In the

District Court of Maryland

June Term, 2018

No. 123

Heart2Heart

Plaintiff,

-v.-

John Smith

Defendant.

Brief for Defendant John Smith

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Defendant's Counsel

Johns Hopkins University

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Maryland 21218

Introduction:

Wayne Rooney, a patient of Maryland Hospital, had a pacemaker installed. This pacemaker was manufactured by Heart2Heart and had a security vulnerability. A pacemaker detects the heart rate of the patient it is attached to. The pacemaker is connected to the hospital network and monitored by the hospital to check its smooth operation. John Smith, the defendant, was working as a technician for Heart2Heart. During his work, he discovered a vulnerability in the pacemaker which could not be fixed in devices already sold and informed Heart2Heart of the potential harm the vulnerability could cause. Heart2Heart, despite knowing about the vulnerability, did not recall the devices as it would harm its financial position. Heart2Heart determined that this vulnerability could be discovered only through internal research and was safe from malicious third-party actors. However, Eden Snoward was able to hack the hospital network and exploit the pacemaker's vulnerability leading to Wanye Rooney's death. Eden Snoward intercepted the network traffic between the pacemaker and the hospital and set up a fake pacemaker to imitate Wanye Rooney's pacemaker to send false data to the hospital. Eden Snoward used a reverse shell which allowed him to send any commands to the device as well. When Wanye Rooney had a heart attack at the hospital, the pacemaker did not generate the signals it was supposed to which led to his death. Upon investigation, it was determined that Eden Snoward had received information about the vulnerability on the dark web. The source who put up the vulnerability on the dark web was John Smith. John Smith was morally frustrated with Heart2Heart and decided to go to the dark web to expose this malpractice. Now that Wayne Rooney's family is suing Heart2Heart, Heart2Heart is suing John Smith as a part of their defense. The issue of this case is whether John Smith is responsible for Wayne Rooney's death instead of Heart2Heart.

Arguments:

1. Heart2Heart has violated the product liability for component manufactured under two clauses[1]:

    a. Design defect under strict liability theory

    According to the case Larsen v. Pacesetter Systems, Inc.[2], amended on other grounds on reh'g in part by, 74 Haw. 650, 843 P.2d 144 (1992) and opinion amended, (Oct. 22, 1992), the court held that the "Programalith III Series Model 241-6" pacemaker implanted in the plaintiff was in a defective and therefore unmerchantable condition sufficient to support an action for breach of the implied warranty of merchantability, stated that where an action in implied warranty sought to recover for personal injury, product unmerchantability was equivalent to defectiveness in a tort action for strict products liability suit. Heart2Heart was responsible of ensuring the security of the devices it sold and thus according to the holding from the case, it is liable for action under tort for strict products liability.

    b. Fraud or Misrepresentation

    Granting summary judgment for the defendant pacemaker manufacturer in an action by a recipient of the manufacturer's pacemaker, seeking to recover damages for cardiac tamponade allegedly caused by the perforation of the recipient's heart wall by the pacemaker's "TENDRIL DX Model 1388TC" atrial lead, the court, in Webster v. Pacesetter, Inc.[3], held that the recipient failed to establish fraud by the

[1] 23 A.L.R.6th 223 (Originally published in 2007)
[2] 74 Haw. 1, 837 P.2d 1273, Prod. Liab. Rep. (CCH) ¶ 13406, 20 U.C.C. Rep. Serv. 2d 877 (1992)
[3] 259 F. Supp. 2d 27, Prod. Liab. Rep. (CCH) ¶ 16640 (D.D.C. 2003)

manufacturer. In the District of Columbia, the court explained, a fraud claim required (1) a false representation, (2) in reference to a material fact, (3) knowledge of falsity, (4) intent to deceive, and (5) action taken in reliance upon the representation. Although this case was ruled in favor of the merchant, the holding used, hold Heart2heart liable under fraud and Misrepresentation as they knew about the vulnerability and their intent to deceive was with the fact that they did not recall the devices in order to avoid monetary loss.

2. Heart2Heart failed to comply with the Medical Device Amendments of 1976 ("MDA")[4], to the Federal Food, Drug and Cosmetic Act[5].[6]

    a. According to the Supremacy Clause of the United States Constitution provides that the "Laws of the United States . shall be the supreme Law of the Land."[7] Hence, "state law that conflicts with federal law is 'without effect.'"[8]. The section 360k of the MDA, which expressly preempts certain state law requirements governing medical devices: No State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement- (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device.[9] In the case of Medtronic, Inc. v. Lohr[10], the Supreme Court addressed the question

[4] 21 U.S.C. §§ 360c et seq.
[5] 21 U.S.C. §§ 301 et seq
[6] Kemp v. Medtronic, Inc., 231 F.3d 216, 218 (6th Cir. 2000)
[7] U.S. Const. art. VI, cl. 2.
[8] Cipollone v. Liggett Group, Inc., 505 U.S. 504, 516, 112 S.Ct. 2608, 120 L.Ed.2d 407 (1992).
[9] 21 U.S.C. § 360k(a).
[10] 518 U.S. 470, 116 S.Ct. 2240, 135 L.Ed.2d 700 (1996)

whether the MDA preempts various common law tort claims. The device in Lohr had not undergone a PMA review, but had instead been approved pursuant to the "substantially equivalent" exception found in § 510(k). In a five to four decision, the Court held that none of the plaintiffs' common law tort claims were preempted by the MDA. Lohr[11]. According to the premarket approval clause of the FDA, "full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective"[12]. Since Heart2Heart provided false reports of it's safety, under the FDA clause 360e, "that such device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling thereof"[13], the market approval of Heart2Heart's pacemaker should be suspended.

Conclusion:

As we can see, Heart2Heart has displayed negligence with respect to their product's security which lead to an innocent man's death. Despite John Smith's warning, the company did not act to recall the devices with a vulnerability and thus, violated the MDA amendment to the FDA. According to the reasons mentioned above and with regard to the United States Rulings, Regulations and Arguments presented in the defence, the death of Wayne Rooney cannot be considered as John Smith's responsibility and we request a motion to dismiss the case.

[11] 518 U.S. at 501-02, 116 S.Ct. 2240
[12] 21 U.S.C.A. § 360e (West)
[13] 21 U.S.C.A. § 360e (West)