[DO NOT PUBLISH]

IN THE UNITED STATES COURT OF APPEALS

FOR THE ELEVENTH CIRCUIT

No. 11-11025
Non-Argument Calendar

FILED
U.S. COURT OF APPEALS
ELEVENTH CIRCUIT
SEPTEMBER 8, 2011
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D.C. Docket No. 8:10-cv-02479-SDM-TBM

DENISE ROUNDS,
THOMAS ROUNDS,

Plaintiffs - Appellants,

versus

GENZYME CORPORATION,
a Foreign Profit Corporation,

Defendant - Appellee.

Appeal from the United States District Court
for the Middle District of Florida

(September 8, 2011)

Before MARCUS, MARTIN and ANDERSON, Circuit Judges.

PER CURIAM:

Plaintiffs-Appellants Denise and Thomas Rounds ("the Rounds") appeal from the district court's final order dismissing for failure to state a claim their negligence action against Defendant-Appellee Genzyme Corporation ("Genzyme"). On appeal, the Rounds argue that the district court erred in dismissing their complaint because: (1) the complaint properly contains a short and plain statement showing that they are entitled to relief; and (2) the learned intermediary doctrine is inapplicable. After careful review, we affirm.

We review de novo the district court's grant of a motion to dismiss for failure to state a claim upon which relief may be granted under Federal Rule of Civil Procedure 12(b)(6), accepting the allegations in the complaint as true and construing them in the light most favorable to the plaintiff. See Harris v. United Auto. Ins. Group, Inc., 579 F.3d 1227, 1230 (11th Cir. 2009). Because this case invoked the district court's diversity jurisdiction, we apply Florida substantive law to the Rounds's claims. See Horowitch v. Diamond Aircraft Indus., Inc., 645 F.3d 1254, __ (11th Cir. 2011).

The relevant, undisputed facts are these. Genzyme manufactures a product called "Carticel," a biologic product comprised of autologous cultured chondrocytes used to repair articular cartilage injuries. Carticel uses the body's own cultured cells to regenerate the articular cartilage in a knee during a surgical procedure called

autologous chrondrocyte implantation ("ACI"). Under the care of Dr. Brian Jurbala, Denise Rounds underwent an ACI procedure involving Carticel on her left knee on May 8, 2006, and on her right knee on May 21, 2007.

Subsequently, the Rounds filed this negligence action, alleging that "the results of both operations were not successful" and that Denise Rounds "was not a proper candidate for such drastic and extreme medical treatment." They further alleged that Genzyme did not give proper training to Dr. Jurbala regarding "which patients are Carticel candidates and which are not Carticel candidates." Genzyme then filed a motion to dismiss, on the grounds that the complaint failed to allege facts showing a causal relationship between Genzyme's conduct and Denise Rounds's injuries, and that the Rounds's claims were barred by the learned intermediary doctrine. In support of its argument regarding the learned intermediary doctrine, Genzyme attached the Carticel package insert, which contained warnings, precautions, and contraindications regarding patient evaluation and use, including identifying as unsuitable patients who have certain medical conditions (e.g., generalized osteoarthritis, a known hypersensitivity to gentamicin, etc.), and advising about the likelihood of the need for subsequent medical treatment and surgeries following the use of Carticel.

The district court granted Genzyme's motion to dismiss on both grounds -- that the Rounds had failed to plead causation, and that the learned intermediary doctrine barred the Rounds's claims. This appeal follows.

We agree with the district court that the Rounds's claims are barred by the learned intermediary doctrine.[1] The learned intermediary doctrine is a "corollary to the rule that a manufacturer of prescription drugs or products discharges its duty to warn by providing the physician with information about risks associated with those products." Christopher v. Cutter Laboratories, 53 F.3d 1184, 1192 (11th Cir. 1995) (citing Felix v. Hoffmann-LaRoche, Inc., 540 So. 2d 102, 104 (Fla. 1989)).[2] The manufacturer's duty to warn of a prescription product's hazards runs to the physician, not directly to the patient. Id.

[1] As a result, we need not also address the district court's alternative holding -- that the claims are dismissed because the Rounds failed to properly allege causation.

[2] Although Florida state case law regarding the learned intermediary has solely dealt with prescription drugs, we see no distinction in this instance between drugs, devices, or other prescription products. See Ellis v. C.R. Bard, Inc., 311 F.3d 1272, 1280 (11th Cir. 2002) (recognizing that applying the learned intermediary rule to both prescription drugs and prescription medical devices is "almost universal"). Prescription products, such as Carticel, do not fall neatly into the category of drug or device, but like a drug or device, patients do not have access to such products without the intervention of a learned intermediary physician. See id. (explaining that the rule applies to both drugs and medical devices because both "are only available to the public by prescription from a physician or dentist") (quotation omitted). Indeed, it is not reasonably conceivable that a patient, such as Denise Rounds, could surgically extract her body's own cultured cartilage cells and then surgically implant the regenerated autologous cultured chondrocytes, without the intervention and assistance of a trained surgeon.

When a manufacturer gives a warning regarding its product, the issue is whether the warning provided to the physician is adequate. Beale v. Biomet, Inc., 492 F. Supp. 2d 1360, 1368 (S.D. Fla. 2007). In Beale, the plaintiffs were implantation recipients of a prescription knee device "suitable for certain patients who, in the treating orthopedic surgeon's judgment, are appropriate candidates based upon the surgeon's evaluation of variables such as the patient's medical history, physical examination, x-rays, disease progression, pain syndrome, gait, age, weight, and activity level." Id. at 1363. The plaintiffs both claimed they were improper candidates for the device, one due to weight, the other due to his activity level. Id. at 1369. The Beale court, in holding that the learned intermediary doctrine barred the plaintiffs' claims, noted that the package insert for the device contained warnings to the physician regarding patient selection, including warnings regarding weight and activity level. Id. at 1368-69. Accordingly, the court found the manufacturer had satisfied its duty to the physician. Id.

Similarly, here, the Rounds's complaint alleges that Denise Rounds's injuries -- the need for subsequent medical treatment and surgeries following the use of Carticel -- were caused by Genzyme's failure to properly train Dr. Jurbala regarding "which patients are Carticel candidates and which are not Carticel candidates." Yet the Carticel package insert expressly contained warnings, precautions, and

contraindications regarding patient evaluation and use, including identifying as unsuitable patients who have certain medical conditions (e.g., generalized osteoarthritis, a known hypersensitivity to gentamicin, etc.). Moreover, the package insert specifically advised Dr. Jurbala of the likelihood of the very injury of which the Rounds complain: the need for subsequent medical treatment and surgeries following the use of Carticel. Specifically, the package insert advised Dr. Jurbala that "[t]he necessity of subsequent surgical procedures, primarily arthroscopic, following Carticel implantation is common. In the STAR study, 49% of patients underwent a subsequent surgical procedure, irrespective of relationship to Carticel." Therefore, because Genzyme expressly and clearly warned Dr. Jurbala about how to identify Carticel patients and about the risk of the exact injury of which the Rounds now complain, the warnings were adequate as a matter of law. See Beale, 492 F. Supp. 2d at 1370.

Further, we are unpersuaded by the Rounds's argument that "[w]hether Dr. Jurbala was a 'learned intermediary' or not as to Autologous Chondrocyte Implantation is precisely the factual question that forms the crux of the case." (Emphasis added). Under Florida law, "the adequacy of warnings can become a question of law where the warning is accurate, clear, and unambiguous." Felix, 540 So. 2d at 105. Because Genzyme's warning to Dr. Jurbala of the likelihood of future

medical surgeries after Carticel treatment was accurate, clear and unambiguous, the adequacy of Genzyme's warning is an issue of law, and not an issue of fact. Indeed, the Rounds have not alleged, or even argued, that the package insert warnings were somehow insufficient, nor explained how the warnings did not cover Denise Rounds's conditions or risks.

The Rounds further argue that Genzyme's representation that doctors performing ACI procedures using Carticel have been trained in the procedure "prevents a court from applying the learned intermediary doctrine as a matter of law." The Rounds cite no authority for this position. Moreover, the Rounds's argument misapprehends the nature of the learned intermediary doctrine itself: Genzyme satisfied the learned intermediary doctrine in this case by informing Dr. Jurbala of the risks associated with Carticel by providing him the package insert which contained clear, unambiguous language about how to identify Carticel patients and about the risk of the injury suffered by Denise Rounds.

The Rounds also contend that Genzyme had a duty to Denise Rounds because her insurance carrier paid Dr. Jurbala for the Carticel therapy. The Rounds not only cite no authority for this position, they again misapprehend the very nature of the learned intermediary doctrine, which states that a manufacturer has no duty directly to a patient to warn of risks associated with the product when the manufacturer has

provided accurate, clear and unambiguous information about the risks associated with a product to the patient's physician. Beale, 492 F. Supp. 2d at 1365. It is then incumbent upon the now-learned physician to evaluate those risks and the use of the product in treating a particular patient. That the Rounds's insurance carrier paid for the procedure is irrelevant.

Finally, the Rounds assert -- again without citing any authority -- that "[i]t is a question of fact for a jury whether the package insert was sufficient 'training' for Dr. Jurbala to perform Carticel procedures . . . ." With this assertion, the Rounds attempt to circumvent the learned intermediary doctrine by characterizing the issue as one of training rather than of warning. As the district court recognized, this is a distinction without a difference -- especially since the Rounds have not alleged that Genzyme gave inadequate training regarding the physical implementation of the procedure itself, but rather in how he should select potential candidates for Carticel. Thus, Genzyme satisfied its duty to Dr. Jurbala by providing clear, unambiguous information concerning the contraindications for Carticel, as well as the risks associated with it. Whether Genzyme was "training" or "warning" Dr. Jurbala of these risks when it provided him the package insert is, as the district court recognized, an issue of semantics only. As a matter of law Genzyme discharged its duty to advise Dr. Jurbala of the risks associated with Carticel by providing clear, unambiguous

information about these risks in the Carticel package insert. Dr. Jurbala then owed a duty to Denise Rounds to read the package insert and exercise judgment in discussing those risks with Ms. Rounds and in using the Carticel product to treat Ms. Rounds.

"[T]he court may dismiss a complaint pursuant to Federal Rule of Civil Procedure 12(b)(6) when, on the basis of a dispositive issue of law, no construction of the factual allegations will support the cause of action." Marshall County Bd. of Educ. v. Marshall County Gas Dist., 992 F.2d 1171, 1174 (11th Cir. 1992). Since the learned intermediary doctrine is a dispositive issue of law in this case, under Florida law the Rounds's complaint may be dismissed pursuant to this doctrine for failure to state a cause of action. Buckner v. Allergan Pharmaceuticals, Inc., 400 So. 2d 820, 821 (Fla. 5th DCA 1981). Therefore, the district court did not err in granting Genzyme's motion to dismiss the Rounds's negligence action on the basis of the learned intermediary doctrine.

AFFIRMED.