2020 IL App (2d) 190403-U
Nos. 2-19-0403 & 2-19-0872 cons.
Order filed October 30, 2020

IN THE

APPELLATE COURT OF ILLINOIS

SECOND DISTRICT

NANCY E. PLASS, Plaintiff-Appellant, v. DEKALB EYE CONSULTANTS, LLC, d/b/a Hauser-Ross Eye Institute; THOMAS W. TILTON; ASICO; IRMA DE LAO; JOHNSON & JOHNSON SURGICAL VISION, INC., f/k/a Abbott Medical Optics, Inc.; and PHIL ARCIERO, Defendants (Johnson & Johnson Surgical Vision, Inc. and Phil Arciero, Defendants-Appellees).	) Appeal from the Circuit Court) of De Kalb County.))) No. 16-L-23)))))))))) Honorable) Bradley J. Waller,) Judge, Presiding.

JUSTICE HUTCHINSON delivered the judgment of the court.
Justices McLaren and Jorgensen concurred in the judgment.

ORDER

¶ 1 *Held*: Appeal dismissed in part for lack of jurisdiction; the circuit court's dismissal of remaining claims against medical device manufacturer and its agent are reversed as the learned intermediary doctrine is inapplicable when the doctor was deceived about the device's prior testing and suitability.

¶ 2 These consolidated appeals present questions regarding the learned intermediary doctrine, which shields drug manufacturers and medical device makers from liability so long as a patient's physician is properly informed of known defects to a product. In this case, the physician was considerably less than fully informed, and therefore the doctrine is inapplicable.

¶ 3 I. BACKGROUND

¶ 4 We take the allegations in Plass's complaint as true at this stage of the proceedings. See *Fillmore v. Taylor*, 2019 IL 122626, ¶ 35. In August 2014, Nancy E. Plass, was scheduled for surgery to remove the mature cataract from her left eye and replace it with a new lens. Dr. Thomas Tilton, D.O., an ophthalmologist at the Hauser-Ross Eye Institute in Sycamore, would perform the procedure.

¶ 5 Unbeknownst to Plass, immediately prior to her surgery Dr. Tilton spoke with Phil Arciero, a sales representative who sold surgical devices for Abbott Medical Optics, Inc.—now, Johnson & Johnson Surgical Vision, Inc. ("Johnson & Johnson"). Arciero had often sold ophthalmologic surgical products to Tilton and told Tilton about a new product for sale—a push-button style injector, which could be used to insert Johnson & Johnson's proprietary lenses. Arciero demonstrated how the device worked for Tilton. Arciero also told Tilton that the device was "FDA approved" and was available for sale on the commercial market. Tilton then decided to use the device on Ms. Plass. Arciero was present in the operating room during Plass's surgery. Arciero "supervised" as the injector was loaded with a Johnson & Johnson lens cartridge. Tilton then activated the injector. Per the complaint: "[T]he implant exploded across the interior chamber and tore through the *** posterior capsule, the equator, the zonules, and hit the ciliary body of the left eye" where it "disappeared from view into the posterior segment of the left eye ***." As a result, Ms. Plass suffered considerable pain and is now blind in her left eye.

¶ 6 Unbeknownst to Tilton, however, Arciero had lied about the device's commercial availability. The injector had *not* been tested and was *not* FDA approved. Arciero and another employee, Irma De Lao, took the prototype device from ASICO, a company which was in the process of developing a push-button injector for Johnson & Johnson. Arciero then offered the device to Tilton who used it on, and injured, Plass.

¶ 7 Plass sued Johnson & Johnson, Arciero, Tilton, Irma De Lao, and others. Separately, Tilton filed a complaint seeking contribution from Johnson & Johnson. These appeals, however, concern only Plass's allegations against Johnson & Johnson and Arciero.

¶ 8 In count II of Plass's sixth amended complaint, Plass alleged that Johnson & Johnson, through Arciero, was negligent after having voluntarily undertaken the duty to provide her with medical care. See generally Restatement (Second) of Torts § 324A (1965). The complaint specifically alleged that Arciero had misrepresented that the injector was safe to use and further that he failed to warn Tilton of the device's known dangerous propensities.

¶ 9 Johnson & Johnson filed a motion to dismiss this count for failure to state a claim. 735 ILCS 5/2-615 (West 2016). Citing the learned intermediary doctrine, Johnson & Johnson contended that it and Arciero owed no duty to Plass. In support of their position, Johnson & Johnson relied on *Kennedy v. Medtronic, Inc.*, 366 Ill. App. 3d 298 (2006), which held that under the learned intermediary doctrine, manufacturers of medical devices have a duty to warn prescribing physicians of the device's known dangerous propensities; it is the doctors, in turn, using their medical judgment, who have a duty to convey those warnings to their patients. See *id*. at 308. The rationale for this rule is that the doctor is in the best position to determine whether the benefits of using the device outweigh its harms, given that he or she is familiar with both the device and the patient's susceptibilities to treatment. *Id*. Put differently, the doctor is the "learned

intermediary" between the patient and the manufacturer. Returning to the motion to dismiss, Johnson & Johnson further argued that it owed no duty to Plass because Arciero had misrepresented the status of the device only to Tilton and never spoke with Plass.

¶ 10 The circuit court stated that it believed *Kennedy* was dispositive of count II and that there was "no duty owed as a matter of law by [Johnson & Johnson] and Arciero to plaintiff ***." The trial court dismissed count II with prejudice and entered an appealability finding (see Ill. S. Ct. R. 304(a) (eff. March 18, 2016)), which generated appeal No. 2-19-0403.

¶ 11 Meanwhile, in the circuit court, Plass, with leave, filed a seventh amended complaint, which included additional claims against Johnson & Johnson and Arciero. (Plass's prior voluntary undertaking claim was reasserted as count II of the seventh amended complaint.) Count III of the new complaint alleged negligence through misrepresentation and count IV alleged "in-concert liability." See generally Restatement (Second) of Torts 876 (1979). Both of the new counts alleged that Arciero failed to warn Tilton of the device's dangerous propensities, and that Arciero substantially assisted during surgery by encouraging Tilton to use the device and by supervising its loading and preparation. Johnson & Johnson in turn filed another motion to dismiss pursuant to 735 ILCS 5/2-615, which cited the learned intermediary doctrine. The trial court again accepted this argument, granted the motion to dismiss with prejudice, and entered appealability findings, which generated appeal No. 2-19-0807.

¶ 12 At Plass's request, we consolidated these appeals. We also granted Tilton leave to file a brief as *amicus curiae*.

¶ 13 II. ANALYSIS

¶ 14 Before turning to the merits, we must first address a challenge to our jurisdiction. Johnson & Johnson contends that we lack jurisdiction to address the dismissal of count III of Plass's seventh

amended complaint, which alleged negligent misrepresentation, because Plass had previously pled negligent misrepresentation in count III of her third amended complaint. That earlier count was dismissed without prejudice and no Rule 304(a) finding was entered. After examining both complaints, we find that they raised nearly identical allegations. That is, both counts alleged that Johnson & Johnson was liable because Arciero made negligent misrepresentations *to Tilton*. We emphasize that fact because both counts seemingly concede that Arciero never made any representations to Plass so Plass likely could not have relied on Arciero to her detriment—though "we cannot say, as a matter of law, that plaintiffs' injuries were so remote or unlikely as to preclude a duty owed by the defendants." *Jane Doe-3 v. McLean County Unit District No. 5 Bd. of Directors*, 2012 IL 112479, ¶ 33 (analyzing negligent misrepresentation claim); see also *Board of Education of City of Chicago v. A, C and S, Inc.*, 131 Ill. 2d 428, 456 (1989) (same). In any event, we need not address the issue. The two counts are indistinguishable and, without a Rule 304(a) appealability finding on the earlier claim, "we lack jurisdiction to consider counts dismissed without prejudice in previous complaints even where those counts are later repled in subsequent complaints." *Ely v. Pivar*, 2018 IL App (1st) 170626, ¶ 34. Accordingly, we dismiss the portion of Plass's appeal concerning count III of her seventh amended complaint.

¶ 15 We now turn to the heart of the matter: the learned intermediary doctrine. As noted, the trial court dismissed Plass's voluntary undertaking claim (count II of the sixth amended complaint) and Plass's in-concert liability claim (count IV of the seventh amended compliant) on the basis that Tilton served as a "learned intermediary" between Plass and Arciero (and by extension Johnson & Johnson). We review *de novo* a dismissal for failure to state a claim. *Fillmore*, 2019 IL 122626, ¶ 35. After careful consideration, we now reverse the judgment of the circuit court.

¶ 16 As an initial matter, we note that Johnson & Johnson was *not* "the manufacturer" of the injector used on Plass; rather, ASICO manufactured the prototype device for Johnson & Johnson. That fact *alone* could potentially warrant reversal, as non-manufacturers cannot claim the benefit of an immunity specific to manufacturers even if they are in the supply chain. See *Friedl v. Airsource, Inc.*, 323 Ill. App. 3d 1039, 1043 (2001) (holding that the learned intermediary doctrine bars actions against manufacturers, not distributors, of prescribed medical devices). As the parties have mutually treated Johnson & Johnson as the device's manufacturer for purposes of its section 2-615 motion to dismiss, we assume without deciding that Johnson & Johnson is the manufacturer for purposes of resolving this appeal.

¶ 17 The learned intermediary doctrine has been adopted in 48 states, including Illinois (see *Kirk v. Michael Reese Hospital and Medical Center*, 117 Ill. 2d 507, 515 (1987); *Walton v. Bayer Corp*., 643 F.3d 994, 1000 (7th Cir. 2011))—Rhode Island and Vermont appear to have no precedent, state or federal, addressing the issue. The gist of the doctrine is that when adequately informed physicians prescribe drugs or medical devices to their patients, they break the chain of liability between the patient and the manufacturer. See *Brooks v. Merck & Co., Inc.*, 443 F.Supp.2d 994, 999 (S.D.Ill. 2006); see also *Hansen v. Baxter Healthcare Corp*., 198 Ill. 2d 420, 430 (2002) (explaining that the doctrine also applies to the use of medical devices). As the first case adopting the doctrine helpfully explained, "[i]f the doctor is *properly warned* *** there is an excellent chance that injury to the patient can be avoided." (Emphasis added.) *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82, 85 (8th Cir. 1966). And, so long as the manufacturer discharges its duty to properly warn the physician, "there is no duty on the part of manufacturers *** to directly warn patients." *Kirk*, 117 Ill. 2d at 519.

¶ 18 Naturally, when a manufacturer or its representatives withholds crucial information about a drug or medical device, it has "breached its duty to warn the medical community because without this information, doctors could not provide appropriate and comprehensive medical advice for their patients." *Hansen*, 198 Ill. 2d at 432. In such a circumstance, the manufacturer has "prevented [doctors] from functioning as 'learned intermediaries' to protect their patients' best medical interests." *Id*. Or, as our supreme court has stated, " '[d]octors who have not been *sufficiently* warned of the harmful effects of a drug cannot be considered 'learned intermediaries' and the adequacy of warnings is a question of fact, not law, for the jury to determine ***.' " *Id*. (emphasis added.) (quoting *Proctor v. Davis*, 291 Ill. App. 3d 265, 283 (1997)).

¶ 19 Our examination of cases reveals no set of facts quite like this one. Ultimately, the learned intermediary doctrine is a shield, which protects drug and device manufacturers that adequately warn the medical community of the known dangers of their products. Each of the cases we have considered, across multiple jurisdictions, seems to give the manufacturer the benefit of some doubt given the rigorous testing such products typically undergo. Here, the allegations—and we emphasize that at this point they are merely allegations–indicate that Arciero, Johnson & Johnson's employee, took a prototype injector, and misrepresented its status to Tilton. That deception, no doubt, was *worse* than a mere failure to warn. "Critical to imposing liability on physicians who prescribe drugs is their failure to communicate warnings to their patients which the manufacturer communicated to them." *AMF, Inc. v. Victor J. Andrew High School*, 172 Ill. App. 3d 337, 343 (1988). Correspondingly, where a manufacturer *never* gives adequate warning to a physician, "the learned intermediary doctrine is, if for no other reason, inapplicable." *Id*.

¶ 20 Furthermore, we find Johnson & Johnson's reliance on *Kennedy v. Medtronic, Inc.*, 366 Ill. App. 3d 298 (2006), to be unpersuasive. In *Kennedy*, a representative of the company that

manufactured a pacemaker was present during a surgery when the pacemaker was installed. *Id*. at 301. The representative was also a registered nurse, there to ensure that the leads were properly calibrated. *Id*. The representative was highly trained and "provided technical support for one to three pacemaker insertion procedures per day, five days a week." *Id.* Ultimately, the patient in *Kennedy* died because the surgeon placed the lead into the wrong ventricle of the patient's heart, but the representative did not know that. *Id*. at 300-09. In finding that the learned intermediary doctrine applied, the court held that it was not reasonably foreseeable to the representative or Medtronic that the surgeon would make such an egregious error. *Id*.

¶ 21 A critical distinguishing feature of *Kennedy* is that, there, the representative was highly trained and the device involved had been approved for commercial medical use. The adequacy of the manufacturer's warnings was not at issue in *Kennedy*; here, they are.

¶ 22 Finally, we note that "[i]mplicit in the duty to warn is the duty to warn with a degree of intensity that would cause a reasonable physician to exercise the caution commensurate with the potential danger." *Mahr v. G. D. Searle & Co.*, 72 Ill. App. 3d 540, 562 (1979) (internal quotation marks, ellipses, and citations omitted). "Ultimately, the sufficiency of form, content and intensity is not resolved by pointing to a single document, but remains a question to be resolved by the trier of fact in the light of all the information provided by the manufacturer and all that was reasonably possible to provide." *Id.* After carefully examining the record, we determine that, at a minimum, both of Plass's claims raise a fair question as to the adequacy of Arciero's "warnings," and therefore the learned intermediary doctrine is inapplicable.

¶ 23 III. CONCLUSION

¶ 24 In sum, the judgment of the circuit court of De Kalb County in case No. 2-19-0403 is reversed and remanded. The appeal in case No. 2-19-0872 is dismissed in part for lack of jurisdiction; the remainder of the case is reversed and remanded.

¶ 25 No. 2-19-0403, Reversed and remanded.

¶ 26 No. 2-19-0872, Dismissed in part; reversed in part, and remanded.