# United States Court of Appeals
## FOR THE EIGHTH CIRCUIT

No. 01-3076

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| Biomedical Systems Corporation, | * | |
| | * | |
| Appellee, | * | Appeal from the United States |
| | * | District Court for the Eastern |
| v. | * | District of Missouri. |
| | * | |
| GE Marquette Medical Systems, Inc., | * | [PUBLISHED] |
| | * | |
| Appellant. | * | |

Submitted: April 16, 2002

Filed: April 23, 2002

Before HANSEN, Chief Judge, McMILLIAN and FAGG, Circuit Judges.

PER CURIAM.

GE Marquette Medical Systems, Inc. (GE) appeals from an adverse jury verdict in this diversity action. Having carefully reviewed the briefs, record, and arguments of counsel, we are satisfied the district court[*] correctly applied state law, and the challenged rulings do not require reversal. Because the parties' submissions show

[*]The Honorable Charles A. Shaw, United States District Judge for the Eastern District of Missouri.

they are thoroughly familiar with the issues before this court, we conclude that an extended opinion in this diversity case would serve no useful purpose.

Before GE acquired Corometrics, Inc. (Corometrics), Corometrics contracted to produce a new home uterine activity monitor (HUAM) based on technology developed by Biomedical Systems Corporation (Biomedical). (Because Corometrics is now part of GE, we refer to Corometrics as GE.) HUAMs are medical devices regulated by the Food and Drug Administration (FDA). The GE-Biomedical contract required GE to obtain "510(k)" premarket notification clearance from the FDA. See Food, Drug, and Cosmetic Act, ch. 675 § 510(k), 76 Stat. 794 (1962) (codified as amended at 21 U.S.C. § 360(k) (1994)). To receive 510(k) clearance, a manufacturer must give the FDA 90 days' notice that the manufacturer intends to market a medical device (1) which is substantially equivalent to a device already approved by the FDA, and (2) which has the same intended use as the approved device. Id. If the FDA agrees, it issues a clearance letter which authorizes the manufacturer to market the device as specified by the FDA.

Rather than seeking 510(k) approval, which would be granted or denied within 90 days, GE asked the FDA to reclassify GE's new HUAM from one class of regulated devices to another class of regulated devices. The reclassification process took three and a half years. Two and a half years after signing the contract, Biomedical sued GE in federal district court alleging fraudulent misrepresentation and breach of contract, and claiming $135 million in damages. The jury found for Biomedical on its breach of contract claim and awarded $75 million in damages. On appeal, GE challenges the district court's rulings barring its illegality and waiver defenses.

First, GE argues it was entitled to judgment as a matter of law because the contract, which GE drafted, required GE illegally to seek 510(k) approval for the new HUAM. Having reviewed this issue de novo, Fogelbach v. Wal-Mart Stores, Inc.,

270 F.3d 696, 700 (8th Cir. 2001), we conclude the district court properly denied GE judgment as a matter of law on its illegality defense. In our view, the contract unambiguously required GE to apply for 510(k) clearance and did not require GE to violate federal law. Indeed, after considering the contractual language in light of extrinsic evidence about the parties' intent when entering into the contract, the jury reached the same conclusion.

Second, GE contends the district court improperly excluded evidence that Biomedical waived GE's breach of the contract provisions requiring GE to seek 510(k) approval. The GE-authored contract, however, expressly forbids waiver of this sort. Because the contract is governed by Connecticut law under which the waiver provision is valid, see Christensen v. Cutaia, 560 A.2d 456, 459 (Conn. 1989), we conclude the district court correctly barred GE's waiver defense.

Having satisfied ourselves that the district court correctly rejected GE's illegality and waiver defenses, we also reject GE's remaining arguments. Because the contract did not require illegal conduct on GE's part, we do not disturb the jury damage award. Further, the district court did not abuse its discretion when it excluded evidence that supported and refused to give requested instructions that explained the illegality and waiver defenses.

In sum, whether discussed or not, we have considered all of GE's arguments. Finding no error that would require reversal, we affirm the judgment of the district court.

A true copy.

Attest:

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