No. XX-XXXX

# In the
# Supreme Court of the United States

FIREFLY SYSTEMS, INC.,

*Petitioner,*

v.

*IN RE* ESTATE OF ZOE WASHBURNE,

*Respondent.*

**On Writ of Certiorari to the United States Court of Appeals For the Thirteenth Circuit**

## BRIEF FOR RESPONDENT

Counsel for
Respondent
Team No. 14

## QUESTIONS PRESENTED

I. Under the state of Haven's conflict of laws analysis, does the state of Haven or the State of Grace's substantive law govern the resolution of this case?

II. Has the Respondent stated a claim for strict products liability upon which relief can be granted, or does the claim require an additional showing?

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## STATEMENT OF THE CASE

This is a wrongful death case that involves an electronic medical recordkeeping system that failed to accurately produce medical records. (R. at 4). Petitioner, Firefly Systems Inc., is a software company that records and digitizes patients medical records which are then stored on Firefly's server. (R. at 3). Firefly fully integrates its system with hospitals that buy the software, but hospitals and doctors aren't paying customers are only able to access the server through a web portal. (R. at 3). However, the medical records that are accessed via the web portal do not always match those stored on Firefly's local server. (R. at 4). In the case at hand, this discrepancy caused the death of Zoe Washburne, a twenty-six year old middle school teacher. (R. at 4).

Respondent, Ms. Washburne's estate, brought this wrongful death action in the Peterson County Court of Common Pleas in Haven against Petitioner. Petitioner's complaint contained three claims: (1) breach of express warranty by Firefly; (2) breach of implied warranty of merchantability; and (3) strict product liability based upon a manufacturing, design, and warning defect. (R. at 4). Petitioner removed the case to the United States District Court for the District of Haven based on diversity of citizenship, pursuant to 28 U.S.C. § 1332. (R. at 4). On March 18, 2009, Petitioner filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief can be granted. (R. at 5). Respondent filed a response the following day. (R. at 5). On March 20, 2009, the Haven district court granted Petitioner's motion, ruling that Haven substantive law applied under Haven's conflict of law rules and that Respondent had failed to state a claim upon which relief can be granted. (R. at 10). Respondent appealed the decision, claiming that Grace substantive law applied to the litigation, and that Respondent had stated a valid claim for relief. (R. at 10). The United States Court of

Appeals for the Thirteenth Circuit—Judge Saff, Nia, and Early presiding—affirmed the district court's dismissal of the express warranty claim but reversed and remanded the strict product liability claims and implied warranty of merchantability claims. (R. at 13).

## SUMMARY OF THE ARGUMENTS

The court of appeals properly held that Grace substantive law governs the resolution of this case. In applying Haven's choice-of-law rules, the court of appeals correctly determined that Grace has the most significant relationship with the litigation. Grace is the location of the injury because Respondent's wrongful death occurred in Grace and Respondent was unaware of the penicillin injection that occurred in Haven. Further, the location of the conduct causing the injury bears little significance to this litigation because Respondent's presence in Haven was merely fortuitous. Respondent was domiciled in Grace, worked in Grace, and her primary care physician is located in Grace. Similarly, the relationship between the parties was established in Grace. Finally, Grace's interest in protecting its citizens from manufacturers of defective products is furthered by the court of appeals decision.

Under Grace's substantive law, the Respondent does not need an additional showing to state a claim for relief. The court of appeals was correct in allowing Mrs. Washburne's strict product liabilities claim to circumvent a Fed. 12(b)(6) motion to dismiss. In Grace, § 402(a) of Restatement (Second) of Torts governs. To establish a design defect claim, Grace requires a hybrid of a risk-utility and consumer expectations test. The Respondent has plead enough facts to comport with the plausibility standard of *Bell Atlantic Co., v. Twombley*. Moreover, regardless of which risk-utility test the Respondent decides to use to establish a claim, either a narrow "cost-benefit" risk-utility test or a broader risk-utility test using the Wade factors, Mrs. Washburne has

still proven enough in her § 402(a) claim so that it rises to the level of plausibility that relief may be granted.

Alternatively, even the Restatement (Third) of Torts applies, Mrs. Washburne still does not need an additional showing because her defective design claim comports with the *Twombly* plausibility standard. Under Haven law, in order to establish a design defect the Respondent needs to show that there is a reasonable alternative design. There are facts on the record that prove a reasonable alternative design is available: the IBM software system. Therefore, there does not need to be an additional showing of facts under the Restatement (Third) of Torts.

## STANDARD OF REVIEW

A dismissal for failure to state a claim pursuant to Fed. R. Civ. P 12(b)(6) is reviewed *de novo. Bell Atlantic Corp., v. Twombly,* 550 U.S. 544 (2007).

## ARGUMENT

### I. The Court of Appeals Properly Held that Grace's Substantive Law Governs the Resolution of this Case

In an action based upon diversity of citizenship a district court must apply the substantive law, including choice-of-law rules, of the state in which it sits. *Klaxon Co. v. Stentor Elec. Mfg. Co*., 313 U.S. 487, 495-96, (1941); *Day & Zimmerman, Inc. v. Challoner*, 423 U.S. 3, 4 (1975). This case came before the United States District Court for the District of Haven, so Haven choice-of-law rules apply. (R. at 4). However, before a conflict-of-laws issue arises, an actual conflict between the laws of the interested states must exist. *Oil Shipping (Bunkering) B.V. v. Sonmez Denizcilik Ve Ticaret A.S.*, 10 F.3d 1015, 1018 (3d Cir. 1993). If the laws of the forum state and those of the other interested state do not differ, there is a "false conflict" and the court need not decide the choice-of-law issue. *In re Complaint of Bankers Trust Co*., 752 F.2d 874, 882 (3d Cir. 1984).

In this case, an actual conflict exists between the relevant products liability laws of Haven and Grace. (R. at 5). Haven uses the Restatement (Third) of Torts: Products Liability, while Grace relies on the Restatement (Second) of Torts § 402A. (R. at 6). Under the Restatement (Third) of Torts: Products Liability, a plaintiff may bring suit against a manufacturer or seller of a defective product under the following theories: (1) manufacturing defect, (2) design defect, (3) inadequate warning or failure to warn. RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIAB. § 2 (1998). Further, Haven law requires a plaintiff to show that a reasonable alternative design was available. *Id*. Conversely, Grace law creates strict liability for sellers of a defective product even if the seller exercised all possible care in the preparation and sale of the product. RESTATEMENT (SECOND) TORTS § 402A cmt. a (1965). Although, Grace law does differentiate between manufacturing, design, and warning defects, a plaintiff is not required to show a reasonable alternative design. (R. at 12). Under these two differing approaches, the outcome of the case could be affected. Therefore, because a true conflict of law exists between Haven and Grace, Haven's choice-of-law rules must apply.

### A. The Court of Appeals' Decision that Grace has the Most Significant Relationship with the Litigation was Correct

The Court of Appeals properly rejected Petitioner's claim that *lex loci delicti* applies in the state of Haven. (R. at 10). According to the Haven Supreme Court in *Booker*, the state of Haven uses the "most significant relationship test" of the Restatement (Second) of Conflict of Laws (1971). *Booker v. InGen*, Inc., 241 Haven 17, 24 (2007). The Restatement (Second) of Conflict of Laws vehemently rejects the rigid rule of *lex loci delicti* as tending to produce unjust and arbitrary results. Michael Ena, Note, *Choice of Law and Predictability of Decisions in Products Liability Cases*, 34 FORDHAM URB. L.J. 1417, 1424 n.50 (2007). Under *lex loci delicti*, a court applies the substantive law of the state where the injury occurred as a matter of course.

*See id.* By ignoring all other relevant facts and interests of the parties, the outcome of cases could be harsh and oftentimes depended on entirely random and fortuitous events. *See id.* In applying the most significant relationship test, Haven courts have rejected *lex loci delicti*, in favor of a more sophisticated interest approach which more accurately reflects the primary goal of the Restatement: to select the substantive law of that jurisdiction which has the superior interest in resolution of a specific substantive issue. *See Millar-Mintz v. Abbott Laboratories,* 268 Ill.App.3d 566, (Ill. App. Ct. 1994).

Haven courts apply the law of the state with the most significant relationship to the occurrence and the parties, as set forth in the Restatement (Second) of Conflicts of Law (1971). *Booker v. InGen*, Inc., 241 Haven 17. The most significant relationship test is a multi-factor inquiry guided by policy considerations that are relevant to the choice of applicable law. *Gutierrez v. Collins*, 583 S.W.2d 312 (Tex. 1979). Section 145 sets forth contacts to be taken into account in determining the law applicable to an issue, including: (a) the place where the injury occurred, (b) the place where the conduct causing the injury occurred, (c) the domicile, residence, nationality, place of incorporation and place of business of the parties, and (d) the place where the relationship, if any, between the parties is centered. RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 145 (1971). These contacts are to be evaluated according to their relative importance with respect to the particular issue. *Id.*

Additionally, Section 6 contains the factors relevant to the choice of the applicable rule of law: (a) the needs of the interstate and international systems, (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of

result, and (g) ease in the determination and application of the law to be applied. RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 6 (1971). These principles are to be applied with respect to the interests of the parties involved, the public policy of the states at issue, and any other factors the court deems relevant.

**1. The Injury Occurred in the State of Grace**

The first contact to be considered in determining the state with the most significant relationship to the litigation is the location of the injury. RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 145(a) (1971). This case arises out of the wrongful death of Zoe Washburne, which unquestionably occurred in the state of Grace. (R. at 4). Ms. Washburne's death is the harm that was caused by Firefly's breach of duty. Therefore, the injury Ms. Washburne suffered was her sudden and tragic death. The court of appeals properly rejected Firefly's argument that the injury at issue was the penicillin injection that occurred in Haven. (R. at 5). With no warning of Ms. Washburne's penicillin allergy, doctors administered penicillin to avoid the risk of infection. (R. at 4). The hospital staff immediately administered epinephrine, alleviating Ms. Washburne's consequent respiratory problems. (R. at 4). Firefly ignores the fact that Respondent seeks recovery for the wrongful death caused by Firefly's defective product. (R. at 4). If Respondent sought recovery for the initial respiratory problems or the epinephrine injection, then perhaps Firefly's argument would stand to reason. The court of appeals properly dismissed this argument and decided that this is not the case. (R. at 11).

Similarly, the court of appeals' decision properly rejected Firefly's argument that Grace could not be the location of the injury because the penicillin injection occurred in Haven. (R. at 11). Many jurisdictions acknowledge that a legally recognized injury only occurs when the plaintiff suffers an actual loss. *Town of Thornton v. Winterhoff,* 406 Ill. 113, 119 (1950); *Heil v.*

*Morrison Knudson Corp.,* 863 F.2d 546, 550 (7th Cir. 1988). A similar principle is reflected in the statute of limitations. For many jurisdictions facing latent or delayed injury cases, a cause of action does not accrue until an injury becomes manifest and a plaintiff learns of it. *Montgomery v. Wyeth,* 580 F.3d 455, 459-61 (6th Cir. 2009); *Millar-Mintz v. Abbott Laboratories,* 268 Ill.App.3d 566 (Ill. App. Ct. 1994)*; Vasalle v. Celotex Corp.,* 515 N.E.2d 684 (1st Dist. 1987); *Leamanczyk v. A.H. Robins Co. Inc.,* 596 F.Supp. 365, 367 (N.D. Ill. 1984); *Hobby v. Johns-Manvilie Sales Corp.,* 573 F.Supp. 53 (S.D. Ill 1983). In *Millar-Mintz*, Marianne Millar's mother lived in New York when she ingested diethylstilbestrol (DES) while pregnant with the Marianne. *Millar-Mintz,* 268 Ill.App.3d at 567. As an adult Marianne was diagnosed with vaginal adenosis, a benign condition associated with prenatal DES exposure. *Id*. After failing to get pregnant, Marianne moved to California where her doctor informed her that the prenatal exposure to DES had rendered her sterile. *Id* at 568. In a products liability suit against the pharmaceutical company, Marianne argued that her place of injury occurred in New York *in utero*, and therefore New York law should apply. *Id* at 570. The court disagreed holding:

> a legally recognized injury occurs only when the plaintiff has suffered an actual "loss." When a plaintiff's injury is latent, i.e., does not manifest itself until some time after defendant's alleged wrongful act occurred, the plaintiff's cause of action is said to accrue when plaintiff knows or reasonably should know he or she has been injured. This "discovery rule" obtains with respect to latent physical injuries regardless of whether the plaintiff's injury is sustained as the result of a single traumatic event or several ostensibly innocuous circumstances.

*Id* at 570-71. The court held Marianne's injury could not have occurred in New York because she did not discover her injury until she left the state. In this case, there is no indication that Ms. Washburne was ever made aware that she was injected with penicillin. (R. at 4). The injection was administered while she was still unconscious following surgery. (R. at 4). Even if Ms. Washburne or her parents had been aware of the penicillin injection, this would not have given them notice of the injury. (R. at 2). Although the second allergic reaction was related to the first,

biphasic anaphylaxis is rare and unpredictable. Due to the impossibility to forecast biphasic anaphylaxis, the hospital staff determined Ms. Washburne had been completely restored to health and she was released from the hospital. (R. at 4). The surgeon, the surgical assistants, and the on-call medical staff all failed to diagnose a potential second reaction. (R. at 4). Therefore, it is unreasonable to argue that Ms. Washburne was ever aware that a second reaction was possible.

### a. The Court of Appeals' Decision Does Not Encourage Forum Shopping

Although biphasic anaphylaxis is rare, latent or delayed injuries are not uncommon in personal injury cases. In *Robinson v. Mcneil Consumer Healthcare*, Judge Richard Posner acknowledged that notice of an injury can determine the place where the injury occurred. *Robinson v. McNeil Consumer Healthcare,* 615 F.3d 861, 866 (7th Cir. 2010). Courts that do not recognize this rationale reason that such practice would encourage forum shopping by the plaintiff. *Id.* The plaintiff in *Robinson* was diagnosed with a debilitating disease while living in Virginia. *Id.* After being made aware of her condition, the plaintiff moved to Illinois and filed suit against a pharmaceutical company. *Id* at 864. Judge Posner rejected plaintiff's claim that the place of injury was Illinois reasoning that to do so would open vistas of forum shopping. Severely injured persons would move to the state whose law was most favorable to their tort claim and argue that that state had the most significant relationship. *Id* at 866. However, the facts in this case are distinguishable from *Robinson*, and forum shopping is not a risk for the court in this case.

Here, Ms. Washburne was driving back home to Grace when she unexpectedly perished (R. at 4). Ms. Washburne had no knowledge of the initial allergic reaction and had no reason to suspect the occurrence of the biphasic anaphylaxis. (R. at 4). Because, Ms. Washburne lived and worked in Grace, her homecoming was a natural occurrence that was not predicated on bad

intentions. (R. at 2). Rejecting Grace as the place of injury would not serve the interest of discouraging forum shopping by plaintiffs as Petitioner claims.

### 2. The Location of the Conduct Causing the Injury is Merely Fortuitous

Section 145 of the Restatement (Second) of Conflicts of law requires courts to consider the location of where the conduct causing the injury occurred. RESTATEMENT (SECOND) OF CONFLICTS OF LAWS § 145(b). If a location of the conduct causing the injury is "merely fortuitous" or cannot be ascertained, the location bears little relation to the occurrence and the parties. RESTATEMENT (SECOND) OF CONFLICTS OF LAWS § 146 cmt. e (1971).

The Restatement (Second) of Conflicts of Law requires a qualitative analysis of all significant contributing factors to resolve a potential ambiguity in determining the location of the conduct causing the injury. *Id.*

In *Hataway v. McKinely*, a Tennessee resident was killed in a scuba diving accident during on a class trip to Arkansas. *Hataway v. McKinley,* 830 S.W. 2d 53, 54 (Tenn. 1992). The Supreme Court of Tennessee rejected the defendant's claim that the conduct causing the injury occurred in Arkansas. *Id* at 60. The court held that the because the scuba diving class consisted of Tennessee residents and the class trip was to begin and end in Tennessee, the fact that the conduct causing the injury occurred in Arkansas was merely a fortuitous circumstance. *Id.* Similarly, an Iowa court found the location of the conduct that caused the wrongful death of a child, was merely fortuitous because the defective motor home that caused the injury was being taken on a trip that was to begin and end in Colorado. *Jones ex rel. Jones v. Winnebago Indus., Inc.,* 460 F. Supp. 2d 953, 963 (N.D. Iowa 2006). In this case, although Ms. Washburne's field trip brought her to Capitol City Haven, the trip was to begin and end in the state of Grace (R. at 3). The fact that Ms. Washburne suddenly struck ill with appendicitis in Haven bears little

relation to the occurrence of the injury. *See Jones*, 460 F. Supp. 2d 963.

Further, University Medical Center in Haven did not have a direct relationship with Firefly. The hospital staff had to retrieve Ms. Washburne's medical file via the web portal access. (R. at 3). Web portal access is distinct from direct access to Firefly's servers, and is reserved for healthcare providers who do not have a direct relationship with Firefly. (R. at 3). It is foreseeable that any hospital in the nation could access Firefly's database to retrieve medical records via the web portal. (R. at 3). So, Ms. Washburne's defective medical records could have found its way into the hands of a doctor in Grace just as easily as Haven. Therefore, the location of the conduct causing the injury is merely fortuitous and bears little significance to the case at hand.

**3. The Remaining Contacts Weigh in Favor of Grace**

Section 145 of the Restatement (Second) of Conflict of Laws requires additional consideration of the following contacts: the domicile, residence, nationality, place of incorporation and place of business of the parties; and the place where the relationship, if any, between the parties is centered. RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 145(c)-(d) (1971). Firefly has no contacts with the state of Haven, other than its principle place of business. (R. at 2). However, even this single contact bears little, if any significance to the litigation. Firefly mass-produces its software and does not customize the program or individually tailor it to fit different hospitals. (R. at 2). Due to Firefly's nationwide business model, the location of its principle place of business is of little importance to Firefly. (R. at 2). Moreover, Firefly did not have any relationship with University Medical Center in Haven, evidenced by the fact that the hospital staff had to obtain the medical record via the web portal. (R. at 3). On the other hand, Ms. Washburne's primary care physician had subscribed to Firefly's software and converted her

practice to Firefly's electronic medical recordkeeping system. (R. at 2). If anything, Firefly had a more significant relationship with Dr. Frye's practice in Grace than University Medical Center in Haven. Finally, the fact that Firefly was incorporated in Delaware bears no significance on this litigation. (R. at 2).

Before her death, Ms. Washburne was a middle school teacher who lived and worked in the state of Grace. (R. at 2). Also, Ms. Washburne's primary care physician, Dr. Frye, operates a medical practice in Grace. (R. at 2). In 2008, Ms. Washburn received a letter from Dr. Frye stating that Dr. Frye's practice would be converting to Firefly's electronic medical record system. (R. at 2). It was at this point that the relationship between Ms. Washburne and Firefly was established. After Ms. Washburne sent a check to Firefly in order to have her medical records digitized, Firefly then shipped the software to Dr. Frye in Grace. (R. at 3). In all likelihood, Ms. Washburne had no idea that Firefly existed until she received the letter. However, because Firefly aggressively marketed its product nationwide and undercut competitors with lower prices, Ms. Washburne and Firefly crossed paths. (R. at 2). Or put another way, Ms. Washburne was minding her own business while living, working, and receiving primary medical care in Grace until Firefly took active steps to enter her life. (R. at 2). While Firefly might deny this illustration as too simplistic, the court of appeals seemed to recognize its truth by stating Ms. Washburne "is domiciled in Grace, works in Grace, her primary care physician is located in Grace, and the relationship between the parties was formed in Grace. As a result of these factors, Grace law applies to the resolution of this case." (R. at 11). The court of appeals properly held that in light of these factors, Grace has the most significant relationship to the litigation.

**4. Policy Interest Supports the Court of Appeals Decision**

The purpose of analyzing the § 145 contacts is to determine their bearing for the guideposts of § 6. *Cornett v. Johnson & Johnson,* 414 N.J. Super. 365, (2010). Section 6 requires courts to consider: (a) the needs of the interstate and international systems (b) the relevant policies of the forum, (c) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue, (d) the protection of justified expectations, (e) the basic policies underlying the particular field of law, (f) certainty, predictability and uniformity of result, and (g) ease in the determination and application of the law to be applied. RESTATEMENT (SECOND) OF CONFLICT OF LAWS § 6 (1971). Both Ms. Washburne and her parents were longtime Grace residents. (R. at 4). Most significantly, Ms. Washburne perished in Grace. (R. at 3). Grace has a substantial interest in providing its residents relief for injury caused by a wrongdoer. In adopting § 402A, Grace's legislature imposed strict liability for sellers of a defective product. (R. at 11). By requiring a lower standard, Grace law focuses on protecting citizens from defective products, by providing an effective means to relief.

Further, Grace's interest in weighing these concerns applies to all in-state conduct by manufacturers, regardless of whether they are residents. Firefly marketed its software in Grace where Dr. Frye utilized Firefly's system. (R. at 2). Grace's interest is supported by requiring manufacturers of defective products to bear the cost of their wrongful conduct, particularly where the wrongdoer is able to spread the social cost of the product among those who consume it and thereby benefit from it. Also, Grace has an interest in preventing future harms from similar manufacturers. Applying Haven law would thus threaten the values of uniformity and predictability that are key interests of Grace's judicial system. Ms. Washburne had an established life in Grace, while Firefly's business is predicated on aggressively marketing nationwide. (R. at

2). Firefly initiated its businiess relationships by marketing to doctors in this like Dr. Frye. (R. at 2). To hold Ms. Wasburne subject to Haven laws would merely because she sent Firefly a check for twenty-five dollars does not stand to reason.

The court of appeals properly rejected Petitioner's argument that the public policy benefits of electronic medical records systems were implicated in this case. (R. at 5). University Medical Center, where Ms. Washburne was treated, did not have Firefly's software. (R. at 3). Even if Haven has an interest in benefiting from electronic medical records systems, these interests would not be affected by allowing this claim.

## II. The Court of Appeals Properly Held that Respondent Stated a Claim for Strict Products Liability upon Which Relief can be Granted.

Strict products liability and the differing standards promulgated in the Restatement (Second) and Restatement (Third) of Torts has led to varying tests to determine what a product defect actually is. The Restatement (Second) of Torts, which the state of Grace adopted, does not differentiate between a manufacturing, warning, or design defect. Rather, it states that "one who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property. . ." RESTATEMENT (SECOND) OF TORTS § 402(A) (1965). In contrast, the Restatement (Third) of Torts, which the state of Haven adopted, explicitly carves out definitive sections for each strict liability claim. RESTATEMENT (THIRD) OF TORTS § 2(A-C) (1998). Thus, the Respondent must show is different depending on whether Grace or Haven substantive law applies.

In order to understand the complexity of the issue at hand, it is important to quickly discuss the development of the two Restatements. First, under § 402(a) of the Restatement

(Second) of Torts, two tests have evolved in order to prove a design defect claim: the risk-utility test and/or the consumer expectations test. There is variance amongst the states regarding what standard is appropriate and, more importantly, what legal factors apply in proving the adopted tests. Dominick Vetri, *Order Out of Chaos: Products Liability Design-Defect Law*, 43 U. Rich. L. Rev. 1373 (2009). Under a risk-utility analysis, some courts have adopted the seven broad "Wade" factors. David G. Owen, *Design Defects*, 73 Mo. L. Rev. 291, 317 (2008). Other courts, however, "almost always properly restrict their analysis to the narrow costs and benefits of some particular untaken design precaution." *Id.* at 315. Thus, the crux of the risk-utility debate is whether or not to apply a narrow test, or the broad "Wade" factors. Over the years, a court's sole usage of the consumer expectation test has been gradually phased out. However, in more recent decisions, courts have fused or allowed a two-pronged risk-utility and consumer expectations tests to establish a design defect. *Id.* at 336. Here, Grace substantive law has adopted a hybrid of the risk-utility and the consumer expectations test. (R. at 12).

Restatement Third of Torts, however, attempts to bring consistency within products liability law. More specifically, Restatement (Third) of Torts §2(b) states that a design is defective when "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe." RESTATEMENT (THIRD) OF TORTS § 2(B) (1998). Thus, Haven law requires there be an alternative design to establish a design defect claim. (R. at 8).

Understanding the evolution of the design defect tests under both Restatements in light of the current case is important in the context of a Fed. R. Civ. P. 12(b)(6) motion to dismiss under *Bell Atlantic Corp., v. Twombly*. Under *Twombly*, the Fed. R. Civ. P. 12(b)(6) motion to dismiss

pleading standard is differentiated from mere "conjecture" to one which establishes that "relief is plausible on its face" given the underlying facts. *Bell Atlantic Corp., v. Twombly,* 550 U.S. 544, 570 (2007). Therefore, all Respondent needs to prove is that the underlying facts are enough to allege a plausible claim for relief. Here, Mrs. Washburne fulfills the *Twombly* standard based on the facts alleged under Grace law, and, in the alternative, Haven law.

### A. Respondent has Successfully Proven that the Facts Pled Below are Sufficient Enough to Establish a Claim for Which Relief May be Granted under a §402(a) Products Design Defect Risk-Utility Analysis.

Grace law has explicitly adopted a combination of the consumer expectations test and a risk-benefit analysis under § 402(a). (R. at 12). However, to fully grasp how a complainant can prove relief under § 402(a), it is important to divide the tests into two separate analysises. First, a product is defectively designed under a risk-benefit test if the risk or danger inherent in the design exceeds the manufacturer's burden in making the design of the product safer. *Barker v. Lull Eng'g Co.,* 573 P.2d 443, 456 (Cal. 1994). Under a narrow "cost-benefit" risk-utility analysis it must be economically feasible for the manufacturer to make a product safer given the harm the product has caused or has the potential to cause. Therefore, even if Grace substantive law applies Mrs. Washburne must prove that the facts alleged below are enough to satisfy a plausibility standard under a "cost-benefit" risk-utility test. Mrs. Washburne has effectively done so.

The mere notion that a product may harm a consumer does not in and of itself make a product defective as a matter of law. The "overall likelihood of injuries and the seriousness of the injuries" is the relevant threshold analysis in determining how unsafe a product is. *Kagan v. Harley Davidson, Inc.,* No. 07-0694, 2008 U.S. Dist. LEXIS 63932, at *9 (D. Pa. Aug. 20, 2008). Mrs. Washburne suffered the ultimate harm directly related to the lack of a warning

system in Firefly's software. Her death by biphasic anaphylaxis was induced by the shot of penicillin due to the absence of her allergy in the Firefly data records that thus did not warn the operator that the known allergy field was left empty. However, the seriousness of one person's injury must also be weighed against the likelihood the harm will reoccur in others. Firefly's system is "mass-produced" and aggressively marketed to hospitals (R. at 2). Therefore, the likelihood, therefore, for harm to occur again is great.

However, the harm suffered must also be weighed against the burden, or economic feasibility, of making the product safer. Under this "cost-benefit" type of risk-utility analysis the burden on Firefly to incorporate a safety device in its software in order to catch potential error is slight. Arguably, the same system with higher safety standards used by IBM is only 10% more costly than Firefly's. (R. at 3). Further, the record did not fully indicate that the increased cost of IBM's software is directly linked to the "final check flag system." (R. at 3). Therefore, the cost of making Firefly's software safer is inconsequential given the likelihood of harm.

The harm Mrs. Washburne suffered, the likelihood of the harm to persist, and the economic feasibility of making the product safer is more than what is required under the plausibility standard. Because Mrs. Washburne does not need any additional showing, the factual allegations are enough to "raise a right of relief above the speculative level." *Twombly*, 550 U.S. at 555. Thus, the court of appeals appropriately allowed a claim for strict products liability to be granted.

**1. Even if the broader "Wade" Factors are applied in the Risk-Utility Analysis, Respondent still has Pled More than Enough Factual Allegations to Make her Claim for Relief Plausible.**

Analyzing the risk-utility test in terms of economic feasibility is only one way in which the courts balance the harm inherent in the design with the risk and utility of the design. Although couching the burden of the manufacturer in economic terms is decidedly narrower, many courts have adopted all or some of the broad "Wade" factors in their own risk-utility tests. Importantly, these factors are not wholly dispositive, that is, if one of the factors tips in favor of the manufacturer, the injured respondent is not explicitly barred from a design defect claim. The "Wade" factors include:

> (1) The usefulness and desirability of the product – its utility to the user and to the public as a whole; (2) The safety aspects of the product – the likelihood that it will cause injury, and the probable seriousness of the injury; (3) The availability of a substitute product which would meet the same need and not be as unsafe; (4) The manufacturer's ability to eliminate the unsafe character of the product without impairing the usefulness or making it too expensive to maintain; (5) The user's ability to avoid danger by the exercise of care in the use of the product; (6) The user's anticipated awareness of the dangers inherent in the product and their avoidability and, (7) The feasibility, on the part of the manufacturer, of spreading the loss or carrying liability insurance.

*Kagan v. Harley Davidson,* No. 07-0694, 2008 U.S. Dist. LEXIS 63932, at *20 (D. Pa. Aug. 20, 2008). The three most important factors in Mrs. Washburne's case are two, three, and four. Even if a court decides to use the "Wade" test to determine a design defect claim, Mrs. Washburne is still able to comport with *Twombly*, thus her claim does not need any additional showing.

Mrs. Washburne has pled enough to satisfy the plausibility standard proffered in *Twombly* under the second "Wade" factor of likelihood of harm. In *Surace v. Caterpillar, Inc.,* a man's foot was partially amputated after it was crushed by construction machinery. *Surace v. Catepillar, Inc.,* 111 F.3d 103, 1044 (3rd Cir. 1997). In weighing the second factor of the Wade test, the *Surace* Court held that the piece of machinery will cause injury every so often, and "if

so, the injury will be serious given the immensity and huge weight of the machine." *Surace*, 111 F.3d at 1049. The *Surace* Court subsequently held that the lower court improperly stated there was not a sufficient "grave risk of harm" under "Wade" factor two. *Id.* Similarly, Mrs. Washburne's injury has the propensity to occur every so often to other persons because of the wide availability of Firefly's product. (R. at 2). Moreover, Mrs. Washburne's death due to her allergic reaction is evidence that the likelihood of harm will be great. (R. at 4).

Secondly, Mrs. Washburne has pled enough to satisfy the plausibility standard proffered in *Twombly* under the third and fourth factors of the "Wade "analysis. The third and fourth factors of the "Wade" analysis are more easily discussed together rather than separately. Therefore, the proper analysis when combining the two elements is: "the availability of a substitute product which would meet the same need and not be as unsafe, and the manufacturers' ability to eliminate the unsafe character of the product without impairing its usefulness." *Street v. Sunbeam,* No. 07-2772, 2008 U.S. Dist. LEXIS 93432, at *30 (D. Pa. Nov. 13, 2008). There is a definitive product discussed in the record. The IBM system is the safer alternative design. (R. at 3). Moreover, it is entirely possible for Firefly to eliminate the unsafe characteristic of its product without impairing its usefulness given facts stated in the record. The purpose of Firefly's software is to provide an "easy and instant transmission between" of medical records in the event of an "emergency." (R. at 2). Adding a flag system will not impair the purpose of Firefly's software.

Under the alternative "Wade" approach to the risk-utility analysis, Mrs. Washburne has yet again proved that the facts alleged are enough to establish relief is plausible on its face, thus not requiring Mrs. Washburne to provide additional showing. Importantly, regardless of which

test under § 402(a) is used, the narrower cost-benefit risk-utility test, or the "Wade" factor approach, there is enough facts to establish a claim.

### B. Under the Consumer Expectations Test, Respondent Facially Establishes a Claim for Which Relief Should be Granted and Does Not Require an Additional Showing.

In analyzing a design defect claim, "Grace Courts use a combination of the consumer expectations test and a risk-benefit analysis" explicitly adopted in *Barker v. Lull Eng'g.* (R. at 12). Although other courts differ in how a complainant must establish a design defect case, Grace courts allow both tests to establish that a claim exists. Under the test, "consumer expectations consist of what an ordinary consumer would expect when using the product in an intended or reasonably foreseeable manner." (R. at 12). Accordingly, the court of appeals was correct in deciding that enough facts were established for a product defect claim under the consumer expectation test. Therefore, Mrs. Washburne does not need to show more.

It can be reasonably assumed that an ordinary consumer would expect that the electronic records should exactly match the paper copies. In fact "the issue is not whether the consumer can determine the reasonable expectations for the *technical* operation of the product, but the consumer's reasonable ability to expect the performance of the product." *Hisrich v. Volvo Cars of North America, Inc.,* 226 F.3d 445, 456 (6th Cir. 2000). The expected performance in this instance is the correct copy of the medical records transposed by Firefly's software. (R. at 12, 13). The Firefly software is manufactured to do one thing only: properly transfer medical records. In contrast a technical product, like a car, uses such a complex design that said design is beyond a layman's knowledge. Therefore, a heightened standard of evidence is not necessary because the Firefly software is not a complex product. The court of appeals properly held, under the given record, that Mrs. Washburn stated a valid claim under the consumer expectations test

and thus no further showing is necessary. Facts exist that an ordinary consumer would expect that the electronic copy of the medical records should be identical to the paper copy.

### C. In the Alternative, if the Restatement (Third) of Torts is Applicable as the Substantive Law, Respondent can Still State a Claim for Which Relief can be Granted Under §2(b).

If this court decides that the law of Haven applies, Respondent still meets the plausibility factor proffered in *Twombly*. Haven has incorporated the entirety of the Restatement (Third) of Torts. (R. at 7). Under a Haven design defects claim "a plaintiff must show that the foreseeable risks of harm by the product could have been reduced by implementing a reasonable alternative design." (R. at 8). In addition, "the omission of a reasonable alternative design renders the product unsafe." (R. at 8).

In applying the Restatement (Third) of Torts as law in Haven, the district court dismissed Mrs. Washburne's claim because she did not specifically allege or show a reasonable alternative design in her complaint. (R. at 8). However, there are enough factual allegations in the record to assume that a reasonable alternative design is stated to comply with the *Twombly* plausibility standard. The IBM system is similar to the one purported by Firefly but it is arguably safer. The "final checks and balances" of the system warns "operator's . . . of potential errors or omissions in converting the patient's record from paper to electronic format." (R. at 3). The "red flag' warning in IBM's system alerts the operator that a more serious omission, such as "known allergies" has been omitted and the system does not allow the operator to continue until he or she fixes the error. (R. at 3). Thus, an alternative design does exist to make it plausible that relief will be granted because there is an alternative warning system that reduces the foreseeable risks of harm.

Petitioner's will argue that, since Haven law applies, the strict products liability claim under a defective design theory should be dismissed under Rule 12(b)(6). However, the purpose of *Twombly* was not intended to heighten the standard of what a plaintiff must plead in his or her complaint. *See Twombly* 550 U.S. 544, 570 (2007). Rather, "it simply calls for enough facts to raise a reasonable expectation that discovery "will reveal the unlawful conduct." *Tombly,* at 556. The district court dismissed Respondent's defective design claim under the Restatement (Third) of Torts in one sentence with no analysis solely on the grounds that an alternative design was not pled (R. at 8). However, an alternative design plainly exists on the record.

## CONCLUSION

Respondents have proven that Grace substantive law applies and therefore a further showing for a products liability claim is unnecessary. For the reasons stated above, Respondents respectfully ask this Court to affirm the decision below.