2018 IL App (1st) 171288-U

SIXTH DIVISION
MARCH 30, 2018

No. 1-17-1288

IN THE
APPELLATE COURT OF ILLINOIS
FIRST JUDICIAL DISTRICT

IWONA JOHNSON, Plaintiff-Appellant, v. ABBOTT LABORATORIES, INC. a foreign corporation; ABBVIE INC., a foreign corporation; Defendants-Appellees (County of Cook, d/b/a John H. Stroger Jr. Hospital of Cook County d/b/a Cook County Fantus Clinic; Carmen Hudson-White, M.D.; Rohiya Latif, PA-C; Unknown Physicians, Nurses and Medical Personnel; and Unknown Manufacturers, Defendants).	)	Appeal from the Circuit Court of Cook County. No. 14 L 3128 Honorable William E. Gomolinski, Judge Presiding.

JUSTICE CUNNINGHAM delivered the judgment of the court.
Justices Connors and Delort concurred in the judgment.

ORDER

¶ 1 *Held*: The circuit court's denial of the plaintiff-appellant's petition under section 2-1401 of the Code of Civil Procedure (735 ILCS 5/2-1401 (West 2016)) is affirmed.

¶ 2 Plaintiff-appellant Iwona Johnson appeals from the dismissal of her section 2-1401 petition, which sought to vacate the trial court's order dismissing with prejudice the counts of her fifth amended complaint against defendants-appellees Abbott Laboratories, Inc. and Abbvie, Inc. (together, "Abbott").

¶ 3 BACKGROUND

¶ 4 This personal injury action arose from Johnson's treatment at the John H. Stroger, Jr. Hospital of Cook County (Stroger Hospital). In 2012, Johnson sought treatment at Stroger Hospital for painful heavy menstrual bleeding. Medical personnel at the hospital prescribed the drug Lupron, which is manufactured by Abbott, for her. Lupron is approved by the U.S. Food and Drug Administration (FDA) for certain uses, including the treatment of endometriosis.[1] However, the parties do not dispute that Lupron is not approved by the FDA for the treatment of heavy menstrual bleeding. Johnson alleges that she suffered harmful effects from the Lupron, including pain in her jaws, teeth, eyes, neck, spine, hands, legs and breast, "burning in her bones" and muscles, blurry vision, nausea, vomiting, diarrhea, fatigue, headaches, and difficulty breathing.

¶ 5 Johnson filed her original complaint in March 2014, which pleaded allegations against several defendants, including Stroger Hospital, two of her treating medical providers, and Abbott. Abbott moved to dismiss the claims asserted against it. The trial court granted Abbott's motion without prejudice, allowing Johnson to replead her claims in an amended complaint. Abbott again filed a motion to dismiss, which was again granted without prejudice to amend.

[1] Endometriosis "is an often painful disorder in which tissue that normally lines the inside of [the] uterus— the endometrium—grows outside [the] uterus." Mayo Clinic, *Endometriosis*, https://www.mayoclinic.org/diseases-conditions/endometriosis/symptoms-causes/syc-20354656.

This pattern repeated several times, resulting in a total of six complaints, the last of which was the fifth amended complaint, filed in April 2016.

¶ 6 The fifth amended complaint included allegations that Abbott advertised or marketed Lupron to Johnson's treating physicians "for the treatment of patients with certain conditions for which Lupron did not have FDA approval," including as treatment for heavy menstrual bleeding. Johnson alleged that Abbott "communicated the purported benefits of Lupron" to Johnson's prescribing healthcare providers "while failing to disclose the serious and dangerous side effects related to the use of Lupron." Johnson's fifth amended complaint pleaded four separate counts against Abbott, including a "Product Liability/Failure to Warn" claim (count VII) alleging that Abbot failed to warn and "misled" Johnson's prescribing healthcare professionals about Lupron's side effects. Count IX alleged negligence by Abbott in marketing Lupron "even though it was dangerous" and failing to provide sufficient information about Lupron's "known dangers and risks" to her healthcare providers and to Johnson herself. Count X alleged that Abbott breached an "implied warranty of fitness for a particular purpose" because Lupron was not safe for its intended use. Count XII alleged that Abbott negligently misrepresented the safety of Lupron in advertising and promotional materials to Johnson's prescribing healthcare providers.

¶ 7 Abbott moved to dismiss the claims asserted against it in the fifth amended complaint for failure to state a claim pursuant to section 2-615 of the Code of Civil Procedure (Code) (735 ILCS 5/2-615 (West 2016); Abbott's motion also sought dismissal based on section 2-619(a)(9) of the Code, which applies if "affirmative matter" avoids or defeats a claim. 735 ILCS 2-619(a)(9) (West 2016)). Abbott's arguments under both sections 2-615 and 2-619 of the Code stemmed from the "learned intermediary" doctrine, under which "the duty to warn of the side

effects of a drug is owed by the manufacturer to the patient's physician, not the patient." *Hernandez v. Schering Corp.*, 2011 IL App (1st) 093306, ¶ 27.

¶ 8 Abbott argued that, because the FDA limits the indications for a particular drug and "limits what drug manufacturers may include on the labeling (or package insert) that accompanies prescription drugs," a manufacturer cannot be held liable when a physician elects to prescribe the drug for treatment of a non-indicated, or "off-label," condition. Since the fifth amended complaint acknowledged that Johnson was prescribed Lupron for an "off-label" use, Abbott argued that dismissal was warranted under section 2-615 for failure to state a claim. Abbott acknowledged that a 1997 decision of our court held that a manufacturer was subject to failure-to-warn liability where it had "promoted, encouraged and advertised" the off-label use of its product "by providing financial and technical assistance to *** members of the medical community without attempting to communicate to these physicians *** the dangers and risks attendant to this use." *Proctor v. Davis*, 291 Ill. App. 3d 265, 283-84 (1997). However, Abbott argued that Johnson's allegations did not fall within the scope of *Proctor*'s exception to the learned intermediary rule.

¶ 9 Abbott additionally and alternatively argued that the counts against it should be dismissed pursuant to section 2-619 of the Code. Abbott's motion attached an affidavit of a physician, Dr. Blackwell, attesting that the Lupron package insert warned of the very same reactions that Johnson allegedly experienced. Thus, Abbott argued that Lupron's warning was adequate as a matter of law. In turn, Abbott claimed that each of the counts asserted against it (all of which alleged a failure to warn) should be dismissed.

¶ 10 On July 12, 2016, the trial court granted Abbott's motion to dismiss the fifth amended complaint, with prejudice. The order stated that the dismissal was granted upon the "grounds

presented in the [Abbott] Memorandum of Law under [section] 2-615 for failure to state a claim and under [section] 2-619 on ground of learned intermediary doctrine/adequacy of warning and non-indicated use."

¶ 11 Following the dismissal of the counts against Abbott, discovery proceeded with respect to the remaining defendants. In January 2017, Johnson deposed the individual defendants, Dr. Carmen Hudson-White and physician assistant Rohiya Lafit.

¶ 12 On March 1, 2017, Johnson filed her "735 ILCS 5/2-1401 motion to vacate this court's July 12, 2016 order and for leave to file plaintiff's sixth amended complaint, instanter" (section 2-1401 petition). The petition asserted that the dismissal of her claims against Abbott should be vacated, and she should be permitted to plead a sixth amended complaint. Her petition relied on "newly discovered evidence" from the depositions of Dr. Hudson-White and Lafit concerning the off-label use of Lupron for heavy menstrual bleeding.

¶ 13 Johnson's section 2-1401 cited the following testimony from Dr. Hudson-White:

> "Q. Lupron was, as you've described, widely diagnosed for women who had abnormal menstrual bleeding?
>
> A. Yes.
>
> Q. And the prescribing of this drug, to your knowledge, was known by the manufacturer Abbott that it was being used for this purpose?
>
> A. Oh, yes.
>
> Q. And how it is that you know that Abbott knew that it was being used for this purpose?

> A. We had detail people come in—especially when the drug—when they made the 11.75. They had detail people come in and tell us how we could use it. It would prolong the interval for patients to, you know, come and get another injection. And so we used it with knowledge.
>
> Q. Of Abbott?
>
> A. Of Abbott."

Johnson's section 2-1401 petition thus claimed that Dr. Hudson-White testified that Lupron "was widely diagnosed for patients with complaints of abnormal menstrual bleeding, with the full knowledge of and encouragement by Abbott drug sales representatives."

¶ 14 Johnson's petition also cited portions of Latif's testimony, in which Latif answered affirmatively when asked if Abbott representatives "suggested" that Lupron be used "to stop heavy menstrual bleeding." Johnson also cited the portion of Latif's deposition in which she was asked:

> "Q. And in - I mean, I know it's difficult since *** this happened nearly five years ago. But as you sit there today *** can you say with a - more probably true than not that these drug manufacturers had been coming to Cook County hospital and suggesting that you use Lupron clinically for heavy menstrual bleeding prior to March of 2012?"

After that question was read back to her, Latif answered: "Probably, yes." Johnson's section 2-1401 petition thus claimed that Latif "testified that representatives of Abbott were aware of and encouraged the use and administration of [Lupron] to patients for indications not approved of by

the FDA and had been coming to Cook County hospital and suggesting that the prescribing health providers there use Lupron to treat patients with complaints of heavy menstrual bleeding prior to March 2012."

¶ 15 Johnson's section 2-1401 petition argued that this new testimony allowed her to allege sufficient facts to support a meritorious claim. She claimed the testimony was evidence "sufficient to support a cause of action against Abbott for the injuries [Johnson] sustained as a result of the administration of [Lupron] for an off-label use" and showed that Abbott "concealed its off-label promotion of [Lupron] and therefore perpetuated a fraud upon this Court."

¶ 16 With her section 2-1401 petition, Johnson submitted a proposed sixth amended complaint which, like the fifth amended complaint, included counts against Abbott for "product liability/failure to warn," negligence, breach of implied warranty, and negligent misrepresentation. However, the proposed sixth amended complaint slightly modified the wording of the allegations regarding off-label use, including the allegation that Abbott "advertised, promoted and/or marketed Lupron to prescribing healthcare professionals at Stroger Hospital for certain 'off-label' or non-FDA approved conditions," including heavy menstrual bleeding.

¶ 17 On March 30, 2017, Abbott filed its opposition to Johnson's section 2-1401 petition. Abbott first argued that the petition must be denied because it did not address the adequacy of the warning, which was one of the independent grounds upon which the trial court granted Abbott's motion to dismiss the claims asserted in the fifth amended complaint. Abbott asserted that the cited deposition testimony did not dispute the conclusion that the Lupron package insert warned of the very same side effects that Johnson allegedly experienced.

¶ 18 Abbott further argued that Johnson's petition did not fulfill the requirements of section 2-1401, including a meritorious claim and due diligence in presenting the claim. Citing *Proctor*, Abbott argued that the deposition testimony did not bring this case within the "narrow exception to the learned intermediary doctrine which would allow suit against a drug manufacturer for an off-label use of the drug where the manufacturer not only knew about the use but extensively promoted, encouraged, and advertised it." Abbott argued that *Proctor* was distinguishable, as in that case the manufacturer encouraged "decades of research and publication concerning an off-label use" that was harmful. In contrast, Dr. Hudson-White merely testified that Abbott *knew* of Lupron's off-label use. Abbott also claimed that Latif's testimony that Abbott representatives "probably" suggested off-label use of Lupron was too "equivocal" to support a meritorious claim. Abbott otherwise argued that Johnson failed to exercise the requisite due diligence in presenting this claim to the trial court, as she had "over two years and six complaints to locate evidence" that Abbott promoted the off-label use of Lupron.

¶ 19 On May 2, 2017, the trial court entered an order that denied Johnson's section 2-1401 petition "on all bases." On May 19, 2017, the plaintiff filed a timely notice of appeal. Accordingly, we have jurisdiction pursuant to Illinois Supreme Court Rule 304(b)(3) (eff. Mar. 8, 2016), which permits appellate review of "[a] judgment or order granting or denying any of the relief prayed in a petition under section 2-1401 of the Code of Civil Procedure."

¶ 20 ANALYSIS

¶ 21 On appeal, the plaintiff argues that her section 2-1401 petition presented a meritorious claim, as the aforementioned deposition testimony supports her previously dismissed claims that Abbott actively promoted and encouraged the prescription of Lupron for the non-indicated, off-label treatment of heavy menstrual bleeding. She claims that the testimony from Dr. Hudson-

White and Rohiya Latif evidenced "that Abbott and its representatives were aware of and actively endorsed the prescription and administration of Lupron for the specific off-label use from which Johnson suffered." She claims that with this "newly discovered evidence," she "is now able to allege that Abbott actively promoted the off-label use of Lupron." Johnson also asserts that she acted with due diligence, because she brought this evidence to the trial court's attention at her earliest opportunity following the depositions of Dr. Hudson-White and Latif. Thus, she asserts that the denial of her section 2-1401 petition should be denied; the dismissal of her fifth amended complaint with prejudice should be vacated; and she should be permitted to file her sixth amended complaint.

¶ 22 In response, Abbott first contends that the section 2-1401 petition was properly dismissed because it failed to address one of the independent grounds for the trial court's dismissal of the claims against Abbott in the fifth amended complaint—that the Lupron warning was adequate as a matter of law. Abbott alternatively argues that the cited deposition testimony in this case did not indicate the extensive, deceptive promotional activity that was found to support the manufacturer's liability in *Proctor*. Thus, Abbott argues that the deposition testimony does not bring this case within the "narrow" exception to the learned intermediary doctrine recognized in *Proctor*. Finally, Abbott asserts that Johnson failed to exercise due diligence in presenting her claim, as she "provides no excuse for failing to find the evidence of the alleged off-label promotion prior to 2017," despite having commenced her lawsuit in 2014 and having filed several earlier complaints.

¶ 23 "Section 2-1401 of the Code of Civil Procedure creates a comprehensive statutory procedure for obtaining relief from final orders and judgments more than 30 days after their entry." *Price v. Philip Morris, Inc.*, 2015 IL 117687, ¶ 22. "Relief under section 2-1401 is

predicated on the showing of a defense or claim that would have precluded rendition of the judgment in the original action as well as diligence in both discovering the defense or claim and presenting the petition. [Citation.]" *Id.* ¶ 23.

¶ 24 "[A] section 2-1401 petition is ordinarily used to bring facts to the attention of the trial court which, if known at the time of judgment would have precluded its entry." *People v. Hayes*, 192 Ill. 2d 437, 464 (2000). "[T]o be entitled to relief from a final judgment or order under section 2-1401, the petition must set forth specific factual allegations supporting each of the following elements: (1) the existence of a meritorious defense; (2) due diligence in presenting this defense or claim to the circuit court in the original action, and (3) due diligence in filing the section 2-1401 petition." *Warren County Soil and Water Conservation District v. Walters*, 2015 IL 117783, ¶ 37. "The question of whether relief should be granted lies within the sound discretion of the circuit court, depending on the facts and equities presented. [Citation.]" *Id.* Thus, "a reviewing court will reverse the circuit court's ruling on the petition only if it constitutes an abuse of discretion. [Citation.]" *Id.* The abuse of discretion standard "is highly deferential to the circuit court." *Taylor v. County of Cook*, 2011 IL App (1st) 093085, ¶ 23. "A circuit court abuses its discretion when its ruling is arbitrary, fanciful, unreasonable, or where no reasonable person would take the view adopted by the trial court." *Id.*

¶ 25 In this case, to set forth a "meritorious" defense or claim, Johnson's petition had to show a defense or claim that would have precluded the judgment in the original action. That is, she was required to present a reason why the trial court was precluded from dismissing the claims against Abbott in the fifth amended complaint. Significantly, the trial court order specified that dismissal was warranted on *multiple, independent* grounds: the order stated that dismissal was granted upon the grounds of the "learned intermediary doctrine/adequacy of warning *and* non-

indicated use." (Emphasis added.) Thus, the trial court indicated its agreement with Abbott that dismissal was warranted because (1) under the learned intermediary doctrine, Abbott was not liable for a physician's decision to prescribe Lupron for an off-label use, and (2) because Abbott's warning for Lupron was adequate as a matter of law.

¶ 26 As Abbott correctly points out, Johnson's section 2-1401 petition, as well as her appellate brief, relies on deposition testimony relating to only *one* of these bases for dismissal—whether Abbott could be liable for injuries from the "off-label" use of Lupron. Nowhere in her section 2-1401 petition or her appellate brief, does she suggest that the testimony of Dr. Hudson-White or physician assistant Latif undermines the trial court's independent conclusion that the Lupron warning was adequate as a matter of law. The trial court clearly agreed with Abbott's argument (supported by Dr. Blackwell's affidavit) that the Lupron package insert warned of the very same reactions that Johnson allegedly experienced, and, in turn, the warning was legally sufficient. Nothing in Johnson's section 2-1401 petition attempts to challenge that finding. Moreover, the deposition testimony relied upon by Johnson simply makes no reference to the contents or adequacy of the Lupron warning. As a result, that alternative basis for dismissal is unaffected by the "new evidence" relied upon by Johnson's petition. Given its failure to address an independent basis for dismissal, the section 2-1401 petition does not set forth a claim that would *preclude* dismissal of the claims against Abbott in the fifth amended complaint. Therefore, we cannot say that the trial court abused its discretion in finding that the petition did not present a meritorious claim.

¶ 27 Because denial of the section 2-1401 petition was warranted for its failure to present a meritorious claim, we need not separately analyze whether Johnson otherwise exercised due

diligence in presenting this claim to the circuit court in the original action, or whether she exercised due diligence in filing the section 2-1401 petition.

¶ 28 In closing, we note that the parties committed a common error when litigating the section 2-1401 petition. A pleading seeking relief under section 2-1401 of the Code is correctly characterized as a "petition," not a "motion." This distinction is important, because a section 2-1401 petition is the initial pleading in a new proceeding, rather than a pleading seeking relief in the midst of an ongoing case. *Sarkissian v. Chicago Board of Education*, 201 Ill. 2d 95, 102 (2002). Because it is an initial pleading, a section 2-1401 petition is "procedurally the counterpart of a complaint and subject to all the rules of civil practice that that character implies." *Blazyk v. Daman Express, Inc.*, 406 Ill. App. 3d 203, 207 (2010). Abbott should not have filed a "response" to the section 2-1401 petition but instead pleaded to it as if it were a complaint, such as by filing an answer or a section 2-615 or 2-619 motion. The parties, and the circuit court, treated the petition as if it were a motion filed in the normal course of litigation. But this error was not fatal. Our supreme court has held that "the character of the pleading should be determined from its content, not its label. Accordingly, when analyzing a party's request for relief, courts should look to what the pleading contains, not what it is called." *In re Haley D.*, 2011 IL 110886, ¶ 67. Although Abbott filed a "response" to the section 2-1401 petition, that response was the functional equivalent of a motion to dismiss, so it sufficed to frame the appropriate legal question for the circuit court and this court. We admonish counsel to follow the appropriate procedure in the future.

¶ 29 For the foregoing reasons, the judgment of the circuit court is affirmed.

¶ 30 Affirmed.