where] we assume that a federal statute has not supplanted state law unless Congress has made such an intention 'clear and manifest.'"[2] Once this presumption is applied, the burden of persuasion then shifts to the Defendant to rebut through a showing of Congressional intent, using the elements of the traditional tripartite preemption analysis. *See Bruesewitz*, 561 F.3d at 240.

In *Bates*, the Plaintiff farmers asserted state law products liability claims sounding in both strict liability and negligence, after a pesticide destroyed their crops. This Court rejected the

[2] *Bates*, 544 U.S. at 449 (citation omitted); *see also Cal. Div. of Labor Standards Enforcement v. Dillingham Constr., N.A., Inc.*, 519 U.S. 316 (1997).; *Bruesewitz*, 561 F.3d at 239; *cf.* Memorandum on Preemption, 74 Fed. Reg. 24693, 24693 (May 22, 2009), *available at* http://www.whitehouse.gov/the_press_office/presidential-memorandum-regarding-preemption/ (stating that it is the "general policy of [President Obama's] Administration that preemption of State law by executive departments and agencies should be undertaken only with full consideration of the legitimate prerogatives of the States and with a sufficient legal basis for preemption).

defendant's preemption argument under the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"). Instead, this Court applied the presumption against preemption, noting that products liability law is traditionally state-regulated, and found that the legislative intent behind FIFRA was not sufficiently "clear and manifest" to rebut this presumption. *Bates*, 544 U.S. at 449. Further, this Court held that "even if [the] alternative [reading of the ambiguous statute] were just as plausible as our reading of that text-we would nevertheless have a duty to accept the reading that disfavors preemption." *Id.* at 449.

Section 22 of the Vaccine Act states, in relevant part:

> (b) Unavoidable adverse side effects; warnings
>
> (1) No vaccine manufacturer shall be liable in a civil action for damages arising from a vaccine-related injury or death associated with the administration of a vaccine after October 1, 1988, if the injury or death resulted from side effects that were unavoidable even though the vaccine was properly prepared and was accompanied by proper directions and warnings.

42 U.S.C. § 300aa-22(a)-(b) (2006). Section 22(b) is ambiguous on its face. *See Bruesewitz*, 561 F.3d at 240. There are two plausible readings of Section 22(b). *See Ferrari*, 668 S.E.2d 236. The first is that design defect claims are only preempted where adverse side-effects are found to be "unavoidable" on a case-by-case basis. *Id.* The second interpretation is that so long as a vaccine was properly prepared and accompanied by proper directions and warnings, the vaccine design process is immunized from claims of design defect, and any adverse side effects are automatically assumed to be "unavoidable." *Id.*

The Georgia Supreme Court applied the Bates analysis to section 22(b)(1) in *Ferrari*, and held that "section (b)(1) clearly does not preempt all design defect claims against vaccine manufacturers, but rather provides that such a manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the particular vaccine was unavoidably

unsafe." 668 S.E.2d at 242. *Ferrari* involved a vaccine injury claim arising from the administration of a thimerosal-containing vaccine, which allegedly caused neurological injuries to the child, much like the facts in this case. 668 S.E.2d at 237.] The court held that the ambiguity in section 22(b) requires an application of the *Bates* presumption against preemption, thereby shifting the burden of persuasion to the defendant. *Id.* at 242. Having applied the presumption, the court then went on to consider evidence of Congressional intent, and found an absence of any clear and manifest Congressional purpose to achieve preemption of design defect claims. *Id.* Therefore, the vaccine defendants in *Ferrari* were unable to rebut the presumption disfavoring preemption, and the court rejected the interpretation preempting design defect claims under section 22(b).

A line of cases interpret section 22(b) as preempting design defect claims for vaccine injuries. *Bruesewitz*, 561 F.3d 233; *Sykes v. Glaxo-SmithKline*, 484 F. Supp.2d 289 (E.D. Pa. 2007); *Militrano*, 26 A.D.3d 475. These cases misapply the Congressional intent behind the Vaccine Act. Notwithstanding, even *Bruesewitz* and *Sykes* acknowledge that at this initial stage of the preemption analysis, the *Bates* presumption against preemption should apply. *See Bruesewitz*, 561 F.3d at 240; *Sykes*, 484 F. Supp.2d at 318.

Vaccine injury suits are traditionally governed by state products liability tort law. It has been established that, "issues of health and safety have traditionally fallen within the province of state regulation is beyond refute. That safety of vaccines is an issue of health and safety is equally clear." *Bruesewitz*, 561 F.3d at 240. The controlling principles in *Bates* guard against overreaching interpretations of federal law which would strip the states of the ability to police traditionally state-regulated matters. The ambiguity of section 22(b) warrants an application of the presumption against preemption of design defect claims, thereby shifting the burden of

persuasion to the Defendant to rebut through a showing of Congressional intent under the traditional tripartite preemption analysis. The Defendant is ultimately unable to rebut this presumption. The ambiguity of section 22(b) warrants an application of the presumption against preemption of the Plaintiff's design defect claims, and the burden of persuasion lies with the Defendants to rebut that presumption.

B. Applying A Traditional Tripartite Preemption Analysis To The Vaccine Act Fails To Rebut The Presumption Against State Law Preemption, Since It Lacks Any Clear And Manifest Intent To Preempt State Design Defect Claims.

Once a court has applied the presumption disfavoring preemption which this Court adopted in *Bates*, the burden of persuasion then shifts to the Defendant to rebut the presumption. *Bruesewitz*, 561 F.3d at 240. The Defendant must make a showing of "clear and manifest" Congressional intent to preempt state design defect claims under the Vaccine Act. *Bates*, 544 U.S. at 449. The line of cases employing the *Bates* doctrine illustrate that, following this burden shift, the traditional tripartite preemption test serves as the means by which the Defendant can make his showing of Congressional intent in order to rebut the preemption. *Bruesewitz*, 561 F.3d at 240. Under this preemption analysis, the Defendant can prove Congressional intent to preempt by showing that either: (1) Congress expressly preempts state law; (2) Congressional intent to preempt may be inferred from existence of a pervasive federal regulatory scheme; or (3) state law conflicts with federal law or its purposes. *Lorillard*, 533 U.S. 541; *Hillsborough*, 471 U.S. 713; *Bruesewitz*, 561 F.3d at 238-39; *Graham*, 666 F. Supp. at 1488-89. There is an absence of any clear and manifest expression of Congressional intent to preempt design defect claims. On the contrary, there is affirmative evidence that Congress intended to preserve state design defect claims under section 22(b), barring only those which stem from "unavoidable" side

effects, which are to be proven on a case-by-case basis. For this reason, the Defendant is unable to rebut the presumption against preemption, and this Court should affirm the judgment of the Court of Appeals holding that the Plaintiffs' design defect claims are not barred by the Vaccine Act.

1. Defendant is Unable to Rebut the Presumption Against Preemption Under The Express Preemption Component of The Tripartite Preemption Analysis.

First, the Defendant fails to demonstrate express preemption. *See Lorillard*, 533 U.S. at 541. Express preemption occurs when Congress preempts state law in "express terms." *Hillsbourough*, 471 U.S. at 713. The language "[n]o vaccine manufacturer shall be liable" makes section 22(b)(1) a preemption clause. 42 U.S.C. § 300aa-22(b)(1). However, this does not end the inquiry. *See Bruesewitz*, 561 F.3d at 243. The express language of section 22(b)(1) is ambiguous as to the *scope* of the preemption, and it is unclear whether all design defect claims are barred, or only those relating to vaccines deemed unavoidably unsafe pursuant to a case-by-case determination. Therefore, there is no express preemption of *design defect claims* on the face of section 22(b)(1).

An interpretation of Section 22(b)(1) of the Vaccine Act which bars all design defect claims regardless of whether or not the injury or death was unavoidable, would render the word "unavoidable" to be meaningless. Such an interpretation of the statute would violate the rules of statutory construction. *Duncan v. Walker*, 533 U.S. 167, 174 (2001) ("It is [the court's] duty 'to give effect, if possible, to every clause and word of a statute.'") (citation omitted). Therefore, in order to give meaning to each word in the statute, whether or not a vaccine's side effects are "unavoidable" must be an independent element of a vaccine manufacturer's immunity. In order to secure immunity from liability for design defect, a vaccine manufacturer must establish that

(1) the vaccine's side effects were unavoidable; (2) the vaccine was properly prepared; and (3) the vaccine was accompanied by proper directions and warnings. 42 U.S.C. § 300aa-22(b)(1).

Further, this Court has held that express preemption of one matter and not of another "supports a reasonable inference-that Congress did not intend to pre-empt other matters." *Cipollone v. Liggett Group*, 505 U.S. 504 (1992); *accord Cartwright v. Pfizer*, 369 F. Supp.2d 876 (E.D. Tex. 2005) ("Clearly, Congress knows how to enact FDA legislation that contains a preemption clause. Thus, the absence of any such clause with respect to prescription drugs demonstrates an implied intent not to preempt cases, such as this."); *Moss v. Merck & Co.*, 381 F.3d 501, 506 (5th Cir. 2004) ("[W]e will not lightly infer that Congress has implicitly preempted state claims using an instrument that explicitly preempts other claims."). In section 22(c), Congress expressed its intent to preempt failure to warn claims based solely on the manufacturer's failure to give warning directly to the injured party or his or her legal representative, rather than merely to the administering physician. Similarly, in section 22(e), Congress specifically preempts states from establishing laws that are more restrictive than the provisions of the Vaccine Act. 42 U.S.C. § 300aa-22(e).

In contrast to the clear and direct language in sections 22(c) and (e), section 22(b) says nothing about preempting *all* design defect claims. 42 U.S.C. § 300aa-22(b). The existence of two other preemption clauses on the face of the Vaccine Act supports an inference that Congress did not intend to preempt that which it did not directly include, namely, *all* design defect claims. *See Cipollone,* 505 U.S. at 517. The Defendant is unable to rebut the presumption against preemption of design defect claims under the first phase of the tripartite analysis.

2. Defendant is Unable to Rebut the Presumption Against Preemption Under the Field Occupation Component of the Tripartite Analysis

The Defendant also fails under the second component of the tripartite rebuttal, field occupation. *See Lorillard*, 533 U.S. at 541. Absent "express pre-emptive language, Congress's intent to pre-empt all state law in a particular area may be inferred where the scheme of federal regulation is sufficiently comprehensive to make reasonable the inference that Congress 'left no room' for supplementary state regulation." *Hillsborough*, 471 U.S. 713 (citation omitted). The precepts of field occupation establish that

> Congress may evidence its intent to occupy a field expressly by words in the statute itself, or in the statute's legislative history. In the absence of express preemption, there is a strong presumption that Congress did not intent to displace state law. However, . . . the scheme of the regulation may be so pervasive that courts will infer a Congressional intent to occupy the field. Or, the nature of the subject matter may be one which demands exclusive federal regulation in order to achieve national uniformity and courts will assume the federal law precludes enforcement of state laws on the same subject.

Graham, 666 F. Supp. at 1489 (citations omitted). The Vaccine Act and the circumstances surrounding it do not fit under any of the aforementioned tests for preemption, and in such an absence of "clear and manifest" intent to preempt state design defect claims, the Defendant fails to rebut the presumption against preemption of design defect claims, warranting an affirmation of the judgment below.

This case does not qualify as an instance under which this Court can find federal occupation of a field of law. *See Graham*, 666 F. Supp. at 1489. Products liability law is an area traditionally regulated by the states. It has been established that, "issues of health and safety have traditionally fallen within the province of state regulation is beyond refute. That safety of vaccines is an issue of health and safety is equally clear." *Bruesewitz*, 561 F.3d at 240. Furthermore, vaccine-related causes of action fall within the purview of state law as recognized

on the face of the Vaccine Act: "Except as provided in sections (b), (c), and (e) of this section *State law shall apply* to a civil action brought for damages for a vaccine-related injury or death." 42 U.S.C. § 300aa-22(a) (emphasis added). Taking these factors into account, the *Graham* court held that Congress clearly intended to allow state tort remedies for vaccine-related injuries. 666 F. Supp. at 1492-93.

The Vaccine Act's intrusion upon this state-regulated area of law is too minimal to warrant a finding of a pervasive regulatory scheme. Sections 22(b) and (c) are the only sections of the Vaccine Act that preempt state law, and they do so narrowly. Section 22(b) precludes liability for vaccine manufacturers only when an injury-causing vaccine is deemed "unavoidably unsafe." 42 U.S.C. § 300aa-22(b). Section 22(c) precludes suits brought *solely* on the basis of the manufacturer's failure to provide warnings directly to the injured party.[3] 42 U.S.C. § 300aa-22(c). The Vaccine Act leaves in place all other aspects of vaccine tort law to the states. *See* 42 U.S.C. § 300aa-22(a). In an area of law traditionally regulated by the states, and with so little carved out by the Vaccine Act, there is no pervasive regulatory scheme to be found relating to vaccine injuries.

The broad authority of the Food and Drug Administration ("FDA") to regulate the sphere of all drugs, including the licensing, manufacture, and distribution of vaccines, is insufficient for a finding of a pervasive federal regulatory scheme. While the authority of the FDA is indeed wide-ranging, the FDA has no power over the tort system. FDA regulation of drugs and the functionality of the tort system exist independently of each other. Moreover, FDA approval of a drug is not the end-all in product safety. Courts have recognized that FDA approval is mere evidence of a product's safety, but that "drugs occasionally prove not so safe as the FDA first

believed." *Toner v. Lederle Labs.*, 732 P.2d 297, 311 (Idaho 1987). In fact, this is evidenced by a line of cases in which an FDA-approved product was found to be unsafe. [4] Clearly, FDA approval is not dispositive of product safety, much less of Congressional intent to infringe upon traditionally state-regulated tort law.

Finally, while FDA regulation of vaccines understandably sets a minimum level of uniformity in vaccine safety standards, uniformity should not come at the expense of product safety. Notably, "tort judgment against a drug manufacturer may in fact accelerate the development of better, safer products." *MacGillivray v. Lederle Labs.*, 667 F. Supp. 743 (D.N.M. 1987).

3. Defendant is Unable to Rebut the Presumption Against Preemption Under the Congressional Purpose Component of the Tripartite Preemption Analysis.

Finally, the Defendant also fails under the third component of the Defendant's tripartite rebuttal of the presumption against preemption, which requires a showing that allowing all design defect claims against vaccine manufacturers to stand would be contrary to the Congressional purpose behind the Vaccine Act. *See Lorillard*, 533 U.S. at 541. This Court held that "[t]he purpose of Congress is the ultimate touchstone in every pre-emption case." *Wyeth v. Levine*, 129 S. Ct. 1187, 1194 (2009) (citation omitted). When Congress has not preempted state regulation, it is limited to only "pre-empt[ing] state law to the extent that the state law actually conflicts with federal law. Such a conflict actually arises . . . when the state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'"

[4] *See e.g., Singer v. Sterling Drug, Inc.*, 461 F.2d 288, 290-91 (7th Cir. 1972) (FDA-certified drug Aralen proves to cause blindness.); *Feldman v. Lederle Labs.*, 479 A.2d 374, 378-79 (N.J. 1984), *cert granted*, 585 A.2d 360 (N.J. 1990), *rev'd on other grounds*, 592 A.2d 1176 (N.J. 1991), *cert granted*, 614 A.2d 620 (N.J. 1992), *aff'd*, 625 A.2d 1066 (N.J. 1993) (Studies showed tetracycline stained teeth well before FDA took action to require warnings.); *Cudmore v. Richardson-Merrell, Inc.*, 398 S.W.2d 640 (Tex. Civ. App. 1965) (FDA-certified drug MER-29 proved to cause cataracts.).

Hillsborough, 471 U.S. at 713 (citations omitted); *Graham*, 666 F. Supp. at 1489 (citations omitted).

When Congress enacted the Vaccine Act in 1986, it had two overriding concerns: "(a) the inadequacy - from both the perspective of the vaccine-injured persons as well as vaccine manufacturers - of the current approach to compensating those who have been damaged by a vaccine; and (b) the instability and unpredictability of the childhood vaccine market." H.R. Rep. No. 99-908 at 5. Indeed, the need to ensure that vaccine manufacturers remain in the market and that the public may continue to benefit from childhood vaccination programs was a strong force behind the enactment of the Vaccine Act. With this purpose, but not to the exclusion of maintaining public health and safety, the Vaccine Act established the National Vaccine Injury Compensation Program ("Compensation Program") under section 15. 42 U.S.C. § 300aa-15. Under the Compensation Program, persons injured by vaccines are incentivized but not required to circumvent the traditional tort system. 42 U.S.C. § 300aa-15. The procedure requires that a person injured directly by a vaccine first bring a proceeding before the established "Vaccine Court." 42 U.S.C. § 300aa-11(a)(2)(A). To recover for his injuries, an injured person need not prove fault, but merely causation. 42 U.S.C. § 300aa-13, 14. After this initial filing, a person has a choice to either accept the Vaccine Court's award and abandon his tort rights, or to reject the judgment and pursue his traditional tort rights in regular court. 42 U.S.C. § 300aa-21(a), 11(a)(2)(A)(i)]. Further, the Vaccine Act sets limitations on compensation for certain kinds of harm. 42 U.S.C. § 300aa-15(a)(2), (4).

The purpose of the Vaccine Act was to modify, not eliminate the traditional tort system. *Shafer*, 20 F.3d. at 3. Congress opined that "[v]accine related persons will now have an appealing alternative to the tort system." 1986 U.S.C.C.A.N. at 6367. Congress envisioned that

given a choice between years of burdensome and uncertain tort litigation in the traditional court system or an expedited, virtually guaranteed recovery, parents "will *choose* the compensation system of this bill and will reduce the liability costs of manufacturers." 132 Cong. Rec. E2461-01 (statement of Rep. Waxman) (emphasis added).

The main protection for vaccine manufacturers under the Vaccine Act exists under the Compensation Program. The main thrust of the protection afforded to vaccine manufacturers under the Vaccine Act is the reduction in litigation, awards, and insurance premiums that the Compensation Program is designed to encourage, resulting from an decrease in litigated design defect, manufacturing defect, and failure to warn claims. Section 22(b) merely supplements this protection with an additional, narrow protection applying only to certain design defect claims. While in general, design defect claims are not barred by section 22(b), it nonetheless establishes an exception that a vaccine manufacturer can raise as an affirmative defense. Section 22(b)(1) effectively states that "if the injury or death resulted from side effects that were unavoidable," it is unfair and imprudent, even arbitrary, to hold the manufacturer liable for design defect, given the current state of knowledge. 42 U.S.C. § 300aa-22 (b)(1). In order to uphold the second purpose of the Vaccine Act, namely, the health and safety of the public, this immunity must apply narrowly. Therefore, what is considered unavoidably unsafe must necessarily be determined on a case-by-case basis. *See Ferrari*, 668 S.E.2d at 236 ("[A] vaccine manufacturer cannot be held liable for defective design if it is determined, on a case-by-case basis, that the injurious side effects of the particular vaccine were unavoidable."). Therefore, to hold that section 22(b) was intended to preempt *all* design defect claims is an overbroad interpretation of the statute, and the Plaintiffs' design defect claims should not be barred prematurely.

Furthermore, Congress explicitly rejected a proposal that the Vaccine Act should preempt *all* design defect claims. *See* H.R. Rep. 100-391 (I) (1987) *reprinted in* U.S.C.C.A.N. 2313-1 ("An amendment to establish as part of this compensation system that a manufacturer's failure to develop safer vaccine was not grounds for liability was rejected by the Committee during its original consideration of the Act."). This Court has held that "[f]ew principles of statutory construction are more compelling than the proposition that Congress does not intent *sub silentio* to enact statutory language that it has earlier discarded in favor of other language." *INS v. Cardoza-Fonseca*, 480 U.S. 421, 442-43 (1987) (citations omitted). This direct evidence of Congressional rejection of the proposal to preempt *all* design defect claims stands firmly in the way of the Defendant's attempt to rebut the presumption against preemption.

A long line of cases supports the Plaintiffs' reading of the Vaccine Act. Courts have held generally that the Vaccine Act does not completely preempt state law. *E.g.*, *Mazur v. Merck & Co.*, 742 F. Supp. 239, 247 (E.D. Pa. 1990), *aff'd*, 964 F.2d 1348 (3d Cir. 1992) ("These sections certainly manifest Congress's intent to preserve traditional state tort remedies for redress of injuries related to vaccine use."); A*bbot v. Am. Cyanamid Co.*, 844 F.2d 1108, 1113 (4th Cir. 1988) ("Congress acted with the understanding that state tort and contract remedies were available and that they continue to be available as modified by the acts."). Examining the Vaccine Act more narrowly, courts have agreed that Congress did not intend to preempt state design defect claims under the Vaccine Act.[5]

[5] *SeeHurley v. Lederle Labs.*, 863 F.2d 1173, (5th Cir. 1988); *Martinkovic v. Wyeth Labs.*, 669 F. Supp. 212 (N.D. Ill. 1987); *Patten v. Lederle Labs.*, 655 F. Supp. 745 (D. Utah 1987); *Morris v. Parke, Davis, & Co.*, 667 F. Supp. 1332 (Cent. D. Cal. 1987).

A final tool for interpretation of the intent to preempt design defect claims under the Vaccine Act is the language and intent behind comment k to section 402A of the Restatement (Second) of Torts of 1965 ("comment k"). Congress has made it clear that section 22(b) is modeled after comment k, and that the purposes underlying comment k also apply to the Vaccine Act: "The Committee . . . intends that the principle in Comment K regarding "unavoidably unsafe" products, i.e., those products which in the present sense of human skill and knowledge cannot be made safe, apply to the vaccines covered in the bill . . . ." 1986 U.S.C.C.A.N at 6367.

Comment K, titled "Unavoidable unsafe products", provides:

> There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. . . . The seller of such products, . . . where the situation calls for it, is not to be held to strict liability for negligence for unfortunate consequences attending their use . . . .

Restatement (Second) of Torts § 402A cmt. k (1965).

Most jurisdictions have held that an application of comment k warrants a case-by-case determination of unavoidability, treating comment k as an affirmative defense available only in narrow circumstances.[6] Only after the defendant shows on a case-by-case basis that the vaccine is unavoidably unsafe is he entitled to the protection from liability afforded by Comment k. Jurisdictions which afford manufacturers with immunity from design defect claims under comment k first conduct a risk-utility analysis in order to determine whether the benefits of the product outweigh its known risks on the date the product is distributed. *See Bryant v. Hoffmann-La Roche, Inc.*, 585 S.E.2d 723, 727 (Ga. Ct. App. 2003); *Tansy v. Dacomed Corp.*, 890 P.2d

[6] *See*, *Hill v. Searle Labs.*, 884 F.2d 1064 (8th Cir. 1989); *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293 (D. Minn. 1988); *Coursen v. A.H. Robins Co.*, 764 F.2d 1329 (9th Cir. 1985), *corrected*, 773 F.2d 1049 (9th Cir. 1985); *Toner*, 112 Idaho 328.

881 (Okla.1994); *Adams v. G.D. Searle & Co.*, 576 So.2d 728 (Fla. Dist. Ct. App. 1991). One jurisdiction has even established an absolute liability for manufacturers under comment k, regardless of whether or not the product is unavoidably unsafe. *Allison v. Merck & Co.*, 878 P.2d 948 (Nev. 1994).

The Eighth Circuit in *Hill* explicitly held that "[c]omment K serves as an affirmative defense." 884 F.2d at 1068. In *Toner*, the Supreme Court of Idaho applied Comment k to vaccine related injuries, and held that "Comment K intends to shield from strict liability products which cannot be designed more safely." 732 P.2d 297 at 305.

Cases interpreting the Vaccine Act as preempting design defect claims properly extract the Congressional intent to afford a needed level of protection to vaccine manufacturers, but *misapply* that purpose. As discussed at length *supra*, the main protection for vaccine manufacturers comes from the establishment of the Compensation Program under section 15 of the Vaccine Act. *See* 42 U.S.C. § 300aa-15. The protection under section 22(b)(1) is only supplemental, and narrowly exempts from liability only manufacturers whose vaccines are *unavoidably* unsafe. By holding that section 22(b)(1) bars *all* design defect claims, these courts apply an overbroad reading of section 22(b)(1) which is unwarranted under the Vaccine Act's legislative history and Congressional intent.[7]

While each of these cases turns on Congressional intent, they all view as dispositive the interests of the vaccine manufacturers as those affect the ability of the public to continue to benefit from the availability of vaccines. However, these cases fail to afford due weight to the other purpose behind the Vaccine Act, in fact, the only purpose which appears on the face of the

[7] *See Brusewitz*, 561 F.3d 233; *Sykes*, 484 F.Supp.2d 289; *Blackmon v. Am. Home Prods. Corp.*, 328 F. Supp.2d 659 (S.D. Tex.) *summary judgment granted*, 346 F. Supp. 2d 907 (S.D. Tex. 2004), *summary judgment granted*, 2005 U.S. Dist. LEXIS 40587 (S.D. Tex. June 8, 2005); *Militrano*, 26 A.D.3d 475.

Act itself, to achieve optimal prevention of human infectious diseases and adverse reactions to vaccines. *See* 42 U.S.C. § 300aa-1.

Notably, each of the aforementioned cases, with the exception of *Blackmon* which predates this Court's holding in *Bates*, acknowledges the presumption against preemption which this Court has adopted. However, their misapplication of Congressional intent prevented the plaintiffs from overcoming this presumption.

In enacting the Vaccine Act, Congress's purpose was not to strip potential plaintiffs of a long available form of compensation, but to ensure that this nation would continue to have safe vaccines readily available. To grant manufacturers immunity from state design defect claims, would infringe on the manufacturer's incentive to manufacture a vaccine as safely as possible. *MacGillivray*, 667 F. Supp. at 745. An interpretation of Section 22(b) of the Vaccine Act which bars design defect claims only when the vaccine was found to be unavoidably unsafe, is the interpretation that furthers the full purpose of Congress. It protects manufacturers who make vaccines as safely as possible, while still providing manufacturers an incentive to take every step necessary to ensure that vaccines in this Country will be made as safe as possible.

For the reasons set forth in this section, the Defendant will be unable to make a showing of a clear and manifest Congressional purpose which would conflict with permitting state law design defect claims. Even under this final component of the traditional tripartite preemption analysis, the Defendant will fail to rebut the presumption against preemption.

In sum, given the traditional state regulation of vaccine injury claims, and the ambiguity of section 22(b)(1) of the Vaccine Act, this Court's pronouncement in *Bates* dictates that a presumption against preemption must be applied. The burden of rebutting this presumption then lies with the Defendant to show clear and manifest intent to preempt all design defect claims.

However, under an analysis of Congress's intentions behind the Vaccine Act, it becomes evident that under section 22(b)(1), Congress did not intend to preempt all design defect claims. Congress merely intended to afford immunity from design defect claims for only those vaccines which, given the present state of knowledge, could not be made safer. Therefore, the Defendant is unable to rebut the presumption against preemption, and this Court should affirm the judgment of the Circuit Court that the Plaintiffs' design defect claims are not preempted.

C. Even if This Court Were to Find That the Intent Behind the Vaccine Act Bars Design Defect Claims Under a Theory of Strict Liability, Claims Under a Theory of Negligence Should Still Be Permitted

As discussed *supra*, it is evident from the express language of the Act and the circumstances surrounding its enactment that section 22(b) does not preempt design defect claims. However, even if this Court were to find that the legislative history and an application of comment k justify preemption of some design defect claims under a strict liability theory, claims for design defect under a theory of negligence should still be permitted.

As previously discussed, section 22(b) is modeled after comment k. A plain reading of the express language of comment k leaves no doubt that it affords a defense only against claims of strict liability, and its coverage does not extend to cases concerning negligence: "The seller of [unavoidably unsafe] products . . . is not to be held to *strict liability* for unfortunate consequences attending their use . . . ." Restatement (Second) of Torts § 402A cmt. k (1965) (emphasis added). Nothing in comment k, nor in section 402A of the Restatement (Second) of Torts to which the comment refers, makes any mention of negligence. In fact, comment a specifically states that "[t]he rule stated [in section 402A] . . . does not preclude liability based upon the alternative ground of negligence of the seller, where such negligence can be proved."

Restatement (Second) of Torts § 402A cmt. a (1965). Therefore, even if Plaintiffs' strict liability claim were preempted, their design defect claim should still be permitted under a theory of negligence.

The District Court's contrary holding in *Blackmon* that "[w]hile comment k is restricted to strict liability claims, § 22(b) is not." 328 F. Supp.2d at 666. However, the court offered little support for this assertion. Its sole argument is that "[s]ection 22(b)(1) states broadly that no manufacturer 'shall be liable in a civil action for damages arising from a vaccine-related injury or death,'" and that "the phrase 'a civil action for damages' encompasses products liability claims based on negligence as well as those based on strict liability." *Id.* Such a broad reading of a narrow part of section 22(b) is completely contrary to the legislative intent, as discussed *supra*. Therefore, *Blackmon* has no persuasive value, and the Court should find that negligence claims for design defect are not preempted by the Vaccine Act.

Furthermore, a reading of section 22 of the Vaccine Act that would preempt negligence causes of action for design defect would be contrary to Congressional purpose. The legislative history outlines a dual purpose behind the Vaccine Act of protecting the financial stability of vaccine manufacturers while also protecting the safety of the public. H.R. Rep. No. 99-908 at 5. Notably, on the face of the Vaccine Act itself, its stated purpose is to "achieve optimal prevention of human infectious diseases through immunization and to achieve optimal prevention against adverse reactions to vaccines." 42 U.S.C. § 300aa-1. The stated purpose to afford protection to vaccine manufacturers appears only in the legislative history which has no effect of law. It should yield to the intent to protect public health, which appears expressly and exclusively on the face of the Vaccine Act. Such prioritization of purpose weighs against the preemption of negligence design defect claims, even if strict liability causes of action are

preempted. Creating immunity for "products deemed unavoidably unsafe pursuant to comment k from negligence claims *would remove needed incentive for safe design*." *Toner*, 732 P.2d 310 (emphasis added) (citing Victor E. Schwartz, *Unavoidably Unsafe products: Clarifying the Meaning Behind Comment K*, 42 Wash. & Lee L. Rev. 1139, 1144-45 (1985). Furthermore, Congress's intent to preserve negligent design defect causes of action is evident from Representative Waxman's introduction of the Vaccine bill before the House of Representatives, where he emphasized his opposition to "any effort to eliminate liability for *negligence* under state and federal law." 132 Cong. Rec. E2461-01 (emphasis added).

Permitting negligence claims for design defect under the Vaccine Act is supported by well-reasoned case law. *See Toner*, 732 P.2d 310. In a holding that is effectively the law of the Ninth Circuit, the Court of Appeals for the Ninth Circuit certified a controlling question of Idaho state law to that state's Supreme Court regarding the relationship between comment k and a negligence cause of action. *Toner*, 732 P.2d at 299. The *Toner* court held that the principles of comment k that apply to strict liability do not preclude a plaintiff from maintaining a negligence cause of action for design defect against a vaccine manufacturer. *Id.* at 311. The Court noted that, "when comment k applies, the plaintiff still may allege negligence." *Id.* at 310. The court in *Graham* agreed with this holding, that even where, for public policy reasons, strict liability design defect claims are prohibited, under special circumstances, "plaintiff may proceed on a design defect theory only on the basis of negligence." 666 F. Supp. at 1497. In its holding, the *Toner* court noted that "comment k achieves [a balance] between encouraging development and promoting safety [of vaccines]-a balance which would topple were there no action in negligence." *Toner*, 732 P.2d at 310.

II. THIS COURT SHOULD REVERSE THE DECISION OF THE COURT OF APPEALS, AS THE PLAINTIFFS IN THIS CASE SUFFICIENTLY STATED A DESIGN DEFECT CLAIM AGAINST THE DEFENDANTS.

In the instant case, the Plaintiffs set forth a claim that the defendant failed to adequately test the effects of a vaccine containing thimerosal, which led to neurological and physical injuries when the vaccine was administered to their twelve-year-old daughter. In considering their claims and the Defendant's subsequent motion to dismiss, the courts below utilized pleading standards that were predicated on cases dissimilar to the case at bar in both fact and nature. (R. at 12.) The use of these new standards overturned long-established doctrines that made sure that pleading requirements were not overly onerous. The use of these standards by the Court of Appeals was an erroneous expansion of the limits of these holdings, and their continued expansion would have profound and far-reaching negative ramifications. Additionally, the Plaintiffs' pleadings were sufficiently detailed and adorned with facts as to preclude dismissal for failure to state a claim, even under the new standards.

A. The Pleading Standards Created In *Bell Atlantic v. Twombly* Should Not Be Applied In The Instant Case, And the Court of Appeals Erred In Utilizing Those Standards.

The Court of Appeals erred in utilizing the pleading requirements established by *Bell Atl. Corp. v. Twombly*, 550 U.S. 544 (2007), as affirmed by *Ashcroft v. Iqbal*, 129 S.Ct. 1937 (2009), to the case at bar. The standards created in *Twombly* should not have been applied when examining the Plaintiffs' claim in the case at bar. The nature of the elements of the claims and the position of the plaintiff what is necessary to successfully plead a product liability defective design claim is entirely distinguishable from *Twombly*, or *Iqbal*. Additionally, expanding the use of *Twombly* pleading standards to defective design cases in general would essentially foreclose

the potential for defective design claims by implementing unreasonably stringent pleading requirements.

1. The Standard Created In *Twombly* Is Inapplicable To A Defective Design Case In That The Instant Case Is Procedurally And Substantively Different Than The Field Of Law Examined In *Twombly*.

The pleading requirements established in *Twombly* marked a shift towards making successful pleading more difficult. By upending the established precedent of *Conley v. Gibson*, 355 U.S. 41 (1957) under which "a complaint should not be dismissed for failure to state a claim unless it appears beyond doubt that the plaintiff can prove no set of facts in support of his claim which would entitle him to relief." *Id.* at 45-46. The *Twombly* decision required that the allegations in a complaint must "be enough to raise a right to relief above a speculative level," forcing plaintiffs to meet heightened requirements of fact-specific allegations. *Twombly*, 550 U.S. at 550. However, this doctrinal shift was predicated on facts and legal elements largely dissimilar to the case at bar. As the instant case presents vastly divergent questions of law, the *Twombly* standards do not apply, and a standard better suited to the nature of a products liability claim needs to be applied to design defect cases.

It is established within the Federal Rules of Civil Procedure that determinations on motions to dismiss are affected by the nature of the case in question. Rule 9 of the Federal Rules of Civil Procedure establishes that the unique nature of fraud cases necessitates separate and more specific pleading requirements. Fed. R. Civ. P. 9(b). It distinguishes fraud cases from general pleadings under Rule 8, requiring that, when alleging fraud, the pleading must "state with particularity the circumstances constituting fraud or mistake." Fed. R. Civ. P. 9(b). Rule 8

does not require that level of particularity, as it only requires short and general statements. Fed. R. Civ. P. 8.

This disparity between Rules 8 and 9 demonstrates that the nature of the case in question is a determining factor when establishing the pleading requirements necessary to survive a motion to dismiss for failure to state a claim. This is indicative of the need for different types of claims to be considered separately, based on the needs of particular types of cases.

The unique characteristics of a particular class of cases might require particularized pleading requirements. As such, it is imperative to examine the differences between the requirements of a defective design claim as in the case at bar and an antitrust case or claim pursuant to *Bivens v. Six Unknown Named Agents of Fed. Bureau of Narcotics*, 403 U.S. 388 (1971), as were the cases in *Twombly* and *Iqbal*. Such an examination inexorably reveals that pleading requirements from *Twombly* cannot be effectively applied to so disparate a type of case as defective design claims.

The case in *Twombly* involved a claim under Section 1 of the Sherman Antitrust Act, alleging the defendants entered into a conspiracy to prevent competitive entry into the local telephone markets. *Twombly*, 550 U.S. at 550. The nature of an antitrust case factored into the Court's decision to retire the *Conley* standard. Antitrust litigation is a highly technical and complex area of law; meaning that litigation is lengthy and often very expensive. *Associated Gen. Contractors of Cal., Inc. v. Cal. State Council of Carpenters*, 459 U.S. 519 (1983). In establishing the heightened pleading, this Court in *Iqbal* cited to the unusually high cost of discovery in antitrust cases and the extensive scope of discovery in antitrust cases. *Twombly*, 550 U.S. at 558 [citations omitted]. These factors were particularly pronounced in *Twombly*, as it involved plaintiffs representing a "putative class of 90 percent of all subscribers to local

telephone or high speed Internet service in the continental United States, in an action against America's largest telecommunications firms." *Twombly,* 550 U.S. at 559.

The potential size and cost of antitrust litigation created a need for increased pleading requirements to ensure courts and defendants would not be forced to bear massive costs of frivolous litigation. *Twombly*, 550 U.S. at *559.* The decision referenced longstanding antitrust precedent that "a district court must retain the power to insist on some specificity in pleading before allowing a potentially massive factual controversy to proceed." *Associated Gen. Contractors of Cal., Inc.,* 459 U.S. at 528. However, those antecedents from *Twombly* that, in part, justified the increased pleading requirements are not present in the case at bar. Applying the *Twombly* standards to the Plaintiffs' case without consideration for the wholly different circumstances would not comport with the justifications for the heightened standards, and therefore those standards should not be applied to the case at bar. *See Twombly,* 550 U.S. at 558-59.

Furthermore, the nature of the element that needs to be pled in a Sherman Act Section 1 pleading is entirely distinguishable from the elements of the Plaintiffs' charge. The pleading in *Twombly* needed to allege "a contract, combination or conspiracy in restraint of trade or commerce." Sherman Antitrust Act of 1980, 15 U.S.C. § 1 (2006). In alleging a Sherman Act violation, the pleader would need to allege an injury caused by the restraint of trade. *Twombly,* 550 U.S. at 555. That restraint of trade would be known to the pleader prior to the drafting of the claim, as the pleader would have seen, felt, or experienced the restraint of trade which induced the injury. This is entirely the opposite of the case at bar, where, in a defective design claim, the Plaintiffs have knowledge of the injury caused, but cannot know the source or cause of the defect that caused the harm. *See Bailey v. Janssen Pharmaceutica, Inc.*, 288 F. App'x 597, 605 (11th

Cir. 2008). It is unfair to hold all plaintiffs to the same high standards found in cases where specific knowledge of the elements of the charge are gained through first-hand experience prior to the time of pleading. Those cases are incompatible with the cases where specific knowledge of the exact cause of the injury cannot be discovered until after discovery.

Additionally, the holding in *Iqbal* is distinguishable on similar grounds. The claim in *Iqbal* was that government agents discriminated against the defendant on the basis of religious affiliation and race. *Iqbal*, 129 S.Ct. at 1942. Discrimination law requires a proof of showing of the act of discrimination that forms the basis of the claim. 129 S.Ct. at 1948. The cause of the harm is evident to the plaintiff because he suffered the discrimination personally. 129 S.Ct. at 1942. Again, this is contrary to the position of the Plaintiffs in the case at bar, where, without opportunity to access discovery, it would be next to impossible for the Plaintiffs to ascertain the cause of the defect in the product and the sufficiency of the Defendant's testing procedures.

For these two cases, it was entirely appropriate to establish higher pleading standards in these highly technical areas of law. The plaintiff in those cases can state fact-specific pleadings because the facts of the act that gave rise to the claim are evident to the plaintiff. *See Iqbal*, 129 S.Ct. at 1942; *Twombly*, 550 U.S. at 550. In the case at bar, the Plaintiffs are in a significantly disadvantaged position that makes it nearly impossible to survive a motion to dismiss. Also, the predicates which existed in *Twombly*, which necessitated the undoing of the precedent established by *Conley*, do not apply to a defective design claim, meaning that imposing those standards upon the Plaintiffs' claim would be improper.

2. Extending The *Twombly* Pleading Standards To Products Liability Cases Would Have Dangerous And Negative Repercussions On Products Liability Litigation And Subsequently On The Interests Of Public Safety.

This Court should not expand the use of the standards set forth in *Twombly* to design defect claims as it would essentially foreclose such claims from being brought in the future. This would remove a vital mechanism for ensuring public and consumer safety. In effectively foreclosing the avenue of a design defect claim against product manufacturers, extension of this standard would decrease the incentive for manufacturers to make safe products and would inexorably damage the purpose and rationale for the products liability system.

Products liability lawsuits serve as a financial and social disincentive to the manufacture of an unsafe or defective product. Companies know that when they place a product into the stream of commerce, they may bear responsibility for any injuries that product may cause. *Asahi Metal Indus. Co. v. Super. Ct. of Cal.*, 480 U.S. 102 (1987). This serves as a check on the actions of the manufacturer, forcing it to meet minimum standards of safety and quality, in order to avoid expensive lawsuits that hold the potential for sizeable damage awards. As such, the products liability system acts as a market force that controls the manufacture and price of goods or services. A potential seller is forced to spend additional resources to ensure that the product will not cause injuries, in order to prevent lawsuits from arising, preventing manufacturers from valuing profit over safety concerns.

Without an effective means for a consumer to seek redress for injuries sustained during use of a defectively designed product, there is no incentive for a company to expend resources to design a safe product. This would pose a serious threat to public safety and would allow corporate malfeasance to go unpunished within the legal system. Furthermore, it would deprive any means for individuals harmed by the failings of the manufacturer to fulfill assurances of safety to seek redress for the injuries they sustained.

If the *Twombly* standards were applied to defective design cases, it would allow manufacturers to abrogate liability for defective designs by effectively foreclosing most valid claims alleging a defective design. It would also force plaintiffs to prove fact-specific elements at a point in proceedings where the plaintiff is not in any position to have such facts before him.

Implementing these heightened requirements of pleading prior to the opportunity of plaintiffs to conduct discovery would run contrary to the purpose and function of the products liability system, namely to provide for public safety and protect consumers from dangerous products

B. Even If The Plaintiffs' Claims Are Viewed Under The Standard Espoused By *Twombly*, The Plaintiffs Stated A Sufficient Cause Of Action And The Court Of Appeals Erred In Granting the Defendant's Motion To Dismiss.

Even if the Court were to consider the motion to dismiss on its merits and apply the applicable sections of the Federal Rules of Civil Procedure and the standards created in *Twombly* and *Iqbal*, the Plaintiffs sufficiently stated a claim of a design defect, and, as such, the Court of Appeals erred in granting the Defendant's motion to dismiss. Under a plain language reading of the sections of the Federal Rules that govern pretrial motions, the Plaintiffs sufficiently pled a cause of action against the Defendant for a design defect regarding the vaccine administered. Additionally, even though the language set forth in *Twombly* and *Iqbal* elevated pleading requirements, the Plaintiffs made fact-specific pleadings that meet even those standards. Under the language of those decisions, the Plaintiffs' claim does not constitute the "legal conclusions" prohibited by *Twombly*. *Twombly*, 550 U.S. at 550. Rather, it complies with the language of *Iqbal*, in that it plausibly states on its face that the injury occurred and that the Defendant was liable for the misconduct alleged. *Iqbal*, 129 S. Ct. at 1949.

1. The Plaintiffs' Pleadings Fully Allege A Valid Claim Against The Defendants, Particularly When Viewed As Governed By The Federal Rules Of Civil Procedure.

The Federal Rules of Civil Procedure that govern motions to dismiss set forth clear and unequivocal language regarding what the motion court must consider when making those decisions. These Rules create a system favorable to plaintiffs, as they do not permit courts to make determinations regarding the likelihood of the plaintiff's success or failure. *See Twombly*, 550 U.S. at 555. They are intended as means of preventing frivolous claims, but "pleading rules are not meant to impose a great burden on the plaintiff." *Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 347 (2005).

The Federal Rules of Civil Procedure lay out the minimum requirements for a claim to be sufficient. Under the Federal Rules of Civil Procedure, in order to state a valid claim for relief, a plaintiff need only make "a short and plain statement of the grounds for a court's jurisdiction, . . . a short and plain statement of the claim showing the pleader is entitled to relief, and a demand for the relief sought . . . ." Fed. R. Civ. P. 8(a)(1)-(3). The decision in *Twombly* did not replace this as the governing language for statements of a sufficient claim – it merely increased the standards needed for a statement to meet the provisions of Rule 8(a)(2). *Iqbal*, 129 S. Ct. at 1955; *see also Twombly*, 550 U.S. at 557. Rule 8(d) further expounds the limited nature of the requirements for a sufficient pleading, as it provides that "[e]ach allegation must be simple, concise, and direct. No technical form is required." Fed. R. Civ. P. 8 (d).

Furthermore, courts adjudicate motions pursuant to Rule 12(b)(6) on a determination of whether the plaintiffs could potentially merit relief, not on the likely outcome of the case. This is achieved through standards imposed on the court when considering these motions. However,

"when a federal court reviews the sufficiency of a complaint, . . . its task is necessarily a limited one. The issue is not whether a plaintiff will ultimately prevail but whether the claimant is entitled to offer evidence to support the claims." *Scheuer v. Rhodes*, 416 U.S. 232, 236 (1974), *aff'd*, 671 F.2d 212 (6th Cir. 1982). Primarily, the facts must be read in the light most favorable to the plaintiff. *Christopher v. Harbury*, 536 U.S. 403 (2002); *see also Leatherman v. Tarrant County Narcotics Intelligence & Coordination Unit*, 507 U.S. 163, 164 (1993). Also, the court must assume that all the facts in the pleading are true.[8] That standard was extended by this Court in *Hishon v. King & Spalding*, 467 U.S. 69, 73 (1984) to establish that the court must consider any facts that could be proven consistent with those allegations, meaning the court cannot dismiss if the claim is sufficient, but lacking in facts that could come out during discovery.[9] The purpose of the pleading is not to provide detail of the evidence to be presented or a detailed description of the plaintiff's case against the defendant. Rather, its purpose is to give the defendant fair notice of the basis of the claims against him and the grounds on which they rest.[10] This Court established a principle that sought to avoid forcing "a plaintiff, in order to survive a motion to dismiss, to plead more facts than he may ultimately need to prove to succeed on the merits." *Swierkiewicz v. Sorema N.A.*, 534 U.S. 506, 506 (2002). These court interpretations of the standards of the Federal Rules of Civil Procedure ensure that in considering motions to dismiss, courts cannot and do not consider the potential outcome of a claim, but rather whether the allegations contained could plausibly constitute a sufficient claim. *See Twombly*, 500 U.S. at 555; *Iqbal*, 129 S. Ct. at 1949.

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[8] *Erickson v. Pardus*, 551 U.S. 89, 93 (2007); *see also Twombly*, 550 U.S. at 555; *Neitzke v. Williams*, 490 U.S. 319, 327 (1989); *Scheuer*, 416 U.S. at 236.

[9] "A court can only dismiss a complaint if it is clear that no relief could be granted under any set of facts that could be proved consistent with the allegations." *Hishon*, 467 U.S. at 73.

[10] *Erickson*, 551 U.S. at 93; *Dura Pharmacuticals, Inc.*, 544 U.S. at 346; *Twombly*, 550 U.S. at 555.

The Plaintiffs in the instant case stated the basis of the claim against the Defendant – namely that the Defendant failed to adequately test the vaccine and that the failure to test did not reveal the design defect, ultimately causing their daughter's injuries. (R. at 4.) This specifically states factual claims that are sufficient to warrant relief if all the facts are proved, as there is a sufficient nexus between the defendant's negligence and the injury caused. If all of the facts in the claim are assumed to be true, then the Plaintiffs stated a claim under the law in showing the injury, the causation and the actions of the defendant that gave rise to the injury. As such, the Plaintiffs' sufficiently pled a claim when viewed in light of the clear language of the Federal Rules of Civil Procedure and the historical interpretations this Court. Therefore, the Court of Appeals erred in granting the Defendant's motion to dismiss on grounds of failure to state a claim.

2. The Plaintiffs' Claim Meets The Standards Established In *Twombly* and *Iqbal* By Stating Sufficient Allegations As To Constitute A Valid Claim.

The Plaintiffs' claims meet the requirement laid out in *Twombly* because they are specific allegations of the Defendant's misconduct and the injury it caused. As Justice Souter described in the dissent in *Iqbal*, "*Twombly* does not require the court to consider whether factual allegations are probably true. We made it clear, on the contrary, that a court must take the allegations as true." *Iqbal*, 129 S. Ct. at 1959. If the allegations made in the Plaintiffs' claim were taken as true, then the Plaintiffs' claim would contain sufficient pleadings and not legal conclusions, meaning that it meets even the heightened pleading standards established by *Twombly*.

In order to proceed to the discovery stage under the new pleading standards, the plaintiff must state enough facts to raise a reasonable expectation that discovery will reveal evidence of

necessary elements. *Twombly*, 550 U.S. at 562. While the claim "must be more than unadorned the-defendant-unlawfully-harmed-me accusations," 129 S. Ct. at 1949, the pleading standards of Rule 8 do "not [require] 'detailed factual allegations.'" *Id.* The standards espoused by *Twombly* and *Iqbal* did not remove the provisions of the Federal Rules of Civil Procedure, but did put new standards into place requiring more fact-specific pleadings in order to survive a motion to dismiss. *See Twombly*, 550 U.S. at 555.

The Plaintiffs make fact-specific allegations of the injuries caused by the defective design – namely the symptoms exhibited by Estella Marie Cooks.[11] These mirror the recognized symptoms of mercury toxicity in children. *See* Department of Health and Human Services, A Warning About Continuing Patterns of Metallic Mercury Exposure, *available at* www.atsdr.cdc.gov/alters/970626.html#hdma. The thimerosal in the vaccine is 50% mercury and the Plaintiffs claim that the mercury in the vaccine caused their daughters' symptoms. (R. at 4.) They make specific claims that the defendant failed to adequately test the safety of administering vaccines with this amount of mercury in it to young children. (R. at 4.) They raise enough facts in alleging the injuries and the timing of those injuries in relation to the administering of the vaccine as to demonstrate a reasonable showing of causality.

Furthermore, the Plaintiffs' allegation that the injuries were caused by mercury toxicity is a factual allegation that must be accepted as true. *Twombly*, 550 U.S. at 555. In light of these factual pleadings, it meets the required standard, in that it raises a reasonable expectation that discovery will reveal evidence of necessary elements. *Id* at *562.* It is a reasonable expectation that discovery will reveal testing procedures and how those procedures either accounted for or

[11] Those symptoms include neurological injuries, developmental delays, learning disabilities, social delays and deficits, the impairment of motor skills, gastrointestinal illness and immune system dysfunction. (R. at 1.)

failed to account for the risks this vaccine and its dose of mercury posed when administered to young children.

This is further demonstrated by the joint statement of the American Academy of Pediatrics and the United States Public Health Service stating that thimerosal containing vaccines should be removed from the market as soon as possible due to the concerns over mercury toxicity among children. Joint Statement of the American Academy of Pediatrics (AAP) and the United States Public Health Service (USPHS), 10 Pediatrics 568 (1999). In light of this warning from the medical community, the Defendant would have been aware of the risk of thirmerosal in vaccines and either failed to account for those risks in its testing procedures, or it understood the risks and adequately tested for those risks. Either way, there is a reasonable expectation that discovery will produce evidence of the necessary element of the adequacy of the testing. As such, the claim contains sufficient pleadings as to meet the high burdens of *Twombly* and *Iqbal*. The Court of Appeals erred in granting a motion to dismiss for failure to state a claim, even if those standards are imposed in a defective design case.

CONCLUSION

For all of the reasons set forth above, this Court should affirm the part of the decision of the Court of Appeals for the Thirteenth Circuit holding that the National Childhood Vaccine Act of 1986 does not preempt state regarding design defect claims. However, this Court should reverse the decision of the Court of Appeals applying the *Twombly* pleading rules and dismissing Plaintiffs' case. This case should be remanded to the United State District Court for the District of Grace for rehearing under applicable pleading requirements.