

No. XX-XXXX

IN THE SUPREME COURT OF THE UNITED STATES

April Term, 2010

FIREFLY SYSTEMS, INC.,

Petitioners

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 PETITIONERS

QUESTIONS PRESENTED

1. Does the state of Haven's conflict-of-law rules require application of the substantive law of Haven or Grace?
2. Depending upon the answer to question one, does the Respondent state a claim for strict products liability upon which relief can be granted?

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STATEMENT OF THE CASE

This wrongful death action arose from the use of an allegedly defective product developed and manufactured by Petitioner-Firefly Systems, Inc. (hereinafter “Firefly”). (R. 3.) Firefly works with hospitals to digitize patients’ medical records to be stored on its servers that can be accessed via secure web portal by physicians and healthcare providers. (R. 2.) Firefly is incorporated in Delaware with its principle place of business in Haven. (R. 1.) Decedent-Zoe Washburne (hereinafter “Ms. Washburne”) was a resident of Grace at all relevant times. (R. 1.)

In 2008, before the incident in question, Ms. Washburne’s doctor in Grace, Dr. Frye, informed her by letter of Firefly’s product, and how it would be used to convert the old paper medical records system to a new electronic medical recordkeeping system, which could be accessed by physicians anywhere in the country in case of emergency. (R. 1.) Firefly’s product is ten percent less costly than its main competitor IBM. (R. 2.) It is mass-produced and is not customized or individually tailored to different hospitals. (R. 1.) IBM’s system on the other hand, requires additional training and is more difficult to operate because it employs a flag warning system that does not permit the transcriber to continue entering information where there are serious omissions, without confirming the data is entered correctly. (R. 2.) The electronic records stored by Firefly include personal and family past medical histories, notes, charts, and records of past and present procedures, integrated both directly with participating hospitals and made accessible on a secure web portal. (R. 2.) As a default, Firefly’s software is designed to insert the word “NONE” in a field where no information is inputted. (R. 3.) Firefly employees are instructed to ensure that the electronic data matches the paper record exactly. (R. 3.)

Dr. Frye informed Ms. Washburne that for a \$25 fee, she could receive a copy of her electronic medical file. (R. 1-2.) Ms. Washburne sent a personal check for \$25 to Firefly’s

office in Haven. (R. 1-2.) Dr. Frye then provided Firefly with Ms. Washburne's medical file for digitization, whereupon Firefly sent Dr. Frye the securely shipped software with delivery confirmation. (R. 2.) Ms. Washburne subsequently received a USB flash-drive containing her medical information and instructions to verify the information before disposal of her paper records. (R. 2.) Ms. Washburne did not review the electronic format of her records and subsequently lost the flash-drive. (R. 2.)

On Wednesday, September 10, 2008, Ms. Washburne traveled to Haven as a chaperone on a school-sponsored field trip, and it was there that she experienced increasing abdominal pain and lost consciousness. (R. 2.) Ms. Washburne was rushed to University Medical Center in Haven, where she was diagnosed by surgeon Dr. Tam as suffering from appendicitis. Believing immediate surgery was required, Dr. Tam removed the appendix (R. 2), possessing and relying upon the electronic version of Ms. Washburne's medical chart obtained from the Firefly server. (R. 3). The chart did not contain a reference to Ms. Washburne's penicillin allergy because the "Known Allergy" field was blank. (R. 3.) It is unclear why the known allergy field of the medical chart obtained by University Medical Center was blank; however, it is undisputed that Ms. Washburne's paper copy and the copy stored on Firefly's servers contained information about her allergy to penicillin. (R. 3)

Following surgery, Dr. Tam and his assistants administered penicillin as common practice to avoid risk of post-surgical infection, unaware of Ms. Washburne's allergy. (R. 3.) Five minutes after the administration of penicillin, she began experiencing respiratory problems which were quickly alleviated by administering epinephrine. (R. 3.) There were no other problems for two days, after which Ms. Washburn was discharged from the hospital. (R. 3.)

While headed home with her parents, sometime after crossing back into Grace, Ms.

Washburne collapsed and could not be revived by her parents or by emergency medical technicians. (R. 3.) She was pronounced dead at the scene due to a combination of an allergic reaction and a delay in treatment. (R. 3.) It was later discovered that Ms. Washburne had suffered a second reaction to the penicillin, a result of biphasic anaphylaxis, a relatively rare form of reaction that can reoccur up to 72 hours without further exposure. (R. 3.)

Respondent-In re Estate of Zoe Washburne (hereinafter “Respondent”), parents of Ms. Washburne, brought suit against Firefly on strict products liability and breach of express and implied warranty, filed initially in the Peterson County of Common Pleas in Haven. (R. 3.) Based on diversity, Firefly removed to the United States District Court for the District of Haven (R. 3-4), which applied Haven’s substantive law and granted Firefly’s motion to dismiss for failure to state a claim upon which relief can be granted. (R. 1, 8.) The Circuit Court, applying Grace’s substantive law instead, reversed the lower court’s dismissal as to the strict products liability and breach of implied warranty claims. (R. 9, 12.) This Court granted Firefly’s petition for writ of certiorari on the two aforementioned questions of law. (R. 14.)

SUMMARY OF ARGUMENT

Haven’s substantive law should be applied under Haven’s choice-of-law rules because there is an actual conflict of law and Haven has the most significant relationship to the action, where Haven is the place of injury, the conduct causing injury occurred in Haven, Firefly is a resident of Haven, and the relationship between the parties for this issue is centered in Haven. Furthermore, consideration of the needs of the interstate system, the relevant policies of the forum and the other interested state, the justified expectations of the parties, the policies underlying strict products liability, the goals of certainty, predictability and uniformity of result, and the ease of applying Haven law also weigh in favor of applying Haven’s substantive law.

The Respondent has failed to state a claim under Federal Rule of Civil Procedure

12(b)(6) for design and warning defects because Respondent failed to allege a reasonable alternative design, a requirement under Haven law. Furthermore, Respondent failed to state a claim for manufacturing defect because they failed to make a preliminary showing of a defect, also a requirement of Haven law, since Firefly's product did not depart from its intended design.

ARGUMENT

I. THE SUBSTANTIVE LAW OF HAVEN SHOULD BE APPLIED UNDER HAVEN'S CHOICE-OF-LAW RULES BECAUSE THERE IS AN ACTUAL CONFLICT OF LAW AND HAVEN HAS THE MOST SIGNIFICANT RELATIONSHIP WITH REGARD TO THE STRICT PRODUCTS LIABILITY CLAIM.

A federal court sitting in diversity applies the substantive law of the forum state, including the forum state's choice of law rules. 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). "The issue of the appropriate choice of law is a question of law for the court." Jones v. Winnebago Indus., Inc., 460 F. Supp. 2d 953, 959 (N.D. Iowa 2006) (citing cases). Before a conflict of law issue arises, there must be an actual conflict between the laws of the interested states. 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 that of the other interested state differ in result, there is a true conflict, and the court must decide the choice-of-law issue. In re Complaint of Bankers Trust Co., 752 F.2d 874, 882 (3d Cir. 1984).

Since Respondent chose to file suit in the state of Haven and Petitioner later removed to federal court, Haven's choice of law rules must be applied, as it is the forum state. In a tort action, Haven follows the Restatement (Second) of Conflict of Laws § 145(2) (1971), which uses the "most significant relationship" methodology to determine which state's substantive law should apply, taking into account also the policy concerns of the interested states under Restatement (Second) of Conflict of Laws § 6 (1971). Analysis of the relevant law weighs

weighs strongly in favor of application of Haven's substantive law.

A. An actual conflict exists between Haven and Grace law because Haven follows the Restatement (Third) of Torts, which requires proof of reasonable alternative design not alleged by Respondent, while Grace follows the Restatement (Second) of Torts, which has no such requirement.

The state of Haven follows the Restatement (Third) of Torts: Products Liability § 2 (1998). See Booker v. InGen, Inc., 241 Haven 17, 24 (2007). However, the state of Grace continues to follow the Restatement (Second) of Torts § 402A (1977). The results under these differing approaches is likely to be inconsistent because Restatement (Third) requires proof of a reasonable alternative design for design and warning defect in strict products liability cases, while the Restatement (Second) does not. Restatement (Third) of Torts: Products Liability § 3 Reporters' Notes to cmt. d, at 178 (Council Draft No. 1A, 1994). Since Respondent has failed to allege or show a reasonable alternative design, explained *infra*, these claims would likely fail under Haven Law.

Furthermore, the Restatement (Second) does not preclude a plaintiff from bringing both a strict products liability claim for manufacturing defect and a claim of implied warranty of merchantability under UCC law, although such UCC claim is considered duplicative under Restatement (Third) and may not be brought in the same action in Haven. Restatement (Third) of Torts: Products Liab. § 2 cmt. n (1998). See e.g., Rice v. Kawasaki Heavy Industries, LTD., 2008 WL 4646184, at *4 (E.D.N.Y.) (an actual conflict existed where New York law permits separate claims for negligence, failure to warn and breach of implied warranty to be brought in connection with products liability, whereas New Jersey law subsumes common law product liability claims into one statutory cause of action for strict liability and does not allow separate claims for strict liability, breach of warranty or failure to warn for injuries caused by allegedly defective products). Therefore, an actual conflict of law exists between the two states.

B. Haven has the most significant relationship to the strict products liability claim because it is the place of injury, the conduct causing injury occurred in Haven, Firefly is a resident of Haven, and the relationship of the parties is centered in Haven.

Haven has the most significant relationship to this litigation. It is undisputed that the Haven Supreme Court joined the majority of states in applying the principles of the Restatement (Second) Conflict of Laws and adopted the “most significant relationship” test for choice-of-law analysis in tort actions. Booker v. InGen, Inc., 241 Haven 17, 24, 26 (2007). Haven begins the analysis with § 146 of the Restatement (Second) Conflict of Laws (1971). Pursuant to this section, the law of the state in which the injury occurred controls unless another jurisdiction has a more significant relationship to the issue in tort. Restatement (Second) of Conflict of Laws § 145 (1971). To determine which state has the “most significant relationship”, a court proceeds to consider the general principles set forth in § 145(2). The same analysis is required in wrongful death actions. Restatement (Second) of Conflict of Laws § 175 (1971). The “most significant relationship” test is outlined in Restatement (Second) of Conflict of Laws § 145:

The rights and liabilities of the parties with respect to an issue in tort are determined by the local law of the state which, with respect to that issue, has the most significant relationship to the occurrence and the parties under the principles stated in this section.

(1) Contacts to be taken into account in applying the principles of section 6 to determine the law applicable to an issue include:

- (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.

These contacts are to be evaluated according to their respective importance with respect to the particular issue. Restatement (Second) of Conflict of Laws § 145.

Furthermore, Restatement (Second) of Conflict of Laws § 6 directs:

- (1) A court, subject to constitutional restrictions, will follow a statutory directive of its own state on choice of law.
- (2) When there is no such directive, the factors relevant to the choice of the applicable rule of law include:

- (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 interest of the states in the determination of the particular issue,
- (d) the protection of justified expectations,
- (e) the basic policies underlining 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.

The Restatement (Second) of Conflicts of Law § 145 does not assign greater importance to a particular type of contact; however, courts that follow the methodology outlined in the Restatement (Second) place different levels of importance on different types of contacts in personal injury cases. See Sico North America, Inc. v. Willis, 2009 WL 3365856 (Tex. App. Houston 14th Dist. 2009)(emphasis placed on location of product design and distribution); Linden v. CNH America LLC, 2010 WL 4840435 (S.D. Iowa)(court focused on the place of manufacture and principal place of business); Torres v. Lucca's Bakery, 487 F. Supp. 2d 507(D.N.J. 2007)(emphasis placed on residence and where the product was used); Cacciola v. Selco Balers, Inc., 127 F. Supp. 2d 175 (E.D.N.Y. 2001)(great weight assigned to the place where the tort occurred); and Hines v. Tenneco Chemicals, Inc., 728 F.2d 729 (5th Cir. 1984)(emphasis on relationship between the parties with regard to the particular issue or service rendered). Since the state of Haven and Grace are hypothetical, and therefore there is no controlling body of law other than what is included in the opinions of the lower courts, we are unable to determine which contact, if any, the state of Haven would assign greater weight. Therefore, we continue analysis predicated upon the belief that the state of Haven would follow the directive in the Restatement (Second) § 145 to evaluate each contact according to its respective importance regarding the particular issue of strict products liability, referencing cases with similar facts from various jurisdictions for guidance. Restatement (Second) of Conflicts of Law § 145.

1. Haven is the place of injury because that is where the allergen Penicillin was administered, and also where the initial adverse reaction occurred, causing respiratory problems.

The state in which the injury occurred is presumed to be the state whose substantive law should be applied in conflicts-of-law issues. Although Haven no longer follows the doctrine of *lex loci delicti*, which placed decisive significance on the place of injury, the place of injury remains a significant contact due to the legal presumption in Restatement (Second) § 146. See Booker, 241 Haven at 24.

Ms. Washburne was injured in the state of Haven when Dr. Tam administered penicillin, an antibiotic to which she was allergic, causing respiratory problems approximately five minutes after it was administered at University Medical Center on Wednesday, September 10, 2008. Although the symptoms from the adverse reaction were alleviated and Ms. Washburne recovered quickly after prompt administration of epinephrine, she was still injured by the introduction of the allergen penicillin, which occurred in Haven. Ms. Washburne's second reaction was the result of biphasic anaphylaxis, a relatively rare form of reaction linked directly to the initial anaphylaxis reaction in Haven. Were it not for the administration of penicillin, Ms. Washburne would not have had a second adverse reaction while crossing into the state of Grace on Friday, September 12, 2008, where she collapsed and perished, after Grace emergency medical technicians were unable to revive her due to the damage caused by the reaction, coupled with the delay in treatment. Furthermore, most of the drive from Haven to Grace after discharge was without incident, and at some point after Ms. Washburne crossed into Grace after leaving Haven, she had the second reaction to penicillin received in Haven. Thus, the state of Grace had only limited contacts with Ms. Washburne and her injury before she died, whereas Haven was intimately connected with the incident, having treated Ms. Washburne for two days after the initial reaction to penicillin administered in Haven.

Additionally, the last event necessary to make Firefly potentially liable occurred in Haven. In Richardson, 1997 WL 461994, at *3, the court held that the plaintiffs' strict liability claim regarding a motorcycle was governed by North Carolina law because that was the jurisdiction in which the last event necessary to make the defendants potentially liable for the plaintiff's injuries, i.e. the motor vehicle accident on I-90 in North Carolina, occurred. Similarly, the accident here was administration of penicillin to which Ms. Washburne was allergic, which occurred in Haven, making Firefly potentially liable. Finally, in a wrongful death action, as in this case, the place where the injury occurs is the place where the force set in motion by the actor first takes effect on the person; thus, the place need not necessarily be where the death occurs. Brewer v. Dodson Aviation, 447 F. Supp. 2d 1166, 1178 (W.D. Washington 2006). See also Restatement (Second) Conflict of Laws § 175 cmn. b. Here, Ms. Washburne first reacted to the effects of penicillin while in the hospital in Haven, and therefore, Haven is a place of injury because it is where the force set in motion (administration of penicillin) by the actor (Dr. Tam) first took effect (respiratory problems). Haven, therefore, is the place of injury and presumptively the state whose substantive law governs the resolution of this case.

- 2. The place where the conduct causing the injury occurred in Haven because the product was designed, manufactured and delivered from Firefly's principal place of business in Haven, and Ms. Washburne was treated in Haven after Dr. Tam accessed her electronic medical records from the Haven medical center.**

In the majority of instances in wrongful death suits, the actor's conduct and the resulting injury will occur in the same state. Restatement (Second) of Conflict of Laws § 175 cmn. e. "In such instances, the local law of this state will usually be applied to determine most issues involving the tort." Id at cmn. e. Section 175 applies to deaths that are caused by conduct for which the actor is responsible on the basis of strict liability. Id at cmn. c.

The conduct causing the injury here occurred in Haven. The issue of liability involves

the alleged conduct of Firefly, which occurred in most significant respects in Haven. Firefly's principal place of business is located in Haven where Ms. Washburne's doctor sent her medical records for transcription by Firefly's employees; the paper copy of Ms. Washburne's medical records were transcribed in Haven; Firefly marketed its product in Haven; it was from Firefly's office in Haven that Ms. Washburne was sent a USB flash-drive containing an electronic copy of her medical records; Dr. Tam, in a Haven hospital, accessed Firefly's secure servers to obtain Ms. Washburne's medical information; Ms. Washburne lost consciousness, and became unresponsive in Haven before being taken to the Haven hospital; it was in Haven where penicillin was given to Ms. Washburne after emergency surgery because Dr. Tam did not observe information regarding the penicillin allergy in Ms. Washburne's electronic medical file; and lastly, University Medical Center surgical assistants and other staff in Haven treated Ms. Washburne for her appendicitis, which in turn resulted in the aforementioned administration of penicillin.

Although Dr. Frye sent the paper copy of Ms. Washburne's medical records from the state of Grace and presumably contracted with Firefly for the transcription service to assist patients in Grace, the majority and most significant events regarding the conduct causing the injury occurred in Haven. Were it not for the alleged defective product that was designed, produced, advertized and sold in Haven, and the conduct of Haven hospital personnel acting on the assumption that Ms. Washburne was not allergic to penicillin, there would be no cause of action. Thus, the alleged conduct causing injury occurred in Haven.

3. Firefly's residency status in Haven outweighs Ms. Washburne's residency status in Grace because of favorable public policy concerning products liability.

Based on Firefly's residence in Haven and favorable public policy in Haven, Haven has a greater relationship to this litigation than Grace, the place of Ms. Washburne's residence.

Firefly's principal place of business is located in Haven, and therefore, Firefly is a resident of the state of Haven. Ms. Washburne was a resident of the state of Grace at the time of her death. Because Firefly is incorporated in Delaware, this fact appears to be neutral. An examination of policy supports the assignment of greater significance to defendant's place of business rather than an individual's residence in a case involving strict products liability. Although Ms. Washburne resided in Grace, the importance of Firefly's place of business "is heightened in a products liability case in which the product is designed, manufactured, advertise, and sold in that state, which is the only state that the defendant can be sure would have some relation to its business transactions." American Law of Products Liability 3d § 46.13 (2010). Furthermore, Ms. Washburne's residence status in Grace has very little to do with the current litigation because it has no impact on the issue of Firefly's liability.

Ms. Washburne's employment is not considered under this section, since Restatement (Second) Conflict of Laws § 145 speaks of "place of business", not place of employment. It would be improper to consider Ms. Washburne's place of employment because Ms. Washburne, as an employee, was not conducting business in Grace, nor was she an employer. Thus, this factor weighs in favor of Haven law due to the relative importance of the residency status of the parties to the issue in tort.

4. The relationship between the parties is centered in Haven because that is where Firefly accepted Ms. Washburne's check, which created the relationship, and Haven is where the medical records were input and from which the USB copy was sent.

The relationship between the two parties is centered in Haven where Firefly accepted and presumably cashed Ms. Washburne's \$25 check for an electronic copy of her medical records, whereupon Firefly transcribed the records and sent Ms. Washburne a USB-Drive containing a copy of her electronic medical records and instructions to review for accuracy from its office in

Haven.

Thus, these four relational factors under §145 favor the use of Haven's substantive law, especially since there is a presumption that Haven's law applies when it is the place of injury, which it is. We now consider the policies that support Haven law over Grace law.

C. Policy concerns of the state of Haven outweigh those of Grace due to Haven's strong connection with the issue in tort, and the important goals of Haven's legislature and Congress with regard to medical information technology.

Policy considerations important to the evaluation of § 6 factors further support application of Haven law over Grace law. The Restatement (Second) of Conflict of Laws requires the forum state to apply and balance seven policy-based factors in addition to § 145 factors in a choice-of-law issue, unless an applicable statutory directives exists on the issue. Restatement (Second) of Conflict of Laws § 6. Since it does not appear from the lower court opinions that Haven has a statutory directive for the application of strict products liability, or even tort law in general, we consider the factors below, retaining in mind that § 145 factors already favor use of Haven law.

1. The needs of the interstate systems are satisfied by application of Haven law because Haven has a substantial connection with the issue in tort.

"Respect for interstate and international systems is maintained when the forum state, when choosing to apply its own law, has a substantial connection with the issue." See e.g., Veasley v. CRST Intern., Inc., 553 N.W.2d 896, 899 (Iowa 1996)(speaking of action for personal injuries involving automobile accident). Because it has already been established that Haven has a substantial connection with the strict products liability issue here, the interests of interstate systems is not hampered by application of Haven law over Grace law. To the contrary, the service Firefly provides, which is transcription of paper medical records for easy and instant access to medical information nationwide, serves the interests of both Haven and Grace. Access

to electronic medical records via Firefly's secure servers helps protect traveling persons who need medical care by an out-of-state or in-state provider who is not familiar with the patient, as in the instant case, by facilitating quick and easy access to a patient's medical history. Thus, as long as Haven has a substantial connection with Respondent's claims, which it does here, the needs of the interstate system are satisfied when Haven's substantive law is applied.

2. The relevant forum policies support Haven law because of Haven's interest in protecting its companies from liability, the importance of electronic medical records in cost saving and advancement of patient health, and the use of Haven's valuable resources.

Haven has a strong interest in promoting electronic medical records systems like Firefly's to promote efficiency, advance patient medical care, and save money. There is an increasing trend for companies, especially medical providers, to go paperless to save money, prevent medical errors, and meet increasing patient demand for greater access to their medical information. David W. Bates et al., The Costs of Adverse Drug Events in Hospitalized Patients, 277 J.A.M.A. 307, 307 (1997). The monetary cost of implementing such systems, however, has proved a substantial barrier for many hospitals. Bates et al., *supra* note 70, at 1311-16. This is why Firefly's product is so attractive, since it costs ten percent less than its main competitor. Transcription of medical records creates a digital copy that can be accessed, updated, corrected and maintained with ease. When medical records are easily created and accessible by providers and patients, healthcare professionals are able to spend less time preparing, filing and retrieving them, and more time with their patients. See e.g., Patients of Paperwork?: The Regulatory Burden Facing America's Hospitals, *American Hospital Association* (2001), available at <http://www.aha.org/aha/content/200/pdf/FinalPaperworkReport.pdf>. Furthermore, in emergency situations, access to critical medical information can save lives. See Charles Safran, Electronic Medical Records: A Decade of Experience, 285 J.A.M.A. 1766 (2001); Christopher C. Tsai &

Justin Starren, Patient Participation in Electronic Medical Records, 285 J.A.M.A. 1765 (2001); See also, Dena E. Rifkin, Electronic Medical Records: Saving Trees, Saving Lives, 285 J.A.M.A. 1764 (2001). Additionally, more time with patients will likely advance patient care by permitting doctors to gain a better understanding of their patient's needs. Since doctor's are notorious for poor handwriting, electronic medical records can reduce, and to some extent eliminate the need for handwritten medical notes and prescriptions, thereby helping healthcare providers better avoid medical errors and prevent deaths caused by mistakes that come from being unable to correctly read a doctor's notes, or a patient's notes for that matter. See e.g., Amy Sokol & Christopher Molzen, Journal of Legal Medicine, The Changing Standard of Care in Medicine, 23 JLEGMED 449, 461 (December 2002); see also, Meg Mitchell, *Handhelds Help with Heart Attacks at Hospital* (Sept. 3, 1999), at http://articles.cnn.com/1999-09-03/tech/9909_03_hospital.idg_1_emergency-department-doctors-emergency-rooms?_s+=PM:TECH.

Medical providers can save a great deal of money by using less paper and preventing medical errors. See David W. Bates et al., The Costs of Adverse Drug Events in Hospitalized Patients, 277 J.A.M.A. 307, 307 (1997). The District Court expressed that Congress has "appropriated funds to encourage medical records cost savings through conversion to information technology. The legislators having decided upon the need for a health care system that operate with lower costs, so it is a matter of public policy in this state [Haven] and nation that reasonable measures to reduce health care costs should be fostered." Digitization of medical records foster the goals of Congress and the State of Haven by saving money that results in lower medical costs, which reduces medical insurance and can make health care available to more people, especially since Firefly's product costs ten percent less than that of IBM.

Furthermore, Haven has a substantial interest in regulating and protecting its resident

businesses from liability. Significantly, “the Restatement (Third) reflects interests concerned to retrench or restrain the application of liability to commercial suppliers of products.” Jane Stapleton, Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective, WASHBURN L.J. 363, 321 (2000). Since Firefly has its principle place of business in Haven, Haven likely receives income tax from companies that reside in its state and has an interest in protecting that source of income. Firefly also likely brings in revenue to the state from advertizing and product development, and provides valuable services to the state of Haven, in furtherance of the goal of its legislature to reduce medical costs.

Importantly, Haven, not Grace, is responsible for regulating Firefly and ensuring that it complies with local laws. Application of Haven law may help ensure proper regulation of companies like Firefly, since it is more likely that local courts would better understand the local needs, industries, and policies of that state.

Lastly, Haven has a sizeable interest in use of its local resources, such as the University Medical Center, including its doctors and medical staff. When Ms. Washburne, a non-resident, was treated for appendicitis in Haven under an emergency situation, she was helped by Dr. Tam, surgical assistants, and other medical staff. Dr. Tam would not have had access Ms. Washburne’s medical records were it not for Firefly’s product and service because Ms. Washburne was unconscious at the time she was taken to the hospital and needed surgery to save her life. This court’s decision will likely significantly impact the medical transcription industry and the product Haven and other states enjoy, Firefly’s product.

3. The relevant policies of Grace and the relative interest of Haven and Grace continue to favor application of Haven law because the interests of Grace are served by use of electronic medical records, both states recognize claims in strict products liability, and more state resources were involved in Haven than in Grace.

Grace may have an interest in protecting alleged tort victims who reside in its state; however, the state of Grace benefits from Firefly's product and service. The interests of Grace and the several states are served when there is easy and instant access to medical information of residents and travelers by helping to maintain the health of its citizens. Even Dr. Frye, a Grace doctor, who introduced Ms. Washburne to Firefly's product recognized its value and benefit. Furthermore, the interest of Grace in compensating tort victims is served because both Haven and Grace recognize actions in strict products liability, and thus provide an equal access to recovery for such claims.

The resources of Grace used with regard to this particular issue in tort are less significant and extensive than those expended in Haven. Dr. Frye is only marginally related to this action, in that she recommended Firefly to her patient and sent her medical records out to be digitized. A school chaperone from Grace went to Haven to take over for Ms. Washburne when she became ill, and the Grace emergency medical technicians arrived too late to treat Ms. Washburne. On the other hand, it was Haven medical personnel that received Ms. Washburne into a Haven medical center where she was treated by Dr. Tam, operated upon, and cared for after her appendicitis and subsequent allergic reaction to penicillin for two full days before release. Thus, on balance, the policies of Grace pale in comparison with those of Haven because of Haven's strong connection to the issue in tort.

4. The justified expectations of the parties are reasonably met because both states recognize strict products liability claims and use of electronic medical records help prevent medical errors common in traditional paper records.

The parties both justifiably expected that Ms. Washburne's electronic medical records would function to save costs and facilitate transmission of medical records in times of emergency. Respondent justifiably expected a correct and accurate digitization of her medical records and for the software to function properly under normal use; however, the source of the error is unknown, and like paper medical records, unexpected errors can occur. It is common knowledge that even some of the most expensive and well-created software, such as that produced by Microsoft or Apple, experience errors. Therefore, it can be rationally said that the expectations of the Ms. Washburne were met by Firefly's product, since medical errors do occur despite best efforts, and electronic medical records are a great step in reducing those errors common in paper records. Additionally, Firefly sent an electronic copy of Ms. Washburne's medical file to her, yet she failed to review it for accuracy or even read the provided instructions. Lastly, both the state of Grace and Haven allow suits in strict products liability, thus allowing Respondent to recover under such theory in either state, as long as her claim has merit.

5. The basic policies underlining strict products liability claims simplify litigation for defective products, and since Respondent chose to file suit in Haven, which recognizes claims in strict product liability, the policy goals in this action are met by application of Haven law.

Strict Products Liability was developed to lessen the evidentiary burden on plaintiffs in having to prove the intent or mental state of the defendant in products liability cases where direct access to such information is challenging or impractical. Seldon Childers, University of Florida Journal of Law and Public Policy, Don't Stop The Music: No Strict Products Liability for Embedded Software, 19 UFLJLPP 125, 130-132 (2008). It was also developed to promote safer product development by holding the manufacturer liable without fault for defective products, and

placing the added monetary cost of creating reasonably safe products on the consumer. Id at 130. Since both states recognize claims for defective products in strict liability, Respondent is well served by application of Haven law, the law of the forum state. Also, Respondent chose to file suit in Haven, either because it was thought to be the state with the greatest contacts or because it was mistakenly believed that Haven law would be more favorable. Either way, litigation is simplified when a federal court sitting in Haven applies Haven law, since it is more likely to be more familiarized with the law of in its own state.

6. The goals of certainty, predictability and uniformity of result are furthered by Haven law because both states follow the Restatement (Second) Conflict of Laws, and Haven's law is not so different from Grace law with regard to strict products liability that the result would be uncertain, unpredictable, or lack uniformity.

The current Restatement (Second) Conflict of Laws regarding tort actions has not produced uniformity, yet it is a better system than that of focusing on the place of injury (the old *lex loci delicti* standard) because that standard worked great injustice where the place of injury was fortuitous. Michael Ena, Note, Choice of Law and Predictability of Decision in Products Liability Cases, 34 Fordham Urb. L.J. 1417, 1447-1448 (2007). As explained previously, both Haven and Grace follow the Restatement (Second) Conflict of Law, and therefore there is a high degree of predictability of result. Also, the presumption that the place of injury controls which state's substantive law will be applied "further the choice-of-law values of certainty, predictability and uniformity of result and, since the state where the injury occurred will usually be readily ascertainable, of ease in the determination and application of the applicable law." Restatement (Second) Conflict of Laws § 175 cmt. d. Furthermore, Haven's law is not so different from Grace law that the result would be uncertain, unpredictable, or lack great uniformity. Had Respondent alleged a reasonable alternative design, it would have had a better chance of surviving summary judgment. Also, as mentioned by Respondent, a handful of states,

including Haven, now follow the Restatement (Third) of Torts. Therefore, there is a reasonable degree of predictability of result because there are cases on the books that indicate the direction of the courts in these jurisdictions, providing guidance to Respondent. Haven law thus satisfies these goals.

7. Haven’s substantive law is easy to apply because the rules on strict products liability are well established and unambiguous.

The issue in this case is liability for a product defect. This particular factor under § 6 is of little importance in this type of suit because the issue is whether the Firefly may or may not be held liable. Here, “no esoteric or complex substantive laws are involved.” See e.g. Veasley, 553 N.W.2d at 898 (speaking of products defect action for personal injuries involving automobile accident). Haven’s substantive law in the area of strict products liability is unambiguous and clearly established. Furthermore, it cannot be said that Grace’s law is any clearer or easier to apply. In effect, therefore, this factor is neutral.

In sum, the § 6 factors add additional support for the application of Haven’s substantive law. Analysis of both § 145 relational factors and § 6 policy factors thus call for the application of Haven’s substantive law under Haven’s conflict-of-law rules. The Circuit Court was therefore incorrect to hold that Grace’s substantive law applies in this case.

II. UNDER HAVEN LAW, RESPONDENT’S COMPLAINT IS INSUFFICIENT TO SURVIVE A 12(b)(6) MOTION TO DISMISS BECAUSE RESPONDANT HAS FAILED TO ALLEGE A REASONABLE ALTERNATIVE DESIGN, AND HAS FAILED TO DEMONSTRATE THE EXISTENCE OF A MANUFACTURING DEFECT.

To survive a 12(b)(6) motion to dismiss, “‘a complaint ... must contain either direct or inferential allegations respecting all the material elements necessary to sustain recovery under some viable legal theory.’” Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 562 (2007), quoting Ascon Properties, Inc. v. Mobil Oil Co., 866 F.2d 1149, 1155 (9th Cir. 1989). A judge must

accept all the factual allegations in a complaint as true. Erickson v. Pardus, 551 U.S. 89, 94 (2007). However, the court is not required to accept legal conclusions that are couched as factual allegations. Bell Atlantic Corp. v. Twombly, 550 U.S. 544, 555 (2007).

A. **Respondent's claims for design and warning defects should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6) because the plaintiff failed to allege a reasonable alternative design, a material element to a strict products liability claim under the Restatement (Third) of Torts: Products Liability.**

Respondent failed to state a claim upon which relief can be granted. In a design or warning defect cause of action, a plaintiff must show that a reasonable alternative design was available to the defendant at the time of manufacture, and, significantly, that the failure to incorporate such design or warning renders the product unreasonably unsafe. Restatement (Third) of Torts: P.L. § 2 (1998). In addition, under Haven law, plaintiff must show that the defendant's product was the "but for" cause and the proximate cause of the plaintiff's harm. Id.; see also Haven Rev. Code § 1018.11.

Alabama courts require proof of a reasonable alternative design much like the Haven courts. Summary judgment has been granted for defendants in numerous cases where the plaintiff failed to meet the requirement. The leading case in Alabama is General Motors Corp. v. Edwards, 482 So.2d 1176, 1190 (Ala. 1985), in which the Alabama Supreme Court held that in order to prove defectiveness, the plaintiff must prove that a safer, practical, alternative design was available to the manufacturer at the time it manufactured the automobile in question. The facts in General Motors Corp. are analogous to the facts in the present case. Because the plaintiff here failed to allege in their complaint that a reasonable alternative design existed at the time Firefly manufactured its software, the design and warning defects claims should be dismissed.

Even if plaintiffs were permitted to argue at this late stage in litigation that a reasonable alternative design existed, such as the IBM product, this claim would still fail because the IBM

system would not have prevented the error that occurred in the electronic medical chart possessed by Dr. Tam. Therefore, IBM's product design and warning system would not be a sufficient reasonable alternative design. IBM's product includes the "final check flag system", which requires the operator to confirm critical information is entered correctly in the electronic medical file before continuing to enter other data. This feature only requires one extra step of IBM's employees than Firefly's employees, who are instructed to ensure the electronic copy matches the exact paper copy. The anonymous Firefly transcriber did, in fact, enter Ms. Washburne's allergy information in the system, as evidenced by the fact that the information was correctly stored on the Firefly servers at the time Dr. Tam accessed the electronic medical chart. Thus, even if Firefly had adopted the "final check flag system", this would not have prevented the unknown glitch that caused the "Known Allergy" field to be erased. Therefore, while the IBM system is an alternative product design, it is not a reasonable one, for it would not have prevented the harm that occurred to Ms. Washburne. Consequently, it cannot be said that failure to adopt the IBM warning system resulted in Firefly's product being defective, as its exclusion has not rendered Firefly's product unreasonably unsafe.

Grace Law employs a combination of the consumer expectations test and the risk-utility test. Barker v. Lull Eng'g, 20 Cal.3d 413 (1978) Under Grace Law, Respondent's design and warning defect claim would still fail because there is an implied requirement of a reasonable alternative design. The Appellate Court itself used the IBM warning system as an alternative design to try and show that the Firefly system's failure to implement it made the product inherently unsafe. Since we have shown that the IBM system would not have prevented the injury, and because no alternative warning or design is alleged, no court could conclude that the Firefly software is inherently unsafe. While it is true that the consumer would expect their medical records to be correctly transcribed, in this instance it is clear that Firefly met that

expectation.

Although their complaint fails to allege it, Respondent will try to argue that an exception to the reasonable alternative design requirement exists in the Restatement (Third) of Torts: Products Liability, which might allow Respondent's claim to survive the 12(b)(6) motion. The exception they are citing is commonly referred to as the "malfunction exception". Restatement (Third) of Torts: P.L. § 2 cmt. b; Restatement (Third) of Torts: P.L. § 3. Under this "exception", a reasonable alternative design could be inferred by the court if the plaintiff proves a product malfunction occurred.

Many argue that the creators of the Restatement (Third) did not intend for § 3 to be used as a way around the requirement of a reasonable alternative design in a design defect claim. This is supported by the inclusion of a comment in the reporter's notes that "reasonable alternative design" is the predominate method of showing product defect. Restatement (Third) of Torts: P.L.-2, Reporters' Notes to cmt. e. Furthermore, the only cases actually employing the malfunction theory involve manufacturing defects, where the courts inferred a malfunction where the product itself was completely destroyed in an accident that normally would not occur in the absence of a malfunction. Jonathan Hoffman, Res Ipsa Loquitur And Indeterminate Product Defects: If They Speak For Themselves, What Are They Saying?, 36 S. TEX. L. REV. 353, 375 (April 1995) citing Restatement (Third) of Torts: Products Liability § 3, Reporters' Notes to cmt. d, at 178 (Council Draft No. 1A, 1994). The only materials supporting Respondent's position that the malfunction theory supports an inference on defective design are the occasional dictum. Id.

Furthermore, under the traditional law of inference, a defect here "would collapse once the defendant brings forth a plausible explanation of the incident that does not involve defect...." Restatement (Third) of Torts: Products Liability, an Anglo-Australian Perspective, WASHBURN

L.J. at 388-389. All Firefly would need to do is merely bring plausible evidence that the incident could have been due to a “non-defective” condition of the product in order to dispel the inference of defect. Id. Thus, since it is entirely plausible that the incident here (a blank field in the “Known Allergy” section of the electronic medical record possessed by Dr. Tam) was due to a computer glitch or communication hiccup involving University Medical Center’s computers or servers when downloading Ms. Washburne’s file from Firefly’s secure server, any inference of defect based on a product malfunction theory falls away. Respondent is still left with the burden of proof, which it has not met because it can provide no other evidence of design defect in Firefly’s software.

Assuming, however, that this Court were to allow Respondent to bring the malfunction theory into the late stages of this case, and even if Petitioners were to concede that the malfunction theory would allow the court to infer a defect without a showing of a reasonable alternative design in the Respondent’s complaint under the facts of this case, the 12(b)(6) motion should still be granted on the grounds that Respondent fails to show causation, a material element in design or warning defect claims under Restatement (Third) of Torts and Haven law.

Respondent alleges that a defect occurred with Firefly’s software, evidenced by the electronic medical record displaying a blank space, where the default setting would have displayed the word “NONE”. However, this argument is flawed in that even if it were true, the alleged defect would not be the “but-for” cause of the plaintiff’s injury. If the electronic medical record displayed the word “NONE” as the software was designed to do, Dr. Tam would have still administered the penicillin to Ms. Washburne, acting on the assumption that there was no allergy. In their complaint, Respondent made the legal conclusion that the alleged malfunction with Firefly’s software caused the injury to Ms. Washburne, and they have couched that legal conclusion as a factual allegation. The Court is not required to accept such legal conclusions

contained in the complaint, and should therefore grant the 12(b)(6) motion to dismiss, regardless of whether Haven or Grace law is applied, since causation is a material element of strict products liability in Grace as well as Haven. Restatement (Second) of Torts 402(A)(1).

In sum, because Respondent's complaint failed to allege that a reasonable alternative design was available to the defendant at the time of manufacture, and because a claim for a malfunction exception would fail under the causation element if it were to be accepted by the Court, their claims for design and warning defects should be dismissed pursuant to the 12(b)(6) motion.

B. Respondent's manufacturing defect claim should be dismissed pursuant to Federal Rule of Civil Procedure 12(b)(6) because the plaintiff failed to demonstrate the existence of a defect, a material element to a strict products liability claim under the Restatement (Third) of Torts: Products Liability.

Respondent failed to state a claim upon which relief can be granted. In a manufacturing defect cause of action, a plaintiff must show that the product departed from its intended design even though all possible care was exercised in preparing and marketing the product. Restatement (Third) of Torts: P.L. § 2(A) (1998). The plaintiff bears the burden of proving the defect's existence; that the product was not manufactured according to its design specifications. Toms v. J.C. Penney Co., 304 Fed. Appx. 121 (3d Cir. 2008).

Before getting into the application of the facts of this case, Petitioners would like to point out a fundamental flaw in both the Respondent's claim and the opinion of the Court of Appeals that accepted it. When setting out their case for manufacturing defect, Respondent and the Court of Appeals were quick to conclude that the product in question is *not* Firefly's software, but rather the particular medical record used by Dr. Tam which did not display penicillin in the allergy field. However, in the application of the design and warning defect claim, the Court of Appeals and the plaintiff changed positions and analyzed the design of the *software*, not the

medical record. Petitioners believe that this Court cannot, in light of principles of justice and equity, accept a strict products liability claim which defines a defendant's product as two separate and distinct things. Petitioner's position is clear: Firefly's one and only product is its software. The Firefly software is mass-produced, and is not tailored to the individual needs of the consumer. It is the only item that Firefly has designed and manufactured, and the only item that Firefly has marketed and sold to the public. When the physicians around the country decide to upgrade their systems, they purchase the Firefly software, not the medical records. Therefore, the Firefly software should be the only item that is scrutinized under this single products liability claim.

With the product designated as Firefly's software, the Respondent's claim for manufacturing defect should be dismissed because the complaint fails to at least make a preliminary showing that the product departed from its intended design. This Court's first inquiry should be what the Firefly software was designed to do, and then whether the software performed according to that design.

The Firefly software was designed to passively accept the inputted information from the user, including the failure to input information. The software was also designed to store the electronic versions of medical records on a secure server that could be accessed around the country by physicians in case a patient were to visit a hospital away from their regular doctor's office. It is undisputed that the copy of the medical records on Firefly's server was accurate in all respects, and thus, it is clear that the Firefly software performed exactly as it was intended to perform, and plaintiff's allegations contained in their complaint do not meet the standards of Haven law requiring a preliminary showing of a departure from the intended design.

If the plaintiff alleges a manufacturing defect that was a result of human error in failing to input penicillin in the allergy field, the claim fails because the software was intended to accept

what the user inputs into it. Therefore, plaintiff's claim for relief should have been in a negligence cause of action, not strict products liability. This claim should be dismissed under the 12(b)(6) motion because the essential element of a defect in the product was clearly not shown.

If however, the plaintiff alleges that the defect was a software malfunction that caused the default "NONE" to be erased, displaying a blank field instead, the claim would still fail the 12(b)(6) motion because there would be no causation. Dr. Tam would have administered penicillin to Ms. Washburne whether the medical record displayed "NONE" or displayed a blank field.

Another reason the complaint is insufficient to survive the Fed. R. Civ. P. 12(b)(6) motion is that the Haven Supreme Court has set forth guiding criteria by which a plaintiff can demonstrate the existence of a manufacturing defect, and plaintiff's complaint fails to meet that criteria. The first way a plaintiff can demonstrate the existence of a manufacturing defect is by direct evidence that the defect arose in the hands of the manufacturer. Plaintiff simply does not have such evidence. In fact, we again point out that contained in the District Court's recitation of the facts is direct evidence that the electronic medical records were stored correctly, with penicillin listed in the allergies field on the secure Firefly server. Therefore, not only does plaintiff lack direct evidence that there was a defect in the software that existed while in the hands of the manufacturer, but there is direct evidence to the contrary, that while in the hands of the manufacturer the electronic medical records were correct. It wasn't until the records were accessed by the software utilized by University Medical Center and given to Dr. Tam that the error in the medical records, the copy possessed by Dr. Tam, came to be.

The second way a plaintiff can demonstrate the existence of a manufacturing defect is by circumstantial evidence that would create an inference of product defect prior to sale. The plaintiff simply has failed to allege any circumstantial evidence which would warrant such an

inference by the Court. The mere existence of the blank field on the medical record obtained by Dr. Tam would not be enough to infer that the Firefly software has in any way departed from its intended design. The direct evidence supplied by Petitioner showing the medical record stored on the Firefly server was correct would negate any inference that the error existed prior to the record being downloaded by University Medical Center. See Restatement (Second) Conflict of Laws § 3 cmn. d (“Evidence may permit the inference that a defect in the product at the time of the harm-causing incident caused the product to malfunction, but not the inference that the defect existed at the time of sale or distribution.”). Moreover, the Respondent is not able to look to the USB flash-drive provided to Ms. Washburne as possible evidence of software defect because it was never reviewed and subsequently lost by Ms. Washburne.

The third way a plaintiff can demonstrate the existence of a manufacturing defect is by negating other causes of the failure of the product for which the defendant would not be responsible, in order to further an inference that the defect was attributable to the manufacturer. Marcus v. Valley Hill Inc., 301 Haven 197 (2006). Here, the plaintiff’s complaint simply does not address any of the other reasonable and plausible causes of the failure. There could have easily been a problem with the computer that University Medical Center used to access Firefly’s secure web portal, or a miscommunication between servers due to a problem with University Medical Center’s server that would have omitted the allergies field when the record was being downloaded. To put it simply, there are multiple possible causes of the error for which the defendant would not be responsible, and the plaintiffs failed to negate any of those causes in their complaint in order to demonstrate a manufacturing defect.

In sum, Respondent’s argument for manufacturing defect is fundamentally flawed because the complaint failed to make a preliminary showing that the Firefly software departed from its intended design, and has also failed to demonstrate the existence of a manufacturing

defect through either of the avenues supplied by the Haven Supreme Court. Therefore, the claim for manufacturing defect should also be dismissed pursuant to the 12(b)(6) motion.

CONCLUSION

In conclusion, the substantive law of Haven should be applied because it is the state with the most significant relationship to the strict products liability claim, and consideration of the policy concerns involved further support application of Haven law. The Respondent has failed to state a claim under Fed. R. Civ. P. 12(b)(6) because it has not alleged a reasonable alternative design, and there is no manufacturing defect because the product did not deviate from its original design. Therefore, the Petitioners respectfully request that this Court reverse the opinion of the Circuit Court of Appeals and order this case dismissed with prejudice.

February 9, 2011

Respectfully submitted,

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