No. XX-XX-XXXXX

IN THE

Supreme Court of the United States

APRIL TERM 2010

FIREFLY SYSTEMS, INC.,

Petitioner,

-versus-

IN RE ESTATE OF ZOE WASHBURNE,

Respondent.

ON WRIT OF CERTIORARI TO THE UNITED STATES
COURT OF APPEALS FOR THE THIRTEENTH CIRCUIT

BRIEF FOR PETITIONER

TEAM 1
COUNSEL FOR PETITIONER
FIREFLY SYSTEMS, INC.

QUESTIONS PRESENTED

I. Whether the state of Haven's substantive law governs this case under Haven's conflict of laws analysis.

II. Whether an additional showing is necessary for Respondent to state a claim for strict products liability upon which relief can be granted.

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STANDARD OF REVIEW

Both issues before this Court present questions of law. As such, these issues require a *de novo* standard of review. Courts of appeals review *de novo* district courts' determinations of state law. *Salve Regina College v. Russell*, 499 U.S. 225, 231 (1991). Courts of appeals review de novo a district court's legal conclusions, including the grant of a motion to dismiss. *Leibowitz v. Cornell Univ.,* 445 F.3d 586, 590 (2d Cir. 2006)

STATEMENT OF THE CASE

Statement of Facts

Ms. Zoe Washburne was thirty-year-old middle school teacher (together with her estate, "Respondent"). (R. at 2.) During childhood, she discovered she was allergic to penicillin. (R. at 2.) In the years following that discovery, she and her parents took active measures to avoid exposure to penicillin. (R. at 2.) These measures included educating herself about the penicillin allergy and notifying new doctors about her allergy. (R. at 2.) In late 2008, Respondent's primary care physician, Dr. Kaylee Frye ("Dr. Frye"), decided to digitize her patient's medical records and convert from a paper system to an electronic record-keeping system. (R. at 2.) Dr. Frye sent a letter to Respondent, explaining that the records would be converted using a system developed by Petitioner, Firefly Systems, Inc. ("Firefly"), and that Respondent could purchase a USB drive with a copy of her medial records for a twenty-five dollar fee. (R. at 2.) Firefly offers the program through mass-produced software, which is not individually tailored to specific hospitals and costs less than other companies charge for the services. (R. at 2.) Respondent purchased the USB copy of her medical records by personal check to Firefly. (R. at 2-3.) Dr. Frye then provided a paper copy of Respondent's medical records to Firefly. (R. at 3.) Once the paper copy of the medical records was given to Firefly and the records transfer was complete, Firefly shipped the software to Dr. Frye. (R. at 3.)

When Firefly receives paper records, the company works with hospitals to convert the records to digital form. (R. at 3.) Employees are instructed to verify the electronic form matches the paper records. (R. at 3.) If the "Known Allergies" field is empty, the program automatically inserts the word "NONE." (R. at 4.) The digital records are securely stored on Firefly's local server and then integrated with subscribing hospital systems. (R. at 3.) The files are also placed on a web portal to allow non-subscribing hospitals and other healthcare providers access to the records. (R. at 3.) Firefly customers are instructed to check the digital copies of the medical records and verify they are correct before disposing of the paper records. (R. at 3.)

Firefly's biggest competitor is IBM, whose product differs from Firefly's, and is ten percent more costly than the Firefly system. (R. at 3.) IBM's product is more difficult to operate and thus requires more training. (R. at 3.) One difference between the programs is that the IBM software utilizes a "final check flag system." (R. at 3.) This system reviews the inputs for possible omissions such as: hair color, eye color, family history and known allergies. (R. at 3.) The data in a flagged field must be verified before continuing with the digitization of the records. (R. at 3.)

On September 10, 2008, Respondent traveled from her home state of Grace to Capitol City, Haven. (R. at 3.) While in Haven, she began to experience acute abdominal pain, fever, and nausea. (R. at 3.) A co-worker took Respondent to the local hospital, University Medical Center ("UMC"). (R. at 3.) Respondent lost consciousness due to pain, so the co-worker provided the hospital staff with Respondent's identification, but he was unaware of her allergy. (R. at 3.) Using Respondent's driver's license, the hospital staff accessed her medical records via the online portal and made a diagnosis of appendicitis. (R. at 3.) The emergency doctor on call, Dr. Simon Tam ("Dr. Tam"), arrived at some point after the online retrieval. (R. at 3.) Dr. Tam verified the diagnosis, and determined that an emergency appendectomy would be necessary. (R. at 3.)

Following the surgery, Dr. Tam administered penicillin as a common practice to avoid post-surgical infection. (R. at 4.) Respondent then suffered a reaction to the penicillin shortly after it was administered. (R. at 4.) The hospital staff then became aware of Respondent's allergy, and she was given epinephrine to alleviate the symptoms. (R. at 4.) Respondent recovered quickly and was discharged two days later. (R. at 4.) Upon release, Respondent met with her parents and traveled back home to Grace. (R. at 4.) After crossing back into Grace, Respondent suffered a rare secondary allergic reaction, known as biphasic anaphylaxis, to the penicillin that had been administered in Haven a couple of days earlier. (R. at 4.) Respondent's parents called 9-1-1 and attempted to revive her, but Respondent did not survive the secondary reaction. (R. at 4.)

The electronic medical records used by Dr. Tam and the UMC staff were completely correct save the fact that it was missing a reference to Respondent's allergy. (R. at 4.) It is unknown why this field was blank because both the paper records and the copy of the records on Firefly's local servers contained the correct reference to the penicillin allergy. (R. at 4.)

Procedural History

Respondent brought a suit in Haven against Firefly for recovery of damages for pain and suffering, as well as wrongful death. (R. at 4.) The complaint alleged breach of express and implied warranties, as well as strict products liability for manufacturing, design and warning defects. (R. at 4.) Firefly removed the case to the United States District Court for the District of Haven. (R. at 4.) Firefly subsequently filed a motion to dismiss pursuant Fed. R. Civ. P. 12(b)(6), and Respondent filed a response the following day. (R. at 5.) The district court granted Firefly's Motion to Dismiss on March 20, 2009. (R. at 9.) Respondent then appealed to the United States Court of Appeals for the Thirteenth Circuit. (R. at 10.) On August 26, 2010, the Thirteenth Circuit affirmed the district court's opinion as to the dismissal of the express warranty claim, but reversed and remanded on the claims of implied

warranty of merchantability and strict products liability. (R. at 13.) Petitioner filed for *writ of certiorari*, and this Court granted it in April 2010. (R. at 14.)

SUMMARY OF THE ARGUMENT

The Haven choice of law analysis is used to identify the state with the most significant relationship. In this case, Haven has the most significant relationship to the case because it bears the most qualitative connection to the occurrence and the parties. Most of the contacts relating to the incident occurred in Haven and the contacts were not fortuitous.

The contacts are used in applying the choice of law principles listed in Restatement (Second) of Conflict of Laws § 6 (1971). While there are seven principles to consider, only four of the seven are relevant. The first principle is the relevant policies of the forum state. As the forum state, Haven has an interest in applying its law to the out-of-state facts in order to address whether or not an injury was caused by one of its citizens. The second principle addressed in section six is the needs of the interstate system, which is satisfied by using the most significant relationship approach. The third principle considers the relevant policies of other interested states. Grace's policies would not be hindered by application of Haven law because both Haven and Grace have adopted laws that ensure compensation for tort victims. The final important principle is whether the law to be applied is easy to determine and apply, and the district court sitting in Haven will have no problem determining and applying Haven law to this case.

There are three other principles in section six that are of lesser importance in products liability cases, but these principles are worth noting because they further support applying Haven law to this case. The principles are: the protection of justified expectations; certainty, predictability and uniformity of result; and the policies underlying tort law. In this case, neither party had a justified expectation of which law would be applied. This case involves software, so uniformity of result is not relevant to this

case. Tort law focuses on compensating tort victims, and this policy would be achieved by applying Haven's use of the Restatement (Third) of Torts: Products Liability § 2 (1998).

Under Haven law, Respondent failed to state a claim upon which relief may be granted because the complaint filed by Respondent was not sufficiently pled. For a manufacturing defect, Respondent failed to plead that Firefly's product departed from its intended design or provide evidence to make a plausible plea that an inference existed. Similarly, Respondent's claim for a design defect fails because there was also no evidence provided to plausibly plead inference of a design defect or that a reasonable alternative design existed. Respondent's claim for a warning defect fails as well because Firefly provided sufficient warnings to prevent the harm and there were no reasonable alternative warnings alleged in the complaint.

Respondent's claim for a manufacturing defect fails under Grace law because Respondent failed to plead in its complaint that the product was in an unreasonably dangerous condition. This failure to properly plead the complaint renders the claim unable to withstand a motion to dismiss under Fed. R. Civ. P. 12(b)(6). Respondent's final two claims for design and warning defects fail under Grace law because Respondent did not allege that the design or warnings did not meet the expectations of a normal consumer, and it did not plead that the risks of Firefly's product outweigh the benefits of its current design. For these reasons, Respondent failed to state a claim under both Haven and Grace law and the decision of the Thirteenth Circuit should be reversed.

ARGUMENT

I. HAVEN'S SUBSTANTIVE LAW GOVERNS THE RESOLUTION OF THIS CASE BECAUSE HAVEN BEARS THE MOST SIGNIFICANT RELATIONSHIP TO THE OCCURRENCE AND THE PARTIES.

A district court must apply the rules of the state in which it sits to determine the substantive state law to use in a diversity action. *Int'l Paper Co. v. Oullette*, 479 U.S. 481, 501 (1987). In this case,

Haven's conflict of laws rules govern the determination of whether Haven or Grace law applies. The court must first determine that an actual conflict exists between the two states before determining a choice of law issue. *Oil Shipping (Bunkering) B.V. v. Sonmez Denizcilik Ve Ticaret A.S.*, 10 F.3d 1015, 1018 (3d Cir. 1993). For an actual conflict to exist, the laws must differ substantially. *In re Complaint of Bankers Trust Co.*, 752 F.2d 874, 882 (3d Cir. 1984).

In this case, a conflict exists between Haven and Grace state tort law. Haven follows the Restatement (Third) of Torts: Products Liability (1998) and Grace follows the Restatement (Second) of Torts (1965). Under Haven tort law, Respondent must allege a reasonable alternative design while under Grace law this is unnecessary. The potential for different outcomes based on applicable state law indicates a true conflict exists.

A. Haven has the most qualitative contacts with the case because the most meaningful contacts to be taken into account in a conflict of laws analysis are located in Haven.

Haven uses the Restatement (Second) of Conflict of Laws (1971) in a choice of law analysis. This analysis begins by applying section 146 of the Restatement. *Booker v. InGen, Inc.*, 241 Haven 17, 24 (2007). Under this section, a presumption is created that the law of the place of injury controls unless another jurisdiction has a more significant relationship to the parties and the occurrence. Restatement (Second) of Conflict of Laws § 146 (1971). Specifically, section 175, states the place of injury presumption is applicable in actions for wrongful death. Restatement (Second) of Conflict of Laws § 175 (1971). This presumption doctrine, known as *lex loci delicti*, provides that the state law that governs in a case is the law of the state where the injury occurred. *Lex loci delicti* is no longer controlling law in Haven. However, through the adoption of sections 146 and 175, *lex loci delicti* is a concept embodied in Haven state law. Some courts, in adopting the Restatement's analysis of conflict of laws problems, have concluded the court should apply *lex loci delicti* in cases where it is difficult to

determine which state has the most significant relationship to the issue. *See Kennedy v. Dixon*, 439 S.W.2d 173, 185 (Mo. 1969); *see also Dorman v. Emerson Elec. Co.*, 23 F.3d 1354, 1359 (8th Cir. 1994).

A court must look to other portions of the Restatement to analyze whether a state has a more significant relationship than the state where the injury occurred, and if it does not, the laws of the place of injury will apply. Section 145 lists the contacts to consider when evaluating whether an interested state has a more significant relationship to the issue than the place of injury. There are four factors to consider under a section 145 analysis: (1) the place of the injury; (2) the place where the conduct causing the injury occurred; (3) domicile, residence, nationality, place of incorporation and place of business of parties; and (4) the place where the relationship between the parties is centered. Restatement (Second) of Conflict of Laws §145 (1971). Section 145 demonstrates that Haven has the most significant contacts to this case.

1. The injury sustained by Respondent occurred in Haven, and there is a presumption that the law of the place of injury should apply.

The injury occurred when Respondent experienced the first allergic reaction to penicillin in Haven. The weight given to the place of injury depends on the nature of the case. *In re Vioxx Prods. Liab. Litig.*, 239 F.R.D. 450, 456 (E.D. La. 2006). While in certain types of cases, such as consumer fraud, "the primary purpose of the tort rule involved is to deter or punish misconduct and therefore the place where the conduct occurred has peculiar significance. . . . On the other hand, in personal injury cases the focus shifts to compensation and therefore the place of injury has peculiar significance." *Id.* The state of injury is fortuitous when that state has no other interest in the case. *Jones v. Winnebago Indus., Inc.,* 460 F. Supp. 2d 953, 970 (N.D. Iowa 2006); *see also Rosenthal v. Ford Motor Co.*, 462 F. Supp. 2d 296 (D. Conn. 2006). However, the place of injury is more significant "when it is something more than the place of injury, i.e., when there is some other basis for that state to have an interest in the

litigation." *Jones*, 460 F. Supp. 2d at 968. In a wrongful death action, the place of the injury is important and not fortuitous when that state has other contacts to the case.

In *Jones*, the court examined a case of conflict of laws when a boy was fatally injured by the slide out room on his grandparents' camper. *Id.* at 957. The grandparents and the grandson were camping in Idaho when the accident occurred, but they planned to return to Iowa. *Id.* Idaho shared no other contacts with the case other than the fact that it was the place of injury. *Id.* The court found, "it was 'fortuitous' that the accident occurred in one state rather than some other state, where the trip began and was to end in another state." *Id.* at 970.

Respondent may try to draw a correlation between *Jones* and this case by pointing out that Respondent was only temporarily visiting Haven when the injury occurred, and she planned on returning to Grace after her trip. However, *Jones* is distinguishable from the instant case in that Idaho had no other contacts to the case; it was only the place of injury. In this case Haven is not only the place of injury; it is also Firefly's domicile, and the place of the alleged conduct causing injury. Therefore the place of injury becomes more significant in determining the choice of law, and favors applying Haven law.

2. The conduct allegedly causing the injury occurred in Haven.

The conduct allegedly giving rise to the injury and the injury itself occurred in Haven, weighing in favor of applying Haven law. When the conduct and the injury occur in the same state, that state's laws will apply unless another state has a "demonstrably dominant interest" and the policies of the other state will not be frustrated. *Vioxx*, 239 F.R.D. at 457. The place of conduct causing injury is given particular weight in ascertaining the state of applicable law in cases where the place of injury cannot be ascertained or is fortuitous. Restatement (Second) of Conflict of Laws § 145 cmt. e (1971). In cases where the conduct occurs in the same state as the injury, the Restatement is "easy to apply,"

and the local law of that state will govern the case. *Dorman*, 23 F.3d at 1358. The place of the conduct causing the injury is in dispute in cases where there are two actions that possibly caused the injury and these actions occur in different states. In cases where the dispute renders the place of the conduct causing injury unclear, some courts need not consider the conduct at all in the choice of law analysis. *Bryant v. Silverman*, 703 P.2d 1190, 1193 (Ariz. 1985). When it is easy to identify the state in which the injury causing conduct occurred, the place of conduct factor is given greater weight.

In *Bryant*, an airplane crashed in Arizona, killing some of its passengers. *Id* at 1191. The airplane manufacturer argued the cause of the crash was pilot error while the decedent's family argued the cause of the crash was the place where the pilots were trained and the policies were developed relating to equipment on the airplane. *Id.* at 1193. The court found that because the place of conduct was unclear, the conduct could have no weight on the choice of law analysis. *Id.*

The *Jones* court explained that in a products liability case, where manufacturing, design or warning defects are alleged, the conduct causing injury is the design, manufacture, and marketing of the particular product. *Jones*, 460 F. Supp. 2d at 970. Also, the place where the allegedly defective product is designed is "not without significance to the choice of law analysis." *Dorman*, 23 F.3d at 1359.

In this case, the alleged conduct causing the injury occurred in the state of Haven when the software was developed at Firefly's principal place of business. Respondent may argue that there is a dispute as to the place of conduct in this case by asserting the conduct causing injury consisted of the sale made in Grace. The product was marketed nation-wide, including in Haven and Grace, so the place of marketing lends no assistance to the analysis of this factor. However, the manufacture and design of the product occurred in the state of Haven, and this weighs further in favor of applying Haven law.

3. Firefly's domicile in Haven carries greater weight than Respondent's domicile in Grace because the injury and conduct occurred in Haven.

Weight should be given to the fact that Haven is the domicile of one of the parties because Haven has other significant contacts with this case. The Restatement tends to give particular weight to domicile in the event that contacts are grouped in one state, where that state is either the place where the conduct occurred or the place where the injury occurred. Restatement (Second) of Conflict of Laws § 146 cmts. d-e (1971).

In *Jones,* the court examined a case where the parties were grouped in different states, and the place of injury bore no relationship to the domicile of the parties. *Jones*, 460 F. Supp. 2d at 970-71. However, the place of conduct causing injury was also the principle place of business of the defendant. *Id.* at 971. The court found that this grouping of conduct and domicile were "by no means fortuitous" and it warranted more weight being given to the defendant's home state. *Id.*

This Court should decide this case in a similar manner to *Jones*, where particular weight is given to domicile when it correlates to injury and conduct. Respondent is domiciled in Grace and Firefly's domicile is in Haven. At first glance, this creates a negation of this factor because the parties have equally significant relationships to their respective domiciles. This case is similar to *Jones* in that the domicile of one of the parties has other significant contacts with the case. Therefore, particular weight should be given to Haven as Firefly's domicile because the domicile is also the place of alleged conduct and injury.

4. The center of the relationship between the parties carries no weight because the relationship is split evenly between Haven.

The ambiguous nature of the relationship between Firefly and Respondent renders the place of the relationship irrelevant in the conflict of laws analysis. When there is no connection between the nature of the relationship of the parties and the alleged defect, no weight should be given to the center

of the relationship factor. It is the relationship between the plaintiff and the defendant that matters in a conflict of laws analysis, not the relationship between or among other parties. Restatement (Second) of Conflict of Laws § 145 cmt. e (1971). When the plaintiff and defendant have no contractual or other relationship, or the injury is caused by an act done outside the course of a relationship, there is little evidence that any relationship existed between the parties. Therefore, "the combination of the plaintiff with the defendant leading to the tragic accident was merely 'fortuitous.'" *Jones*, 460 F. Supp. 2d at 971-72. In *Jones*, the contract relating to the accident involved the plaintiff's grandparents and the defendant, but the relationship between the plaintiff and the defendant was fortuitous. *Id.* at 971.

Other courts have weighed several factors in determining the center of a relationship when the nature of the relationship is not readily clear: the place of purchase, place of prescription, place of consumption, and place of harm of the product. *Vioxx*, 239 F.R.D. at 458. The court in *Vioxx* found that the center of the relationship between the parties was in the state where each plaintiff was domiciled because the domicile was likely the place where each plaintiff was prescribed, purchased, ingested and allegedly harmed by the product. *Id*. However, the court noted that the center of the relationship would likely be in the state where the manufacturer was located if the plaintiff had traveled to the state of the manufacturer, saw a doctor in that state, and been prescribed, purchased and consumed the product in the state. *Id*.

It is unclear if there is a true relationship between the parties in this case. The *Jones* holding pointed out that, in cases such as this one, the relationship can be considered fortuitous between the parties, especially when the incident does not involve a contract between the parties. The only relationship between the parties, contractual or otherwise, is the relationship that was created when Respondent wrote a check to Petitioner to purchase a USB drive copy of her medical records. Even if Respondent had not decided to purchase a copy of her medical records, Dr. Frye made the decision to

digitize all of the records in her office under the Firefly system. Dr. Tam used the medical records placed on the online portal pursuant to the relationship between Firefly and Dr. Frye. In this case, the combination of Petitioner and Respondent was merely fortuitous, and there is little basis to find any relationship between the parties.

The *Vioxx* case further demonstrates that the center of the relationship is ambiguous in this case, even if several factors are weighed in an attempt at its determination. While the product in this case cannot be prescribed or consumed as it was in *Vioxx*, there was a place of purchase and a place of harm. This provides further ambiguity to the place of relationship in the case at hand because the place of purchase was Grace and the place of harm was Haven. For these reasons, the center of relationship factor is irrelevant in this analysis.

B. The principles underlying products liability law favor application of Haven law because Haven has the superior interest in seeing its substantive law applied.

The factors under Restatement (Second) of Conflict of Laws § 6 (1971) must also be considered in order to achieve a comprehensive choice of law analysis. Section six provides that a court deciding a choice of law issue must examine: (1) the relevant policies of the forum; (2) the needs of the interstate and international forum; (3) the relevant policies of other interested states and the relative interests of those states in the determination of the particular issue; (4) ease of the determination and application of the law to be applied; (5) the protection of justified expectations; (6) basic policies underlying the particular field of law; and (7) certainty, predictability, and uniformity of result. Restatement (Second) of Conflict of Laws § 6 (1971). While it is prudent to analyze all these factors, they are not necessarily given equal weight. There are certain factors under section six that are of relatively greater importance in a tort action. *Jones*, 460 F. Supp. 2d at 972. Courts should focus on the first four factors when resolving a tort case such as this one. *Id.*

1. The relevant policies of Haven, as the forum state, favor application of Haven law.

Haven has a superior interest in applying its own law to this case. When the forum state has a dominant interest in the case through its contacts, the presumption is in favor of applying the forum state's substantive law. Courts must consider the policies of the forum state when making a choice of law determination. Restatement (Second) of Conflict of Laws § 6 (1971). A weighty reason to apply a local statute to out of state facts exists if the purposes sought to be achieved by that law would be furthered by applying it to out-of-state facts. Restatement (Second) of Conflict of Laws § 6 cmt. e (1971). The *Jones* court examined this factor and concluded forum state policies should be considered together with whether the state has the dominant interest in the determination of the particular issue. *Jones*, 460 F. Supp. 2d at 973. The court observed that this factor becomes of particular importance when the forum state is also the state that has the dominant interest in the issues in the case. *Id.* Furthermore, the defendant's home state always has a strong interest in providing a forum for redress of injuries caused by its citizens. *Jones*, 460 F. Supp. 2d at 974 (citing Stewart, *Forum Non Conveniens: A Doctrine in Search of a Role*, 74 Cal. L. Rev. 1259, 1283-84 (1986)).

In *Dorman*, the Eighth Circuit, in applying Missouri's choice of law rules under the Restatement, observed that Missouri had an interest in applying its own tort law, not only because of its interest in deterring wrongful conduct of one of its corporate citizens, but even more so because of its concern with compensating the tort victim and protecting the victim's interests. *Dorman*, 23 F.3d at 1360. Haven has a superior interest in applying its law to the case at bar by resolving an action that resulted from an injury within its borders involving the actions of one of its corporate citizens. If Firefly had anything to do with Respondent's injury, the state of Haven has a superior interest in deciding this issue and providing a forum for any redress necessary.

2. The needs of the interstate system are maintained through applying Haven law because it has a substantive connection with the issue.

As the forum state, application of Haven law would achieve the needs of the interstate system. The needs of the interstate system weigh heavily on the choice of law analysis when one state's law is so abnormal that its application would disrupt the interstate order. *Veasley v. CRST Int'l Inc.*, 553 N.W.2d 896, 899 (Iowa 1996). In addition, respect for the interstate system is maintained when the forum state has a substantive connection with the issue and chooses to apply its own law. *Id.* When a visitor to a state travels to a destination in that state, the visitor should ordinarily expect that the state's law would govern any tort that results from injury and conduct occurring there. *Malena v. Marriott Intern., Inc.*, 651 N.W.2d 850, 858 (Neb. 2002).

Haven's legislature adopted the Restatement (Third) of Torts: Products Liability (1998), so abnormality of law is not an issue. Haven has a substantive connection to the issue because it was the place of injury and the place of conduct. The needs of the interstate system would be achieved by applying Haven law to this case because Haven has these connections, Respondent voluntarily entered Haven, and the Restatement (Third) of Torts: Products Liability (1998) is a heavily accepted interpretation of the law.

3. Application of Haven law does not hinder the relevant policies of Grace.

Applying Haven law will achieve the policies of both Haven and Grace. When a forum state's applicable law would serve the interests of all the concerned states and the forum state has the most significant relationship to the case, the forum state's substantive law should be applied. In analyzing the relevant policies of other interested states, it is important that the forum state seek to reach a result that will achieve the best possible accommodation of its own policies and the policies of other interested states. Restatement (Second) of Conflict of Laws § 6 cmt. f (1971). Concurrently, it is fitting that the state whose interests are most deeply affected should have its local law applied. *Id.*

Furthermore, the content of the relevant local law of a state may be significant in determining whether that state is the one with the dominant interest. *Id.* In *Jones*, the court chose to apply Iowa law rather than Idaho law, reasoning that the policy goal of Iowa was to fully compensate tort victims, and the goal of full compensation would be thwarted by applying Idaho law, because Idaho placed caps on damages for tort cases. *Jones*, 460 F. Supp. 2d at 973-74.

In this case, the policy goals of the Restatement (Second) of Torts (1965) and the Restatement (Third) of Torts: Products Liability (1998) are congruent. They both seek to compensate tort victims of product liability cases and there is no cap on recoverable damages. Unlike *Jones*, Haven law does not put caps on the amount that can be recovered by tort victims. Therefore, the application of Haven law will adequately achieve the policies of both interested states.

4. Haven law is easy to determine and apply.

Haven's use of the Restatement (Third) of Torts: Products Liability (1998) is easy to apply in this case. The substantive law should be simple and easy to apply, but this policy should not be overemphasized since it is more important that desirable results are achieved. Restatement (Second) of Conflict of Laws § 6 cmt. j (1971). In *Jones*, the court stated that this factor is "of little importance" when there is no significant impediment in determining and applying either law. *Jones*, 460 F. Supp. 2d at 974.

There is no evidence that the Haven court will have any difficulty applying either Grace or Haven law in this case. Haven will certainly have no difficulty in applying its own law because it is the law of the state with the most significant relationship. Therefore, this factor is also likely to be of little importance in this case, but weighs in favor of applying Haven law.

C. Other principles, less relevant to products liability law, nonetheless favor application of Haven law.

While the final three factors listed in the Restatement (Second) of Conflict of Laws § 6 (1971) are less relevant in tort cases, the factors are worth consideration because they address the competing interests that states can have in the application of its laws to a particular case. These final factors lean in the favor of applying Haven law, so the presumption that the place of injury will apply is not overcome by any Grace interest.

1. Neither party had a justified expectation of the law to be applied, but the parties should have expected that Haven law would apply because the conduct and the injury occurred in Haven.

Neither party had a justified expectation, prior to the injury, of which state's law would be applied to this type of occurrence. When a person molds certain conduct to be in conformity with the laws of one state, it would be unfair to hold that person liable under the local laws of another state. Restatement (Second) of Conflict of Laws § 6 cmt. g (1971). However, this factor has no bearing on the choice of law analysis when the parties had no justified expectation of the law to be applied, and they each acted without consideration of the legal consequences of the law to be applied to their conduct. *Id.* This factor usually has no bearing in accident cases because courts recognize that accidents cannot be planned for. *Veasley*, 553 N.W.2d at 896; *see also Gordon v. Gordon*, 387 A.2d 339, 340 (N.H. 1978); *Milkovich v. Saari*, 203 N.W.2d 408, 412 (Minn. 1973).

In this case, like the automobile example stated in *Veasley,* the accident that occurred could not have been planned for. There is no evidence in this case to show that either party conducted itself in a particular way in anticipation of litigation or other legal repercussions. Nevertheless, in the context of the conflict of laws analysis, both parties should expect that the party with the most significant relationship to the litigation should apply. Haven has the most significant relationship to the case and should have its substantive laws applied.

2. Certainty, predictability and uniformity of result are not relevant concerns in the choice of law analysis because this case involves a mobile product.

Applying either Haven or Grace law would provide certainty, predictability and uniformity. The combination of the nation's federal system and a mobile society naturally results in conflicting laws. *See Jones*, 460 F. Supp. 2d at 975; *see also Veasley*, 553 N.W.2d at 896; *Cooney v. Osgood Mach., Inc.*, 612 N.E.2d 277, 279 (1993). Consequently, in cases involving mobile products, certainty, predictability, and uniformity are not realistic concerns. *Id.* Furthermore, Restatement (Second) of Conflict of Laws § 145 cmt. i (1971) comes very close to self-invalidating this factor because it observes that in choice of law, and other developing areas of the law, the development of "good rules" is more important than adhering to existing rules in the name of predictability and uniformity. Therefore, this factor should have no bearing on this case.

3. The policy of full compensation of tort victims will be achieved by application of Haven law.

Haven law should be applied to advance the policy of compensating tort victims. When both states in a choice of law problem would equally achieve the basic policies underlying the relevant field of law, the court should apply the law that has the most significant contacts with the case. The basic policies underlying the particular field of law are "of particular importance" when the interested states have policies that are basically the same, but the states have minor differences in the local laws. Restatement (Second) of Conflict of Laws § 6 cmt. h (1971); *see also Phillips v. GMC*, 995 P.2d 1002, 1014 (Mont 2000). When this happens, the court should apply the law that will best achieve the basic policy. *Id.*

In *Jones*, the court observed that products liability law is concerned with compensation of victims, whether fully or under certain caps. *Jones*, 460 F. Supp. 2d at 975. The court found that while one state, Iowa, had laws that fully compensated tort victims, and the other state, Idaho, had laws that

placed certain caps on recovery, each of these states had laws that furthered the basic policy of compensation of tort victims. *Id.* The court then decided that, because Iowa had the most significant relationship to the case, and "Iowa tort and products liability law is not so abnormal that it is out of step with the policies underlying the particular fields of law at issue here," the court could apply Iowa law. *Id*.

This case is similar to *Jones* in that the laws of both Haven and Grace seek to fully compensate tort victims. While there were subtle differences in compensation in *Jones*, there are no caps on recovery in either Grace or Haven. The minor differences in the laws of these states deal with the requirements in stating a claim to prove that a product manufacturer should be held strictly liable. Each state has requirements that tort victims must meet before stating a claim, and each state provides recovery for those victims. For these reasons, this factor weighs in favor of applying Haven substantive law to this case.

II. RESPONDENT FAILED TO STATE A VALID CLAIM UPON WHICH RELIEF MAY BE GRANTED BECAUSE RESPONDENT DID NOT SUFFICIENTLY PLEAD THE COMPLAINT.

Relief cannot be granted in this case because Respondent failed to properly state a claim under the Federal Rules of Civil Procedure and applicable state law. In addition, Haven and Grace state laws provide that certain elements of a manufacturing, design, and warning defect claims must be alleged in the complaint for the claim to move to trial. Respondent's failure to meet the applicable requirements of both the Restatement (Third) of Torts: Products Liability (1998) and the Restatement (Second) of Torts (1965) warrants a reversal of the judgment of the Thirteenth Circuit Court of Appeals.

Respondent inadequately pled its complaint, and this error warrants granting Firefly's motion to dismiss. When a plaintiff files a complaint in a complex case, and the complaint does not provide factual allegations beyond the speculative level that the plaintiff is entitled to relief, the claim is not

plausible on its face. A complaint alleging a claim for relief must contain a short and plain statement showing that the complainant is entitled to relief. Fed. R. Civ. P. 8(a)(2). A court may dismiss a claim when the plaintiff fails to state a claim upon which relief may be granted. Fed. R. Civ. P. 12(b)(6). When ruling on a motion to dismiss under Rule 12(b)(6), a court must view the facts alleged in the complaint in the light most favorable to the plaintiff. *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). A district court weighing a motion to dismiss asks "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).

While a complaint attacked by a Rule 12(b)(6) motion to dismiss does not need detailed factual allegations to survive, a plaintiff's obligation to provide the grounds of his entitlement to relief requires more than labels and conclusions. *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 545 (2007). There is a difference between merely alleging a claim and actually showing that the complainant is entitled to relief. *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1950 (2009). Factual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint's allegations are true. *Id.* When the pleader has only provided facts that allow the court to "infer the mere possibility of misconduct," the burden to show entitlement to relief has not been met. *Ashcroft*, 129 S. Ct. at 1949-50. The context of the asserted claim bears on the amount of factual detail necessary to make a claim plausible on its face. *Limestone Dev. Corp. v. Vill. of Lemont*, 520 F.3d 797, 803 (7th Cir. 2008).

A. Respondent's claim fails because Haven law requires an additional showing for Respondent to bring a claim based on strict products liability under Restatement (Third) of Torts: Product Liability (1998).

Under the choice of law determination that Haven law governs the resolution of this case, Respondent failed to establish that Firefly's product contained a defect. In products liability cases, Haven applies the Restatement (Third) of Torts: Products Liability (1998). This law requires that in a

manufacturing defect claim, a plaintiff must show that the product departed from its intended design. Restatement (Third) of Torts: Products Liability § 2 (1998). Under a design defect claim, a plaintiff must show there is a reasonable alternative design that would have reduced or avoided the harm. *Id.* To assert a warning or instruction defect claim, a plaintiff must demonstrate the existence of inadequate warnings, and that reasonable instructions or warnings would have reduced or avoided the harm. *Id.* In addition to the requirements listed in section 2, a plaintiff must also show that the product defect was both the actual and proximate cause of the harm under section 1. While some jurisdictions use a negligence standard in design and warning defects, the Haven district court made clear that Haven aligns itself with jurisdictions that describe manufacturing, design and warning defects under a strict liability standard. Restatement (Third) of Torts: Products Liability § 1 cmt. a (1998); (R. at 7.)

In analyzing Respondent's claims, it is important to identify the product at issue before delving into the alleged defects of that product. The Thirteenth Circuit observed, "[i]n the present case, there are no concerns about the software as a service. The software is mass-produced with no product differentiation. It is the medical records, a product, at issue, and not the incidental service of transferring the records." (R. at 12.) Therefore, the products at issue are the software and the static copy of the medical records. However, Respondent is not entitled to relief because it failed to plead that either product contained a defect.

1. Respondent's claim for a manufacturing defect fails because Respondent failed to show that Firefly's product departed from its intended design at the time it left the hands of the manufacturer.

Respondent failed to state a claim for manufacturing defect because it failed to correctly plead that the product departed from its intended design in the complaint. To establish a manufacturing defect, a plaintiff must show that the product departed from the intended design, and that the defect causing the deviation was present when the product left the hands of the manufacturer. Restatement

(Third) of Torts: Products Liability § 2 cmt. c (1998). A plaintiff must also show that the product at issue was the actual and proximate cause of the harm. Haven Rev. Code § 1018.11; *see also* Restatement (Third) of Torts: Products Liability § 2 cmt. q (1998). A plaintiff may rely on an inference that the harm was caused by a manufacturing defect when the incident, ordinarily occurring as a result of product defect, was not solely the result of other causes. Restatement (Third) of Torts: Products Liability § 3 (1998). Respondent's failure to state a claim for departure from intended design, through evidence or inference of the defect, renders the claim insufficient to survive a motion to dismiss.

a. Respondent failed to show that Firefly's product departed from its intended design and that the departure was the actual and proximate cause of the harm.

Respondent has not asserted any evidence to show Firefly's software departed from its intended design or that the harm was not caused by other factors, so the claim cannot prevail on the theory of a manufacturing defect. A cause of action fails when a plaintiff fails to allege a departure from intended design supported by allegations to show that the defect actually exists. To successfully plead a departure from intended design, the complaint must allege that the product was not manufactured according to its design specifications. *Toms v. J.C. Penney Co.*, 304 F. App'x 121, 125 (3d Cir. 2008). To show a departure from design, a plaintiff must provide actual allegations that either direct or circumstantial evidence exists, or a showing that there could not be another cause of the harm. *Marcus v. Valley Hill, Inc.*, 301 Haven 197 (2006); *see also Toms*, 304 F. App'x at 125.

In *Toms*, a woman was injured when her bathrobe caught fire. *Id.* at 122. The woman alleged the conclusion that the robe was defective because of its unreasonable flammability. *Id.* at 125. The court found that summary judgment in favor of the seller of the robe was proper because the woman failed to prove the robe was unreasonably flammable through direct evidence, circumstantial evidence, or negation of other causes. *Id*. at 127.

In the instant case, Firefly's mass-produced software was designed to passively accept entry of a patient's medical records by Firefly employees, and the software performed as intended. The copy of the records stored locally on Firefly's servers containing the correct allergy information evidences this performance. Because this allergy was present on the local server, a Firefly employee correctly input the allergy, and the software correctly displayed it on the digital copy. This case is like *Toms* in that Respondent concluded that the defect was present in the product but it failed to show through evidence or inference that the defect actually existed. Respondent failed to plausibly plead that the product departed from its intended design, and that the cause of harm could not be the result of other factors.

b. Respondent failed to allege the existence of a manufacturing defect by inference pursuant to Restatement (Third) of Torts: Product Liability § 3 (1998).

Respondent failed to provide any inference that Firefly's product was defective. An inference may be drawn that the harm was caused by a manufacturing defect when the incident, ordinarily occurring as a result of a product defect, was not solely the result of other causes. Restatement (Third) of Torts: Products Liability § 3 (1998). This inference may only be drawn in cases where the plaintiff cannot prove a specific defect. *Toms*, 304 F. App'x at 125 (holding that no inference could be drawn under section 3 because plaintiff identified the defect as the unreasonable flammability of a bathrobe). The inference standard is comparable to the *res ipsa loquitor* concept in that it allows for circumstantial proof in the causation element of a claim. *Myrlak v. Port Auth.*, 723 A.2d 45, 55-56 (N.J. 1999).

Respondent has not alleged a specific defect in this case. Respondent may assert that the blank "Known Allergies" field on the copy used by Dr. Tam at UMC circumstantially proves there was a defect with the product because it should have displayed "NONE." However, this assertion overlooks the nature of the product at issue. The record on appeal states that Dr. Tam and the UMC hospital staff retrieved a "static copy" of Respondent's medical records from the online portal. (R. at 4.) Because it

was a static copy, it was not subject to change once Firefly placed it on the portal. Had the allergies field read "NONE," this would evidence a defect in the product because it would show the product itself deleted the word "PENICILLIN" after a Firefly employee entered it and then changed the field to "NONE." The fact that the copy displayed a blank space shows that something happened during retrieval of the records.

With the uncertainty of the reliability of UMC's computer system and the electronic transmission of the file across the internet, it is likely the error occurred during transmission or retrieval. The only facts stated in the record on appeal support that the error occurred after the product left the hands of the manufacturer. Therefore, Respondent has not pled sufficient facts to show through inference that Firefly's product departed from its intended design.

2. Respondent's claim for a design defect fails because Respondent failed to show a reasonable alternative design that would have prevented or reduced the Respondent's harm.

Respondent did not plead the presence of a reasonable alternative design to Firefly's product or show that the product was the cause of harm. To establish a claim for design defect, a plaintiff must show in the complaint that there was a practical and feasible alternative design that would have prevented or reduced the plaintiff's harm. *See* Restatement (Third) of Torts: Products Liability § 2 cmt. f (1998). The inference of a defect is allowed to establish that the defect was the cause of harm when the incident, ordinarily occurring as a result of product defect, was not solely the result of other causes. Restatement (Third) of Torts: Products Liability § 3 (1998).

There are other possible causes for the harm besides a defect in Firefly's product, and a medical record error is not an occurrence that is usually caused by a product defect. Therefore, there was no showing of a design defect in Firefly's product, and this claim was properly dismissed at the trial level.

a. Respondent failed to show Firefly's product design was the actual and proximate cause of the harm and that there was a practical and feasible alternative design available at the time of sale.

Respondent did not plead the presence of a reasonable alternative design to Firefly's product. When a product poses a limited amount of foreseeable danger to the consumer, and there is no reasonable alternative design to reduce this danger at the time of sale, the product is not unreasonably dangerous. To establish a claim for design defect, the alternative asserted must be a practical and feasible alternative design that would have prevented or reduced the plaintiff's harm. Restatement (Third) of Torts: Products Liability § 2 cmt. f (1998). The plaintiff must plead that the reasonable alternative was available at the time of distribution or sale, or that it could have been available. *Toms*, 304 F. App'x at 124. A product is not reasonably safe when it is not reasonably suited or fit for its intended purpose. *Id.* In order to analyze whether a product is reasonably safe, an independent assessment of the benefits and risks of the product is necessary. Restatement (Third) of Torts: Products Liability § 2 cmt a (1998). The appropriate test is whether a reasonable alternative, at a reasonable cost, would "have reduced the foreseeable risks of harm posed by the product and, if so, whether the omission of the alternative design … rendered the product not reasonably safe." *Id.* at cmt. d.; *see also Hernandez v. Tokai Corp.*, 2 S.W.3d 251, 259 (Tex. 1999). An overwhelming majority of states recognizing strict products liability utilize some form of risk-benefit analysis in cases of design defect. *Braham v. Ford Motor Co.*, 701 S.E.2d 5, 15 (S.C. 2010). As a matter of public policy, products are not defective merely because they are dangerous, and society does not benefit from products that are excessively safe. Restatement (Third) of Torts: Products Liability § 2 cmt. a (1998).

In *Hernandez*, a plaintiff brought suit against the manufacturer of disposable butane lighters when a fire severely burned her son after her five-year-old daughter started the fire with the lighter. *Hernandez*, 2 S.W.3d at 255. The plaintiff alleged the lighter was unreasonably dangerous because of

the absence of a safety mechanism, and the court applied a risk-benefit test to determine the issue. *Id*. The court found that although a safer alternative was available, the product was not unreasonably dangerous because the plaintiff should have known the lighter was for adult use only and guarded against it falling into the hands of her children. *Id.* at 258-59. The court reasoned that, in determining whether the product is unreasonably dangerous, it was important to consider that a plaintiff should have been aware of the existence and avoidability of dangers inherent in a product's use that are obvious, commonly known, or warned against. *Id.* at 258.

In this case, the district court correctly observed that Respondent did not allege a reasonable alternative design in the complaint. The failure turns on both the fact that there is no evidence Respondent was the party that introduced the IBM system to the court, as well as the inapplicability of the IBM design as a remedy to the harm caused. The flag system used by IBM alerts the employee that there may be a potential error or omission when the employee leaves a certain field blank. (R. at 3.) However, the record on appeal states Firefly's employee correctly typed Respondent's allergy into the digital medical records. (R. at 4.) If the IBM system had been used instead of the Firefly system to digitize the Respondent's medical records, the flag system may have alerted the employee of errors during input of data. However, the IBM system does not have any type of flag system alerting customers of possible errors after records are digitized and the static copies are produced. Although IBM offers a similar product that digitizes patients' medical records, there is no evidence that IBM offers access to the product via an online portal for non-subscribing physicians and healthcare providers.

While it is unfortunate that when Dr. Tam retrieved the copy of the medical records it was not in the condition it had been in when it left Firefly's control, the Firefly system provided Dr. Tam with the patient's medical records when the patient was unable to personally provide the doctor with any

information. This is a significant development in medical record technology, and the benefits derived from instantaneous internet access to patient records largely outweighs the risk of errors in the records. This case is comparable to *Hernandez* in that the risks inherent in the product were reasonably foreseeable to the consumer, and the consumer should have guarded against the risks. It is reasonably foreseeable that medical records may contain a limited amount of error. Without taking on the inherent risk that medical records may appear unfinished when they are transferred via the internet, there is a higher risk that the doctor would have to treat the patient with no medical records at all. Respondent has not stated a claim for a design defect upon which relief can be granted because Respondent has failed to show any reasonable alternative design, or that an alternative design would have reduced the harm.

b. Respondent failed to allege the existence of a design defect by inference pursuant to Restatement (Third) of Torts: Products Liability § 3 (1998).

Respondent failed to provide any inference that Firefly's product contained a design defect. An inference may be drawn that harm was caused by a manufacturing defect when the incident, ordinarily occurring as a result of product defect, was not solely the result of other causes. When a plaintiff cannot identify a specific product defect, the plaintiff must plead an inference of the defect in the complaint to survive a Rule 12(b)(6) motion to dismiss. Restatement (Third) of Torts: Products Liability § 3 (1998). Although the assertion of an inference is usually only applicable in cases of manufacturing defect, sometimes a product design causes the product to malfunction in a manner identical to a manufacturing defect. *Id.* at § 3 cmt. b. In cases where it is unclear whether the product contained a manufacturing or design defect, the inference can be drawn without the need to specify whether the defect occurred during design or manufacture. *Id.*

In the instant case, Respondent alleged both a design and warning defect. Therefore, the assertion of inference was available under either claim [see Section II (B)(1)(b) above]. The missing allergy from the patient records does not usually occur due to a product defect, as errors and omissions in medical records can occur from human error as well. Also, the inference is not available in this case because Respondent has not plausibly pled that the missing allergy information was solely caused by a defect in Firefly's product. Respondent cannot establish a claim for design defect through inference because these pleading requirements have not been met.

3. Respondent's claim for warning defect fails because sufficient warnings were provided to prevent the alleged harm.

A sufficient warning was provided to Firefly's customers, and Respondent has failed to plead that a reasonable alternative warning would have reduced or avoided the harm. When a plaintiff files a complaint for a warning defect, the plaintiff must plead that a danger existed, and that the danger would have been reduced or avoided if the seller gave reasonable warnings as to the danger and safe use of the product. The analysis of a warning defect is similar to the analysis of a design defect under the Restatement in the sense that the availability of a reasonable alternative must be shown for a plaintiff to state a claim upon which relief may be granted. Restatement (Third) of Torts: Products Liability § 2 (1998). However, a plaintiff must also show sufficient instructions or warnings were not provided. *Id.* at cmt. j. A sufficient warning is one a reasonable person would have provided to communicate ample information on the safe use and dangers of the product, taking into account the common knowledge and characteristics of the intended user. *Toms*, 304 F. App'x at 126. The defect in a failure to warn claim is the absence of a warning that the product can cause injury to the unsuspecting user. *Id.* Before addressing the question of whether the product contained a sufficient warning, the plaintiff must satisfy the burden of pleading that a danger existed. *Id.*

In this case, Firefly instructed its customers to verify the electronic records before disposing of the paper copies. (R. at 3.) This warning, like the warning described in *Toms*, was sufficient to put Respondent on notice of the safe use and dangers of the product. Respondent failed to verify the accuracy of her USB copy of the records. (R. at 3.) Firefly gave this instruction to avoid the exact type of harm that occurred. Therefore, Respondent's claim cannot stand because it failed to meet the burden of showing there was any reasonable alternative warning that would have done more to reduce or avoid the harm caused.

There are no facts in the record on appeal pertaining to the content of the online portal. In the event that warnings were not provided on the portal for non-subscribing users, the presence of a warning likely would not have reduced or avoided the harm caused. Verification of the medical records was not a plausible option in the context of the emergency situation. Respondent's appendicitis was so severe that "Dr. Tam concluded that immediate surgery was required." (R. at 3.) Respondent has failed to state a claim for a warning defect, because it has failed to show that there were insufficient warnings or instructions, that there was a reasonable alternative, or that the implementation of additional warnings or instructions would have reduced the harm.

B. Respondent failed to state a valid claim under Grace law because the complaint did not satisfy federal pleading standards for a strict products liability claim under Restatement (Second) of Torts § 402A (1965).

Even if this Court decides Grace substantive law should apply, Respondent has not stated a claim upon which relief may be granted. In cases of manufacturing, design or warning defects, Grace law adheres to the Restatement (Second) of Torts § 402A (1965). The law states that when a product is sold in an unreasonably dangerous defective condition, the seller of the product is liable for physical harm caused to the ultimate consumer or user. *Id.*

1. Respondent failed to state a claim for manufacturing defect because Respondent did not plead that the product was in an unreasonably dangerous defective condition when it left Firefly's control.

Respondent's claim for manufacturing defect fails under Grace law because Respondent has not pled that the product was in a defective condition when it left the hands of Firefly and that it was unreasonably dangerous under the consumer expectations test. A defective condition means that, at the time the product left the seller's hands, the product was in an unreasonably dangerous condition not contemplated by the consumer. *Id.* at cmt. g. Unreasonably dangerous means "the article must be dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." *Id.* at cmt i. The burden is on the plaintiff to plead that the product was in an unreasonably dangerous condition when it left the hands of the seller. *Id.* at cmt. g.

In addition to the concepts set forth by the Restatement (Second) of Torts (1965), Grace law integrates a consumer expectations test to decide whether the product was in a condition contemplated by the consumer. *Turner v. Smith Bros., Inc.*, 30 Grace 144 (2006). This consumer expectations test considers what an ordinary consumer would expect when using the product in an intended or reasonably foreseeable manner. *Barker v. Lull Eng'g*, 573 P.2d 443, 455 (Cal. 1978). Respondent failed to plead or infer that the product deviated from the expectations of a normal consumer.

a. Respondent failed to properly plead that Firefly's product did not meet the consumer expectations test.

Under the consumer expectations test, the product was not unreasonably dangerous. The plaintiff has the burden to show the product was in an unreasonably dangerous condition when it left the seller's control. When a plaintiff fails to allege sufficient facts that show a product is dangerous to an extent beyond consumer expectations, the plaintiff cannot prevail on a manufacturing defect claim. Restatement (Second) of Torts § 402A cmt. g (1965). In *Barker*, the court recognized, "[a]

manufacturing or production defect is readily identifiable because a defective product is one that differs from the manufacturer's intended result or from other ostensibly identical units of the same product line." *Barker*, 573 P.2d at 455.

The record on appeal shows that the Firefly employee correctly entered the Respondent's allergy information into the electronic medical form. The copy of the electronic records was then placed on a USB drive for the patient's personal use, on a local server for subscribing hospitals and medical providers, and on an online portal for non-subscribing users. (R. at 3.) Although the copy UMC retrieved from the online portal did not contain the allergy information, the evidence shows the product was in the correct condition when it left the hands of Firefly because the copy on the Firefly's local server was correct. (R. at 4.) As referenced in *Barker*, there is no identifiable manufacturing defect in this case because the product performed according to Firefly's intended result. This shows that something likely happened during internet transmission or hospital retrieval, after the product was out of Firefly's control. Therefore, Respondent has not satisfied the burden of alleging sufficient facts to show the product was unreasonably dangerous while in the control of Firefly.

b. Respondent did not properly established a manufacturing defect through inference.

Although Grace law allows for the pleading of a manufacturing defect through inference, Respondent failed to properly plead this inference. If there is evidence in a record from which a court can draw a reasonable inference, and this inference could be drawn in favor of the non-moving party, judgment is improper. *Rosenthal*, 462 F. Supp. 2d at 299. However, if a rational juror could not find for the non-moving party, then entry of judgment is appropriate because there is no genuine issue of material fact. *Suburban Propane v. Proctor Gas, Inc.*, 953 F.2d 780, 788 (2d Cir. 1992). Some courts have recognized that the presence of a defect can be inferred in order to establish a prima facie case. *Nationwide Mutual Fire Ins. Co. v. GMC*, 415 F. Supp. 2d 769, 776 (N.D. Ohio 2006) (citing *Cassisi v.*

Maytag, 396 So. 2d 1140, 1149-51 (Fla. App. 1981); *Greco v. Bucciconi Eng'g Co.*, 283 F. Supp. 978 (W.D. Pa. 1967)). However, just because a product may break does not mean that it malfunctioned. *Id.* In order to gain the benefit of this inference, the plaintiff must provide evidence that a malfunction occurred. *Id.*

In this case, there is no circumstantial evidence that the product malfunctioned. Even in viewing every fact in the light most favorable to Respondent, the product operated normally while it was in Firefly's control. Respondent asserts that a malfunction is evidenced by the fact that the penicillin allergy was not present on the copy obtained by UMC. However, the absence of the allergy on the static copy lends no evidence to a software malfunction or to the malfunction of the medical records.

Medical records, in any form, are subject to error, and the level of expectancy for these types of errors is remedied by Firefly's instruction to customers to verify the electronic records. (R. at 3.) The district court correctly observed that there is a limited level of expectancy for errors in medical records. (R. at 8.) Similar to the holding in *Nationwide*, just because there was an error on the medical records, this does not mean that it was due to a defect in Firefly's product. It was also reasonably foreseeable that these errors could affect treatment in an emergency situation because Respondent knew active steps would be necessary to avoid exposure to penicillin. (R. at 2.) The medical records were not in a condition beyond contemplation of a normal consumer. The Firefly product line is not designed to automatically check for potential errors or omissions after it has left the hands of Firefly. (R. at 3.) There was no differentiation in the product, and it did not depart from its intended design because. It adequately converted the records and it was in the correct condition while in the hands of Firefly. Therefore, Respondent has not satisfied its burden to show an inference of a defect, and the claim cannot prevail.

2. Respondent's claims for design and warning defects fail because the expectations of a normal consumer were met and the benefits of the design currently used by Firefly outweigh any risk posed to the consumer.

Relief cannot be granted for Respondent's claims for design and warning defects because it failed to meet the consumer expectations test and assert that the risk of Firefly's product outweighed its benefit. Grace uses a combination of the consumer expectations test and a risk-benefit analysis. *Barker*, 573 P.2d at 455-56. Therefore, Respondent failed to plead the proper elements of a design or warning defect claim.

a. Respondent failed to properly plead that Firefly's design and warnings did not meet the expectations of a normal consumer.

The expectations of a consumer were met in this case because the possibility of error was evident, and Respondent received a sufficient warning of this possibility. Consumer expectations are what an ordinary consumer would anticipate when using the product in a reasonable foreseeable or intended manner. *Turner*, 30 Grace at 153. A defect is readily identifiable in a product because it renders the product different from the manufacturer's intended result. *Barker*, 573 P.2d at 455. When a product confirms to the manufacturers intended result, and it operates according to what a normal consumer should reasonably foresee, the product does not contain a design or warning defect.

Under the *Turner* holding, Respondent should have anticipated that the process of medical records transmission over the internet and retrieval from third-party computers included the possibility of errors and that using the product in its intended manner required that she check the electronic medical records. Instructions were given for Dr. Frye and Respondent to verify electronic records. (R. at 3.) Under the consumer expectations test, Respondent knew the product was designed with the possibility of errors in transmitting paper records to electronic form because use of the product required verification of the accuracy of the electronic information. Respondent voluntarily encountered a known danger when Respondent knew active steps were necessary to avoid exposure to penicillin, yet

she failed to verify the electronic records. (R. at 2.) Therefore, Respondent's claim for a warning defect cannot prevail based on the theory of consumer expectation.

b. Respondent's claim fails because the benefits of Firefly's design outweigh any alleged risk.

The benefits provided by Firefly's product outweigh any alleged risk. A plaintiff has the burden of showing the product was in an unreasonably dangerous condition when it left the seller's control. Restatement (Second) of Torts § 402A cmt. g (1965). When a product bears a warning that renders the product safe for use if the warning is followed, the product is not unreasonably dangerous, and it is reasonable for the seller to assume the warning will be read and heeded. *Id.* cmt. j. The product may be unreasonably dangerous, even if it conforms to all others in the product line, if there is an absence of a necessary safety device or a warning. *Barker*, 573 P.2d at 455. In addition to the consumer expectations test, in cases where design or warning defects are at issue, Grace law applies a risk-benefit test to determine whether the product was unreasonably dangerous. *Id.* This test aids the court in determining whether the danger the product poses is reasonable in light of its benefit or unreasonable in light of its risk. The factors are: (1) the gravity of the danger posed by the challenged design; (2) the likelihood that such danger would occur; (3) the mechanical feasibility of a safer alternative design; (4) the financial cost of an improved design; and (5) the adverse consequences to the product and to the consumer that would result from an alternative design. *Id.* When these factors are weighed, and the benefits outweigh the risks, the product is not unreasonably dangerous.

The first factor to consider is the gravity of the danger posed by the challenged design. If the danger posed is that the medical records may be incorrect, the software poses no more danger to the electronic medical records than a doctor poses to paper medical records. Respondent believes there is a possibility the product malfunctioned and this resulted in incorrect medical records. Medical records are subject to error, and the possibility of error does not outweigh the benefit derived from the medical

records being readily available for access anywhere in the country. The only information provided to UMC when Respondent entered the hospital was her driver's license. (R. at 3.) Furthermore, the co-worker, who accompanied Respondent to the hospital, had no knowledge of her allergy. Had Firefly not made the medical records available via the internet portal, it is likely Dr. Tam still would have administered penicillin because he would have had no way of knowing any of Respondent's medical history or who to contact to find out the history.

Under the second factor, the likelihood the danger would occur is also very low. With proper product use, it is unlikely the danger would occur. Because customers are instructed to verify their medical records, the danger would not likely occur unless it was due to customer oversight or faulty internet transmission out of Firefly's control. The absence of a warning, as contemplated in *Barker*, is not applicable in this case because the warning Firefly provided was designed to reduce the type of harm that occurred in this case.

The third factor, the mechanical feasibility of a safer alternative design, leads back to the same analysis of why Respondent's claim fails under Haven's alternative design requirement. The only alternative design mentioned is the design used by IBM. However, this design is not reasonable to combat the specific danger alleged. While an alternative flag system is mechanically feasible to prevent human input of incorrect data, the record on appeal indicates the data was input correctly.

The fourth factor, the financial cost of an improved design, is an unresolved factor in this case. The record on appeal does not state whether IBM provides the exact same products and services as Firefly. There is no information as to what Dr. Frye paid for Firefly's products and services, or as to what the IBM products and services ultimately cost. With so little financial information, this factor lends little help in the risk-benefit analysis.

The final factor considers the adverse consequences to the product and to the consumer that would result from an alternative design. Firefly employees would require more training if the company were to adopt the IBM design because the IBM system is more difficult to operate. The burden of additional training and a more difficult operating system would cause the cost of the product to increase, while it is not clear as to what extent this would occur. This higher price could result in many customers' inability or reluctance to purchase the product. Also, product development could take longer, resulting in a less efficient product for society as a whole. Society benefits from affordable digitization of medical records because medical records are able to exist in a more efficient medium. In recognizing this benefit, Congress and the Haven legislature encourage health information technology through appropriated funding. (R. at 8.) The benefits derived from Firefly's product outweigh the adverse consequences that may result from an alternative design, thereby rendering the product reasonably safe.

CONCLUSION

Firefly Systems, Inc. asks that this Court reverse the decision of the United States Court of Appeals for the Thirteenth Circuit and hold that Haven's substantive law governs this case, and that an additional showing is necessary for Respondent to state a claim for strict products liability upon which relief can be granted.

Respectfully submitted,

/s/ Team 1
Team 1
Counsel for Petitioner